

**Cephapirin Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 28.09.2024  |
| 6.2     | 14.04.2025     | 420300-00025 | Date of first issue: 28.01.2016 |

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Cephapirin Formulation

Other means of identification : Metricure (A007394)  
METRICURE BENZATHINE CEPHAPIRIN INTRA-UTERINE  
SUSPENSION (47091)

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

**1.3 Details of the supplier of the safety data sheet**

Company : MSD  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

**1.4 Emergency telephone number**

+1-908-423-6000

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**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Precautionary statements : **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.

Hazardous components which must be listed on the label:  
Cefapirin

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification          | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|-------------------------|--------------------------|
| Cefapirin     | 21593-23-7<br>244-466-5                               | Resp. Sens. 1A;<br>H334 | >= 1 - < 10              |

For explanation of abbreviations see section 16.

**SECTION 4: First aid measures****4.1 Description of 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.                      |
| 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). |
| 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 as a precaution.<br>Get medical attention if symptoms occur.                                                                                       |

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|                        |   |                                                                                                                         |
|------------------------|---|-------------------------------------------------------------------------------------------------------------------------|
| In case of eye contact | : | Flush eyes with water as a precaution.<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. |

**4.2 Most important symptoms and effects, both acute and delayed**

|       |   |                                                                                                                                                                                                                                            |
|-------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : | Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br><br>May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
|-------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**4.3 Indication of any immediate medical attention and special treatment needed**

|           |   |                                         |
|-----------|---|-----------------------------------------|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|-----------------------------------------|

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

|                                |   |                                                                                            |
|--------------------------------|---|--------------------------------------------------------------------------------------------|
| Suitable extinguishing media   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.                                                                                |

**5.2 Special hazards arising from the substance or mixture**

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

**5.3 Advice for firefighters**

|                                               |   |                                                                                                                                                                                                                                                 |
|-----------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

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

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust 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 respira-

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tory irritants or sensitisers.  
 Take care to prevent spills, waste and minimize release to the environment.  
 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.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Keep in properly labelled containers. Keep tightly closed.  
 Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.  
 Advice on common storage : Do not store with the following product types:  
 Strong oxidizing agents  
 Gases

**7.3 Specific end use(s)**

Specific use(s) : No data available

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

| Components                | CAS-No.    | Value type (Form of exposure) | Control parameters            | Basis    |
|---------------------------|------------|-------------------------------|-------------------------------|----------|
| Cefapirin                 | 21593-23-7 | TWA                           | 0.4 mg/m <sup>3</sup> (OEB 2) | Internal |
| Further information: RSEN |            |                               |                               |          |

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006**

| Substance name                          | End Use   | Exposure routes | Potential health effects   | Value                    |
|-----------------------------------------|-----------|-----------------|----------------------------|--------------------------|
| Glycerides, mixed decanoyl and octanoyl | Workers   | Inhalation      | Long-term systemic effects | 177,79 mg/m <sup>3</sup> |
|                                         | Workers   | Skin contact    | Long-term systemic effects | 25,21 mg/kg bw/day       |
|                                         | Consumers | Inhalation      | Long-term systemic effects | 43,84 mg/m <sup>3</sup>  |
|                                         | Consumers | Skin contact    | Long-term systemic effects | 12,61 mg/kg bw/day       |
|                                         | Consumers | Ingestion       | Long-term systemic effects | 12,61 mg/kg bw/day       |

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006**

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------|
|----------------|---------------------------|-------|

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|                                         |                            |                 |
|-----------------------------------------|----------------------------|-----------------|
| Glycerides, mixed decanoyl and octanoyl | Oral (Secondary Poisoning) | 0,03 mg/kg food |
|-----------------------------------------|----------------------------|-----------------|

## 8.2 Exposure controls

## Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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

Laboratory operations do not require special containment.

## Personal protective equipment

|                          |   |                                                                                                                                                                                                                                                                                                                |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection          | : |                                                                                                                                                                                                                                                                                                                |
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                                      |
| Skin and body protection | : | Work uniform or laboratory coat.                                                                                                                                                                                                                                                                               |
| 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 (A-P)                                                                                                                                                                                                                                                            |

## SECTION 9: Physical and chemical properties

## 9.1 Information on basic physical and chemical properties

|                                                  |   |                   |
|--------------------------------------------------|---|-------------------|
| Appearance                                       | : | suspension        |
| Colour                                           | : | No data available |
| Odour                                            | : | No data available |
| Odour Threshold                                  | : | No data available |
| pH                                               | : | No data available |
| Melting point/freezing point                     | : | No data available |
| Initial boiling point and boiling range          | : | No data available |
| Flash point                                      | : | No data available |
| Evaporation rate                                 | : | No data available |
| Flammability (solid, gas)                        | : | Not applicable    |
| Flammability (liquids)                           | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Vapour pressure                        | : | No data available                                        |
| Relative vapour density                | : | No data available                                        |
| Relative 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. |

**9.2 Other information**

|                  |   |                   |
|------------------|---|-------------------|
| Molecular weight | : | No data available |
| Particle size    | : | No data available |

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

|                     |   |                                         |
|---------------------|---|-----------------------------------------|
| Hazardous reactions | : | Can react with strong oxidizing agents. |
|---------------------|---|-----------------------------------------|

**10.4 Conditions to avoid**

|                     |   |             |
|---------------------|---|-------------|
| Conditions to avoid | : | None known. |
|---------------------|---|-------------|

**10.5 Incompatible materials**

|                    |   |                  |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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

**Acute toxicity**

Not classified based on available information.

**Components:****Cefapirin:**

Acute oral toxicity : LD50 (Mouse): 26.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): > 7.600 mg/kg  
Application Route: Intraperitoneal

LD50 (Rat): 7.800 mg/kg  
Application Route: Intraperitoneal

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

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

**Components:****Cefapirin:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cefapirin:**

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

**Carcinogenicity**

Not classified based on available information.

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**Reproductive toxicity**

Not classified based on available information.

**Components:****Cefapirin:**

|                               |   |                                                                                                                                                                                                  |
|-------------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Intraperitoneal injection<br>Fertility: LOAEL: > 500 mg/kg body weight<br>Result: No effects on fertility |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal injection<br>Developmental Toxicity: LOAEL: > 200 mg/kg body weight                                   |

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****Cefapirin:**

|                   |   |                               |
|-------------------|---|-------------------------------|
| Species           | : | Rat                           |
| LOAEL             | : | >= 200 mg/kg                  |
| Application Route | : | Intraperitoneal               |
| Target Organs     | : | Blood                         |
| Remarks           | : | anemia                        |
| Species           | : | Dog                           |
| LOAEL             | : | 20 mg/kg                      |
| Application Route | : | Oral                          |
| Exposure time     | : | 4 Months                      |
| Target Organs     | : | Gastrointestinal tract        |
| Species           | : | Dog                           |
| LOAEL             | : | 100 mg/kg                     |
| Application Route | : | Intramuscular                 |
| Exposure time     | : | 10 Months                     |
| Target Organs     | : | Blood, Gastrointestinal tract |
| Remarks           | : | anemia                        |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Cefapirin:**

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Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, vaginitis, colitis, anorexia, Rash, anaphylaxis

**SECTION 12: Ecological information****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

|                        |                                                                                                                                                                                                                                                                                                             |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.                                                                                                                                                  |

**SECTION 14: Transport information****14.1 UN number**

ADN : Not regulated as a dangerous good

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|      |   |                                   |
|------|---|-----------------------------------|
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.2 UN proper shipping name**

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.3 Transport hazard class(es)**

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

**14.4 Packing group**

|                  |   |                                   |
|------------------|---|-----------------------------------|
| ADN              | : | Not regulated as a dangerous good |
| ADR              | : | Not regulated as a dangerous good |
| RID              | : | Not regulated as a dangerous good |
| IMDG             | : | Not regulated as a dangerous good |
| IATA (Cargo)     | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | Not regulated as a dangerous good |

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

DSL : not determined

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IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Full text of other abbreviations

Resp. Sens. : Respiratory sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### Further information

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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/>

**Classification of the mixture:**

Resp. Sens. 1

H334

**Classification procedure:**

Calculation method

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.

ZA / EN