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## Sulfamethoxazole / Trimethoprim Injection **Formulation**

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#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name Sulfamethoxazole / Trimethoprim Injection Formulation

Manufacturer or supplier's details

MSD Company

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

EHSDATASTEWARD@msd.com E-mail address

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

### 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Acute toxicity (Oral) Category 5

Skin corrosion/irritation Sub-category 1B

Serious eye damage/eye irri-

tation

Category 1

Reproductive toxicity Category 2

Specific target organ toxicity - :

single exposure

Category 3

Specific target organ toxicity - :

repeated exposure

Category 2 (Bone marrow)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic Category 1

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hazard

#### **GHS** label elements

Hazard pictograms









Signal word Danger

Hazard statements H303 May be harmful if swallowed.

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 (Bone marrow) through

prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements Prevention:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe mist or vapours.

P264 Wash hands thoroughly after handling.

P271 Use only outdoors or with adequate ventilation.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P330 + P331 + P316 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get emergency medical help imme-

P302 + P361 + P354 + P316 IF ON SKIN: Take off immediately all contaminated clothing. Immediately rinse with water for several minutes. Get emergency medical help immediately.

P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical help immediately.

P305 + P354 + P338 + P316 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get emergency medical help immediately.

P318 IF exposed or concerned, get medical advice. P363 Wash contaminated clothing before reuse.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

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

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#### Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,3-Dioxan-5-ol	4740-78-7	>= 70 - < 90
Sulfamethoxazole	723-46-6	>= 10 - < 20
Ethanolamine	141-43-5	>= 5 - < 10
Trimethoprim	738-70-5	>= 3 - < 5

#### 4. 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.

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.

Most important symptoms and effects, both acute and

delayed

May be harmful if swallowed.

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.

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).

Notes to physician : Treat symptomatically and supportively.

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#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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

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.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 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.

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Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 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 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.

Conditions for safe storage : 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.

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

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Explosives

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components 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	ACGIH
		STEL	6 ppm	ACGIH
Trimethoprim	738-70-5	TWA	400 μg/m3 (OEB 2)	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing

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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

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter 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.

Work uniform or laboratory coat. Skin and body protection

Hygiene measures If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures. industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance liquid

Colour light yellow

Odour No data available

Odour Threshold No data available

pН 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

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No data available Evaporation rate

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

Vapour pressure No data available

Relative vapour density No data available

Relative density No data available

1.050 - 1.230 g/cm3 Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

No data available Decomposition temperature

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 characteristics

Particle size Not applicable

#### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known.

Incompatible materials Oxidizing agents Acids

Hazardous decomposition No hazardous decomposition products are known.

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products

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

May be harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 4,368 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 40 mg/l

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

Acute dermal toxicity : Acute toxicity estimate: > 5,000 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: 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

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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.

#### **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.

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#### 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.

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

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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

#### Carcinogenicity

Not classified based on available information.

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#### **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 foetal develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

men

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

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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 (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

Species : Rat

NOAEL : >= 0.15 mg/l

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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

#### **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

#### 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

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

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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

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.

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aquatic invertebrates

Toxicity to daphnia and other : 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

Exposure time: 72 h

Method: OECD Test Guideline 201

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

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-

ic toxicity)

NOEC: 0.85 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

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): 92 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3

ma/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 microorganisms EC10: 16.7 mg/l

Exposure time: 3 hrs

Test Type: Respiration inhibition

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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)

### 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

according to the Globally Harmonized System



# Sulfamethoxazole / Trimethoprim Injection Formulation

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#### 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-

octanol/water

: log Pow: -2.3

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

### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

#### **International Regulations**

**UNRTDG** 

UN number : UN 2491

Proper shipping name : ETHANOLAMINE SOLUTION

Class : 8
Packing group : III
Labels : 8
Environmentally hazardous : no

according to the Globally Harmonized System



## Sulfamethoxazole / Trimethoprim Injection **Formulation**

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**IATA-DGR** 

UN/ID No. UN 2491

Proper shipping name Ethanolamine solution

Class 8 Packing group Ш

Labels Corrosive 856

Packing instruction (cargo

aircraft)

Packing instruction (passen-852

ger aircraft)

**IMDG-Code** 

**UN** number UN 2491

Proper shipping name ETHANOLAMINE SOLUTION

(Sulfamethoxazole)

Class 8 Ш Packing group Labels 8 EmS Code

F-A, S-B Marine pollutant yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### 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.

#### 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-

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

**DSL** not determined

**AICS** not determined

**IECSC** not determined

#### 16. OTHER INFORMATION

**Revision Date** 28.09.2024

**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/

according to the Globally Harmonized System



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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.

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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

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.

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