

## Cephapirin / Prednisolone Formulation

Version 4.9      Revision Date: 30.09.2023      SDS Number: 766828-00015      Date of last issue: 04.04.2023  
Date of first issue: 16.06.2016

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephapirin / Prednisolone Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### 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

Respiratory sensitisation : Category 1

##### GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**  
P261 Avoid breathing mist or vapours.  
P284 Wear respiratory protection.  
**Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and

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keep comfortable for breathing.  
P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately.

### Disposal:

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

### 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)
Glyceryl monostearate	123-94-4	$\geq 5 - < 10$
Zeolites	1318-02-1	$\geq 5 - < 10$
Cefapirin	21593-23-7	$\geq 1 - < 5$
prednisolone	50-24-8	$\geq 0.25 - < 1$

## 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 : 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 soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- 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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Metal oxides  
Silicon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 emergency 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 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 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.

### 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

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Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
Advice on safe handling : Use only with adequate ventilation.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
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 respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glyceryl monostearate	123-94-4	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Zeolites	1318-02-1	TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminium)	ACGIH
Cefapirin	21593-23-7	TWA	0.4 mg/m <sup>3</sup> (OEB 2)	Internal
	Further information: RSEN			
prednisolone	50-24-8	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	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.  
Containment technologies suitable for controlling compounds

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are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- 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 : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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.
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Colour : No data available
- 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

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Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

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### 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Components:**

##### **Glyceryl monostearate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

##### **Zeolites:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 3.35 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

##### **Cefapirin:**

Acute oral toxicity : LD50 (Mouse): 26,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): > 7,600 mg/kg  
Application Route: Intraperitoneal

LD50 (Rat): 7,800 mg/kg  
Application Route: Intraperitoneal

##### **prednisolone:**

Acute oral toxicity : LD50 (Mouse): 1,680 mg/kg  
LD50 (Rat): > 3,857 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 147 mg/kg  
Application Route: Subcutaneous

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LD50 (Mouse): 767 mg/kg  
Application Route: Intraperitoneal

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Glyceryl monostearate:**

Species : Rabbit  
Result : No skin irritation  
Remarks : Based on data from similar materials

##### **Zeolites:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

##### **prednisolone:**

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **Glyceryl monostearate:**

Species : Rabbit  
Result : No eye irritation  
Remarks : Based on data from similar materials

##### **Zeolites:**

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

##### **prednisolone:**

Remarks : No data available

### 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:

##### **Glyceryl monostearate:**



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Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

### **Zeolites:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

### **Cefapirin:**

Assessment : Probability or evidence of high respiratory sensitisation rate in humans

### **prednisolone:**

Remarks : No data available

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Glyceryl monostearate:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

#### **Zeolites:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: positive

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476

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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

### **Cefapirin:**

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

### **prednisolone:**

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

Test Type: Mouse Lymphoma  
Result: negative

Test Type: sister chromatid exchange assay  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Oral  
Result: negative

Test Type: sister chromatid exchange assay  
Species: Humans  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Zeolites:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 104 weeks  
Result : negative

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 22 Months  
Result : negative

#### **prednisolone:**

Species : Rat  
Application Route : Oral

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Exposure time : 18 Months  
Result : negative

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### **Glyceryl monostearate:**

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  
Remarks: Based on data from similar materials

Effects on foetal development : 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  
Remarks: Based on data from similar materials

##### **Zeolites:**

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

##### **Cefapirin:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intraperitoneal injection  
Fertility: LOAEL: > 500 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal injection  
Developmental Toxicity: LOAEL: > 200 mg/kg body weight

##### **prednisolone:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 1 mg/kg body weight  
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse

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Application Route: Oral  
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight  
Result: Malformations were observed., Cleft palate

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 30 mg/kg body weight  
Result: decreased blood formation

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: NOAEL: 25 mg/kg body weight  
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### **Zeolites:**

Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

#### **prednisolone:**

Target Organs : Bone marrow, Adrenal gland, Liver  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### **Glyceryl monostearate:**

Species : Rat  
NOAEL : >= 12,500 mg/kg  
Application Route : Ingestion  
Exposure time : 84 Days  
Remarks : Based on data from similar materials

#### **Zeolites:**

Species : Rat  
NOAEL : 250 - 300 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

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Species : Monkey  
LOAEL : 0.001 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 24 Months

### **Cefapirin:**

Species : Rat  
LOAEL :  $\geq 200$  mg/kg  
Application Route : Intraperitoneal  
Target Organs : Blood  
Remarks : anemia

Species : Dog  
LOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 4 Months  
Target Organs : Gastrointestinal tract

Species : Dog  
LOAEL : 100 mg/kg  
Application Route : Intramuscular  
Exposure time : 10 Months  
Target Organs : Blood, Gastrointestinal tract  
Remarks : anemia

### **prednisolone:**

Species : Rat  
LOAEL : 0.6 mg/kg  
Application Route : Oral  
Exposure time : 63 Days  
Target Organs : Bone marrow

Species : Dog  
LOAEL : 2.5 mg/kg  
Application Route : Oral  
Exposure time : 6 Weeks  
Target Organs : Adrenal gland

Species : Rabbit  
LOAEL : 1 mg/kg  
Application Route : Oral  
Exposure time : 24 Weeks  
Target Organs : Liver

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### **Components:**

#### **Cefapirin:**

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea,

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vaginitis, colitis, anorexia, Rash, anaphylaxis

**prednisolone:**

Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Glyceryl monostearate:**

- Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 32 mg/l  
Exposure time: 47 h  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: No toxicity at the limit of solubility  
Based on data from similar materials
- Toxicity to algae/aquatic plants : EL50 ( Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility
- NOELR ( Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility
- Toxicity to microorganisms : EC10 (Pseudomonas putida): > 1 mg/l  
Exposure time: 18 h  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.22 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility  
Based on data from similar materials

##### **Zeolites:**

- Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 100 mg/l

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- aquatic invertebrates      Exposure time: 48 h  
Method: ISO 6341
- Toxicity to algae/aquatic plants      :    EL50 ( Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201
- NOELR ( Desmodesmus subspicatus (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201
- Toxicity to microorganisms      :    EC50 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Method: DIN 38 412 Part 8
- Toxicity to fish (Chronic toxicity)      :    NOELR: > 1 mg/l  
Exposure time: 30 d  
Species: Pimephales promelas (fathead minnow)
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)      :    NOELR: > 1 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### **prednisolone:**

- Toxicity to daphnia and other aquatic invertebrates      :    EC50 (Daphnia magna (Water flea)): > 85 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants      :    NOEC ( Pseudokirchneriella subcapitata (green algae)): 160 mg/l  
Exposure time: 72 h
- EC50 ( Pseudokirchneriella subcapitata (green algae)): > 160 mg/l  
Exposure time: 72 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)      :    NOEC: 0.23 mg/l  
Exposure time: 7 d  
Species: Ceriodaphnia dubia (water flea)

### **Persistence and degradability**

#### **Components:**

#### **Glyceryl monostearate:**

- Biodegradability      :    Result: Readily biodegradable.  
Remarks: Based on data from similar materials

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### Bioaccumulative potential

#### Components:

##### **Glyceryl monostearate:**

Partition coefficient: n-octanol/water : log Pow: 6.1

##### **Zeolites:**

Bioaccumulation : Species: Oysters  
Bioconcentration factor (BCF): 0.34 - 1.44

Partition coefficient: n-octanol/water : Remarks: No data available

##### **prednisolone:**

Partition coefficient: n-octanol/water : log Pow: 1.46

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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## 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.

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## 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

#### **Transport in bulk according to IMO instruments**

Not applicable for product as supplied.

#### **Special precautions for user**

Not applicable

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# SAFETY DATA SHEET

according to the Globally Harmonized System



## Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.9	30.09.2023	766828-00015	Date of first issue: 16.06.2016

### 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 16. OTHER INFORMATION

Revision Date : 30.09.2023

#### 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/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIC - 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,

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tion, 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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