Sulfamic Acid

Extended Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 4/25/2023 Revision date: 4/25/2023 Version: 1.0 eSDS number: P2023041901

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	:	Substance
Product name	:	Sulfamic Acid
Chemical name	:	Sulphamidic acid
IUPAC Name	:	Sulfamic acid
EC Index-No.	:	016-026-00-0
EC-No.	:	226-218-8
CAS-No.	:	5329-14-6
REACH Registration Number	:	01-2119488633-28-0003
Formula	:	H3NO3S

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture	:	Cleaning agent.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Laizhou Zhongda Chemical Co., Ltd.
Yongan Industry Zone, Laizhou, Yantai, Shandong, P.R. China
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1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Hazardous to the aquatic environment – Chronic Hazard, Category 3	H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P264 - Wash hands, forearms and face thoroughly after handling.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see supplemental first aid instruction on this label).

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Name : Sulfamic Acid
EC-No. : 226-218-8
CAS-No. : 5329-14-6

Name	Product identifier	%
Sulfamic acid	CAS-No.: 5329-14-6 EC-No.: 226-218-8 EC Index-No.: 016-026-00-0 REACH No.: 01-2119488633-28-0003	99.5 – 99.8

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. Allow the victim to rest. Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention. Seek medical attention if ill effect or irritation develops.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Seek medical attention if ill effect or irritation develops.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after skin contact : Irritation.

Symptoms/effects after eye contact : Eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : On combustion forms: carbon oxides, nitrogen oxides, sulfur oxides.

Hazardous decomposition products in case of fire : Toxic fumes may be released. Thermal decomposition can lead to the release of irritating gases and vapours.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. For further information refer to section 8: "Exposure controls/personal protection". Wear suitable protective clothing. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Mechanically recover the product. On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Provide good ventilation in process area to prevent formation of vapour. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep container closed when not in use. Store in a well-ventilated place. Keep cool.

Suitable packaging material : PP PE

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Sulfamic acid	Inhalation 70.5 mg/m³ (Systemic, Chronic) Dermal 10 mg/kg bw/day (Systemic, Chronic) Inhalation 17.4 mg/m³ (Systemic, Chronic) * Dermal 5 mg/kg bw/day (Systemic, Chronic) * Oral 5 mg/kg bw/day (Systemic, Chronic) *	1.8 mg/L (Water (Fresh)) 0.48 mg/L (Water - Intermittent release) 0.18 mg/L (Water (Marine)) 8.36 mg/kg sediment dw (Sediment (Fresh Water)) 0.84 mg/kg sediment dw (Sediment (Marine)) 5 mg/kg soil dw (Soil) 20 mg/L (STP)

* Values for General Population

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:
Avoid all unnecessary exposure.

8.2.2.1. Eye and face protection

Eye protection:
Chemical goggles or safety glasses. Use eye protection according to EN 166. Safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Wear protective gloves. Wear suitable gloves tested to EN374. protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:
Wear appropriate mask. Wear suitable respiratory equipment in case of insufficient ventilation

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	White.
Appearance	:	White crystal
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	205 °C
Freezing point	:	Not applicable
Boiling point	:	Decomposes at 209 °C before boiling.
Flammability	:	Not flammable.
Explosive properties	:	Non explosive.
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: 181.4 g/L 20 °C
Vapour pressure	:	0.8 Pa at 20 °C
Vapour pressure at 50°C	:	Not available
Density (g/cm^3)	:	2.13
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size distribution (Granulometry)	:	505.28 µm (L_{50} Median diameter)
Dissociation constant	:	pKa = -0.9974 (K = 0.1006) at 25 °C
Oxidising properties	:	Not oxidizing

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Sulfamic acid (5329-14-6)	
LD50 oral rat	2065 mg/kg OECD Guideline 401 (Acute Oral Toxicity)
LD50 dermal rat	> 2000 mg/kg OECD Guideline 402 (Acute Dermal Toxicity)

Skin corrosion/irritation : Causes skin irritation.
Human: irritating.

Serious eye damage/irritation : Causes serious eye irritation.
Rabbit: irritating. (OECD Guideline 405 (Acute Eye Irritation / Corrosion))

Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
In vitro: S. typhimurium TA 1535, TA 1537, TA 98 and TA 100: negative. (OECD Guideline 471 (Bacterial Reverse Mutation Assay))
In vivo: Mouse: negative. (OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
Oral rat NOAEL: 200 mg/kg bw/day (OECD Guideline 414 (Prenatal Developmental Toxicity Study))

STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Oral rat NOAEL: 1000 mg/kg bw/day (OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents))

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long–term (chronic) : Harmful to aquatic life with long lasting effects.

Sulfamic acid (5329-14-6)	
LC50 - Fish [1]	70.3 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static]) OECD Guideline 203 (Fish, Acute Toxicity Test)
EC50 - aquatic invertebrates [1]	71.6 mg/l (Exposure time: 48 h - Species: Daphnia magna) OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)
EC50 72h - Algae [1]	48 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) OECD Guideline 201 (Alga, Growth Inhibition Test)

12.2. Persistence and degradability

Sulfamic Acid	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Sulfamic Acid	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

PBT assessment does not apply.

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector’s sorting instructions.

Product/Packaging disposal recommendations : Dispose of in a safe manner in accordance with local/national regulations.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

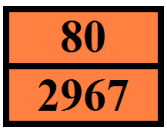
In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 2967	UN 2967	UN 2967	UN 2967	UN 2967
14.2. UN proper shipping name				
SULPHAMIC ACID	SULPHAMIC ACID	Sulphamic acid	SULPHAMIC ACID	SULPHAMIC ACID
Transport document description				
UN 2967 SULPHAMIC ACID, 8, III, (E)	UN 2967 SULPHAMIC ACID, 8, III	UN 2967 Sulphamic acid, 8, III	UN 2967 SULPHAMIC ACID, 8, III	UN 2967 SULPHAMIC ACID, 8, III
14.3. Transport hazard class(es)				
8	8	8	8	8
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : C2
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P002, IBC08, LP02, R001
Special packing provisions (ADR) : B3
Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1
Portable tank and bulk container special provisions (ADR) : TP33
Tank code (ADR) : SGAV
Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7
Hazard identification number (Kemler No.) : 80
Orange plates :



Tunnel restriction code (ADR) : E
EAC code : 2X

Transport by sea

Limited quantities (IMDG)	:	5 kg
Excepted quantities (IMDG)	:	E1
Packing instructions (IMDG)	:	P002, LP02
IBC packing instructions (IMDG)	:	IBC08
IBC special provisions (IMDG)	:	B3
Tank instructions (IMDG)	:	T1
Tank special provisions (IMDG)	:	TP33
EmS-No. (Fire)	:	F-A
EmS-No. (Spillage)	:	S-B
Stowage category (IMDG)	:	A
Segregation (IMDG)	:	SGG1, SG36, SG49
Properties and observations (IMDG)	:	White crystalline powder. Soluble in water. Decomposes when heated, evolving toxic fumes. Causes burns to skin, eyes and mucous membranes.

Air transport

PCA Excepted quantities (IATA)	:	E1
PCA Limited quantities (IATA)	:	Y845
PCA limited quantity max net quantity (IATA)	:	5kg
PCA packing instructions (IATA)	:	860
PCA max net quantity (IATA)	:	25kg
CAO packing instructions (IATA)	:	864
CAO max net quantity (IATA)	:	100kg
Special provisions (IATA)	:	A803
ERG code (IATA)	:	8L

Inland waterway transport

Classification code (ADN)	:	C2
Limited quantities (ADN)	:	5 kg
Excepted quantities (ADN)	:	E1
Equipment required (ADN)	:	PP, EP
Number of blue cones/lights (ADN)	:	0

Rail transport

Classification code (RID)	:	C2
Limited quantities (RID)	:	5kg
Excepted quantities (RID)	:	E1
Packing instructions (RID)	:	P002, IBC08, LP02, R001
Special packing provisions (RID)	:	B3
Mixed packing provisions (RID)	:	MP10
Portable tank and bulk container instructions (RID)	:	T1
Portable tank and bulk container special provisions (RID)	:	TP33
Tank codes for RID tanks (RID)	:	SGAV
Transport category (RID)	:	3
Special provisions for carriage – Bulk (RID)	:	VC1, VC2, AP7
Colis express (express parcels) (RID)	:	CE11
Hazard identification number (RID)	:	80

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Employment restrictions	:	Observe restrictions according Act on the Protection of Working Mothers (MuSchG). Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK)	:	WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	The substance is not listed

Switzerland

Storage class (LK)	:	LK 8 - Corrosive materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level

Abbreviations and acronyms:	
EC-No.	European Community number
EC50	Effective concentration for 50 percent of test population (median effective concentration)
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Lethal concentration for 50 percent of test population (median lethal concentration)
LD50	Lethal dose for 50 percent of test population (median lethal dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulation concerning the International Carriage of Dangerous Goods by Railways
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Annex: EXPOSURE ASSESSMENT

1.1 Exposure scenario 1: Formulation - Formulation of cleaning and maintenance products, surface treatment products and/or biocidal products

Environment contributing scenario(s):	
Formulation of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 2
Worker contributing scenario(s):	
closed batch formulation	PROC 3
batch formulation, exposure opportunity	PROC 4
Mixing or blending	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Use as laboratory agent	PROC 15

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.1.1 Environmental contributing scenario 1: Formulation of cleaning and maintenance products, surface treatment products and/or biocidal products

1.1.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 9 tonnes/day

Based on worst case input of "big formulator" formulating 2000 T/a and an annual formulation activity of 220 days/a, 9 tons/day are formulated as worst case.

• Annual use at a site: <= 2E3 tonnes/year

Sulphamidic acid is formulated in more than 100 facilities within the EU. Thus, based on an annual tonnage of 20000 T/a imported to Europe and a conservative approach of "big formulators" consuming 10% of this amount, a local value of2000 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 *%*

• Use days per Year: >= 220 days/year *A*

use rate of >= 220 days is assumed

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]

Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal

according to national/local legislation is sufficient.) **Other**

conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.1.1.2 Releases

The local releases to the environment are reported in the following table.

Table 1. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 2% **Final release factor:** 0.2% **Local release rate:** 9 kg/day
Air	ERC based	**Initial release factor:** 2.5% **Final release factor:** 2.5% **Local release rate:** 112.5 kg/day
Soil	ERC based	**Final release factor:** 0.01%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment).

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.1.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 2. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 1.11 mg/L	RCR = 0.617
Sediment (freshwater)	**Local PEC:** 5.158 mg/kg dw	RCR = 0.617
Marine water	**Local PEC:** 0.111 mg/L	RCR = 0.615
Sediment (marine water)	**Local PEC:** 0.515 mg/kg dw	RCR = 0.613
Sewage treatment plant	**Local PEC:** 8.988 mg/L	RCR = 0.449
Agricultural soil	**Local PEC:** 0.238 mg/kg dw	RCR = 0.048
Man via Environment - Inhalation	**Local PEC:** 0.038 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 2.839 mg/kg bw/day	RCR = 0.568
Man via environment - combined routes		RCR = 0.57

Table 3. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.022 mg/kg bw/day	0.758 mg/L
Fish	0.002 mg/kg bw/day	1.071 mg/kg ww
Leaf crops	2.811 mg/kg bw/day	164 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.612 mg/kg ww
Meat	3.798E-5 mg/kg bw/day	0.009 mg/kg ww
Milk	7.079E-4 mg/kg bw/day	0.088 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.2 Worker contributing scenario 1: closed batch formulation (PROC 3)

Formulation in closed batch processes in dedicated facilities

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	

1.1.2.1 Conditions of use

	Method
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 4. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.3 Worker contributing scenario 2: batch formulation, exposure opportunity (PROC 4)

1.1.3.1 Conditions of use

Use in batch processes in open or semi-open equipment

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 5. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.4 Worker contributing scenario 3: Mixing or blending (PROC 5)

1.1.4.1 Conditions of use

Mixing or blending in batch processes

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	

	Method
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 6. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.5 Worker contributing scenario 4: Transfer using non-dedicated facilities (PROC 8a)

1.1.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3

	Method
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 7. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.

Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.6 Worker contributing scenario 5: Transfer using dedicated facilities (PROC 8b)

1.1.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 8. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.7 Worker contributing scenario 6: Transfer to small containers (PROC 9)

1.1.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 9. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed.
Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.1.8 Worker contributing scenario 7: Use as laboratory agent (PROC 15)

1.1.8.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *The material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.1.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 10. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Dermal, systemic, long-term	**0.34 mg/kg bw/day** (TRA Worker v3)	RCR = 0.034
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.035

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2 Exposure scenario 2: Use at industrial site - Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

Sector of use:
SU 5, Manufacture of textiles, leather, fur
SU 6b, Manufacture of pulp, paper and paper products
SU 8, Manufacture of bulk, large scale chemicals (including petroleum products)
SU 15, Manufacture of fabricated metal products, except machinery and equipment

Environment contributing scenario(s):	
Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 6b
Worker contributing scenario(s):	
Closed system used with occasional exposure	PROC 2
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Mixing or blending in industrial use	PROC 5
Industrial spraying in aqueous solution	PROC 7
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Roller or brushing application	PROC 10
Article treatment by dipping and pouring (aqueous solutions)	PROC 13
Use as laboratory agent	PROC 15
Hand-mixing	PROC 19

Description of the activities and technical processes covered in the exposure scenario:

Metal surface treatment products, e.g. electroplating pH regulator
Pulp and paper industry as a chloride stabilizer
Cleaning metals and ceramics
Surface disinfectant
Laundry aid, laundry detergent
Welding and soldering products, flux products
Leather tanning industry for leather finishing

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.2.1 Environmental contributing scenario 1: Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.2.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 4.5 tonnes/day

Based on wo^st case input of "big companies" using 1500 T/a and an annual use activity of330 days/a, 4.5 tons/day are formulated as worst case.

• Annual use at a site: <= 1.5E3 tonnes/year

Sulphamidic acid is used in more than 100 facilities within the EU. Thus, based on an annual tonnage of 15'000 T/a for this use in Europe and a conservative approach of "big companies ” consuming 10% of this amount, a local value of 1'500 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %

• Use days per Year: >= 220 days/year *A*

use rate of >= 220 days is assumed

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]

Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.2.1.2 Releases

The local releases to the environment are reported in the following table.

Table 11. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 5% **Final release factor:** 0.5% **Local release rate:** 15.15 kg/day
Air	ERC based	**Initial release factor:** 0.1% **Final release factor:** 0.1% **Local release rate:** 3.03 kg/day
Soil	ERC based	**Final release factor:** 0.025%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.2.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 12. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: 1.335 mg/L	RCR = 0.742
Sediment (freshwater)	Local PEC: 6.202 mg/kg dw	RCR = 0.742
Marine water	Local PEC: 0.133 mg/L	RCR = 0.74
Sediment (marine water)	Local PEC: 0.619 mg/kg dw	RCR = 0.737
Sewage treatment plant	Local PEC: 11.24 mg/L	RCR = 0.562
Agricultural soil	Local PEC: 0.206 mg/kg dw	RCR = 0.041
Man via Environment - Inhalation	Local PEC: 0.001 mg/m^3	RCR < 0.01
Man via Environment - Oral	Exposure via food consumption: 0.146 mg/kg bw/day	RCR = 0.029
Man via environment - combined routes		RCR = 0.029

Table 13. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.035 mg/kg bw/day	1.237 mg/L
Fish	0.003 mg/kg bw/day	1.748 mg/kg ww
Leaf crops	0.105 mg/kg bw/day	6.119 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.512 mg/kg ww
Meat	1.591E-6 mg/kg bw/day	3.701E-4 mg/kg ww
Milk	2.966E-5 mg/kg bw/day	0.004 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.2 Worker contributing scenario 1: Closed system used with occasional exposure (PROC 2)

1.2.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed continuous process with occasional controlled exposure	TRA Worker v3

	Method
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 14. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.01 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Worker v3)	RCR = 0.014
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.014

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are

considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.3 Worker contributing scenario 2: Closed batch operations (PROC 3)

1.2.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.4 Worker contributing scenario 3: batch operations with occasional exposure (PROC 4)

1.2.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3

	Method
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 16. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.5 Worker contributing scenario 4: Mixing or blending in industrial use (PROC 5)

1.2.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 17. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.6 Worker contributing scenario 5: Industrial spraying in aqueous solution (PROC 7)

1.2.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal*	TRA Worker v3

	Method
protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 18. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1 mg/m3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**4.286 mg/kg bw/day** (TRA Worker v3)	RCR = 0.429
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.443

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.7 Worker contributing scenario 6: Transfer using non-dedicated facilities (PROC 8a)

1.2.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 19. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.8 Worker contributing scenario 7: Transfer using dedicated facilities (PROC 8b)

1.2.8.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall*	TRA Worker v3

	Method
be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 20. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.9 Worker contributing scenario 8: Transfer to small containers (PROC 9)

1.2.9.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.9.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 21. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.10 Worker contributing scenario 9: Roller or brushing application (PROC 10)

1.2.10.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3

	Method
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.10.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 22. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.743 mg/kg bw/day** (TRA Worker v3)	RCR = 0.274
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.281

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.11 Worker contributing scenario 10: Article treatment by dipping and pouring (aqueous solutions) (PROC 13)

1.2.11.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.11.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 23. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.12 Worker contributing scenario 11: Use as laboratory agent (PROC 15)

1.2.12.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material:*	TRA Worker v3

	Method
Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.12.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 24. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.2.13 Worker contributing scenario 12: Hand-mixing (PROC 19)

1.2.13.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and forearms (1980 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.2.13.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 25. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.3 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**8.486 mg/kg bw/day** (TRA Worker v3)	RCR = 0.849
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.853

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3 Exposure scenario 3: Use at industrial site - Industrial use of sulphamidic acid as foam cleaner in food process

Sector of use:
SU 4, Manufacture of food products (Use in manufacture of food products as water recycling additive) SU 0, Other (Use in manufacture of food products as water recycling additive)

Environment contributing scenario(s):	
Industrial use of Sulphamidic acid as foam cleaner in food process	ERC 4
Worker contributing scenario(s):	
Closed system use	PROC 1
batch operations with occasional exposure	PROC 4
Industrial spraying in aqueous solution	PROC 7
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Article treatment by dipping and pouring (aqueous solutions)	PROC 13

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.3.1 Environmental contributing scenario 1: Industrial use of Sulphamidic acid as foam cleaner in food process

1.3.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 2.27 tonnes/day
Based on wo^st case input of "big companies" using 500 T/a and an annual use activity of220 days/a, 2.27 tons/day

are formulated as worst case.

• Annual use at a site: <= 500 tonnes/year
Sulphamidic acid is used in more than 100 facilities within the EU. Thus, based on an annual tonnage of5000 T/a for this use in Europe and a conservative approach of "big companies" consuming 10% of this amount, a local value of 500 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %
• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 99 (high efficiency waste water treatment required) [Effectiveness Water: 99%] *Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 99% by neutralisation is very conservative, anticipating an increase of 2 pH unit during waste water treatment only, if waste water is acidic.*

Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

1.3.1.2 Releases

The local releases to the environment are reported in the following table.

Table 26. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 1% **Local release rate:** 22.7 kg/day
Air	Release factor	**Initial release factor:** 10% **Final release factor:** 10% **Local release rate:** 227 kg/day **Explanation / Justification:** Sulfamic acid has a low vapour pressure (0.8 Pa) and is used in aqueous aersol applications only in small amounts and locally in use. Thus, a 10% release factor to air is considered very conservative, certainly overestimating the real exposure.
Soil	ERC based	**Final release factor:** 5%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.3.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 27. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 1.345 mg/L	RCR = 0.747
Sediment (freshwater)	**Local PEC:** 6.248 mg/kg dw	RCR = 0.747
Marine water	**Local PEC:** 0.134 mg/L	RCR = 0.746
Sediment (marine water)	**Local PEC:** 0.624 mg/kg dw	RCR = 0.742
Sewage treatment plant	**Local PEC:** 11.34 mg/L	RCR = 0.567
Agricultural soil	**Local PEC:** 0.253 mg/kg dw	RCR = 0.051
Man via Environment - Inhalation	**Local PEC:** 0.038 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 2.844 mg/kg bw/day	RCR = 0.569
Protection target	**Exposure concentration**	**Risk characterisation**
Man via environment - combined routes		RCR = 0.571

Table 28. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.026 mg/kg bw/day	0.895 mg/L
Fish	0.002 mg/kg bw/day	1.264 mg/kg ww
Leaf crops	2.812 mg/kg bw/day	164.1 mg/kg ww
Root crops	0.004 mg/kg bw/day	0.641 mg/kg ww
Meat	3.801E-5 mg/kg bw/day	0.009 mg/kg ww
Milk	7.084E-4 mg/kg bw/day	0.088 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.2 Worker contributing scenario 1: Closed system use (PROC 1)

1.3.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed system (minimal contact during routine operations)	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3

	Method
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.003 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.3 Worker contributing scenario 2: batch operations with occasional exposure (PROC 4)

1.3.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour*	TRA Worker v3

	Method
pressure (0.8 Pa).	
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 30. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.4 Worker contributing scenario 3: Industrial spraying in aqueous solution (PROC 7)

1.3.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3

	Method
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 31. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1 mg/m3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**4.286 mg/kg bw/day** (TRA Worker v3)	RCR = 0.429
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.443

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.5 Worker contributing scenario 4: Transfer using non-dedicated facilities (PROC 8a)

1.3.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3

	Method
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 32. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.6 Worker contributing scenario 5: Transfer using dedicated facilities (PROC 8b)

1.3.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3

	Method
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 33. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.7 Worker contributing scenario 6: Transfer to small containers (PROC 9)

1.3.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 34. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.3.8 Worker contributing scenario 7: Article treatment by dipping and pouring (aqueous solutions) (PROC 13)

1.3.8.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	

	Method
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.3.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 35. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4 Exposure scenario 4: Use at industrial site - Industrial use of sulphamidic acid for manufacture of urea-formaldehyde resins

Sector of use:
SU 8, Manufacture of bulk, large scale chemicals (including petroleum products)

Environment contributing scenario(s):	
Industrial use of Sulphamidic acid for manufacture of urea-formaldehyde resins	ERC 6d
Worker contributing scenario(s):	
Closed system use	PROC 1
Closed system used with occasional exposure	PROC 2
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Mixing or blending in industrial use	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Use as laboratory agent	PROC 15

Subsequent service life exposure scenario(s):

ES14: Service life (consumers) - sulphamidic acid as component in plastic articles (consumers)

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.4.1 Environmental contributing scenario 1: Industrial use of Sulphamidic acid for manufacture of urea-formaldehyde resins

1.4.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 1.14 tonnes/day
Based on wo^st case input of "big companies" using 300 T/a and an annual use activity of220 days/a, 1.14 tons/day are formulated as worst case.

• Annual use at a site: <= 250 tonnes/year
Sulphamidic acid is used in 10 -100 facilities within the EU. Thus, based on an annual tonnage of2500 T/a for this use in Europe and a conservative approach of "big companies ” consuming 10% of this amount, a local value of 250 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 *%*

• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]
Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.4.1.2 Releases

The local releases to the environment are reported in the following table.

Table 36. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 0.005% **Final release factor:** 5E-4% **Local release rate:** 0.006 kg/day
Air	ERC based	**Initial release factor:** 35% **Final release factor:** 35% **Local release rate:** 399 kg/day
Soil	ERC based	**Final release factor:** 0.025%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.4.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 37. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.211 mg/L	RCR = 0.117
Sediment (freshwater)	**Local PEC:** 0.982 mg/kg dw	RCR = 0.118
Marine water	**Local PEC:** 0.021 mg/L	RCR = 0.116
Sediment (marine water)	**Local PEC:** 0.097 mg/kg dw	RCR = 0.116
Sewage treatment plant	**Local PEC:** 0.003 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.218 mg/kg dw	RCR = 0.044
Man via Environment - Inhalation	**Local PEC:** 0.067 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 4.924 mg/kg bw/day	RCR = 0.985
Protection target	**Exposure concentration**	**Risk characterisation**
Man via environment - combined routes		RCR = 0.989

Table 38. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.018 mg/kg bw/day	0.636 mg/L
Fish	4.903E-4 mg/kg bw/day	0.298 mg/kg ww
Leaf crops	4.901 mg/kg bw/day	285.9 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.599 mg/kg ww
Meat	6.615E-5 mg/kg bw/day	0.015 mg/kg ww
Milk	0.001 mg/kg bw/day	0.154 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.2 Worker contributing scenario 1: Closed system use (PROC 1)

1.4.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed system (minimal contact during routine operations)	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3

	Method
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 39. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.01 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.003 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.3 Worker contributing scenario 2: Closed system used with occasional exposure (PROC 2)

1.4.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour*	TRA Worker v3

	Method
pressure (0.8 Pa).	
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed continuous process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.3.2 Exposure and risks for workers

Table 40. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.01 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Worker v3)	RCR = 0.014
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.014

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.4 Worker contributing scenario 3: Closed batch operations (PROC 3)

1.4.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3

	Method
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 41. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.5 Worker contributing scenario 4: batch operations with occasional exposure (PROC 4)

1.4.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3

	Method
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 42. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.6 Worker contributing scenario 5: Mixing or blending in industrial use (PROC 5)

1.4.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3

	Method
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 43. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.7 Worker contributing scenario 6: Transfer using non-dedicated facilities (PROC 8a)

1.4.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 44. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.8 Worker contributing scenario 7: Transfer using dedicated facilities (PROC 8b)

1.4.8.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of	

	Method
equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 45. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.4.9 Worker contributing scenario 8: Use as laboratory agent (PROC 15)

1.4.9.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	

	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• PPE: Wear suitable gloves (tested to EN374) and eye protection *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) is recommended whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.4.9.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 46. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5 Exposure scenario 5: Use at industrial site - Industrial use of sulphamidic acid as nitrite remover in dye and pigment manufacture

Sector of use:
SU 5, Manufacture of textiles, leather, fur SU 9, Manufacture of fine chemicals

Environment contributing scenario(s):	
Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 4
Worker contributing scenario(s):	
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Mixing or blending in industrial use	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9

Description of the activities and technical processes covered in the exposure scenario:

Nitrite remover in dye and pigment manufacture

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.5.1 Environmental contributing scenario 1: Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.5.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.24 tonnes/day
Based on wo^st case input of "big companies" using 80 T/a and an annual use activity of330 days/a, 0.24 tons/day are formulated as worst case.

• Annual use at a site: <= 80 tonnes/year
Sulphamidic acid is used in 10 -100 facilities within the EU. Thus, based on an annual tonnage of800 T/a for this use in Europe and a conservative approach of "big companies " consuming 10% of this amount, a local value of 80 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %
• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes
• Waste Water Treatment: 90 [Effectiveness Water: 90%]
Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.5.1.2 Releases

The local releases to the environment are reported in the following table.

Table 47. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 10% **Local release rate:** 24 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 240 kg/day
Soil	ERC based	**Final release factor:** 5%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.5.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 48. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 1.41 mg/L	RCR = 0.783
Sediment (freshwater)	**Local PEC:** 6.55 mg/kg dw	RCR = 0.784
Marine water	**Local PEC:** 0.141 mg/L	RCR = 0.782
Sediment (marine water)	**Local PEC:** 0.654 mg/kg dw	RCR = 0.778
Sewage treatment plant	**Local PEC:** 11.98 mg/L	RCR = 0.599
Agricultural soil	**Local PEC:** 0.286 mg/kg dw	RCR = 0.057
Man via Environment - Inhalation	**Local PEC:** 0.061 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 4.533 mg/kg bw/day	RCR = 0.907
Man via environment - combined routes		RCR = 0.91

Table 49. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.037 mg/kg bw/day	1.306 mg/L
Fish	0.003 mg/kg bw/day	1.844 mg/kg ww
Leaf crops	4.488 mg/kg bw/day	261.8 mg/kg ww
Root crops	0.004 mg/kg bw/day	0.728 mg/kg ww
Meat	6.066E-5 mg/kg bw/day	0.014 mg/kg ww
Milk	0.001 mg/kg bw/day	0.141 mg/kg ww

Conclusion <u>on risk</u> characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5.2 Worker contributing scenario 1: Closed batch operations (PROC 3)

1.5.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	

	Method
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 50. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5.3 Worker contributing scenario 2: batch operations with occasional exposure (PROC 4)

1.5.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	

	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 51. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5

mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5.4 Worker contributing scenario 3: Mixing or blending in industrial use (PROC 5)

1.5.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 52. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5.5 Worker contributing scenario 4: Transfer using non-dedicated facilities (PROC 8a)

1.5.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 53. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk

assessment, the use of sulphamidic acid in considered safe.

1.5.6 Worker contributing scenario 5: Transfer using dedicated facilities (PROC 8b)

1.5.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 54. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.5.7 Worker contributing scenario 6: Transfer to small containers (PROC 9)

1.5.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall*	TRA Worker v3

	Method
be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.5.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 55. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6 Exposure scenario 6: Use at industrial site - Industrial use of sulphamidic acid for synthesis of sweeteners

Sector of use:

SU 4, Manufacture of food products

Environment contributing scenario(s):	
Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 6a
Worker contributing scenario(s):	
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Mixing or blending in industrial use	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Use as laboratory agent	PROC 15

Description of the activities and technical processes covered in the exposure scenario:

Synthesis of sweeteners

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.6.1 Environmental contributing scenario 1: Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.6.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 3.03 tonnes/day

Based on wo^st case input of "big companies" using 1000 T/a and an annual use activity of330 days/a, 3.03 tons/day are formulated as worst case.

• Annual use at a site: <= 1E3 tonnes/year

Sulphamidic acid is used in 10 -100 facilities within the EU. Thus, based on an annual tonnage of10000 T/a for this use in Europe and a conservative approach of "big companies " consuming 10% of this amount, a local value of 1000 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %

• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]

Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.6.1.2 Releases

The local releases to the environment are reported in the following table.

Table 56. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 2% **Final release factor:** 0.2% **Local release rate:** 6.06 kg/day
Air	ERC based	**Initial release factor:** 5% **Final release factor:** 5% **Local release rate:** 151.5 kg/day
Soil	ERC based	**Final release factor:** 0.1%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.6.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 57. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.514 mg/L	RCR = 0.285
Sediment (freshwater)	**Local PEC:** 2.387 mg/kg dw	RCR = 0.286
Marine water	**Local PEC:** 0.051 mg/L	RCR = 0.284
Sediment (marine water)	**Local PEC:** 0.238 mg/kg dw	RCR = 0.283
Sewage treatment plant	**Local PEC:** 3.026 mg/L	RCR = 0.151
Agricultural soil	**Local PEC:** 0.201 mg/kg dw	RCR = 0.04
Man via Environment - Inhalation	**Local PEC:** 0.038 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 2.83 mg/kg bw/day	RCR = 0.566
Man via environment - combined routes		RCR = 0.568

Table 58. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.016 mg/kg bw/day	0.57 mg/L
Fish	0.001 mg/kg bw/day	0.685 mg/kg ww
Leaf crops	2.809 mg/kg bw/day	163.8 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.538 mg/kg ww
Meat	3.794E-5 mg/kg bw/day	0.009 mg/kg ww
Milk	7.071E-4 mg/kg bw/day	0.088 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.2 Worker contributing scenario 1: Closed batch operations (PROC 3)

1.6.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	

	Method
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 59. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m³** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.3 Worker contributing scenario 2: batch operations with occasional exposure (PROC 4)

1.6.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	

	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 60. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break

through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.4 Worker contributing scenario 3: Mixing or blending in industrial use (PROC 5)

1.6.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	

	Method
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 61. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.5 Worker contributing scenario 4: Transfer using non-dedicated facilities (PROC 8a)

1.6.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	

	Method
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 62. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5

mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.6 Worker contributing scenario 5: Transfer using dedicated facilities (PROC 8b)

1.6.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 63. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.7 Worker contributing scenario 6: Transfer to small containers (PROC 9)

1.6.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 64. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed.
Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.6.8 Worker contributing scenario 7: Use as laboratory agent (PROC 15)

1.6.8.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.6.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 65. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7 Exposure scenario 7: Use at industrial site - Industrial use of sulphamidic acid as composite additive for hardening control of amino resins

Sector of use:
SU 9, Manufacture of fine chemicals

Environment contributing scenario(s):	
Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 6d
Worker contributing scenario(s):	
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Mixing or blending in industrial use	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Use as laboratory agent	PROC 15

Subsequent service life exposure scenario(s):

ES14: Service life (consumers) - sulphamidic acid as component in plastic articles (consumers)

Description of the activities and technical processes covered in the exposure scenario:

Composite additive for hardening control of amino resins **Explanation on the approach taken for the ES**
Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire

European Economic Area (EEA).

1.7.1 Environmental contributing scenario 1: Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.7.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 0.91 tonnes/day

Based on wo^st case input of "big companies" using 200 T/a and an annual use activity of220 days/a, 0.91 tons/day are formulated as worst case.

• Annual use at a site: <= 200 tonnes/year

Sulphamidic acid is used in 10 -100 facilities within the EU. Thus, based on an annual tonnage of2000 T/a for this use in Europe and a conservative approach of "big companies ” consuming 10% of this amount, a local value of 200 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %

• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]

Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.7.1.2 Releases

The local releases to the environment are reported in the following table.

Table 66. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 0.005% **Final release factor:** 5E-4% **Local release rate:** 0.002 kg/day
Air	ERC based	**Initial release factor:** 35% **Final release factor:** 35% **Local release rate:** 157.5 kg/day
Soil	ERC based	**Final release factor:** 0.025%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.7.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 67. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.211 mg/L	RCR = 0.117
Sediment (freshwater)	**Local PEC:** 0.982 mg/kg dw	RCR = 0.118
Marine water	**Local PEC:** 0.021 mg/L	RCR = 0.116
Sediment (marine water)	**Local PEC:** 0.097 mg/kg dw	RCR = 0.116
Sewage treatment plant	**Local PEC:** 0.002 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.201 mg/kg dw	RCR = 0.04
Man via Environment - Inhalation	**Local PEC:** 0.053 mg/m^3	RCR < 0.01
Protection target	**Exposure concentration**	**Risk characterisation**
Man via Environment - Oral	**Exposure via food consumption:** 3.945 mg/kg bw/day	RCR = 0.789
Man via environment - combined routes		RCR = 0.792

Table 68. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.017 mg/kg bw/day	0.587 mg/L
Fish	4.902E-4 mg/kg bw/day	0.298 mg/kg ww
Leaf crops	3. 924 mg/kg bw/day	228.9 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.553 mg/kg ww
Meat	5.298E-5 mg/kg bw/day	0.012 mg/kg ww
Milk	9.874E-4 mg/kg bw/day	0.123 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.2 Worker contributing scenario 1: Closed batch operations (PROC 3)

1.7.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	

	Method
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 69. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.3 Worker contributing scenario 2: batch operations with occasional exposure (PROC 4)

1.7.3.1 Conditions of use

	Method
Product (article) characteristics	

	Method
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 70. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.4 Worker contributing scenario 3: Mixing or blending in industrial use (PROC 5)

1.7.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	

	Method
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 71. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.5 Worker contributing scenario 4: Transfer using non-dedicated facilities (PROC 8a)

1.7.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 72. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.6 Worker contributing scenario 5: Transfer using dedicated facilities (PROC 8b)

1.7.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR*	TRA Worker v3

	Method
(0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 73. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.7 Worker contributing scenario 6: Transfer to small containers (PROC 9)

1.7.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 74. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.7.8 Worker contributing scenario 7: Use as laboratory agent (PROC 15)

1.7.8.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a*	TRA Worker v3

	Method
break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.7.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 75. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8 Exposure scenario 8: Use at industrial site - Industrial use of sulphamidic acid as plasticizer in the production of thermosetting plastics (e.g. phenolics)

Sector of use:
SU 12, Manufacture of plastics products, including compounding and conversion

Environment contributing scenario(s):	
Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 5
Worker contributing scenario(s):	
Closed system used with occasional exposure	PROC 2
Industrial spraying in aqueous solution	PROC 7
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Roller or brushing application	PROC 10
Article treatment by dipping and pouring (aqueous solutions)	PROC 13
Use as laboratory agent	PROC 15
Hand-mixing	PROC 19
Lubrication at elevated temperature	PROC 17
Heat and pressure transfer fluid	PROC 20

Subsequent service life exposure scenario(s):

ES14: Service life (consumers) - sulphamidic acid as component in plastic articles (consumers)

Description of the activities and technical processes covered in the exposure scenario:

Plasticizer

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.8.1 Environmental contributing scenario 1: Industrial use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.8.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 1.36 tonnes/day

Based on wo^st case input of "big companies" using 300 T/a and an annual use activity of220 days/a, 1.36 tons/day are formulated as worst case.

• Annual use at a site: <= 300 tonnes/year

Sulphamidic acid is used in 10 -100 facilities within the EU. Thus, based on an annual tonnage of3000 T/a for this use in Europe and a conservative approach of "big companies ” consuming 10% of this amount, a local value of 300 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %

• Use days per Year: >= 220 days/year *A*

use rate of >= 220 days is assumed

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 99 (high efficiency waste water treatment required) [Effectiveness Water: 99%] *Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 99% by neutralisation is very conservative, anticipating an increase of 2 pH unit during waste water treatment only, if waste water is acidic.*

Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

1.8.1.2 Releases

The local releases to the environment are reported in the following table.

Table 76. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 50% **Final release factor:** 0.5% **Local release rate:** 4.55 kg/day
Air	Release factor	**Initial release factor:** 10% **Final release factor:** 10% **Local release rate:** 91 kg/day **Explanation / Justification:** Sulfamic acid has a low vapour pressure (0.8 Pa) and is used in aqueous aersol applications only in small amounts and locally in use. Thus, a 10% release factor to air is considered very conservative, certainly overestimating the real exposure.
Soil	ERC based	**Final release factor:** 1%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.8.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 77. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.551 mg/L	RCR = 0.306
Sediment (freshwater)	**Local PEC:** 2.559 mg/kg dw	RCR = 0.306
Marine water	**Local PEC:** 0.055 mg/L	RCR = 0.304
Sediment (marine water)	**Local PEC:** 0.255 mg/kg dw	RCR = 0.303
Sewage treatment plant	**Local PEC:** 3.396 mg/L	RCR = 0.17
Agricultural soil	**Local PEC:** 0.184 mg/kg dw	RCR = 0.037
Man via Environment - Inhalation	**Local PEC:** 0.023 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 1.711 mg/kg bw/day	RCR = 0.342
Man via environment - combined routes		RCR = 0.344

Table 78. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.015 mg/kg bw/day	0.519 mg/L
Fish	9.661E-4 mg/kg bw/day	0.588 mg/kg ww
Leaf crops	1.692 mg/kg bw/day	98.71 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.49 mg/kg ww
Meat	2.288E-5 mg/kg bw/day	0.005 mg/kg ww
Milk	4.265E-4 mg/kg bw/day	0.053 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.2 Worker contributing scenario 1: Closed system used with occasional exposure (PROC 2)

1.8.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed continuous process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3

	Method
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 79. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.01 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.137 mg/kg bw/day** (TRA Worker v3)	RCR = 0.014
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.014

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.3 Worker contributing scenario 2: Industrial spraying in aqueous solution (PROC 7)

1.8.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 80. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1 mg/m^3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**4.286 mg/kg bw/day** (TRA Worker v3)	RCR = 0.429
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.443

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.4 Worker contributing scenario 3: Transfer using non-dedicated facilities (PROC 8a)

1.8.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Worker v3

	Method
As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 81. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.5 Worker contributing scenario 4: Transfer using dedicated facilities (PROC 8b)

1.8.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 82. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.6 Worker contributing scenario 5: Roller or brushing application (PROC 10)

1.8.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Worker v3

	Method
As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 83. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.743 mg/kg bw/day** (TRA Worker v3)	RCR = 0.274
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.281

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.7 Worker contributing scenario 6: Article treatment by dipping and pouring (aqueous solutions) (PROC 13)

1.8.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 84. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.8 Worker contributing scenario 7: Use as laboratory agent (PROC 15)

1.8.8.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 85. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed.
Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk

assessment, the use of sulphamidic acid in considered safe.

1.8.9 Worker contributing scenario 8: Hand-mixing (PROC 19)

1.8.9.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and forearms (1980 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.9.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 86. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.3 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**8.486 mg/kg bw/day** (TRA Worker v3)	RCR = 0.849
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.853

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.10 Worker contributing scenario 9: Lubrication at elevated temperature (PROC 17)

1.8.10.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%]	TRA Worker v3

	Method
As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.10.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 87. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**1 mg/m^3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.743 mg/kg bw/day** (TRA Worker v3)	RCR = 0.274
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.289

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.8.11 Worker contributing scenario 10: Heat and pressure transfer fluid (PROC 20)

1.8.11.1 Conditions of use

	Method
Product (article) characteristics	
• Concentration of substance in mixture: >25% *Amounts of plasticizer >25% are taken into account as worst case.*	External Tool (MEASE)
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	External Tool (MEASE)
Technical and organisational conditions and measures	
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	External Tool (MEASE)
Conditions and measures related to personal protection, hygiene and health evaluation	
• PPE: Wear suitable gloves (tested to EN374) and eye protection *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	External Tool (MEASE)
Other conditions affecting workers exposure	
• Skin surface potentially exposed: Two hands face (480 cm2)	External Tool (MEASE)
• Process temperature (for solid): Elevated temperature < melting point	External Tool (MEASE)
• Place of use: Indoor	External Tool (MEASE)
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.8.11.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 88. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.005 mg/m^3** (External Tool (MEASE))	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.4 mg/kg bw/day** (External Tool (MEASE))	RCR = 0.04
Dermal, systemic, acute		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.04

Remarks on exposure data External

Tool (MEASE)

- Inhalation, systemic, long-term:
  MEASE 1.02.01 was used for assessment. Parameters: Molecular weight sulphamidic acid is 97.09, MP: 205 °C Vapour pressure estimate 0.8 Pa Physical form: Liquid (as worst case for plastics in heat converting process) Content in preparation: >25% Process temperature: ca. 200 °C Industrial Use Duration of exposure: >240 minutes Pattern of use: Wide-dispersive use as worst case. Pattern of exposure control: Direct handling Contact level: Extensive (as worst case) Implemented RMMs: LEV (generic) based on ECETOC 2009, no respiratory protective equipment but use of properly designed and selected gloves. Body weight adjustment for dermal exposure: 60 kg/person

- Dermal, systemic, long-term:
  see inhalation, systemic, long-term above

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9 Exposure scenario 9: Use at industrial site - Industrial use of sulphamidic acid an intermediate

Sector of use:
SU 9, Manufacture of fine chemicals

Environment contributing scenario(s):	
Industrial use of sulphamidic acid as an intermediate in fine chemical synthesis	ERC 6a
Worker contributing scenario(s):	
Closed batch operations	PROC 3
batch operations with occasional exposure	PROC 4
Transfer using non-dedicated facilities	PROC 8a
Transfer using dedicated facilities	PROC 8b
Transfer to small containers	PROC 9
Use as laboratory agent	PROC 15

Description of the activities and technical processes covered in the exposure scenario:

Synthesis of fine chemicals

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the

environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.9.1 Environmental contributing scenario 1: Industrial use of sulphamidic acid as an intermediate in fine chemical synthesis

1.9.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily use at site: <= 3.03 tonnes/day

Based on wo^st case input of "big companies" using 1000 T/a and an annual use activity of330 days/a, 3.03 tons/day are formulated as worst case.

• Annual use at a site: <= 1E3 tonnes/year

Sulphamidic acid is used in 1 -10 facilities as intermediate within the EU. Thus, based on an annual tonnage of1000 T/a for this use in Europe and a conservative approach of "a big company" consuming all (i.e. 100%) of this amount, a local value of 1000 T/a as worst case is used for risk assessment.

• Percentage of tonnage used at regional scale: = 100 %

• Use days per Year: >= 220 days/year *A use rate of >= 220 days is assumed*

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Waste Water Treatment: 90 [Effectiveness Water: 90%]

Whereas sulphamidic acid is dangerous to aquatic organisms only at low pH, it is standard practice to neutralize run-off water before discharging to rivers, etc. An efficiency of only 90% by neutralisation is very conservative, anticipating an increase of 1 pH unit during waste water treatment only, if waste water is acidic.

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.9.1.2 Releases

The local releases to the environment are reported in the following table.

Table 89. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 2% **Final release factor:** 0.2% **Local release rate:** 6.06 kg/day
Air	ERC based	**Initial release factor:** 5% **Final release factor:** 5% **Local release rate:** 151.5 kg/day
Soil	ERC based	**Final release factor:** 0.1%

Releases to waste

Release factor to waste from the process: 0.5%

The product is delivered in coarse crystals and eventual spills or residues from cleaning operations would be disposed of as waste and residues removed with water when cleaning contaminated site; 0.5% loss to waste is assumed and 0.1% loss to waste water (considered in quantitative water assessment). When delivered as mixture (aqueous solutions) residues are considered even lower.

Release factor to waste from on site treatment: 0.1%

A max. of 0.1% from filter dusts if local exhaust ventilation is applied (not required).

1.9.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 90. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.514 mg/L	RCR = 0.285
Sediment (freshwater)	**Local PEC:** 2.387 mg/kg dw	RCR = 0.286
Marine water	**Local PEC:** 0.051 mg/L	RCR = 0.284
Sediment (marine water)	**Local PEC:** 0.238 mg/kg dw	RCR = 0.283
Sewage treatment plant	**Local PEC:** 3.026 mg/L	RCR = 0.151
Agricultural soil	**Local PEC:** 0.201 mg/kg dw	RCR = 0.04
Man via Environment - Inhalation	**Local PEC:** 0.038 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 2.83 mg/kg bw/day	RCR = 0.566
Man via environment - combined routes		RCR = 0.568

Table 91. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.016 mg/kg bw/day	0.57 mg/L
Fish	0.001 mg/kg bw/day	0.685 mg/kg ww
Leaf crops	2.809 mg/kg bw/day	163.8 mg/kg ww
Root crops	0.003 mg/kg bw/day	0.538 mg/kg ww
Meat	3.794E-5 mg/kg bw/day	0.009 mg/kg ww
Milk	7.071E-4 mg/kg bw/day	0.088 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.2 Worker contributing scenario 1: Closed batch operations (PROC 3)

1.9.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Closed batch process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3

	Method
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 92. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.069 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.3 Worker contributing scenario 2: batch operations with occasional exposure (PROC 4)

1.9.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3

	Method
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 93. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.4 Worker contributing scenario 3: Transfer using non-dedicated facilities (PROC 8a)

1.9.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of	

	Method
equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 94. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.5 Worker contributing scenario 4: Transfer using dedicated facilities (PROC 8b)

1.9.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3

	Method
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 95. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.138

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5

mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.6 Worker contributing scenario 5: Transfer to small containers (PROC 9)

1.9.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 96. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.07

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.9.7 Worker contributing scenario 6: Use as laboratory agent (PROC 15)

1.9.7.1 Conditions of use

R&D-laboratories and quality control

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as such, the material is supplied in coarse crystals with very low vapour pressure (0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3

	Method
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: One hand face only (240 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.9.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 97. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.034 mg/kg bw/day** (TRA Worker v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR < 0.01

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be

considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10 Exposure scenario 10: Use by professional worker - Professional use of processing aid in cleaning and maintenance products, surface treatment products and/or biocidal products

Sector of use:
SU 2b, Offshore industries
SU 20, Health services

Environment contributing scenario(s):	
Professional use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 8d, ERC 8a
Worker contributing scenario(s):	
Mixing and blending	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer to small containers	PROC 9
Roller or brushing application	PROC 10
Non-industrial spraying	PROC 11
Article treatment by dipping and pouring (aqueous solutions)	PROC 13
Hand mixing with PPE	PROC 19

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.10.1 Environmental contributing scenario 1: Professional use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.10.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 0.006 tonnes/day
calculated value based on EUSES default

• Percentage of tonnage used at regional scale: = 10 %

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

1.10.1.2 Releases

The local releases to the environment are reported in the following table.

Table 98. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 5.5 kg/day
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%
Soil	ERC based	**Final release factor:** 20%

Releases to waste

Release factor to waste from the process: 0%

The ERC release factors already do assume as a worst case scenario that all material is released to waste water, considered realistic for cleaning and maintenance products in professional use. Thus, no additional waste releases are required.

Release factor to waste from on site treatment: 0%

For professional use in cleaning and maintenance operations no additional waste resulting from on-site risk management measures is expected.

1.10.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 99. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.486 mg/L	RCR = 0.27
Sediment (freshwater)	**Local PEC:** 2.257 mg/kg dw	RCR = 0.27
Marine water	**Local PEC:** 0.048 mg/L	RCR = 0.268
Sediment (marine water)	**Local PEC:** 0.224 mg/kg dw	RCR = 0.267
Sewage treatment plant	**Local PEC:** 2.746 mg/L	RCR = 0.137
Agricultural soil	**Local PEC:** 0.151 mg/kg dw	RCR = 0.03
Man via Environment - Inhalation	**Local PEC:** 2.24E-5 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.034 mg/kg bw/day	RCR < 0.01
Man via environment - combined routes		RCR < 0.01

Table 100. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.014 mg/kg bw/day	0.486 mg/L
Fish	0.001 mg/kg bw/day	0.686 mg/kg ww
Leaf crops	0.017 mg/kg bw/day	0.998 mg/kg ww
Root crops	0.002 mg/kg bw/day	0.403 mg/kg ww
Meat	3.086E-7 mg/kg bw/day	7.176E-5 mg/kg ww
Milk	5.751E-6 mg/kg bw/day	7.176E-4 mg/kg ww

Conclusion <u>on risk</u> characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.2 Worker contributing scenario 1: Mixing and blending (PROC 5)

1.10.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 101. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1 mg/m^3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.151

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.3 Worker contributing scenario 2: Transfer using non-dedicated facilities (PROC 8a)

1.10.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with	TRA Worker v3

	Method
basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 102. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.4 Worker contributing scenario 3: Transfer to small containers (PROC 9)

1.10.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 103. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.5 Worker contributing scenario 4: Roller or brushing application (PROC 10)

1.10.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with	TRA Worker v3

	Method
basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 104. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.743 mg/kg bw/day** (TRA Worker v3)	RCR = 0.274
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.281

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.6 Worker contributing scenario 5: Non-industrial spraying (PROC 11)

1.10.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: 1-5%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 105. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.2 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.143 mg/kg bw/day** (TRA Worker v3)	RCR = 0.214
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.217

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.10.7 Worker contributing scenario 6: Article treatment by dipping and pouring (aqueous solutions) (PROC 13)

1.10.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 106. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed.
Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk

assessment, the use of sulphamidic acid in considered safe.

1.10.8 Worker contributing scenario 7: Hand mixing with PPE (PROC 19)

1.10.8.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: 1-5%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and forearms (1980 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.10.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 107. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.829 mg/kg bw/day** (TRA Worker v3)	RCR = 0.283
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.284

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11 Exposure scenario 11: Use by professional worker - Professional use of reactive in cleaning and maintenance products, surface treatment products and/or biocidal products

Sector of use:
SU 2b, Offshore industries SU 20, Health services

Environment contributing scenario(s):	
Professional use of cleaning and maintenance products, surface treatment products and/or biocidal products	ERC 8e, ERC 8b
Worker contributing scenario(s):	
Mixing and blending	PROC 5
Transfer using non-dedicated facilities	PROC 8a
Transfer to small containers	PROC 9
Roller or brushing application	PROC 10
Non-industrial spraying	PROC 11
Article treatment by dipping and pouring (aqueous solutions)	PROC 13
Hand mixing with PPE	PROC 19

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.11.1 Environmental contributing scenario 1: Professional use of cleaning and maintenance products, surface treatment products and/or biocidal products

1.11.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: <= 0.006 tonnes/day *calculated value based on EUSES default*

• Percentage of tonnage used at regional scale: = 10 %

Conditions and measures related to sewage treatment plant

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

1.11.1.2 Releases

The local releases to the environment are reported in the following table.

Table 108. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 2% **Final release factor:** 2% **Local release rate:** 0.11 kg/day
Air	ERC based	**Initial release factor:** 0.1% **Final release factor:** 0.1%
Soil	ERC based	**Final release factor:** 1%

Releases to waste

Release factor to waste from the process: 0%

The ERC release factors already do assume as a worst case scenario that all material is released to waste water, considered realistic for cleaning and maintenance products in professional use. Thus, no additional waste releases are required.

Release factor to waste from on site treatment: 0%

For professional use in cleaning and maintenance operations no additional waste resulting from on-site risk management measures is expected.

1.11.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 109. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.217 mg/L	RCR = 0.12
Sediment (freshwater)	**Local PEC:** 1.007 mg/kg dw	RCR = 0.12
Marine water	**Local PEC:** 0.021 mg/L	RCR = 0.119
Sediment (marine water)	**Local PEC:** 0.099 mg/kg dw	RCR = 0.118
Sewage treatment plant	**Local PEC:** 0.055 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.134 mg/kg dw	RCR = 0.027
Man via Environment - Inhalation	**Local PEC:** 2.239E-5 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.03 mg/kg bw/day	RCR < 0.01
Man via environment - combined routes		RCR < 0.01

Table 110. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.011 mg/kg bw/day	0.392 mg/L
Fish	5.027E-4 mg/kg bw/day	0.306 mg/kg ww
Leaf crops	0.016 mg/kg bw/day	0.923 mg/kg ww
Root crops	0.002 mg/kg bw/day	0.369 mg/kg ww
Meat	2.867E-7 mg/kg bw/day	6.667E-5 mg/kg ww
Milk	5.343E-6 mg/kg bw/day	6.667E-4 mg/kg ww

Conclusion <u>on risk</u> characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.2 Worker contributing scenario 1: Mixing and blending (PROC 5)

1.11.2.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.2.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 111. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1 mg/m^3** (TRA Worker v3)	RCR = 0.014
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.151

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.3 Worker contributing scenario 2: Transfer using non-dedicated facilities (PROC 8a)

1.11.3.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with	TRA Worker v3

	Method
basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.3.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 112. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m^3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists.
Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.4 Worker contributing scenario 3: Transfer to small containers (PROC 9)

1.11.4.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.4.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 113. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0.686 mg/kg bw/day** (TRA Worker v3)	RCR = 0.069
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.076

Conclusion <u>on risk</u> characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.5 Worker contributing scenario 4: Roller or brushing application (PROC 10)

1.11.5.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with	TRA Worker v3

	Method
basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands (960 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.5.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 114. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.743 mg/kg bw/day** (TRA Worker v3)	RCR = 0.274
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.281

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.
Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.6 Worker contributing scenario 5: Non-industrial spraying (PROC 11)

1.11.6.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: 1-5%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.6.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 115. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.2 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.143 mg/kg bw/day** (TRA Worker v3)	RCR = 0.214
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.217

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN 166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.11.7 Worker contributing scenario 6: Article treatment by dipping and pouring (aqueous solutions) (PROC 13)

1.11.7.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: >25%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands face (480 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.7.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 116. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.5 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.371 mg/kg bw/day** (TRA Worker v3)	RCR = 0.137
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.144

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed.
Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk

assessment, the use of sulphamidic acid in considered safe.

1.11.8 Worker contributing scenario 7: Hand mixing with PPE (PROC 19)

1.11.8.1 Conditions of use

	Method
Product (article) characteristics	
• Dustiness of material: Low *If used as mixture, the material is supplied in aqueous solution with very low fugacity (vapour pressure <0.8 Pa).*	TRA Worker v3
• Concentration of substance in mixture: 1-5%	TRA Worker v3
• Solid in solid mixtures: Yes	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Basic general ventilation (1-3 air changes per hour)	TRA Worker v3
• Containment: No	TRA Worker v3
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	TRA Worker v3
• Occupational Health and Safety Management System: Basic	TRA Worker v3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Dermal Protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training) [Effectiveness Dermal: 90%] *As the substance is strongly acidic and irritant to skin and eyes, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene - CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of 90% is assumed.*	TRA Worker v3
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for solid): Ambient	TRA Worker v3
• Skin surface potentially exposed: Two hands and forearms (1980 cm2)	TRA Worker v3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Wear protective clothing: Wearing protective clothing is recommended (e.g. overal, shirt with arms covered) and keeping work clothes separate from other clothes. Regular cleaning of work clothes is recommended.	
• Regular cleaning of equipment and work area: Regular cleaning/wet-cleaning of equipment and work area contributes to minimising exposure and should be considered as standard operating procedure in the workplace.	

1.11.8.2 Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 117. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0.1 mg/m3** (TRA Worker v3)	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.829 mg/kg bw/day** (TRA Worker v3)	RCR = 0.283
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Combined routes, systemic, long-term		RCR = 0.284

Conclusion on risk characterisation

Sulfamic acid is strongly acidic and classified as irritant to skin and eyes. Therefore, personal protective equipment (at least gloves (EN 374) and safety glasses (EN166)) shall be worn whenever potential for exposure exists. Recommended glove material: Nitrile rubber/Natural latex with 0.5 mm thickness are recommended, having a break through time of > 480 minutes; alternative glove materials with same protective level are Polychloroprene -CR (0,5 mm), Nitrile rubber/Nitrile latex - NBR (0,35 mm), Butyl rubber - Butyl (0,5 mm), Fluoro carbon rubber - FKM (0,4 mm), and Polyvinyl chloride - PVC (0,5 mm). A protection level of >90% is assumed. Vapour pressure and fugacity are considered low but when used as aerosol (e.g. as spray) inhalation shall be avoided and particle mask P2 shall be considered to be worn.

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12Exposure scenario 12: Consumer Use - Consumer use as processing aid in cleaning and maintenance products

Environment contributing scenario(s):	
Consumer use of cleaning and maintenance products	ERC 8d, ERC 8a
Consumer contributing scenario(s):	
Air care products	PC 3
Use in Biocidal products	PC 8
Use in coating, paints, etc.	PC 9a
Use as pH-regulator	PC 20
Use in polish and wax	PC 31
Use in textile dyes and finishing products	PC 34
Use in washing and cleaning products	PC 35

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.12.1 Environmental contributing scenario 1: Consumer use of cleaning and maintenance products

1.12.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily wide dispersive use: <= 0.006 tonnes/day *calculated value based on EUSES default*
• Percentage of tonnage used at regional scale: = 10 %

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.12.1.2 Releases

The local releases to the environment are reported in the following table.

Table 118. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 100% **Final release factor:** 100% **Local release rate:** 5.5 kg/day

Release	Release factor estimation method	Explanation / Justification
Air	ERC based	**Initial release factor:** 100% **Final release factor:** 100%
Soil	ERC based	**Final release factor:** 20%

Releases to waste

Release factor to waste from the process: 0%

The ERC release factors already do assume as a worst case scenario that all material is released to waste water, considered realistic for cleaning and maintenance products in consumer use. Thus, no additional waste releases are required.

Release factor to waste from on site treatment: 0%

For consumer use in cleaning and maintenance operations no additional waste resulting from on-site risk management measures is expected.

1.12.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 119. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.486 mg/L	RCR = 0.27
Sediment (freshwater)	**Local PEC:** 2.257 mg/kg dw	RCR = 0.27
Marine water	**Local PEC:** 0.048 mg/L	RCR = 0.268
Sediment (marine water)	**Local PEC:** 0.224 mg/kg dw	RCR = 0.267
Sewage treatment plant	**Local PEC:** 2.746 mg/L	RCR = 0.137
Agricultural soil	**Local PEC:** 0.151 mg/kg dw	RCR = 0.03
Man via Environment - Inhalation	**Local PEC:** 2.24E-5 mg/m^3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.034 mg/kg bw/day	RCR < 0.01
Man via environment - combined routes		RCR < 0.01

Table 120. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.014 mg/kg bw/day	0.486 mg/L
Fish	0.001 mg/kg bw/day	0.686 mg/kg ww
Leaf crops	0.017 mg/kg bw/day	0.998 mg/kg ww
Root crops	0.002 mg/kg bw/day	0.403 mg/kg ww
Meat	3.086E-7 mg/kg bw/day	7.176E-5 mg/kg ww
Milk	5.751E-6 mg/kg bw/day	7.176E-4 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.2 Consumer contributing scenario 1: Air care products (PC 3)

1.12.2.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Aircare, instant action (aerosol sprays)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.01 g/g *Sulfamic acid is only used in small amounts (<1 %) and typically is neutralized within solution.*	TRA Consumer v3
• Dermal exposure negligible compared to inhalation: Yes	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 10 g/event	TRA Consumer v3
• Exposure time: = 0.25 hr	TRA Consumer v3
• Frequency of use: = 4 events/day	TRA Consumer v3

1.12.2.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 121. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**17.22 mg/m^3** (TRA Consumer v3) **Additional data not used for RCR:** 0.216 mg/m^3 (TRA Consumer v3)	RCR = 0.99
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0.03 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.99

Conclusion <u>on risk</u> characterisation

Sulphamidic acid, when used in air care products, is sufficiently diluted (<5%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.3 Consumer contributing scenario 2: Use in Biocidal products (PC 8)

1.12.3.1 Conditions of use

	Method
Product (article) characteristics	
• Concentration in product: <= 0.1 g/g *covers concentration in product up to 10%*	External Tool (ECETOC TRA consumers v2)
• Product is a spray ?: Yes	External Tool (ECETOC TRA consumers v2)
Amount used, frequency and duration of use/exposure	
• Frequency of use (events / day): <= 0.35 events/day *covers 0.35 events per day (128 events per year)*	External Tool (ECETOC TRA consumers v2)
• Amount used per application/event [g/event]: <= 35 g/event *TRA default*	External Tool (ECETOC TRA consumers v2)
• exposure time [hours]: <= 0.17 hours *exposure up to 0.17 hours per event (10 minutes) (HERA and SDA maximum use time)*	External Tool (ECETOC TRA consumers v2)
Other conditions affecting consumers exposure	
• room volume in m3: >= 20 m3 *TRA default*	External Tool (ECETOC TRA consumers v2)
• Skin contact area up to : <= 428 cm2 *estimated lower skin contact for spray than liquid, wiping with one hand*	External Tool (ECETOC TRA consumers v2)
• Thickness layer [cm]: = 0.01 cm *TRA default*	External Tool (ECETOC TRA consumers v2)
• Room ventilation: = 0.6 Air change(s)/hour *RIVM Fact Sheets*	External Tool (ECETOC TRA consumers v2)
• Dermal transfer factor: = 1 *TRA default*	External Tool (ECETOC TRA consumers v2)

1.12.3.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 122. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.076 mg/m³** (External Tool (ECETOC TRA consumers v2)) **Additional data not used for RCR:** 0.003 mg/m3 (External Tool (ECETOC TRA consumers v2))	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.5 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2)) **Additional data not used for RCR:** 2.5 mg/kg bw/day (External Tool (ECETOC TRA consumers v2))	RCR = 0.5

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2)) **Additional data not used for RCR:** 0 mg/kg bw/day (External Tool (ECETOC TRA consumers v2))	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.504

Remarks on exposure data External Tool

(ECETOC TRA consumers v2)

Remark on exposure estimation

- Inhalation, systemic, long-term: mean inhalation concentration (yearly)
- Dermal, systemic, long-term: predicted dermal exposure, chronic
- Oral, systemic, long-term: predicted oral exposure, chronic

Conditions of use leading to the exposure:

- Concentration in product: <= 0.05 g/g
- Product is a spray ?: No
- Frequency of use (events / day): <= 0.35 events/day
- Amount used per application/event [g/event]: <= 27 g/event
- exposure time [hours]: <= 0.33 hours
- room volume in m3: >= 20 m3
- skin surface area: hands (857.5 cm2): = 857.5 cm2
- Thickness layer [cm]: = 0.01 cm
- Room ventilation: = 0.6 Air change(s)/hour
- Dermal transfer factor: = 1

External Tool (ECETOC TRA consumers v2)

- Inhalation, systemic, long-term: mean inhalation concentration, yearly
- Dermal, systemic, long-term: predicted dermal exposure, chronic
- Oral, systemic, long-term: predicted oral exposure, chronic

Conclusion on risk characterisation

Sulphamidic acid, when used in biocidal products, is sufficiently diluted (<10% for spray and <5% for liquids, respectively) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.4 Consumer contributing scenario 3: Use in coating, paints, etc. (PC 9a)

1.12.4.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Waterborne latex wall paint	TRA Consumer v3
• Spray: No	TRA Consumer v3
• Concentration of substance in mixture: = 0.02 g/g *use of up to 2%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 2.76E3 g/event *est. 400 sq ft per gallon, for walls of 20 m3 room est. 304 sq ft or 0.76 gallons = 2760 g; consistent with EPA 2009 EFH 75th percentile*	TRA Consumer v3
• Exposure time: = 2.2 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Inside hands / one hand / palm of hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.12.4.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 123. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**11.9 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 8.405 mg/m^3 (TRA Consumer v3) 5.008 mg/m3 (TRA Consumer v3) 2.166 mg/m3 (TRA Consumer v3)	RCR = 0.684
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.429 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 2.144 mg/kg bw/day (TRA Consumer v3)	RCR = 0.286

Route of exposure and type of effects	Exposure concentration	Risk characterisation
	0 mg/kg bw/day (TRA Consumer v3) 4.288 mg/kg bw/day (TRA Consumer v3)	
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.97

Conclusion on risk characterisation

Sulphamidic acid, when used in coating & paint products, is sufficiently diluted (<10%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.5 Consumer contributing scenario 4: Use as pH-regulator (PC 20)

1.12.5.1 Conditions of use

Not defined.

1.12.5.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 124. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0 mg/m3** (External Tool (Use consideration))	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0 mg/kg bw/day** (External Tool (Use consideration))	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (Use consideration))	RCR < 0.01
Combined routes, systemic, long-term		RCR < 0.01

Remarks on exposure data External Tool (Use

consideration)

- Inhalation, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

- Dermal, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

- Oral, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

Conclusion on risk characterisation

The consideration of exposure of consumers and professionals from the use of sulfamic acid as pH-regulator is not required in this chemical safety assessment. When used for this purpose, by definition sulfamic acid becomes neutralized and converted to sulfamates and the low pH, responsible for skin and eye-irritation properties of the substance, disappears.
Thus, no hazards from sulfamic acid is expected.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.6 Consumer contributing scenario 5: Use in polish and wax (PC 31)

1.12.6.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Polishes, spray (furniture, shoes)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.02 g/g *covers concentration in product up to 2%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 35 g/event *value (35 g/event) taken from USEPA 2009 Draft Exposure Factors Handbook*	TRA Consumer v3
• Exposure time: = 4 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Inside hands / one hand / palm of hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.12.6.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 125. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**10.29 mg/m3** (TRA Consumer v3)	RCR = 0.592

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.429 mg/kg bw/day** (TRA Consumer v3)	RCR = 0.286
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.878

Conclusion on risk characterisation

Sulphamidic acid, when used in polish and wax products, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.7 Consumer contributing scenario 6: Use in textile dyes and finishing products (PC 34)

1.12.7.1 Conditions of use

	Method
Product (article) characteristics	
• Concentration in product: <= 0.03 g/g *Considered concentration up to 3%*	External Tool (ECETOC TRA consumers v2)
Amount used, frequency and duration of use/exposure	
• Frequency of use (events / day): <= 1 events/day	External Tool (ECETOC TRA consumers v2)
• Amount used per application/event [g/event]: <= 115 g/event	External Tool (ECETOC TRA consumers v2)
• exposure time [hours]: <= 1 hours	External Tool (ECETOC TRA consumers v2)
Other conditions affecting consumers exposure	
• Thickness layer [cm]: = 0.01 cm	External Tool (ECETOC TRA consumers v2)
• room volume in m3: >= 20 m3 *ECETOC TRA default*	External Tool (ECETOC TRA consumers v2)
• Fraction released to air : = 0.01 g/g *Weight fraction estimates amount released to the air. Depends on default vapour pressure (0.8 Pa for sulfamic acid).*	External Tool (ECETOC TRA consumers v2)
• Inhalation rate: = 1.37 m3/h	External Tool (ECETOC TRA consumers v2)
• skin surface area: hands (857.5 cm2): = 857.5 cm2	External Tool (ECETOC TRA consumers v2)

1.12.7.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 126. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1.725 mg/m3** (External Tool (ECETOC TRA consumers v2))	RCR = 0.099
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**4.29 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2))	RCR = 0.858
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2))	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.957

Conclusion <u>on risk</u> characterisation

Sulphamidic acid, when used in textile dye products, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.12.8 Consumer contributing scenario 7: Use in washing and cleaning products (PC 35)

1.12.8.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.015 g/g *covers concentration in product up to 1.5%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 35 g/event	TRA Consumer v3
• Exposure time: = 4 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.12.8.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 127. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**7.721 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 0.469 mg/m3 (TRA Consumer v3) 2.609 mg/m3 (TRA Consumer v3)	RCR = 0.444
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.144 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 4.288 mg/kg bw/day (TRA Consumer v3) 3.573 mg/kg bw/day (TRA Consumer v3)	RCR = 0.429
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.872

Conclusion on risk characterisation

Sulphamidic acid, when used in washing and cleaning products for consumers, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.
However, for special purpose cleaners such as stain removers, softening agents for coffee machines, etc. concentrations may exceed 3%. However, in such cases use frequency, and duration of exposure is much lower, which may be considered for exposure assessment. Nevertheless, for such special purpose cleaners use of gloves is recommended.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13Exposure scenario 13: Consumer Use - Consumer use as reactive substance in cleaning and maintenance products

Environment contributing scenario(s):	
Consumer use of cleaning and maintenance products	ERC 8e, ERC 8b
Consumer contributing scenario(s):	
Air care products	PC 3
Use in Biocidal products	PC 8
Use in coating, paints, etc.	PC 9a
Use as pH-regulator	PC 20
Use in polish and wax	PC 31
Use in textile dyes and finishing products	PC 34
Use in washing and cleaning products	PC 35

Explanation on the approach taken for the ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.13.1 Environmental contributing scenario 1: Consumer use of cleaning and maintenance products

1.13.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily wide dispersive use: <= 0.006 tonnes/day *calculated value based on EUSES default*
• Percentage of tonnage used at regional scale: = 10 %

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.13.1.2 Releases

The local releases to the environment are reported in the following table.

Table 128. Local releases to the environment

Release	**Release factor estimation method**	**Explanation / Justification**
Water	ERC based	**Initial release factor:** 2% **Final release factor:** 2% **Local release rate:** 0.11 kg/day
Release	**Release factor estimation method**	**Explanation / Justification**
Air	ERC based	**Initial release factor:** 0.1% **Final release factor:** 0.1%
Soil	ERC based	**Final release factor:** 1%

1.13.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 129. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.217 mg/L	RCR = 0.12
Sediment (freshwater)	**Local PEC:** 1.007 mg/kg dw	RCR = 0.12
Marine water	**Local PEC:** 0.021 mg/L	RCR = 0.119
Sediment (marine water)	**Local PEC:** 0.099 mg/kg dw	RCR = 0.118
Sewage treatment plant	**Local PEC:** 0.055 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.134 mg/kg dw	RCR = 0.027
Man via Environment - Inhalation	**Local PEC:** 2.239E-5 mg/m3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.03 mg/kg bw/day	RCR < 0.01
Man via environment - combined routes		RCR < 0.01

Table 130. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.011 mg/kg bw/day	0.392 mg/L
Fish	5.027E-4 mg/kg bw/day	0.306 mg/kg ww
Leaf crops	0.016 mg/kg bw/day	0.923 mg/kg ww
Root crops	0.002 mg/kg bw/day	0.369 mg/kg ww
Meat	2.867E-7 mg/kg bw/day	6.667E-5 mg/kg ww
Milk	5.343E-6 mg/kg bw/day	6.667E-4 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.2 Consumer contributing scenario 1: Air care products (PC 3)

1.13.2.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Aircare, instant action (aerosol sprays)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.01 g/g *Sulfamic acid is only used in small amounts (<1 %) and typically is neutralized within solution.*	TRA Consumer v3

	Method
• Dermal exposure negligible compared to inhalation: Yes	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 10 g/event	TRA Consumer v3
• Exposure time: = 0.25 hr	TRA Consumer v3
• Frequency of use: = 4 events/day	TRA Consumer v3

1.13.2.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 131. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**17.22 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 0.216 mg/m3 (TRA Consumer v3)	RCR = 0.99
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0.03 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.99

Conclusion <u>on risk</u> characterisation

Sulphamidic acid, when used in air care products, is sufficiently diluted (<5%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.3 Consumer contributing scenario 2: Use in Biocidal products (PC 8)

1.13.3.1 Conditions of use

	Method
Product (article) characteristics	
• Concentration in product: <= 0.1 g/g *covers concentration in product up to 10%*	External Tool (ECETOC TRA consumers v2)

	Method
• Product is a spray ?: Yes	External Tool (ECETOC TRA consumers v2)
Amount used, frequency and duration of use/exposure	
• Frequency of use (events / day): <= 0.35 events/day *covers 0.35 events per day (128 events per year)*	External Tool (ECETOC TRA consumers v2)
• Amount used per application/event [g/event]: <= 35 g/event *TRA default*	External Tool (ECETOC TRA consumers v2)
• exposure time [hours]: <= 0.17 hours *exposure up to 0.17 hours per event (10 minutes) (HERA and SDA maximum use time)*	External Tool (ECETOC TRA consumers v2)
Other conditions affecting consumers exposure	
• room volume in m3: >= 20 m3 *TRA default*	External Tool (ECETOC TRA consumers v2)
• Skin contact area up to : <= 428 cm2 *estimated lower skin contact for spray than liquid, wiping with one hand*	External Tool (ECETOC TRA consumers v2)
• Thickness layer [cm]: = 0.01 cm *TRA default*	External Tool (ECETOC TRA consumers v2)
• Room ventilation: = 0.6 Air change(s)/hour *RIVM Fact Sheets*	External Tool (ECETOC TRA consumers v2)
• Dermal transfer factor: = 1 *TRA default*	External Tool (ECETOC TRA consumers v2)

1.13.3.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 132. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**0.076 mg/m³** (External Tool (ECETOC TRA consumers v2)) **Additional data not used for RCR:** 0.003 mg/m³ (External Tool (ECETOC TRA consumers v2))	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**2.5 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2)) **Additional data not used for RCR:** 2.5 mg/kg bw/day (External Tool (ECETOC TRA consumers v2))	RCR = 0.5
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2))	RCR < 0.01

Route of exposure and type of effects	Exposure concentration	Risk characterisation
	Additional data not used for RCR: 0 mg/kg bw/day (External Tool (ECETOC TRA consumers v2))	
Combined routes, systemic, long-term		RCR = 0.504

Remarks on exposure data External Tool

(ECETOC TRA consumers v2)

Remark on exposure estimation

- Inhalation, systemic, long-term: mean inhalation concentration (yearly)
- Dermal, systemic, long-term: predicted dermal exposure, chronic
- Oral, systemic, long-term: predicted oral exposure, chronic

Conditions of use leading to the exposure:

- Concentration in product: <= 0.05 g/g
- Product is a spray ?: No
- Frequency of use (events / day): <= 0.35 events/day
- Amount used per application/event [g/event]: <= 27 g/event
- exposure time [hours]: <= 0.33 hours
- room volume in m3: >= 20 m3
- skin surface area: hands (857.5 cm2): = 857.5 cm2
- Thickness layer [cm]: = 0.01 cm
- Room ventilation: = 0.6 Air change(s)/hour
- Dermal transfer factor: = 1

External Tool (ECETOC TRA consumers v2)

- Inhalation, systemic, long-term: mean inhalation concentration, yearly
- Dermal, systemic, long-term: predicted dermal exposure, chronic
- Oral, systemic, long-term: predicted oral exposure, chronic

Conclusion on risk characterisation

Sulphamidic acid, when used in biocidal products, is sufficiently diluted (<10% for spray and <5% for liquids, respectively) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.4 Consumer contributing scenario 3: Use in coating, paints, etc. (PC 9a)

1.13.4.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Waterborne latex wall paint	TRA Consumer v3
• Spray: No	TRA Consumer v3
• Concentration of substance in mixture: = 0.02 g/g *use of up to 2%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 2.76E3 g/event *est. 400 sq ft per gallon, for walls of 20 m3 room est. 304 sq ft or 0.76 gallons = 2760 g; consistent with EPA 2009 EFH 75th percentile*	TRA Consumer v3
• Exposure time: = 2.2 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Inside hands / one hand / palm of hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.13.4.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 133. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**11.9 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 8.405 mg/m3 (TRA Consumer v3) 5.008 mg/m3 (TRA Consumer v3) 2.166 mg/m3 (TRA Consumer v3)	RCR = 0.684
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.429 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 2.144 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3) 4.288 mg/kg bw/day (TRA Consumer v3)	RCR = 0.286
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.97

Conclusion on risk characterisation

Sulphamidic acid, when used in coating & paint products, is sufficiently diluted (<10%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.5 Consumer contributing scenario 4: Use as pH-regulator (PC 20)

1.13.5.1 Conditions of use

Not defined.

1.13.5.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 134. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**0 mg/m³** (External Tool (Use consideration))	RCR < 0.01
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**0 mg/kg bw/day** (External Tool (Use consideration))	RCR < 0.01
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (Use consideration))	RCR < 0.01
Combined routes, systemic, long-term		RCR < 0.01

Remarks on exposure data

External Tool (Use consideration)

- Inhalation, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

- Dermal, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

- Oral, systemic, long-term:

When used as pH-regulator, sulfamic acid becomes converted to sulfamates by neutralisation and concentration of sulfamic acid turns to zero.

Conclusion <u>on risk</u> characterisation

The consideration of exposure of consumers and professionals from the use of sulfamic acid as pH-regulator is not required in this chemical safety assessment. When used for this purpose, by definition sulfamic acid becomes neutralized and converted to sulfamates and the low pH, responsible for skin and eye-irritation properties of the substance, disappears.
Thus, no hazards from sulfamic acid is expected.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.6 Consumer contributing scenario 5: Use in polish and wax (PC 31)

1.13.6.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Polishes, spray (furniture, shoes)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.02 g/g *covers concentration in product up to 2%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 35 g/event *value (35 g/event) taken from USEPA 2009 Draft Exposure Factors Handbook*	TRA Consumer v3
• Exposure time: = 4 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Inside hands / one hand / palm of hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.13.6.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 135. Exposure concentrations and risks for consumers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, long-term	**10.29 mg/m3** (TRA Consumer v3)	RCR = 0.592
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.429 mg/kg bw/day** (TRA Consumer v3)	RCR = 0.286
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.878

Conclusion on risk characterisation

Sulphamidic acid, when used in polish and wax products, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.7 Consumer contributing scenario 6: Use in textile dyes and finishing products (PC 34)

1.13.7.1 Conditions of use

	Method
Product (article) characteristics	
• Concentration in product: <= 0.03 g/g *Considered concentration up to 3%*	External Tool (ECETOC TRA consumers v2)
Amount used, frequency and duration of use/exposure	
• Frequency of use (events / day): <= 1 events/day	External Tool (ECETOC TRA consumers v2)
• Amount used per application/event [g/event]: <= 115 g/event	External Tool (ECETOC TRA consumers v2)
• exposure time [hours]: <= 1 hours	External Tool (ECETOC TRA consumers v2)
Other conditions affecting consumers exposure	
• Thickness layer [cm]: = 0.01 cm	External Tool (ECETOC TRA consumers v2)
• room volume in m3: >= 20 m3 *ECETOC TRA default*	External Tool (ECETOC TRA consumers v2)
• Fraction released to air : = 0.01 g/g *Weight fraction estimates amount released to the air. Depends on default vapour pressure (0.8 Pa for sulfamic acid).*	External Tool (ECETOC TRA consumers v2)
• Inhalation rate: = 1.37 m3/h	External Tool (ECETOC TRA consumers v2)
• skin surface area: hands (857.5 cm2): = 857.5 cm2	External Tool (ECETOC TRA consumers v2)

1.13.7.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 136. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1.725 mg/m3** (External Tool (ECETOC TRA consumers v2))	RCR = 0.099

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**4.29 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2))	RCR = 0.858
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (External Tool (ECETOC TRA consumers v2))	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.957

Conclusion on risk characterisation

Sulphamidic acid, when used in textile dye products, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.13.8 Consumer contributing scenario 7: Use in washing and cleaning products (PC 35)

1.13.8.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	TRA Consumer v3
• Spray: Yes	TRA Consumer v3
• Concentration of substance in mixture: = 0.01 g/g *covers concentration in product up to 1%*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 35 g/event	TRA Consumer v3
• Exposure time: = 4 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Hands	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.13.8.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 137. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**5.147 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 0.156 mg/m^3 (TRA Consumer v3) 1.043 mg/m3 (TRA Consumer v3)	RCR = 0.296
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.429 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 1.429 mg/kg bw/day (TRA Consumer v3) 1.429 mg/kg bw/day (TRA Consumer v3)	RCR = 0.286
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/kg bw/day (TRA Consumer v3) 0 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.582

Conclusion on risk characterisation

Sulphamidic acid, when used in washing and cleaning products for consumers, is sufficiently diluted (<3%) in order to be not considered irritant to skin and eyes. Thus, no personal protective equipment is required.
However, for special purpose cleaners such as stain removers, softening agents for coffee machines, etc. concentrations may exceed 3%. However, in such cases use frequency, and duration of exposure is much lower, which may be considered for exposure assessment. Nevertheless, for such special purpose cleaners use of gloves is recommended.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.14Exposure scenario 14: Service life (consumers) - sulphamidic acid as component in plastic articles (consumers)

Environment contributing scenario(s):	
sulphamidic acid as component in plastic articles (consumers)	ERC 10a, ERC 11a
Consumer contributing scenario(s):	
Use of plastic articles by consumers	AC 13

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s):

ES4: Use at industrial site - Industrial use of sulphamidic acid for manufacture of urea-formaldehyde resins

ES7: Use at industrial site - Industrial use of sulphamidic acid as composite additive for hardening control of amino resins

ES8: Use at industrial site - Industrial use of sulphamidic acid as plasticizer in the production of thermosetting plastics (e.g. phenolics)

Description of the activities and technical processes covered in the exposure scenario:

Covers also use by professionals and industrial workers of plastic articles **Explanation on the approach taken for the**

ES

Considering the CSR being a shared CSR amongst all registrants of sulphamidic acid, the tonnages considered for the environmental assessment of this use are based on the sum of tonnages reported by the three biggest importers amended by a considerable margin of safety to reflect the total amount of sulfamidic acid for this use in the entire European Economic Area (EEA).

1.14.1 Environmental contributing scenario 1: sulphamidic acid as component in plastic articles (consumers)

1.14.1.1 Conditions of use

Amount used, frequency and duration of use (or from service life)

• Daily wide dispersive use: <= 0.006 tonnes/day *calculated value based on EUSES default*

• Percentage of tonnage used at regional scale: = 10 %

Conditions and measures related to treatment of waste (including article waste)

• Particular considerations on the waste treatment operations: No (low risk) (ERC based assessment demonstrating control of risk with default conditions. Low risk assumed for waste life stage. Waste disposal according to national/local legislation is sufficient.)

Other conditions affecting environmental exposure

• Municipal STP: Yes [Effectiveness Water: 0.131%]

• Discharge rate of STP: >= 2E3 m3/d

• Application of the STP sludge on agricultural soil: Yes

• Receiving surface water flow rate: >= 1.8E4 m3/d

1.14.1.2 Releases

The local releases to the environment are reported in the following table.

Table 138. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	ERC based	**Initial release factor:** 3.2% **Final release factor:** 3.2% **Local release rate:** 0.176 kg/day
Air	ERC based	**Initial release factor:** 0.05% **Final release factor:** 0.05%
Soil	ERC based	**Final release factor:** 3.2%

Releases to waste

Release factor to waste from the process: 0%

Not applicable to service life of plastic articles **Release**

factor to waste from on site treatment: 0%

Not applicable to service life of plastic articles

1.14.1.3 Exposure and risks for the environment and man via the environment

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 139. Exposure concentrations and risks for the environment

Protection target	Exposure concentration	Risk characterisation
Freshwater	**Local PEC:** 0.22 mg/L	RCR = 0.122
Sediment (freshwater)	**Local PEC:** 1.022 mg/kg dw	RCR = 0.122
Marine water	**Local PEC:** 0.022 mg/L	RCR = 0.121
Sediment (marine water)	**Local PEC:** 0.101 mg/kg dw	RCR = 0.12
Sewage treatment plant	**Local PEC:** 0.088 mg/L	RCR < 0.01
Agricultural soil	**Local PEC:** 0.134 mg/kg dw	RCR = 0.027
Man via Environment - Inhalation	**Local PEC:** 2.239E-5 mg/m3	RCR < 0.01
Man via Environment - Oral	**Exposure via food consumption:** 0.03 mg/kg bw/day	RCR < 0.01
Man via environment - combined routes		RCR < 0.01

Table 140. Contribution to oral intake for man via the environment from local contribution

Type of food	Estimated daily dose	Concentration in food
Drinking water	0.011 mg/kg bw/day	0.392 mg/L
Fish	5.103E-4 mg/kg bw/day	0.311 mg/kg ww
Leaf crops	0.016 mg/kg bw/day	0.924 mg/kg ww
Root crops	0.002 mg/kg bw/day	0.37 mg/kg ww
Meat	2.868E-7 mg/kg bw/day	6.671E-5 mg/kg ww
Milk	5.346E-6 mg/kg bw/day	6.671E-4 mg/kg ww

Conclusion on risk characterisation

Respecting the operational conditions and risk management measures, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.

1.14.2 Consumer contributing scenario 1: Use of plastic articles by consumers (AC 13)

1.14.2.1 Conditions of use

	Method
Product (article) characteristics	
• Product/Article subcategory: Plastic, larger articles (plastic chair, PVC-flooring, lawn mower, PC)	TRA Consumer v3
• Concentration of substance in mixture: = 0.01 g/g *Concentration in final plastic article is less than 1 %.*	TRA Consumer v3
• Oral contact foreseen: No	TRA Consumer v3
Amount used, frequency and duration of use/exposure	
• Amount of product used per application: = 8E3 g/event	TRA Consumer v3
• Exposure time: = 8 hr	TRA Consumer v3
• Frequency of use: = 1 events/day	TRA Consumer v3
Other conditions affecting consumers exposure	
• Body parts potentially exposed: Upper part of the body	TRA Consumer v3
• Dermal transfer factor: = 1	TRA Consumer v3

1.14.2.2 Exposure and risks for consumers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 141. Exposure concentrations and risks for consumers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**6.897 mg/m3** (TRA Consumer v3) **Additional data not used for RCR:** 0 mg/m3 (TRA Consumer v3) 0.065 mg/m3 (TRA Consumer v3)	RCR = 0.396
Inhalation, systemic, acute		Qualitative (see below)
Inhalation, local, long-term		Qualitative (see below)
Inhalation, local, acute		Qualitative (see below)
Dermal, systemic, long-term	**1.458 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0.557 mg/kg bw/day (TRA Consumer v3) 0.006 mg/kg bw/day (TRA Consumer v3)	RCR = 0.292
Dermal, systemic, acute		Qualitative (see below)
Dermal, local, long-term		Qualitative (see below)
Dermal, local, acute		Qualitative (see below)
Eye, local		Qualitative (see below)
Oral, systemic, long-term	**0 mg/kg bw/day** (TRA Consumer v3) **Additional data not used for RCR:** 0.01 mg/kg bw/day (TRA Consumer v3) 0.017 mg/kg bw/day (TRA Consumer v3)	RCR < 0.01
Combined routes, systemic, long-term		RCR = 0.688

Conclusion <u>on risk</u> characterisation

Concentration of sulfamic acid in final plastic article is less than 1% and thus the presence of the substance does not trigger any hazard classification.

Respecting the operational conditions, derived by quantitative and qualitative risk assessment, the use of sulphamidic acid in considered safe.