according to the Hazardous Products Regulations



# Sulfamethoxazole / Trimethoprim Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 04/04/2023 3.0 09/30/2023 7848282-00009 Date of first issue: 03/03/2021

### **SECTION 1. IDENTIFICATION**

Product name : Sulfamethoxazole / Trimethoprim Injection Formulation

Other means of identification : No data available

## Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### **SECTION 2. HAZARDS IDENTIFICATION**

### GHS classification in accordance with the Hazardous Products Regulations

Skin corrosion : Category 1

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity : Cate

- single exposure

Category 3

Specific target organ toxicity

- repeated exposure

Category 1 (Bone marrow)

#### **GHS** label elements

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.

H372 Causes damage to organs (Bone marrow) through pro-

longed or repeated exposure.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

according to the Hazardous Products Regulations



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P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P301 + P330 + P331 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER. P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a POISON CENTER.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER.

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.

P308 + P313 IF exposed or concerned: Get medical attention. P363 Wash contaminated clothing before reuse.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	No data availa- ble	4740-78-7	>= 65.0407 - <= 76.1905
Sulfamethoxazole	No data availa- ble	723-46-6	>= 16.2602 - <= 19.0476
Ethanolamine	2-Aminoethanol	141-43-5	>= 6.5041 - <= 7.619
Trimethoprim	2,4- Pyrimidinedia- mine, 5-[(3,4,5- trimethoxy- phenyl)methyl]-	738-70-5	>= 3.252 - <= 3.8095

according to the Hazardous Products Regulations



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**SECTION 4. 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.

If inhaled, remove to fresh air. If inhaled

> 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 contact, immediately flush eyes with plenty of water In case of eye contact

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 center immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delayed

If swallowed

Causes serious eye damage. May cause respiratory irritation.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Causes severe burns.

Causes digestive tract burns.

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).

Treat symptomatically and supportively. Notes to physician

**SECTION 5. FIRE-FIGHTING MEASURES** 

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fiahtina

ucts

Hazardous combustion prod-

Exposure to combustion products may be a hazard to health.

Nitrogen oxides (NOx)

Sulfur oxides Carbon oxides

according to the Hazardous Products Regulations



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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

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- : tive equipment and emer-

gency procedures

Use personal protective equipment.

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

**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.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked 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.

#### **SECTION 7. HANDLING AND STORAGE**

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 vapors.

Do not swallow. Do not get in eves.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety

practice, based on the results of the workplace exposure

assessment

according to the Hazardous Products Regulations



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Keep container tightly closed.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sulfamethoxazole	723-46-6	TWA	OEB 2 (>= 100 < 1000 μg/m3)	Internal
Ethanolamine	141-43-5	TWA	3 ppm 7.5 mg/m <sup>3</sup>	CA AB OEL
		STEL	6 ppm 15 mg/m³	CA AB OEL
		TWA	3 ppm	CA BC OEL
		STEL	6 ppm	CA BC OEL
		TWAEV	3 ppm 7.5 mg/m <sup>3</sup>	CA QC OEL
		STEV	6 ppm 15 mg/m³	CA QC OEL
		TWA	3 ppm	ACGIH
		STEL	6 ppm	ACGIH
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal

**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.

according to the Hazardous Products Regulations



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Personal protective equipment

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type and protection : Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

Eye 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.

Skin and body protection

Hygiene measures

: Work uniform or laboratory coat.

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : light yellow

Odor : No data available

Odor 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

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available

according to the Hazardous Products Regulations



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flammability limit

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor 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-

octanol/water

Not applicable

Autoignition 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.

Molecular weight : No data available

Particle size : Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Acids

Hazardous decomposition

products

: No hazardous decomposition products are known.

according to the Hazardous Products Regulations



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### **SECTION 11. TOXICOLOGICAL INFORMATION**

### 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: vapor
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:

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: vapor
Method: Expert judgment

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

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

administration)

LD50 (Rat): 400 - 500 mg/kg Application Route: Intraperitoneal

Application Route. Intrapentoriea

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.

### **Components:**

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

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

### **Ethanolamine:**

Species : Rabbit

Result : Irreversible effects on the eye

### Respiratory or skin sensitization

### Skin sensitization

Not classified based on available information.

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### Respiratory sensitization

Not classified based on available information.

### Components:

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

Test Type : Maximization Test
Routes of exposure : 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

Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

**Ethanolamine:** 

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Trimethoprim:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

### 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:

according to the Hazardous Products Regulations



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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)

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

according to the Hazardous Products Regulations



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### Carcinogenicity

Not classified based on available information.

### **Components:**

### Sulfamethoxazole:

Species: MouseApplication Route: IngestionExposure time: 26 weeksResult: 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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

### 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 fetal 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

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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

Causes damage to organs (Bone marrow) through prolonged or repeated exposure.

#### 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

according to the Hazardous Products Regulations



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**Species** Rat

NOAEL >= 0.15 mg/l

Application Route
Exposure time : inhalation (dust/mist/fume)

: 28 Days

: OECD Test Guideline 412 Method

Trimethoprim:

Species Rat NOAEL 100 mg/kg LOAEL 300 mg/kg Application Route : Oral Exposure time : 6 Months

: Bone marrow, Liver, Pituitary gland, Thyroid Target Organs

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

Species Dog NOAEL LOAEL Application Route 2.5 mg/kg 45 mg/kg Oral Exposure time 3 Months Target Organs Blood, Thyroid

## **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**

### **Ecotoxicity**

## **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

according to the Hazardous Products Regulations



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aquatic invertebrates

Toxicity to daphnia and other : 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

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

aquatic invertebrates

Toxicity to daphnia and other : 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 ma/l

Exposure time: 96 h

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

0.0059 mg/l

Exposure time: 96 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Danio rerio (zebra fish)): 0.533 mg/l

Exposure time: 21 d

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.01 mg/l

Exposure time: 30 d

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

Method: OECD Test Guideline 301D

**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.

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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 fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Orange-red killifish)): 1.24 mg/l

Exposure time: 41 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.85 mg/l

Exposure time: 21 d

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

Exposure time: 30 min

Method: OECD Test Guideline 209

Trimethoprim:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna Straus (Water flea)): 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

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 fish (Chronic tox-

NOEC (Zebrafish): 0.157 mg/l

Exposure time: 21 d

Toxicity to daphnia and other: aguatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 6 mg/l

Exposure time: 21 d

Toxicity to microorganisms EC10: 16.7 mg/l

Exposure time: 3 hrs

Test Type: Respiration inhibition Method: OECD Test Guideline 209

according to the Hazardous Products Regulations



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EC50: > 1,000 mg/l Exposure time: 3 hrs

Test Type: Respiration inhibition Method: OECD Test Guideline 209

### Persistence and degradability

### **Components:**

1,3-Dioxan-5-ol:

Biodegradability : Result: Inherently biodegradable.

Remarks: Based on data from similar materials

Sulfamethoxazole:

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

### **Bioaccumulative potential**

### **Components:**

1,3-Dioxan-5-ol:

Partition coefficient: n- : log Pow: -0.65

octanol/water

Sulfamethoxazole:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): < 120

Partition coefficient: n- : log Pow: 0.89

according to the Hazardous Products Regulations



## Sulfamethoxazole / Trimethoprim Injection **Formulation**

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octanol/water

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

Mobility in soil

No data available

Other adverse effects

No data available

### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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**

## **International Regulations**

**UNRTDG** 

UN number UN 2491

Proper shipping name ETHANOLAMINE SOLUTION

Class 8 Ш Packing group Labels 8 Environmentally hazardous

**IATA-DGR** 

UN/ID No. UN 2491

Proper shipping name Ethanolamine solution

Class 8 Ш Packing group Corrosive Labels

Packing instruction (cargo

aircraft)

852

Packing instruction (passen-

ger aircraft)

**IMDG-Code** 

**UN** number UN 2491

Proper shipping name ETHANOLAMINE SOLUTION

856

(Sulfamethoxazole)

Class

according to the Hazardous Products Regulations



# Sulfamethoxazole / Trimethoprim Injection Formulation

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

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### **Domestic regulation**

**TDG** 

UN number : UN 2491

Proper shipping name : ETHANOLAMINE SOLUTION

Class : 8
Packing group : III
Labels : 8
ERG Code : 153

Marine pollutant : yes(Sulfamethoxazole)

### 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.

### **SECTION 15. REGULATORY INFORMATION**

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

DSL : not determined

AICS : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

## Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

CA AB OEL / TWA : 8-hour Occupational exposure limit
CA AB OEL / STEL : 15-minute occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average CA BC OEL / STEL : short-term exposure limit

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CA QC OEL / TWAEV : Time-weighted average exposure value

CA QC OEL / STEV : Short-term exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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: SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material 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/

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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

according to the Hazardous Products Regulations



# **Sulfamethoxazole / Trimethoprim Injection Formulation**

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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.

CA / Z8