

# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephapirin (with Peanut Oil) Formulation

Other means of identification : CEFA-SAFE (A007158)

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS 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.

P342 + P311 If experiencing respiratory symptoms: Call a



# **Cephapirin (with Peanut Oil) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cefapirin	21593-23-7	>= 0.1 -< 10
Aluminum tristearate	637-12-7	< 10

#### 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

## 5. FIREFIGHTING MEASURES



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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.

#### **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.



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

#### 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.

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				
Aluminum tristearate	637-12-7	NAB	10 mg/m3	ID OEL	
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		NAB (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ID OEL	
	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals				
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH	
		TWA (Res- pirable par-	3 mg/m3	ACGIH	



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

ticulate mat- ter)		
TWA (Res- pirable par- ticulate mat- ter)	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.

Hygiene measures : If exposure to chemical is likely

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 : suspension

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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

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

#### 10. STABILITY AND REACTIVITY



## **Cephapirin (with Peanut Oil) Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

#### 11. TOXICOLOGICAL INFORMATION

Inhalation Information on likely routes of :

exposure 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:

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

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



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

#### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

#### Aluminum tristearate:

Species : Rabbit

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

## 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



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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 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.



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

#### Repeated dose toxicity

## **Components:**

Cefapirin:

Species : Rat

LOAEL : >= 200 mg/kg Application Route : Intraperitoneal

Target Organs : Blood : 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

#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

#### Aluminum tristearate:

## **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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

#### 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
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-

ger aircraft)

: Not applicable

IMDG-Code

UN number : Not applicable Proper shipping name : Not applicable Class : Not applicable



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

#### 15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control. Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION



# **Cephapirin (with Peanut Oil) Formulation**

SDS Number: Date of last issue: 2023/12/04 Version Revision Date: 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

**Revision Date** 2024/09/28

**Further information** 

Sources of key data used to

compile the Safety Data

Sheet

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

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

Date format yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA, ACGIH Threshold Limit Values (TLV) **ID OEL** Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB Long term exposure limit

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.



# Cephapirin (with Peanut Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/12/04 3.3 2024/09/28 4037822-00013 Date of first issue: 2019/03/01

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.

ID / EN