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

1.1 Product identifier

Trade name : Sulfadiazine / Trimethoprim Solid 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)

H315: Causes skin irritation. Skin irritation, Category 2

Eye irritation, Category 2 H319: Causes serious eye irritation.

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

H335: May cause respiratory irritation. Specific target organ toxicity - single ex-

posure, Category 3 Specific target organ toxicity - repeated

exposure, Category 2

Short-term (acute) aguatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-

egory 1

H373: May cause damage to organs through pro-

longed or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting

effects.

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#### 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 : H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

H335 May cause respiratory irritation.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh

air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P391 Collect spillage.

Hazardous components which must be listed on the label:

sulfadiazine

Trimethoprim

#### 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.

May form explosive dust-air mixture during processing, handling or other means.

### **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration

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	EC-No. Index-No. Registration number		(% w/w)
sulfadiazine	68-35-9 200-685-8	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	33.34
Trimethoprim	738-70-5 212-006-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow) Aquatic Chronic 2; H411	6.66
Substances with a workplace exposur Calcium carbonate	e limit : 471-34-1 207-439-9		60

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).

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

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.

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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.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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

Risks : Causes skin irritation.

Causes serious eye irritation.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

May cause respiratory irritation.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

#### 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.

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

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

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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. 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 : Surround spill with absorbents and place a damp covering

over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 6.4 Reference to other sections

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

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### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

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 dust. 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.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. 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)

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Specific use(s) : No data available

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

### 8.1 Control parameters

### **Occupational Exposure Limits**

dust of any kind 10 mg/m3

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

4 mg/m3

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Calcium carbonate	471-34-1	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
sulfadiazine	68-35-9	TWA	2 mg/m3 (OEB 1)	Internal
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
Calcium carbonate	Workers	Inhalation	Long-term systemic effects	6.36 mg/m3
	Consumers	Ingestion	Acute systemic effects	6.1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.06 mg/m3
	Consumers	Ingestion	Long-term systemic effects	6.1 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
sulfadiazine	Water	0.01 mg/l
Trimethoprim	Water	0.9 mg/l
Calcium carbonate	Sewage treatment plant	100 mg/l

### 8.2 Exposure controls

### **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

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

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

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If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to BS EN 143

Filter type : Particulates type (P)

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

### 9.1 Information on basic physical and chemical properties

Appearance : powder Colour : light yellow

Odour : No data available Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

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Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Particle size : No data available

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

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 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

Ingestion
Eye contact

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**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

**Components:** 

sulfadiazine:

Acute oral toxicity : LD50 (Mouse): 1,500 mg/kg

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

Remarks: Based on data from similar materials

Acute toxicity (other routes of :

administration)

LD50 (Rat): 880 mg/kg

Application Route: Intravenous

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

Trimethoprim:

Acute oral toxicity : LD50 (Rat): 1,500 - 5,300 mg/kg

LD50 (Mouse): 1,910 - 7,000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 400 - 500 mg/kg

Application Route: Intraperitoneal

LD50 (Dog): 90 mg/kg

Application Route: Intravenous

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

Calcium carbonate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 420

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity : LC50 (Rat): > 3 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

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toxicity

Skin corrosion/irritation

Causes skin irritation.

**Components:** 

sulfadiazine:

Result : Skin irritation

Remarks : Based on data from similar materials

Calcium carbonate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

sulfadiazine:

Species : Rabbit

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

Calcium carbonate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

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

**Components:** 

sulfadiazine:

Test Type : Maximisation Test Species : Guinea pig

Result : Not a skin sensitizer.

Remarks : Based on data from similar materials

Trimethoprim:

Test Type : Maximisation Test

Exposure routes : Dermal

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Species : Guinea pig

Result : Not a skin sensitizer.

Calcium carbonate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

sulfadiazine:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: negative

Remarks: Based on data from similar materials

Trimethoprim:

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

Result: negative

Test Type: Chromosomal aberration

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

Calcium carbonate:

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

Method: OECD Test Guideline 471

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Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging the unborn child.

#### **Components:**

#### sulfadiazine:

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

General Toxicity Maternal: NOAEL: 1,000 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

### Trimethoprim:

Effects on fertility : Test Type: Fertility

Species: Rat

**Application Route: Oral** 

Fertility: NOAEL: 70 mg/kg body weight

Result: No effects on fertility

Effects on foetal 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

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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.

Calcium carbonate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

### STOT - single exposure

May cause respiratory irritation.

#### **Components:**

sulfadiazine:

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### **Components:**

**Trimethoprim:** 

Target Organs : Bone marrow

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

## **Components:**

### **Trimethoprim:**

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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

Calcium carbonate:

Species : Rat

NOAEL : > 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Method : OECD Test Guideline 422

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

sulfadiazine:

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

Trimethoprim:

Ingestion : Target Organs: Bone marrow

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

**SECTION 12: Ecological information** 

12.1 Toxicity

**Components:** 

sulfadiazine:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

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Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 3.9 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Microcystis aeruginosa (blue-green algae)): 0.135 mg/l

Exposure time: 7 Days Method: ISO 8692

M-Factor (Acute aquatic tox-

icity)

Toxicity to microorganisms EC50 : > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 6.2 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1

**Trimethoprim:** 

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

Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna Straus): 92 mg/l

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aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3

mg/l

Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16

mg/l

Exposure time: 72 h

EC50 (Anabaena flos-aquae): 253 mg/l

Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC10 : 16.7 mg/l

Exposure time: 3 hrs

Test Type: Respiration inhibition Method: OECD Test Guideline 209

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

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.157 mg/l Exposure time: 21 d

Species: Zebrafish

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 6 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea)

Calcium carbonate:

Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

NOELR (Pseudokirchneriella subcapitata (green algae)): 50

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

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

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mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC: 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

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

Method: OECD Test Guideline 209

### 12.2 Persistence and degradability

#### **Components:**

sulfadiazine:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 314

Trimethoprim:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Result: Not inherently biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 302B

### 12.3 Bioaccumulative potential

#### Components:

sulfadiazine:

Partition coefficient: n-

log Pow: 0.12

octanol/water
Trimethoprim:

Partition coefficient: n-

: log Pow: 0.91

octanol/water

12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

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> 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 considered 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 3077 **ADR** UN 3077 RID UN 3077 **IMDG** UN 3077 **IATA** UN 3077

14.2 UN proper shipping name

**ADN** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(sulfadiazine)

**ADR** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(sulfadiazine)

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, **RID** 

N.O.S.

(sulfadiazine)

**IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(sulfadiazine)

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

(sulfadiazine)

14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

14.4 Packing group

**ADN** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

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Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

### 14.6 Special precautions for user

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

### 14.7 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) : 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-

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

laver

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** 

#### 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.

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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:

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

### **Full text of H-Statements**

H302 : Harmful if swallowed. H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties 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.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA 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 -

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

#### Classification of the mixture:

#### Classification procedure: Skin Irrit. 2 H315 Calculation method Eye Irrit. 2 H319 Calculation method Resp. Sens. 1 H334 Calculation method Repr. 2 H361d Calculation method STOT SE 3 H335 Calculation method STOT RE 2 Calculation method H373 Aquatic Acute 1 H400 Calculation method Aquatic 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.

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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