According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Sulfamethoxazole / Trimethoprim Injection 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

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin corrosion, Sub-category 1B H314: Causes severe skin burns and eye damage.

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 - single ex- H335: May cause respiratory irritation.

posure, Category 3

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate- H400: Very toxic to aquatic life.

gory 1

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1 effects.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :









Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very 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

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.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Ethanolamine

Trimethoprim

#### 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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Sulfamethoxazole / Trimethoprim Injection Formulation**

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

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	>= 70 - < 90
Sulfamethoxazole	723-46-6 211-963-3	Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 10 - < 20
Ethanolamine	141-43-5 205-483-3 603-030-00-8	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 Aquatic Chronic 3; H412 specific concentration limit STOT SE 3; H335 >= 5 %	>= 5 - < 10
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

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.

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).

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. 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, 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 serious eye damage.

May cause respiratory irritation.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Causes severe burns.

Causes digestive tract 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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

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 prod: :

ucts

Nitrogen oxides (NOx)

Sulphur oxides Carbon 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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

#### 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 as-

sessment

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 respira-

tory 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 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. 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)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Sulfamethoxazole / Trimethoprim Injection Formulation**

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

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 of exposure)	Control parameters	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000 µg/m3)	Internal
Ethanolamine	141-43-5	TWA	1 ppm 2.5 mg/m3	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	3 ppm 7.6 mg/m3	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		TWA	1 ppm 2.5 mg/m3	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
		STEL	3 ppm 7.6 mg/m3	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			ficant uptake
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal

## **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanolamine	Workers	Inhalation	Long-term local ef- fects	3.3 mg/m3
	Workers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Inhalation	Long-term local ef- fects	2 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.24 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	3.75 mg/kg bw/day

## **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Trimethoprim	Water	0.9 mg/l

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

Ethanolamine	Fresh water	0.085 mg/l
	Freshwater - intermittent	0.028 mg/l
	Marine water	0.0085 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.434 mg/kg dry weight (d.w.)
	Marine sediment	0.0434 mg/kg dry weight (d.w.)
	Soil	0.0367 mg/kg dry weight (d.w.)

### 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

Filter type

Material : Chemical-resistant gloves

Skin and body protection

: Work uniform or laboratory coat.

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 BS EN 14387

: Combined particulates and organic vapour type (A-P)

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

# 9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : light yellow
Odour : No data available
Odour Threshold : No data available

pH : 9.5 - 10.5

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

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 : 1.050 - 1.230 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

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

Molecular weight : No data available

Particle size : Not applicable

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

### 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 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

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal 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

Sulfamethoxazole:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

Acute oral toxicity : LD50 (Mouse): 2,300 mg/kg

**Ethanolamine:** 

Acute oral toxicity : LD50 (Rat): 1,089 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 11 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute dermal toxicity : LD50 (Rabbit, female): 1,018 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

### Skin corrosion/irritation

Causes severe burns.

### **Components:**

1,3-Dioxan-5-ol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Sulfamethoxazole:

Species : Rabbit

Result : No skin irritation

**Ethanolamine:** 

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

## Serious eye damage/eye irritation

Causes serious eye damage.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

### **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

**Ethanolamine:** 

Species : Rabbit

Result : Irreversible effects on the eye

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

### **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

#### Sulfamethoxazole:

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

### **Ethanolamine:**

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

### **Trimethoprim:**

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

### 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

Sulfamethoxazole:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Humans Result: negative

Ethanolamine:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Trimethoprim:

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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

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.

### Components:

### Sulfamethoxazole:

Species : Mouse
Application Route : Ingestion
Exposure time : 26 weeks
Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

#### Components:

#### **Ethanolamine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

#### **Trimethoprim:**

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

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.

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

May cause respiratory irritation.

#### Components:

### **Ethanolamine:**

Assessment : May cause respiratory irritation.

## STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

**Components:** 

**Ethanolamine:** 

Assessment : No significant health effects observed in animals at concentra-

tions of 0.2 mg/l/6h/d or less.

Trimethoprim:

Target Organs : Bone marrow

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Ethanolamine:

Species : Rat

NOAEL : > 120 mg/kg
Application Route : Ingestion
Exposure time : > 75 Days

Remarks : Based on data from similar materials

Species : Rat

NOAEL : >= 0.15 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

**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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

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:

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

Sulfamethoxazole:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0268 mg/l

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

Exposure time: 96 h

NOEC (Synechococcus leopoliensis (blue-green algae)):

0.0059 mg/l

Exposure time: 96 h

M-Factor (Acute aquatic tox-

icity)

10

Toxicity to microorganisms : NOEC (activated sludge): 3.76 mg/l

Method: OECD Test Guideline 301D

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.533 mg/l Exposure time: 21 d

Species: Danio rerio (zebra fish)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.01 mg/l Exposure time: 30 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

10

**Ethanolamine:** 

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 65 mg/l

Exposure time: 48 h

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 2.8

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1,000 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 1.24 mg/l Exposure time: 41 d

Species: Oryzias latipes (Orange-red killifish)

Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chron-

NOEC: 0.85 mg/l Exposure time: 21 d

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

ic toxicity) Species: Daphnia magna (Water flea)

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/I

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

### Sulfamethoxazole:

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 301D

**Ethanolamine:** 

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 21 d

Method: OECD Test Guideline 301A

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

Sulfamethoxazole:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): < 120

Partition coefficient: n-

octanol/water

log Pow: 0.89

**Ethanolamine:** 

Partition coefficient: n-

: log Pow: -2.3

octanol/water

Method: OECD Test Guideline 107

Trimethoprim:

Partition coefficient: n-

octanol/water

log Pow: 0.91

12.4 Mobility in soil

No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

### 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 poten-

tial

This substance/mixture does not contain components consid-

ered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

## **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

ADN : UN 2491
ADR : UN 2491
RID : UN 2491
IMDG : UN 2491
IATA : UN 2491

### 14.2 UN proper shipping name

ADN : ETHANOLAMINE, SOLUTION
ADR : ETHANOLAMINE, SOLUTION
RID : ETHANOLAMINE, SOLUTION
IMDG : ETHANOLAMINE SOLUTION

(Sulfamethoxazole)

IATA : Ethanolamine solution

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

### 14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 8

ADR : 8

8

RID : 8
IMDG : 8

### 14.4 Packing group

ADN

IATA

Packing group : III
Classification Code : C7
Hazard Identification Number : 80
Labels : 8

**ADR** 

Packing group : III
Classification Code : C7
Hazard Identification Number : 80
Labels : 8
Tunnel restriction code : (E)

**RID** 

Packing group : III
Classification Code : C7
Hazard Identification Number : 80
Labels : 8

**IMDG** 

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

IATA (Cargo)

Packing instruction (cargo : 856

aircraft)

Packing instruction (LQ) : Y841
Packing group : III

Labels : Corrosive

IATA (Passenger)

Packing instruction (passen- : 852

ger aircraft)

Packing instruction (LQ) : Y841
Packing group : III
Labels : Corrosive

### 14.5 Environmental hazards

**ADN** 

Environmentally hazardous : yes

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection **Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 06.04.2024 28.09.2024 9374600-00010 Date of first issue: 27.08.2021 4.4

ADR

Environmentally hazardous yes

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) Conditions of restriction for the fol-

lowing 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

UK REACH Candidate list of substances of very high Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Not applicable Regulation (EU) 2019/1021 as amended for Great Brit-

Regulation (EC) on substances that deplete the ozone

layer

UK REACH List of substances subject to authorisation Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2 E1

**ENVIRONMENTAL** 100 t 200 t

**HAZARDS** 

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.4 28.09.2024 9374600-00010 Date of first issue: 27.08.2021

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

DSL : not determined

AICS : 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**

H302 : Harmful if swallowed.

H312 : Harmful in contact with skin.

H314 : Causes severe skin burns and eye damage.

H318 : Causes serious eye damage. H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

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.
 H412 : Harmful 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

Eve Dam. : Serious eve damage

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity Skin Corr. : Skin corrosion

STOT RE : Specific target organ toxicity - repeated exposure

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

 4.4
 28.09.2024
 9374600-00010
 Date of first issue: 27.08.2021

STOT SE : Specific target organ toxicity - single exposure 2006/15/EC : Europe. Indicative occupational exposure limit values GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

2006/15/EC / TWA : Limit Value - eight hours 2006/15/EC / STEL : Short term exposure limit

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

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**

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 Agen-

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

## Classification of the mixture:

## Classification procedure:

Skin Corr. 1B H314 Calculation method Eye Dam. 1 H318 Calculation method Repr. 2 H361d Calculation method

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version 4.4	Revision Date: 28.09.2024	SDS Number: 9374600-00010	Date of last issue: 06.04.2024 Date of first issue: 27.08.2021	
STOT	SE 3	H335	Calculation method	
STOT	RE 2	H373	Calculation method	
Aquat	ic Acute 1	H400	Calculation method	
Aquat	ic Chronic 1	H410	Calculation method	

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.

GB / EN