

# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

#### **SECTION 1. IDENTIFICATION**

Product name : Cephapirin Formulation

Other means of identification : Metricure (A007394)

METRICURE BENZATHINE CEPHAPIRIN INTRA-UTERINE

SUSPENSION (47091)

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



# **Cephapirin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 4.0
 06.07.2024
 493761-00021
 Date of first issue: 28.01.2016

POISON CENTER/ doctor.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

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 -< 5
Alcohols, C16-18, ethoxylated	68439-49-6	>= 1 -< 2,5

#### **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.

Ninse moduli thoroughly with wa

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire : Exposure to combustion products may be a hazard to health.



# **Cephapirin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 4.0
 06.07.2024
 493761-00021
 Date of first issue: 28.01.2016

fighting

Hazardous combustion prod- :

ucts

Carbon 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 fire-fighters

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

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal 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.

unamen.

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

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : U Advice on safe handling : A

Use only with adequate ventilation. 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

assessment



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

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	
Cefapirin	21593-23-7	TWA	0.4 mg/m3 (OEB 2)	Internal	
	Further information: RSEN				

**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

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



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

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

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

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive



# **Cephapirin Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 16.05.2024 06.07.2024 493761-00021 Date of first issue: 28.01.2016 4.0

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

Molecular weight No data available

Particle characteristics

Particle size No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

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

Possibility of hazardous reac- :

tions

None known.

Incompatible materials Oxidizing agents Hazardous decomposition

products

Conditions to avoid

No hazardous decomposition products are known.

## **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:**

### Cefapirin:

Acute oral toxicity LD50 (Mouse): 26.000 mg/kg

administration)

Acute toxicity (other routes of : LD50 (Mouse): > 7.600 mg/kg Application Route: Intraperitoneal

LD50 (Rat): 7.800 mg/kg

Application Route: Intraperitoneal

## Alcohols, C16-18, ethoxylated:

Acute oral toxicity LD50 (Rat): > 2.000 mg/kg

Remarks: Based on data from similar materials

## Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

## Alcohols, C16-18, ethoxylated:

Species Rabbit

Method **OECD Test Guideline 404** 



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

Result : No skin irritation

Remarks : Based on data from similar materials

## Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

#### Alcohols, C16-18, ethoxylated:

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

## Alcohols, C16-18, ethoxylated:

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

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

#### Alcohols, C16-18, ethoxylated:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

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

#### Alcohols, C16-18, ethoxylated:

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

Species: Rat

Application Route: Skin contact

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Skin contact

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



# **Cephapirin Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 16.05.2024 06.07.2024 493761-00021 Date of first issue: 28.01.2016 4.0

Application Route Intraperitoneal

Target Organs Blood Remarks anemia

Species Dog 20 mg/kg LOAEL 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

Alcohols, C16-18, ethoxylated:

**Species** Rat

NOAEL > 100 mg/kg Application Route : Inaestion Exposure time 90 Davs

Method **OECD Test Guideline 408** 

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:** 

Alcohols, C16-18, ethoxylated:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l

Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l aquatic invertebrates

Exposure time: 48 h

Remarks: Based on data from similar materials



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

### Persistence and degradability

#### **Components:**

#### Alcohols, C16-18, ethoxylated:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 60 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

#### Bioaccumulative potential

#### **Components:**

## Alcohols, C16-18, ethoxylated:

Bioaccumulation : Species: Fish

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

: log Pow: > 4

# 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



# **Cephapirin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 16.05.2024

 4.0
 06.07.2024
 493761-00021
 Date of first issue: 28.01.2016

#### **SECTION 15. REGULATORY INFORMATION**

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

## 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 : 06.07.2024 Date format : dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

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

Data Sheet cy, 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

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



# **Cephapirin Formulation**

Version Revision Date: SDS Number: Date of last issue: 16.05.2024 4.0 06.07.2024 493761-00021 Date of first issue: 28.01.2016

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.

AR / Z8