

# SAFETY DATA SHEET



## Cimetidine Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
4242359-00011

Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Cimetidine Formulation

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

Use of the Substance/Mixture : Pharmaceutical

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)

Reproductive toxicity, Category 1B : H360D: May damage the unborn child.

Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 4242359-00011 Date of last issue: 30.09.2023 Date of first issue: 03.05.2019

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
**Storage:**  
P405 Store locked up.

Hazardous components which must be listed on the label:

cimetidine

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 40 %

### 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.

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.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
cimetidine	51481-61-9 257-232-2	Repr. 1B; H360D STOT RE 2; H373 (Liver, Kidney, Testis)	>= 30 - < 50

For explanation of abbreviations see section 16.

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## 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.  
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,

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0	Revision Date: 14.04.2025	SDS Number: 4242359-00011	Date of last issue: 30.09.2023 Date of first issue: 03.05.2019
----------------	------------------------------	------------------------------	---

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

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

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

Risks : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
  
May damage the unborn child.  
May cause damage to organs through prolonged or repeated exposure.

### 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  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

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  
Nitrogen oxides (NO<sub>x</sub>)

**Cimetidine Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
4242359-00011Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

Sulphur oxides  
Metal oxides

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

**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. 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal. 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. 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.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.

**Cimetidine Formulation**

Version 3.0	Revision Date: 14.04.2025	SDS Number: 4242359-00011	Date of last issue: 30.09.2023 Date of first issue: 03.05.2019
----------------	------------------------------	------------------------------	---

Local/Total ventilation	Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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.
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. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases

**7.3 Specific end use(s)**

Specific use(s)	: No data available
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**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
cimetidine	51481-61-9	TWA	1000 µg/m <sup>3</sup> (OEB 1)	
Cellulose	9004-34-6	OEL-RL	10 mg/m <sup>3</sup>	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For				

# SAFETY DATA SHEET



## Cimetidine Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
4242359-00011

Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

Hazardous Chemical Agents				
Starch	9005-25-8	OEL-RL	10 mg/m3	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				

### 8.2 Exposure controls

#### 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

Eye/face 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.
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	: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	: powder
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	: 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

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 4242359-00011      Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

---

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)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
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	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
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### 10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
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### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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**Cimetidine Formulation**

Version 3.0 Revision Date: 14.04.2025 SDS Number: 4242359-00011 Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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**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:****cimetidine:**

Acute oral toxicity	: LD50 (Rat): > 5.000 mg/kg
	LD50 (Mouse): 2.550 mg/kg
	LD50 (Hamster): > 4.000 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 106 mg/kg Application Route: Intravenous
	LD50 (Rabbit): 164 mg/kg Application Route: Intravenous
	LD50 (Rat): 860 mg/kg Application Route: Subcutaneous
	LD50 (Mouse): 437 mg/kg Application Route: Subcutaneous Symptoms: Convulsions

**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**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****cimetidine:**

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 4242359-00011 Date of last issue: 30.09.2023 Date of first issue: 03.05.2019

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Chromosomal aberration Result: negative
	Test Type: unscheduled DNA synthesis assay Test system: rat hepatocytes Result: negative
	Test Type: unscheduled DNA synthesis assay Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### cimetidine:

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
Target Organs	: Testis
Remarks	: Benign tumor(s)
Carcinogenicity - Assessment	: No evidence of carcinogenicity in animal studies.

### Reproductive toxicity

May damage the unborn child.

### Components:

#### cimetidine:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: NOAEL: 950 mg/kg body weight Result: No effect on reproduction capacity
Effects on foetal development	: Test Type: Development Species: Rat Application Route: Oral Developmental Toxicity: LOAEL: 17 mg/kg body weight Symptoms: male reproductive effects Remarks: Adverse effects were observed in males only.
Reproductive toxicity - Assessment	: May damage the unborn child.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

**Cimetidine Formulation**Version  
3.0Revision Date:  
14.04.2025SDS Number:  
4242359-00011Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019**Components:****cimetidine:**

Exposure routes	:	Oral
Target Organs	:	Liver, Kidney, Testis
Assessment	:	May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****cimetidine:**

Species	:	Rat
LOAEL	:	160 mg/kg
Application Route	:	Oral
Exposure time	:	2 Months
Target Organs	:	Gastrointestinal tract
Remarks	:	May cause damage to organs.

Species	:	Rat
NOAEL	:	200 mg/kg
Application Route	:	Oral
Exposure time	:	12 Months
Symptoms	:	No adverse effects

Species	:	Rat
LOAEL	:	950 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr
Target Organs	:	Liver, Testis, Prostate
Remarks	:	May cause damage to organs.

Species	:	Dog
NOAEL	:	366 mg/kg
Application Route	:	Oral
Exposure time	:	12 Months
Target Organs	:	Liver, Kidney, Prostate
Remarks	:	May cause damage to organs.

Species	:	Dog
NOAEL	:	144 mg/kg
Application Route	:	Oral
Exposure time	:	4 yr
Symptoms	:	No adverse effects

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****cimetidine:**

Ingestion	:	Symptoms: The most common side effects are:, Headache,
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# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0 Revision Date: 14.04.2025 SDS Number: 4242359-00011 Date of last issue: 30.09.2023 Date of first issue: 03.05.2019

Dizziness, Nausea, skin rash, Itching, May cause, central nervous system effects, gynecomastia, impotence, kidney effects  
Remarks: May cause harm to breast-fed children.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### cimetidine:

#### **Ecotoxicology Assessment**

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

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

##### cimetidine:

Partition coefficient: n-octanol/water : log Pow: 0,40

### 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.

# SAFETY DATA SHEET



## Cimetidine Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
4242359-00011

Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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  
**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

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 4242359-00011      Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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

Remarks : Not applicable for product as supplied.

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## 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  
IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## 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

H360D : May damage the unborn child.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

#### Full text of other abbreviations

Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
ZA OEL : South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits  
ZA OEL / OEL-RL : Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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;

# SAFETY DATA SHEET



## Cimetidine Formulation

Version  
3.0

Revision Date:  
14.04.2025

SDS Number:  
4242359-00011

Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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

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:

Repr. 1B H360D  
STOT RE 2 H373

### Classification procedure:

Calculation method  
Calculation method

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.

ZA / EN