according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

## **SECTION 1. IDENTIFICATION**

Product name : Cefadroxil Monohydrate Formulation

Other means of identification : No data available

## Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

## Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

### GHS classification in accordance with the Hazardous Products Regulations

Respiratory sensitization : Category 1

#### **GHS** label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing dust. 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 doc-

tor.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

according to the Hazardous Products Regulations



# Cefadroxil Monohydrate Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

## Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Cellulose	No data availa- ble	9004-34-6	>= 30 - < 60 *
Cefadroxil	(6R,7R)-7-((R)- 2-Amino-2-(p- hydroxy- phe- nyl)acetamido)- 3-methyl-8-oxo- 5-thia-1- azabicy- clo(4.2.0)oct-2- ene-2-carboxylic acid monohy- drat	66592-87-8	>= 30 - < 60 *
Magnesium stearate	Octadecanoic acid, magnesi- um salt (2:1)	557-04-0	>= 1 - < 5 *

Actual concentration or concentration range is withheld as a trade secret

## **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact Wash with water and soap.

Get medical attention if symptoms occur.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

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).

Contact with dust can cause mechanical irritation or drying of

the skin.

according to the Hazardous Products Regulations



# Cefadroxil Monohydrate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04/14/2025 06/17/2025 10679092-00008 Date of first issue: 05/06/2022 4.0

Dust contact with the eyes can lead to mechanical irritation.

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.

## **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Sodium oxides

Nitrogen oxides (NOx)

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

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

Use personal protective equipment.

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

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions** Avoid release to the environment.

> Prevent further leakage or spillage if safe to do so. 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 Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not breathe dust.

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 sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components CAS-No.	Value type	Control parame-	Basis	
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according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

		/F	( / D ' ''		
		(Form of	ters / Permissible		
		exposure)	concentration		
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	CA AB OEL	
		TWA (Total	10 mg/m <sup>3</sup>	CA BC OEL	
		dust)			
		TWA (respir-	3 mg/m³	CA BC OEL	
		able dust			
		fraction)			
		TWAEV (to-	10 mg/m <sup>3</sup>	CA QC OEL	
		tal dust)		·	
		TWA	10 mg/m <sup>3</sup>	ACGIH	
Cefadroxil	66592-87-8	TWA	500 mcg/m3	Internal	
			(OEB 2)		
	Further information: RSEN				
Magnesium stearate	557-04-0	TWA	10 mg/m <sup>3</sup>	CA AB OEL	
		TWA (Inhal-	10 mg/m <sup>3</sup>	CA BC OEL	
		able) `			
		TWA (Res-	3 mg/m³	CA BC OEL	
		pirable)			
		TWAEV (in-	10 mg/m <sup>3</sup>	CA QC OEL	
		halable dust)		·	
		TWAEV	3 mg/m³	CA QC OEL	
		(respirable	Jg,		
		aerosol frac-			
		tion)			
		TWA	10 mg/m³	ACGIH	
		(Inhalable		7.30	
		particulate			
		matter)			
		TWA	3 mg/m³	ACGIH	
		(Respirable	Jg/		
		particulate			
		matter)			
		···attor)			

**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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
Hand protection

Particulates type

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

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 04/14/2025 06/17/2025 10679092-00008 Date of first issue: 05/06/2022 4.0

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance powder

Color white

Odor No data available

No data available Odor Threshold

No data available pН

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flash point Not applicable

**Evaporation rate** Not applicable

Flammability (solid, gas) May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

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

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

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

# **Acute toxicity**

Not classified based on available information.

## **Components:**

## Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Cefadroxil:

Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg

LD50 (Mouse): > 7,000 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): > 6,000 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): > 7,000 mg/kg Application Route: Intraperitoneal

LD50 (Rat): > 1,000 mg/kg Application Route: Intravenous

LD50 (Mouse): > 1,500 mg/kg Application Route: Intravenous

Magnesium stearate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icitv

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

### Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

## Serious eye damage/eye irritation

Not classified based on available information.

# **Components:**

### Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

## Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

## Respiratory sensitization

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

### Components:

#### Cefadroxil:

Result : Sensitizer

## Magnesium stearate:

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

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

## Germ cell mutagenicity

Not classified based on available information.

## **Components:**

## Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

#### Magnesium stearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

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

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

## Carcinogenicity

Not classified based on available information.

#### Components:

#### Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

## Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### Cellulose:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

## Cefadroxil:

Effects on fertility : Test Type: Fertility

Species: Mouse

Application Route: Intraperitoneal Fertility: NOAEL: 400 mg/kg body weight

Result: No adverse effects.

Effects on fetal development: Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 500 mg/kg body weight

Result: No adverse effects.

#### Magnesium stearate:

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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

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:**

#### Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

## Cefadroxil:

Species : Mouse
NOAEL : 200 mg/kg
Application Route : Oral
Exposure time : 14 W
Target Organs

Target Organs : Prostate, male reproductive organs, Liver, Adrenal gland

Species : Rat

NOAEL : 100 mg/kg

Application Route : Oral

Exposure time : 26 W

Target Organs : Kidney

Species : Rat

LOAEL : > 316 mg/kg

Application Route : Oral
Exposure time : 26 W
Target Organs : Kidney

Species: DogLOAEL: 200 mg/kgExposure time: 26 WTarget Organs: Blood, Liver

Remarks : May cause damage to organs.

#### Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

## **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### **Components:**

#### Cefadroxil:

Inhalation : Symptoms: Nausea, Vomiting, vaginitis, Headache, Dizziness,

dry mouth, Fatigue, constipation, colitis, Gastrointestinal dis-

turbance

#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

## **Components:**

#### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

## Cefadroxil:

## **Ecotoxicology Assessment**

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

## Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

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# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

### Persistence and degradability

### **Components:**

Cellulose:

Biodegradability : Result: Readily biodegradable.

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

## **Bioaccumulative potential**

## Components:

Magnesium stearate:

Partition coefficient: n-

octanol/water

: log Pow: > 4

Mobility in soil
No data available

Other adverse effects

No data available

### **SECTION 13. DISPOSAL CONSIDERATIONS**

## **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## **SECTION 14. TRANSPORT INFORMATION**

### **International Regulations**

### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### **Domestic regulation**

**TDG** 

Not regulated as a dangerous good

## Special precautions for user

Not applicable

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

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 Or-

according to the Hazardous Products Regulations



# **Cefadroxil Monohydrate Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/17/2025 10679092-00008 Date of first issue: 05/06/2022

ganisation 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

Sources of key data used to compile the Material Safety

Data Sheet

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

cy, http://echa.europa.eu/

Revision Date : 06/17/2025 Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8