

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

### 1. PRODUCT AND COMPANY 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 : No. 485 Jing Tai Road  
Pu Tuo District - Shanghai - China 200331  
Telephone : +1-908-740-4000  
Emergency telephone number : 86-571-87268110  
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

#### Emergency Overview

Appearance : suspension  
Colour : No data available  
Odour : No data available

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

#### 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.

# SAFETY DATA SHEET

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### Precautionary statements

#### : Prevention:

P233 Keep container tightly closed.  
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 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately.

#### : Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards

Not classified based on available information.

### Health hazards

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

### Environmental hazards

Not classified based on available information.

### 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	>= 1 -< 10
Alcohols, C16-18, ethoxylated	68439-49-6	>= 1 -< 2.5

## 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
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420287-00024

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If swallowed	Get medical attention if irritation develops and persists. : 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.

## 5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) 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
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 firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

## 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



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Version  
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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 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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## 7. HANDLING AND STORAGE

### Handling

Technical measures

: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

: If sufficient ventilation is unavailable, use with local exhaust 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 assessment

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 respiratory irritants or sensitisers.

Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact

: Oxidizing agents

### Storage

Conditions for safe storage

: Keep in properly labelled containers.

Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid

: Do not store with the following product types:

Strong oxidizing agents

Packaging material

: Unsuitable material: None known.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



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---

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Cefapirin	21593-23-7	TWA	0.4 mg/m <sup>3</sup> (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

Eye/face protection : Combined particulates and organic vapour type  
: 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

Hand protection

Material

: Work uniform or laboratory coat.

: Chemical-resistant gloves

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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Colour : No data available

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version 5.0      Revision Date: 2025/04/14      SDS Number: 420287-00024      Date of last issue: 2024/09/28  
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---

Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
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
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
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		

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

Particle size : No data available

## 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.

## 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### Cefapirin:

Acute oral toxicity : LD50 (Mouse): 26,000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Mouse): > 7,600 mg/kg  
Application Route: Intraperitoneal  
LD50 (Rat): 7,800 mg/kg  
Application Route: Intraperitoneal

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

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

Test Type	:	Buehler Test
Exposure routes	:	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
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##### 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
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Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

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 foetal development	: Test Type: Embryo-foetal 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 foetal 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.

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

### 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

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

Species	:	Rat
NOAEL	:	> 100 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
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, Diarrhoea, vaginitis, colitis, anorexia, Rash, anaphylaxis
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## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

---

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l  
Exposure time: 96 h

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

### 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

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## 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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## 14. TRANSPORT INFORMATION

#### International Regulations

UNRTDG

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version 5.0	Revision Date: 2025/04/14	SDS Number: 420287-00024	Date of last issue: 2024/09/28 Date of first issue: 2016/01/28
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**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 aircraft)** : Not applicable  
**Packing instruction (passenger aircraft)** : Not applicable

### IMDG-Code

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Class** : Not applicable  
**Subsidiary risk** : Not applicable  
**Packing group** : Not applicable  
**Labels** : Not applicable  
**EmS Code** : Not applicable  
**Marine pollutant** : no

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

Not applicable for product as supplied.

### National Regulations

#### GB 6944/12268

**UN number** : Not applicable  
**Proper shipping name** : Not applicable  
**Class** : Not applicable  
**Subsidiary risk** : Not applicable  
**Packing group** : Not applicable  
**Labels** : Not applicable  
**Marine pollutant** : no

### Special precautions for user

Not applicable

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## 15. REGULATORY INFORMATION

### National regulatory information

Law on the Prevention and Control of Occupational Diseases

Regulations on Safety Management of Hazardous Chemicals

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

### Catalogue of Hazardous Chemicals

: This product is not listed in the catalogue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles of determination.

### Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)

: Not listed

### Hazardous Chemicals for Priority Management under SAWs

: Not listed

### Catalogue of Specially Controlled Hazardous Chemicals

: Not listed

### List of Explosive Precursors

: Not listed

### Regulations on Labour Protection in Workplaces where Toxic Substances are Used

### Catalogue of Highly Toxic Chemicals

: Not listed

### Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

### China Severely Restricted Toxic Chemicals for Import and Export

: Not listed

### Regulation on the Administration of Precursor Chemicals

### Catalogue and Classification of Precursor Chemicals

: Not listed

### Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

### Regulations of Ozone Depleting Substances Management

### List of Controlled Ozone Depleting Substances Import and Export

: Not listed

### List of Controlled Ozone Depleting Substances

: Not listed

### Environmental Protection Law

### List of Priority Controlled Chemicals

: Not listed

### List of Key Controlled New Pollutants

: Listed

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

AICS : not determined

DSL : not determined

IECSC : not determined

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

Date of last issue: 2024/09/28  
Date of first issue: 2016/01/28

---

### 16. OTHER INFORMATION

Revision Date : 2025/04/14

#### 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 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.

Date format : yyyy/mm/dd

#### 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 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

# SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



## Cephapirin Formulation

Version  
5.0

Revision Date:  
2025/04/14

SDS Number:  
420287-00024

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---

### Disclaimer

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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