

# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.2 28.09.2024 4037827-00013 Date of first issue: 01.03.2019

#### **Section 1: Identification**

Product name : Cephapirin (with Peanut Oil) Formulation

Other means of identification : CEFA-SAFE (A007158)

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

## **Section 2: Hazard identification**

**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

keep comfortable for breathing.



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P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### **Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 3.2 %

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

None known.

#### Section 3: Composition/information on ingredients

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cefapirin	21593-23-7	>= 1 -< 10
Aluminum tristearate	637-12-7	>= 1 -< 10

#### Section 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.

Wash with water and soap as a precaution. In case of skin contact

> Get medical attention if symptoms occur. 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 if symptoms occur.

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

## Section 5: Fire-fighting measures



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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

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for firefighters

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

Use personal protective equipment.

#### Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.



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### Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : 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.

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.

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

## Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				
Aluminum tristearate	637-12-7	WES-TWA	10 mg/m3	NZ OEL	
		WES-TWA (Respirable dust)	1 mg/m3 (Aluminium)	NZ OEL	
		TWA (Inhal- able particu-	10 mg/m3	ACGIH	



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late matter)		
TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
TWA (Respirable particulate matter)	1 mg/m3 (Aluminium)	ACGIH

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

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

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

Filter type
Hand protection

Material : Chemical-resistant gloves

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

### Section 9: Physical and chemical properties

Appearance : suspension

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



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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

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

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 : Not applicable

## Section 10: Stability and reactivity

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

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

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

Hazardous decomposition : No hazardous decomposition products are known.



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products

## **Section 11: Toxicological information**

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

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

Aluminum tristearate:

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

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Aluminum tristearate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Aluminum tristearate:

Species : Rabbit



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Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

## 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:**

## Cefapirin:

Assessment : Probability or evidence of high respiratory sensitisation rate in

humans

#### Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

## **Chronic toxicity**

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

## Cefapirin:

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

Result: negative

#### Aluminum tristearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

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

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

cytogenetic assay)

Species: Rat



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Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

## Carcinogenicity

Not classified based on available information.

## Reproductive toxicity

Not classified based on available information.

## **Components:**

## 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

## Aluminum tristearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

## **Components:**

## Cefapirin:

Species : Rat

LOAEL : >= 200 mg/kg



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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

Aluminum tristearate:

Species : Rat

NOAEL : >= 5,000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Remarks : Based on data from similar materials

**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

**Section 12: Ecological information** 

**Ecotoxicity** 

**Components:** 

Aluminum tristearate:

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability

No data available



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### Bioaccumulative potential

No data available

## Mobility in soil

No data available

### Other adverse effects

No data available

#### Section 13: Disposal considerations

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **Section 14: Transport information**

### **International Regulations**

## **UNRTDG**

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

Environmentally hazardous no

IATA-DGR

UN/ID No. Not applicable Not applicable Proper shipping name Not applicable Class 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 Not applicable Proper shipping name Class Not applicable Subsidiary risk Not applicable Not applicable Packing group Not applicable Labels EmS Code Not applicable Marine pollutant Not applicable



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

Not applicable for product as supplied.

## **National Regulations**

NZS 5433

**UN** number Not applicable Not applicable Proper shipping name Not applicable Class Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable Not applicable Hazchem Code

## Special precautions for user

Not applicable

### **Section 15: Regulatory information**

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

## **HSNO Approval Number**

HSR100757 Veterinary Medicines Limited Pack Size Finished Dose Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further in-

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

**AICS** : not determined

DSL not determined

**IECSC** not determined

#### Section 16: Other information

**Revision Date** 28.09.2024

**Further information** 

Sources of key data used to

compile the Safety Data

eChem Portal search results and European Chemicals Agen-Sheet cy, http://echa.europa.eu/

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Internal technical data, data from raw material SDSs, OECD



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Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - 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

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.

NZ / EN