

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Cephapirin Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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 POISON CENTER/ doctor.

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

Disposal:

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

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)	ENCS No.
Cefapirin	21593-23-7	>= 1 - < 10	
Alcohols, C16-18, ethoxylated	68439-49-6	1.6	

4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.
- In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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. 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.

7. HANDLING AND STORAGE**Handling**

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	Use only with adequate ventilation.
Advice on safe handling	:	Avoid breathing mist or vapours. Do not swallow.

Cephapirin Formulation

Version 5.2	Revision Date: 2023/09/30	SDS Number: 420293-00018	Date of last issue: 2023/04/04 Date of first issue: 2016/01/28
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- 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
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.
- Storage**
- 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
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis
Cefapirin	21593-23-7	TWA	0.4 mg/m ³ (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

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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 vapour 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-
octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Relative vapour density : 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 : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-
tions : 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

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

Acute toxicity

Not classified based on available information.

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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

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

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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 Result: negative Remarks: Based on data from similar materials
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	: Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
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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
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Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Intraperitoneal injection
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Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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.

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

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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:****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 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

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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.

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

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	:	Not applicable

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
[alpha-(Alkyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl) or alpha-(alkenyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl)]	250

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Cephapirin Formulation

Version 5.2 Revision Date: 2023/09/30 SDS Number: 420293-00018 Date of last issue: 2023/04/04
 Date of first issue: 2016/01/28

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**Class I Designated Chemical Substances**

Chemical name	Administration number	Concentration (%)
alpha-Alkyl-omega-hydroxypoly(oxyethane-1,2-diyl) (limited to those the alkyl group is C=16-18 and the mixture thereof, and the number average molecular weight is less than 1,000), alpha-alkenyl-omega-hydroxypoly(oxyethane-1,2-diyl) (limited to those the alkenyl group is C=16-18 and the mixture thereof, and the number average molecular weight is less than 1,000), and the mixture thereof	578	1.6

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION**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/>

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; 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

Cephapirin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
5.2	2023/09/30	420293-00018	Date of first issue: 2016/01/28

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