

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephapirin / Prednisolone Formulation

Other means of identification : Mastiplan (A011329)

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.
P260 Do not breathe mist or vapours.
P271 Use only outdoors or with adequate ventilation.

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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.

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)
Glyceryl monostearate	123-94-4	$\geq 5 - < 10$
Cefapirin	21593-23-7	$\geq 1 - < 5$
prednisolone	50-24-8	$\geq 0.25 - < 1$

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. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
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. 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).

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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 (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

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

Hazardous combustion products : Carbon oxides
Metal oxides
Silicon 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-

Cephapirin / Prednisolone Formulation

Version 5.1 Revision Date: 14.04.2025 SDS Number: 766828-00018 Date of last issue: 28.09.2024
Date of first issue: 16.06.2016

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 parameters / Permissible concentration	Basis
Glyceryl monostearate	123-94-4	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Cephapirin	21593-23-7	TWA	0.4 mg/m ³ (OEB 2)	Internal
Further information: RSEN				
prednisolone	50-24-8	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	100 µg/100 cm ²	Internal

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

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

Remarks : Consider double gloving.

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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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, oily

Colour : No data available

Odour : No data available

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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
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		
Particle size	:	No data available

10. STABILITY AND REACTIVITY

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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

Acute toxicity

Not classified based on available information.

Components:

Glyceryl monostearate:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2,000 mg/kg Remarks: Based on data from similar materials

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

prednisolone:

Acute oral toxicity	:	LD50 (Mouse): 1,680 mg/kg LD50 (Rat): > 3,857 mg/kg
Acute inhalation toxicity	:	Remarks: No data available
Acute dermal toxicity	:	Remarks: No data available
Acute toxicity (other routes of administration)	:	LD50 (Rat): 147 mg/kg Application Route: Subcutaneous LD50 (Mouse): 767 mg/kg Application Route: Intraperitoneal

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Skin corrosion/irritation

Not classified based on available information.

Components:

Glyceryl monostearate:

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

prednisolone:

Remarks	:	No data available
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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Glyceryl monostearate:

Species	:	Rabbit
Result	:	No eye irritation
Remarks	:	Based on data from similar materials

prednisolone:

Remarks	:	No data available
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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:

Glyceryl monostearate:

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Cefapirin:

Assessment	:	Probability or evidence of high respiratory sensitisation rate in humans
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prednisolone:

Remarks	:	No data available
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Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Germ cell mutagenicity

Not classified based on available information.

Components:

Glyceryl monostearate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

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
Result: negative
Remarks: Based on data from similar materials

Cefapirin:

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

prednisolone:

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: sister chromatid exchange assay
Species: Humans
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

prednisolone:

Species : Rat
Application Route : Oral
Exposure time : 18 Months

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Glyceryl monostearate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

prednisolone:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 1 mg/kg body weight
Result: No effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
Result: Malformations were observed., Cleft palate

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral

SAFETY DATA SHEET

according to the Globally Harmonized System



Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: decreased blood formation

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

prednisolone:

Target Organs : Bone marrow, Adrenal gland, Liver
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Glyceryl monostearate:

Species : Rat
NOAEL : $\geq 12,500$ mg/kg
Application Route : Ingestion
Exposure time : 84 Days
Remarks : Based on data from similar materials

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

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Remarks : anemia

prednisolone:

Species : Rat
LOAEL : 0.6 mg/kg
Application Route : Oral
Exposure time : 63 Days
Target Organs : Bone marrow

Species : Dog
LOAEL : 2.5 mg/kg
Application Route : Oral
Exposure time : 6 Weeks
Target Organs : Adrenal gland

Species : Rabbit
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 24 Weeks
Target Organs : Liver

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

prednisolone:

Ingestion : Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glyceryl monostearate:

Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 32 mg/l
aquatic invertebrates : Exposure time: 47 h
Method: Directive 67/548/EEC, Annex V, C.2.
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Toxicity to algae/aquatic plants : EL50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOELR (*Pseudokirchneriella subcapitata* (green algae)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC10 (*Pseudomonas putida*): > 1 mg/l
Exposure time: 18 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.22 mg/l
Exposure time: 21 d
Species: *Daphnia magna* (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

prednisolone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 85 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (*Pseudokirchneriella subcapitata* (green algae)): 160 mg/l
Exposure time: 72 h

EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 160 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.23 mg/l
Exposure time: 7 d
Species: *Ceriodaphnia dubia* (water flea)

Persistence and degradability

Components:

Glyceryl monostearate:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

Bioaccumulative potential

Components:

Glyceryl monostearate:

Partition coefficient: n-octanol/water : log Pow: 6.1

prednisolone:

Partition coefficient: n-octanol/water : log Pow: 1.46

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	: Empty containers should be taken to an approved waste 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

Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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/>

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Cephapirin / Prednisolone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
5.1	14.04.2025	766828-00018	Date of first issue: 16.06.2016

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.

IN / EN