

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

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

1.1 Product identifier

Trade name : Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Skin corrosion, Sub-category 1B	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Respiratory sensitisation, Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H314 Causes severe skin burns and eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.
- Supplemental Hazard Statements : EUH071 Corrosive to the respiratory tract.
- Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:

sulfadiazine
Trimethoprim
Sodium hydroxide

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

	Index-No. Registration number		
sulfadiazine	68-35-9 200-685-8	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	20
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411	4
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318	3
2,2'-Iminodiethanol	111-42-2 203-868-0 603-071-00-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Repr. 2; H361 STOT RE 2; H373 (Kidney, Blood, Liver, Nervous sys- tem)	0,6

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0	Revision Date: 04.04.2023	SDS Number: 1737588-00020	Date of last issue: 01.10.2022 Date of first issue: 08.06.2017
----------------	------------------------------	------------------------------	---

- If breathing is difficult, give oxygen.
Get medical attention immediately.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention immediately.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes digestive tract burns.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Corrosive to the respiratory tract.
Causes severe burns.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides
Nitrogen oxides (NOx)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sulfadiazine	68-35-9	TWA	2 mg/m ³ (OEB 1)	Internal
Trimethoprim	738-70-5	TWA	400 µg/m ³ (OEB 2)	Internal
Sodium hydroxide	1310-73-2	OEL- RL STEL/C	4 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
2,2'-Iminodiethanol	111-42-2	OEL-RL (inhalable fraction and vapour)	2 mg/m ³	ZA OEL
Further information: danger of cutaneous absorption, Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents, denotes carcinogenicity, which is based on GHS categorisation, including category 1A, 1B				

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³
2,2'-Iminodiethanol	Workers	Inhalation	Long-term systemic effects	0,75 mg/m ³
	Workers	Inhalation	Long-term local effects	0,5 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0,13 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,125 mg/m ³
	Consumers	Inhalation	Long-term local effects	0,125 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	0,07 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,06 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
sulfadiazine	Water	0,01 mg/l
Trimethoprim	Water	0,9 mg/l
2,2'-Iminodiethanol	Fresh water	0,021 mg/l
	Freshwater - intermittent	0,095 mg/l
	Marine water	0,002 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0,096 mg/kg dry weight (d.w.)

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

	Marine sediment	0,009 mg/kg dry weight (d.w.)
	Soil	1,63 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	1,04 mg/kg food

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	off-white to beige
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	10,0 - 10,5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids)	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
---------------------	---	---

10.4 Conditions to avoid

Conditions to avoid	:	None known.
---------------------	---	-------------

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents Acids
--------------------	---	---------------------------

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

sulfadiazine:

Acute oral toxicity : LD50 (Mouse): 1.500 mg/kg

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg
Remarks: Based on data from similar materials

Acute toxicity (other routes of administration) : LD50 (Rat): 880 mg/kg
Application Route: Intravenous

LD50 (Mouse): 180 mg/kg
Application Route: Intravenous

Trimethoprim:

Acute oral toxicity : LD50 (Rat): 1.500 - 5.300 mg/kg

LD50 (Mouse): 1.910 - 7.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 400 - 500 mg/kg
Application Route: Intraperitoneal

LD50 (Dog): 90 mg/kg
Application Route: Intravenous

LD50 (Mouse): 132 mg/kg
Application Route: Intravenous

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

2,2'-Iminodiethanol:

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Acute oral toxicity : LD50 (Rat): 1.600 mg/kg
Acute inhalation toxicity : LC50 (Rat, male): > 3,35 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Skin corrosion/irritation

Causes severe burns.

Components:**sulfadiazine:**

Result : Skin irritation
Remarks : Based on data from similar materials

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

2,2'-Iminodiethanol:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:**sulfadiazine:**

Species : Rabbit
Result : Irritation to eyes, reversing within 7 days
Remarks : Based on data from similar materials

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

2,2'-Iminodiethanol:

Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Components:

sulfadiazine:

Test Type	: Maximisation Test
Species	: Guinea pig
Result	: Not a skin sensitizer.
Remarks	: Based on data from similar materials

Trimethoprim:

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

Sodium hydroxide:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Result	: negative

2,2'-Iminodiethanol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

sulfadiazine:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on data from similar materials
	: Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative Remarks: Based on data from similar materials

Trimethoprim:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	: Test Type: Chromosomal aberration Result: negative
	: Test Type: In vitro mammalian cell gene mutation test Result: negative

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Genotoxicity in vivo	: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative
	: Test Type: Micronucleus test Species: Rat Result: negative
	Test Type: Chromosomal aberration Species: Humans Result: negative

2,2'-Iminodiethanol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: In vitro mammalian cell gene mutation test Result: negative
	Test Type: Chromosome aberration test in vitro Result: negative
	Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Skin contact Result: negative

Carcinogenicity

Not classified based on available information.

Components:

2,2'-Iminodiethanol:

Species	: Mouse
Application Route	: Skin contact
Exposure time	: 103 weeks
Result	: positive
Remarks	: The mechanism or mode of action may not be relevant in humans.

Species	: Rat
Application Route	: Skin contact
Exposure time	: 103 weeks
Result	: negative

Carcinogenicity - Assessment	: Weight of evidence does not support classification as a carcinogen
------------------------------	--

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version
7.0

Revision Date:
04.04.2023

SDS Number:
1737588-00020

Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

II

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

sulfadiazine:

Effects on foetal development : Test Type: Development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: NOAEL: 1.000 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Trimethoprim:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 70 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Effects on newborn
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Embryotoxic effects.
Remarks: Maternal toxicity observed.

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 15 mg/kg body weight
Result: Embryotoxic effects., Teratogenic effects

Test Type: Development
Species: Hamster
Application Route: Oral
Developmental Toxicity: LOAEL: 1,7 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects., No teratogenic effects

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

2,2'-Iminodiethanol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: positive

Effects on foetal development : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

STOT - single exposure

May cause respiratory irritation.
Corrosive to the respiratory tract.

Components:

sulfadiazine:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Trimethoprim:

Target Organs : Bone marrow
Assessment : Causes damage to organs through prolonged or repeated exposure.

2,2'-Iminodiethanol:

Exposure routes : Ingestion
Target Organs : Kidney, Blood, Liver, Nervous system
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Kidney, Blood
Assessment : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

Exposure routes : Skin contact
Target Organs : Blood, Liver, Kidney
Assessment : Shown to produce significant health effects in animals at concentrations of >20 to 200 mg/kg bw.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Repeated dose toxicity**Components:****Trimethoprim:**

Species : Rat
NOAEL : 100 mg/kg
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Bone marrow, Liver, Pituitary gland, Thyroid

Species : Rat
LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Bone marrow

Species : Dog
NOAEL : 2,5 mg/kg
LOAEL : 45 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Blood, Thyroid

2,2'-Iminodiethanol:

Species : Rat, female
LOAEL : 14 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Species : Rat
NOAEL : 0,015 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 90 Days
Method : OECD Test Guideline 413

Species : Rat
LOAEL : 32 mg/kg
Application Route : Skin contact
Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****sulfadiazine:**

General Information : May cause eye, skin, and respiratory tract irritation.

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

Trimethoprim:

Ingestion : Target Organs: Bone marrow
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

SECTION 12: Ecological information

12.1 Toxicity

Components:

sulfadiazine:

Toxicity to fish	: LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Anabaena flos-aquae): 17 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Anabaena flos-aquae): 3,9 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l Exposure time: 7 Days Method: ISO 8692
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1737588-00020 Date of last issue: 01.10.2022
Date of first issue: 08.06.2017

		Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 6,2 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1
Trimethoprim:		
Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna Straus): 92 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (microalgae)): 80,3 mg/l Exposure time: 72 h
		NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l Exposure time: 72 h
		EC50 (Anabaena flos-aquae): 253 mg/l Exposure time: 72 h
		EC10 (Anabaena flos-aquae): 26 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC10 : 16,7 mg/l Exposure time: 3 hrs Test Type: Respiration inhibition Method: OECD Test Guideline 209
		EC50 : > 1.000 mg/l Exposure time: 3 hrs Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,157 mg/l Exposure time: 21 d Species: Zebrafish
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 6 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
2,2'-Iminodiethanol:		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l Exposure time: 96 h

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 30,1 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 9,5 mg/l Exposure time: 72 h
		EC10 (Pseudokirchneriella subcapitata (green algae)): 1,1 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC10 (activated sludge): > 1.000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10: 1,05 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

12.2 Persistence and degradability

Components:

sulfadiazine:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 314
------------------	---	---

Trimethoprim:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 4 % Exposure time: 28 d Method: OECD Test Guideline 301D
		Result: Not inherently biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 302B

2,2'-Iminodiethanol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 93 % Exposure time: 28 d Method: OECD Test Guideline 301F
------------------	---	---

12.3 Bioaccumulative potential

Components:

sulfadiazine:

Partition coefficient: n-	:	log Pow: 0,12
---------------------------	---	---------------

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

|| octanol/water

Trimethoprim:

|| Partition coefficient: n-
|| octanol/water : log Pow: 0,91

2,2'-Iminodiethanol:

|| Partition coefficient: n-
|| octanol/water : log Pow: -2,46
Method: OECD Test Guideline 107

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

|| Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

|| Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : UN 1824
ADR : UN 1824
RID : UN 1824

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0	Revision Date: 04.04.2023	SDS Number: 1737588-00020	Date of last issue: 01.10.2022 Date of first issue: 08.06.2017
----------------	------------------------------	------------------------------	---

IMDG : UN 1824

IATA : UN 1824

14.2 UN proper shipping name

ADN : SODIUM HYDROXIDE SOLUTION

ADR : SODIUM HYDROXIDE SOLUTION

RID : SODIUM HYDROXIDE SOLUTION

IMDG : SODIUM HYDROXIDE SOLUTION
II (sulfadiazine, Trimethoprim)

IATA : Sodium hydroxide solution

14.3 Transport hazard class(es)

ADN : 8

ADR : 8

RID : 8

IMDG : 8

IATA : 8

14.4 Packing group

ADN

Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8

ADR

Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8
Tunnel restriction code : (E)

RID

Packing group : II
Classification Code : C5
Hazard Identification Number : 80
Labels : 8

IMDG

Packing group : II
Labels : 8
EmS Code : F-A, S-B

IATA (Cargo)

Packing instruction (cargo aircraft) : 855
Packing instruction (LQ) : Y840
Packing group : II
Labels : Corrosive

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

IATA (Passenger)

Packing instruction (passenger aircraft)	:	851
Packing instruction (LQ)	:	Y840
Packing group	:	II
Labels	:	Corrosive

14.5 Environmental hazards

ADN

Environmentally hazardous	:	yes
---------------------------	---	-----

ADR

Environmentally hazardous	:	yes
---------------------------	---	-----

RID

Environmentally hazardous	:	yes
---------------------------	---	-----

IMDG

Marine pollutant	:	yes
------------------	---	-----

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks	:	Not applicable for product as supplied.
---------	---	---

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

AICS	:	not determined
------	---	----------------

DSL	:	not determined
-----	---	----------------

IECSC	:	not determined
-------	---	----------------

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
-------------------	---	--

Full text of H-Statements

H290	:	May be corrosive to metals.
------	---	-----------------------------

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version 7.0	Revision Date: 04.04.2023	SDS Number: 1737588-00020	Date of last issue: 01.10.2022 Date of first issue: 08.06.2017
----------------	------------------------------	------------------------------	---

H302	: Harmful if swallowed.
H314	: Causes severe skin burns and eye damage.
H315	: Causes skin irritation.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H334	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	: May cause respiratory irritation.
H361	: Suspected of damaging fertility or the unborn child.
H361d	: Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.
H373	: May cause damage to organs through prolonged or repeated exposure.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H411	: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Met. Corr.	: Corrosive to metals
Repr.	: Reproductive toxicity
Resp. Sens.	: Respiratory sensitisation
Skin Corr.	: Skin corrosion
Skin Irrit.	: Skin irritation
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure
ZA OEL	: South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	: Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)
ZA OEL / OEL- RL STEL/C	: Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization;

Sulfadiazine (20%) / Trimethoprim (4%) Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01.10.2022
7.0	04.04.2023	1737588-00020	Date of first issue: 08.06.2017

KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Skin Corr. 1B	H314
Eye Dam. 1	H318
Resp. Sens. 1	H334
Repr. 2	H361d
STOT SE 3	H335
STOT RE 2	H373
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

ZA / EN