

SAFETY DATA SHEET

according to the Globally Harmonized System



Cefuroxime Formulation

Version
4.0

Revision Date:
14.04.2025

SDS Number:
10844578-00007

Date of last issue: 28.09.2024
Date of first issue: 06.09.2022

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cefuroxime Formulation
Other means of identification : Spectrazol Milking Cow (A005270)
Coopers Cepravin LC Lactating Cow Intramammary Antibiotic (47941)

Manufacturer or supplier's details

Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : +1-908-740-4000
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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:**
P233 Keep container tightly closed.

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P260 Do not breathe mist or vapours.
P271 Use only outdoors or with adequate ventilation.
P280 Wear protective gloves/ protective clothing.
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.

Storage:

P403 Store in a well-ventilated place.

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: 8.33 %

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)
Cefuroxime	55268-75-2	>= 5 - < 10

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 : In case of contact, immediately flush skin with soap and plenty of water.
Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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Protection of first-aiders	May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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 ₂) 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 Nitrogen oxides (NO _x) Sulphur 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 absor-

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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 determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 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.
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 parame- ters / Permissible concentration	Basis
Cefuroxime	55268-75-2	TWA	100 µg/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 protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

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Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Particulates type
Hand protection	: Chemical-resistant gloves
Material	
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: white
	off-white
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

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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

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

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

Not classified based on available information.

Components:

Cefuroxime:

Acute oral toxicity	: LD50 (Rat): > 10,000 mg/kg
	LD50 (Mouse): > 10,000 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): > 4,000 mg/kg Application Route: Intravenous
	LD50 (Mouse): > 10,000 mg/kg Application Route: Intravenous
	LD50 (Rabbit): > 1,500 mg/kg Application Route: Intravenous
	LD50 (Dog): > 1,500 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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:

Cefuroxime:

Result	: Sensitiser
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Germ cell mutagenicity

Not classified based on available information.

Components:

Cefuroxime:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Result: positive
	Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells

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Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Cefuroxime:

Effects on fertility : Test Type: Fertility
Species: Mouse
Application Route: Oral
Fertility: NOAEL: 6,400 mg/kg body weight
Symptoms: No adverse effects

Test Type: Fertility
Species: Rabbit
Application Route: Oral
Fertility: NOAEL: 400 mg/kg body weight
Symptoms: No adverse effects

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

Cefuroxime:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Cefuroxime:

Species : Rat
NOAEL : 900 mg/kg
Application Route : Subcutaneous
Exposure time : 3 M
Symptoms : No adverse effects

Species : Dog
NOAEL : 400 mg/kg
LOAEL : 1,600 mg/kg
Application Route : Oral

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Exposure time	:	27 W
Target Organs	:	Blood
Symptoms	:	Gastrointestinal disturbance
Species	:	Monkey
NOAEL	:	450 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	1 M
Target Organs	:	Blood, Urinary tract
Remarks	:	May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Cefuroxime:

General Information	:	Repeated contact may cause allergic reactions in very susceptible persons.
Inhalation	:	Symptoms: Nausea, Vomiting, Abdominal pain, vaginitis, Headache, Dizziness, dry mouth, Fatigue, constipation, colitis

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cefuroxime:

Ecotoxicology Assessment

Acute aquatic toxicity	:	Toxic effects cannot be excluded
Chronic aquatic toxicity	:	Toxic effects cannot be excluded

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Cefuroxime:

Partition coefficient: n-octanol/water	:	log Pow: -0.429
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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.

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 IMO instruments

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 14.04.2025

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 : dd.mm.yyyy

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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

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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