

**Cephapirin (with Peanut Oil) Formulation**

Version 1.9      Revision Date: 30.09.2023      SDS Number: 4037819-00010      Date of last issue: 04.04.2023  
Date of first issue: 01.03.2019

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**SECTION 1. IDENTIFICATION**

Product name : Cephapirin (with Peanut Oil) Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 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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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Respiratory sensitization : 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 vapors.

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

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disposal plant.

### Additional Labeling

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) |
|----------------------|------------|-----------------------|
| Peanut oil           | 8002-03-7  | >= 90 -<= 100         |
| Cefapirin            | 21593-23-7 | >= 1 -< 5             |
| Aluminum tristearate | 637-12-7   | >= 1 -< 5             |

## SECTION 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 : Wash with water and soap as a precaution.  
 Get medical attention if symptoms occur.
- 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 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 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.

## SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing : None known.

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media  
Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.  
Hazardous combustion products : Carbon oxides  
Metal 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

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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 : Avoid breathing mist or vapors.  
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

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- assessment  
 Keep container tightly closed.  
 Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled 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  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

| Components   | CAS-No.    | Value type (Form of exposure)       | Control parameters / Permissible concentration | Basis    |
|--|------------|-------------------------------------|--|----------|
| Peanut oil   | 8002-03-7  | CMP (Mist)                          | 10 mg/m <sup>3</sup>                           | AR OEL   |
| Cefapirin  | 21593-23-7 | TWA                                 | 0.4 mg/m <sup>3</sup> (OEB 2)                  | Internal |
| Further information: RSEN  |            |                                     |  |          |
| Aluminum tristearate   | 637-12-7   | CMP                                 | 10 mg/m <sup>3</sup>                           | AR OEL   |
| Further information: A4 - Not classifiable as a human carcinogen |            |                                     |  |          |
|  |            | TWA (Inhalable particulate matter)  | 10 mg/m <sup>3</sup>                           | ACGIH    |
|  |            | TWA (Respirable particulate matter) | 3 mg/m <sup>3</sup>                            | ACGIH    |
|  |            | TWA (Respirable particulate matter) | 1 mg/m <sup>3</sup> (Aluminum)                 | 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapor type

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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  
Hygiene measures : Work uniform or laboratory coat.  
: 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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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : suspension

Color : No data available

Odor : No data available

Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

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Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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 : Not applicable

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**SECTION 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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**SECTION 11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Components:****Peanut oil:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

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Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Remarks: Based on data from similar materials

**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:****Peanut oil:**

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

**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:****Peanut oil:**

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

**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 sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

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

**Components:****Cefapirin:**

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

**Aluminum tristearate:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Peanut oil:**

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

**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 fetal development : Test Type: Embryo-fetal 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 fetal development : 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  
Application Route : Intraperitoneal  
Target Organs : Blood

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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 :  $\geq 5.000$  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, Diarrhea, vaginitis, colitis, anorexia, Rash, anaphylaxis

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

### Components:

#### Peanut oil:

Toxicity to fish : LC50 (Danio rerio (zebra fish)):  $> 10.000$  mg/l  
 Exposure time: 96 h  
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)):  $> 100$  mg/l  
 Exposure time: 48 h  
 Remarks: Based on data from similar materials

#### Aluminum tristearate:

### Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

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Chronic aquatic toxicity      :    Toxic effects cannot be excluded

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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  
handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**SECTION 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 Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry.      :    Not applicable

Control of precursors and essential chemicals for the preparation of drugs.      :    Not applicable

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

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|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

**SECTION 16. OTHER INFORMATION**

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 30.09.2023 |
| Date format   | : | dd.mm.yyyy |

**Further information**

|  |   |   |
|--|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a> |
|--|---|---|

**Full text of other abbreviations**

|              |   |   |
|--------------|---|---|
| ACGIH        | : | USA. ACGIH Threshold Limit Values (TLV) |
| AR OEL       | : | Argentina. Occupational Exposure Limits |
| ACGIH / TWA  | : | 8-hour, time-weighted average           |
| AR OEL / CMP | : | TLV (Threshold Limit Value)             |

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; TECl - 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

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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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