according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

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

1.1 Product identifier

Trade name : Sulfadoxine / Trimethoprim Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions :

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

Serious eye damage, Category 1 H318: Causes serious eye damage.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child. Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-H411: Toxic to aquatic life with long lasting effects.

egory 2

#### 2.2 Label elements

## Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

Hazard statements : H318 Causes serious eve damage.

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.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

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.

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7 225-248-9	Eye Irrit. 2; H319	>= 30 - < 50

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

1,3-Dioxolan-4-ylmethanol	5464-28-8 226-758-4	Eye Irrit. 2; H319	>= 30 - < 50
Sulfadoxine	2447-57-6 219-504-9	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	>= 10 - < 20
		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411	>= 3 - < 10
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH014, EUH071	>= 2 - < 3
		specific concentration limit Skin Corr. 1A; H314 >= 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0,5 - < 2 % Eye Irrit. 2; H319 0,5 - < 2 % EUH071 >= 2 %	

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 ad-

vice immediately.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 1686809-00023 Date of first issue: 17.05.2017 4.5

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.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

Remove contaminated clothing and shoes.

Get medical attention. 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.

Get medical attention.

Rinse mouth thoroughly with water.

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

Causes serious eye damage. Risks

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

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

: Treat symptomatically and supportively. Treatment

# **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.

### 5.2 Special hazards arising from the substance or mixture

fighting

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

## **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 : Use only with adequate ventilation. Advice on safe handling : Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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 contami-

nated 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. 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

## **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components CAS-No. Value type (Form Control parameters of exposure)	Basis
---	-------

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Sulfadoxine	2447-57-6	TWA	30 μg/m3 (OEB 3)	Internal
		Wipe limit	300 μg/100 cm <sup>2</sup>	Internal
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	Т	2 mg/m3	FOR-2011-
				12-06-1358

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

Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Sodium hydroxide	Consumers	Inhalation	Long-term local ef- fects	1 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1 mg/m3

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

Substance name	Environmental Compartment	Value
Sulfadoxine	Water	0,0006 mg/l
Trimethoprim	Water	0,9 mg/l

#### 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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### 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

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Filter type : Particulates type (P)

## **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : light brown, yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : Not applicable

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 9,3 - 10,0

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Vapour pressure : No data available

Relative density : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Density : 1,210 - 1,250 g/cm<sup>3</sup>

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

# **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation exposure Skin contact

Ingestion

Eye contact

#### Acute toxicity

Not classified based on available information.

### **Product:**

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

**Components:** 

1,3-Dioxan-5-ol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Remarks: Based on data from similar materials

Sulfadoxine:

Acute oral toxicity : LD50 (Mouse): 5.200 mg/kg

**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.

Skin corrosion/irritation

Not classified based on available information.

**Product:** 

Result : No skin irritation

Components:

1,3-Dioxan-5-ol:

Species : Rabbit

Method : OECD Test Guideline 404

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

Result : No skin irritation

Remarks : Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Sulfadoxine:

Species : Rabbit

Method : OECD Test Guideline 404

Result : irritating

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

## Serious eye damage/eye irritation

Causes serious eye damage.

#### **Components:**

#### 1,3-Dioxan-5-ol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials

Sulfadoxine:

Result : irritating

Sodium hydroxide:

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

### Respiratory or skin sensitisation

### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

Not classified based on available information.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

**Components:** 

1,3-Dioxan-5-ol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

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

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

1,3-Dioxan-5-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Result: negative

Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Result: negative

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

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

Test Type: Chromosomal aberration

Species: Humans Result: negative

#### Carcinogenicity

Not classified based on available information.

## Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

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 develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 70 mg/kg body weight

Result: Effects on newborn

Remarks: Maternal toxicity observed.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

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

Reproductive toxicity - As-

sessment

Suspected of damaging the unborn child.

## STOT - single exposure

Not classified based on available information.

### **Components:**

### Sulfadoxine:

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.

#### Repeated dose toxicity

### **Components:**

Trimethoprim:

Species : Rat

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

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

### **Aspiration toxicity**

Not classified based on available information.

#### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

#### Experience with human exposure

#### **Components:**

#### Sulfadoxine:

Ingestion : Target Organs: Blood

Symptoms: The most common side effects are:, Nausea, Vomiting, Headache, anemia, Rash, Stevens-Johnson syn-

drome

Trimethoprim:

Ingestion : Target Organs: Bone marrow

Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

## **SECTION 12: Ecological information**

## 12.1 Toxicity

#### Components:

1,3-Dioxan-5-ol:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 : > 1.000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

1,3-Dioxolan-4-ylmethanol:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 : > 1.000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Remarks: Based on data from similar materials

Sulfadoxine:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 17 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Anabaena flos-aquae (cyanobacterium)): 3,9 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,13

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC50 (Microcystis aeruginosa (blue-green algae)): 0,135 mg/l

Exposure time: 7 d Method: ISO 8692

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

icity)

1

Toxicity to microorganisms : EC50 : > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

NOEC: 1.000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

Toxicity to daphnia and other : NOEC: 6,2 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

aquatic invertebrates (Chron-

ic toxicity)

Exposure time: 21 d

Species: Daphnia magna (Water flea)

Remarks: Based on data from similar materials

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 tox-

icity)

NOEC: 0,157 mg/l Exposure time: 21 d

Species: Zebrafish

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 6 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea)

#### 12.2 Persistence and degradability

#### **Components:**

1,3-Dioxan-5-ol:

Biodegradability : Result: Inherently biodegradable.

Remarks: Based on data from similar materials

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

1,3-Dioxolan-4-ylmethanol:

Biodegradability : Result: Inherently biodegradable.

Remarks: Based on data from similar materials

Sulfadoxine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 5 % Exposure time: 28 d

Remarks: Based on data from similar materials

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

#### 12.3 Bioaccumulative potential

#### **Components:**

1,3-Dioxan-5-ol:

Partition coefficient: n-

octanol/water

log Pow: -0,65

**Trimethoprim:** 

Partition coefficient: n-

octanol/water

log Pow: 0,91

## 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 Endocrine disrupting properties

## **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

### **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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

#### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Sulfadoxine, Trimethoprim)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Sulfadoxine, Trimethoprim)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Sulfadoxine, Trimethoprim)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Sulfadoxine, Trimethoprim)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(Sulfadoxine, Trimethoprim)

#### 14.3 Transport hazard class(es)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

# 14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Environmentally hazardous yes

**IMDG** 

Marine pollutant yes

IATA (Passenger)

Environmentally hazardous ves

IATA (Cargo)

Environmentally hazardous 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 Maritime transport in bulk according to IMO instruments

: Not applicable for product as supplied. Remarks

## **SECTION 15: Regulatory information**

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances. mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

Regulation (EU) 2019/1021 on persistent organic pollu-Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

Not applicable

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2 500 t E2 ENVIRONMENTAL 200 t

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Sulfadoxine / Trimethoprim Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

#### **HAZARDS**

## Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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.

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.
H335 : May cause respiratory irritation.

H361d : Suspected of damaging the unborn child.

H372 : Causes 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.

EUH014 : Reacts violently with water. EUH071 : Corrosive to the respiratory tract.

# 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

Skin Corr. : Skin corrosion

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.5 28.09.2024 1686809-00023 Date of first issue: 17.05.2017

Skin Irrit. Skin irritation

STOT RE Specific target organ toxicity - repeated exposure STOT SE Specific target organ toxicity - single exposure

Norway. Occupational Exposure limits FOR-2011-12-06-1358

FOR-2011-12-06-1358 / T Ceiling

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; 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; TECI -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**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture:

#### Classification procedure:

Eye Dam. 1 H318 Calculation method Repr. 2 H361d Calculation method STOT RE 2 H373 Calculation method Aquatic Chronic 2 H411 Calculation method

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Sulfadoxine / Trimethoprim Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.5
 28.09.2024
 1686809-00023
 Date of first issue: 17.05.2017

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.

NO / EN