

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	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 : 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

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.

Cephapirin (with Peanut Oil) Formulation

Version 2.0 Revision Date: 14.04.2025 SDS Number: 4037819-00013 Date of last issue: 28.09.2024
Date of first issue: 01.03.2019

Disposal:

P501 Dispose of contents/ container to an approved waste 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 : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- 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 (CO₂)

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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
- 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.

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.

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

Cephapirin (with Peanut Oil) Formulation

Version 2.0 Revision Date: 14.04.2025 SDS Number: 4037819-00013 Date of last issue: 28.09.2024
 Date of first issue: 01.03.2019

Local/Total ventilation : Use only with adequate ventilation.
 Advice on safe handling : Do not breathe 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 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 ³	AR OEL
Cefapirin	21593-23-7	TWA	0.4 mg/m ³ (OEB 2)	Internal
Further information: RSEN				
Aluminum tristearate	637-12-7	CMP	10 mg/m ³	AR OEL
Further information: A4 - Not classifiable as a human carcinogen				
		TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	1 mg/m ³ (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

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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
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.
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.

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

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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
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 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 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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
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.

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

Components:**Peanut oil:**

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

Aluminum tristearate:

Species	:	Rabbit
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
-----------------------	---	--

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

	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
	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.

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

Repeated dose toxicity**Components:****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
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, 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	: EC50 (Daphnia magna (Water flea)): > 100 mg/l

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

aquatic invertebrates

Exposure time: 48 h

Remarks: Based on data from similar materials

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

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

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

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

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
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, <http://echa.europa.eu/>

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

Full text of 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

Cephapirin (with Peanut Oil) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
2.0	14.04.2025	4037819-00013	Date of first issue: 01.03.2019

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

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.

AR / Z8