

**Cefadroxil Monohydrate Formulation**

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue:             |
| 3.0     | 2025/04/14     | 10679103-00007 | 2024/09/28                      |
|         |                |                | Date of first issue: 2022/05/06 |

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Cefadroxil Monohydrate Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

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

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**2. HAZARDS IDENTIFICATION****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:**

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 POISON CENTER/ doctor.

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**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: 42 %

**Other hazards which do not result in classification**

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.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name      | CAS-No.    | Concentration (% w/w) |
|--------------------|------------|-----------------------|
| Cellulose          | 9004-34-6  | >= 30 -< 60           |
| Cefadroxil         | 66592-87-8 | >= 30 -< 60           |
| Magnesium stearate | 557-04-0   | < 10                  |

**4. FIRST AID MEASURES**

- |                                                             |                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General advice                                              | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                                                                                                                                                                              |
| If inhaled                                                  | : If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                                                                                                                                                                                                                             |
| In case of skin contact                                     | : Wash with water and soap.<br>Get medical attention if symptoms occur.                                                                                                                                                                                                                                                                                                               |
| In case of eye contact                                      | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.                                                                                                                                                                                                                                                                                    |
| If swallowed                                                | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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).<br>Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.<br>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                                                                                                                                                                                                                                                                 |

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Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

**5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : 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 products : Carbon oxides  
Sodium oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Metal 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.  
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 minimise entry of the material into the air.  
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).

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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.

7. HANDLING AND STORAGE

- Technical measures

Local/Total ventilation

Advice on safe handling

Conditions for safe storage

Materials to avoid
- : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

: 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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
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.

: Keep in properly labelled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

: 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<br>(Form of exposure) | Control parameters / Permissible concentration | Basis  |
|------------|-----------|----------------------------------|------------------------------------------------|--------|
| Cellulose  | 9004-34-6 | NAB                              | 10 mg/m3                                       | ID OEL |

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|                    |                                                                                                                                                 |                                     |                    |          |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------|----------|
|                    |                                                                                                                                                 | TWA                                 | 10 mg/m3           | ACGIH    |
| Cefadroxil         | 66592-87-8                                                                                                                                      | TWA                                 | 500 mcg/m3 (OEB 2) | Internal |
|                    | Further information: RSEN                                                                                                                       |                                     |                    |          |
| Magnesium stearate | 557-04-0                                                                                                                                        | NAB                                 | 10 mg/m3           | ID OEL   |
|                    | Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals |                                     |                    |          |
|                    |                                                                                                                                                 | TWA (Inhalable particulate matter)  | 10 mg/m3           | ACGIH    |
|                    |                                                                                                                                                 | TWA (Respirable particulate matter) | 3 mg/m3            | ACGIH    |

**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** : Particulates type

**Hand protection** : Chemical-resistant gloves

**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.

**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** : powder

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|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Colour                                           | : | 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                                      | : | 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                                                               |
| Vapour pressure                                  | : | Not applicable                                                                  |
| Relative vapour density                          | : | Not applicable                                                                  |
| Relative density                                 | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)<br>Water solubility              | : | No data available                                                               |
| Partition coefficient: n-octanol/water           | : | Not applicable                                                                  |
| Auto-ignition temperature                        | : | No data available                                                               |
| Decomposition temperature                        | : | No data available                                                               |
| Viscosity<br>Viscosity, kinematic                | : | Not applicable                                                                  |
| Explosive properties                             | : | Not explosive                                                                   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |

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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 reactions : 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.

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:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
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

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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<br>Method: OECD Test Guideline 423<br>Assessment: The substance or mixture has no acute oral toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : LD50 (Rabbit): > 2,000 mg/kg<br>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 |

**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:****Cefadroxil:**

|        |              |
|--------|--------------|
| Result | : Sensitiser |
|--------|--------------|

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**Magnesium stearate:**

|                 |                                        |
|-----------------|----------------------------------------|
| Test Type       | : Maximisation 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:****Cellulose:**

|                       |                                                                                                                                                           |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                                                  |
|                       | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative                                                                                 |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Magnesium stearate:**

|                       |                                                                                                                                                        |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br>Remarks: Based on data from similar materials                           |
|                       | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative<br>Remarks: Based on data from similar materials |
|                       | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br>Remarks: Based on data from similar materials                                |

**Carcinogenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

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**Reproductive toxicity**

Not classified based on available information.

**Components:****Cellulose:**

|                               |                                                                                                                             |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative      |

**Cefadroxil:**

|                               |                                                                                                                                                           |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : Test Type: Fertility<br>Species: Mouse<br>Application Route: Intraperitoneal<br>Fertility: NOAEL: 400 mg/kg body weight<br>Result: No adverse effects   |
| Effects on foetal development | : Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 500 mg/kg body weight<br>Result: No adverse effects |

**Magnesium stearate:**

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

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**Repeated dose toxicity****Components:****Cellulose:**

|                   |                      |
|-------------------|----------------------|
| Species           | : Rat                |
| NOAEL             | : $\geq 9,000$ 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     | : 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       | : Dog                         |
| LOAEL         | : 200 mg/kg                   |
| Exposure time | : 26 W                        |
| Target 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 |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Cefadroxil:**

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

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dry mouth, Fatigue, constipation, colitis, Gastrointestinal disturbance

## 12. ECOLOGICAL INFORMATION

## Ecotoxicity

Components:

## Cellulose:

|                  |   |                                                                                                                                      |
|------------------|---|--------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish | : | LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h<br>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 ( <i>Leuciscus idus</i> (Golden orfe)): > 100 mg/l<br>Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials |
|------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                     |   |                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 ( <i>Daphnia magna</i> (Water flea)): > 1 mg/l<br>Exposure time: 47 h<br>Test substance: Water Accommodated Fraction<br>Method: Directive 67/548/EEC, Annex V, C.2.<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility |
|-----------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                  |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to algae/aquatic plants | : | EL50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility<br><br>NOELR ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
|----------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                            |   |                                                                       |
|----------------------------|---|-----------------------------------------------------------------------|
| Toxicity to microorganisms | : | EC10 ( <i>Pseudomonas putida</i> ): > 100 mg/l<br>Exposure time: 16 h |
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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

**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**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

**IATA-DGR**

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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

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

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**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable  
Prohibited substances : Not applicable  
Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**Cefadroxil Monohydrate Formulation**

|         |                |                |                                 |
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**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 : 2025/04/14

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

|        |   |                                         |
|--------|---|-----------------------------------------|
| ACGIH  | : | USA. ACGIH Threshold Limit Values (TLV) |
| ID OEL | : | Indonesia. Occupational Exposure Limits |

|              |   |                               |
|--------------|---|-------------------------------|
| ACGIH / TWA  | : | 8-hour, time-weighted average |
| ID OEL / NAB | : | Long term exposure limit      |

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, Evalua-

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tion, 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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