according to GB/T 16483 and GB/T 17519



## **Cephapirin / Prednisolone Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 4.0 2024/09/28 764050-00018 Date of first issue: 2016/06/16

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephapirin / Prednisolone Formulation

Other means of identification : Mastiplan (A011329)

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

## **Emergency Overview**

Appearance : liquid, oily

Colour: No data availableOdour: No data available

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

**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.

according to GB/T 16483 and GB/T 17519



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Precautionary statements : **Prevention:** 

P261 Avoid breathing mist or vapours. P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Physical and chemical hazards

Not classified based on available information.

#### **Health hazards**

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

#### **Environmental hazards**

Not classified based on available information.

#### 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	>= 1 -< 10	
Zeolites	1318-02-1	>= 1 -< 10	
Cefapirin	21593-23-7	>= 1 -< 10	
prednisolone	50-24-8	>= 0.25 -< 1	

### 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.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

according to GB/T 16483 and GB/T 17519



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Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

In case of eye contact

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 difficul-

ties if inhaled.

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

tive 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).

Treat symptomatically and supportively. Notes to physician

#### 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

Carbon oxides Metal oxides

Silicon 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

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, protec- : tive 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).

according to GB/T 16483 and GB/T 17519



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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.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation
Advice on safe handling

Use only with adequate ventilation. Do not breathe mist or vapours.

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 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.

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

environment.

Avoidance of contact : Oxidizing agents

Storage

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

according to GB/T 16483 and GB/T 17519



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Packaging material : Unsuitable material: None known.

#### 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 (Inhal- able particu- late matter)	10 mg/m3	ACGIH		
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH		
Zeolites	1318-02-1	PC-TWA (Total dust)	5 mg/m3	CN OEL		
	Further inform	Further information: G1 - Carcinogenic to humans				
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal		
	Further inform	Further information: RSEN				
prednisolone	50-24-8	TWA	10 μg/m3 (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 are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

tainment devices).

Minimize open handling.

#### 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.

Filter type : Combined particulates and organic vapour type Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the

according to GB/T 16483 and GB/T 17519



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task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

eye flushing systems and safety showers close to the work-

ing 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, oily

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

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

according to GB/T 16483 and GB/T 17519



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Relative vapour density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n- : No data available

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : No data available

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

ions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

### 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Glyceryl monostearate:

according to GB/T 16483 and GB/T 17519



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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:

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

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

administration)

Acute toxicity (other routes of : 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

LD50 (Mouse): 767 mg/kg

Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:

**Glyceryl monostearate:** 

according to GB/T 16483 and GB/T 17519



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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

Result : No eye irritation

Method : OECD Test Guideline 405

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:

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

Remarks : Based on data from similar materials

according to GB/T 16483 and GB/T 17519



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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

Result: negative

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

according to GB/T 16483 and GB/T 17519



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> 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

according to GB/T 16483 and GB/T 17519



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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 develop-

ment

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:

ment

Effects on foetal develop-

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 develop-

ment

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

according to GB/T 16483 and GB/T 17519



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Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

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 - As-

sessment

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 concentra-

tions 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:

according to GB/T 16483 and GB/T 17519



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Species Rat

NOAEL 250 - 300 mg/kg

NOAEL
Application Route Ingestion Exposure time 90 Days

Monkey Species LOAEL 0.001 mg/l

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

Exposure time 24 Months

Cefapirin:

**Species** Rat

LOAEL >= 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 100 mg/kg LOAEL 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

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

according to GB/T 16483 and GB/T 17519



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### **Aspiration toxicity**

Not classified based on available information.

## Experience with human exposure

#### **Components:**

Cefapirin:

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

vaginitis, colitis, anorexia, Rash, anaphylaxis

prednisolone:

Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid reten-

tion, 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 daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): > 0.22 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility Based on data from similar materials

according to GB/T 16483 and GB/T 17519



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

Exposure time: 18 h

Remarks: 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:

aquatic invertebrates

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

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 fish (Chronic tox-

icity)

NOELR (Pimephales promelas (fathead minnow)): > 1 mg/l

Exposure time: 30 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOELR (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h Method: DIN 38 412 Part 8

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 (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l

Exposure time: 7 d

according to GB/T 16483 and GB/T 17519



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Persistence and degradability

**Components:** 

Glyceryl monostearate:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

**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

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 : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

according to GB/T 16483 and GB/T 17519



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Packing group : Not applicable Labels : Not applicable

Environmentally hazardous : no

**IATA-DGR** 

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable

Marine pollutant : no

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

Not applicable for product as supplied.

## **National Regulations**

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Marine pollutant : no

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

### National regulatory information

Law on the Prevention and Control of Occupational Diseases

### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals : This

This product is not listed in the catalogue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles

according to GB/T 16483 and GB/T 17519



## **Cephapirin / Prednisolone Formulation**

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of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

**Regulation on the Administration of Precursor Chemicals** 

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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** : 2024/09/28

**Further information** 

Sources of key data used to : compile the Safety Data

Sheet

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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

**CN OEL** Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

according to GB/T 16483 and GB/T 17519



# **Cephapirin / Prednisolone Formulation**

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

CN OEL / PC-TWA : Permissible concentration - time weighted average

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

### **Disclaimer**

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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