

# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version 2.0 Revision Date: 14.04.2025 SDS Number: 3976732-00011 Date of last issue: 30.09.2023 Date of first issue: 14.02.2019

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

#### 1.1 Product identifier

Trade name : Ketamine (5%) Formulation

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

Use of the Substance/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)

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.

P280 Wear protective gloves/ protective clothing/ eye protec-

# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version 2.0	Revision Date: 14.04.2025	SDS Number: 3976732-00011	Date of last issue: 30.09.2023 Date of first issue: 14.02.2019
----------------	------------------------------	------------------------------	---

tion/ 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:

Ketamine hydrochloride

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 5 %

### 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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ketamine hydrochloride	1867-66-9 217-484-6	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 2; H373 (Kidney, Liver, Brain)	>= 3 - < 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.

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.  
Get medical attention.

**Ketamine (5%) Formulation**

Version 2.0	Revision Date: 14.04.2025	SDS Number: 3976732-00011	Date of last issue: 30.09.2023 Date of first issue: 14.02.2019
----------------	------------------------------	------------------------------	---

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

In case of eye contact : Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

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

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

Risks : Suspected of damaging the unborn child.

**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 : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NO<sub>x</sub>)

**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.

**Ketamine (5%) Formulation**Version  
2.0Revision Date:  
14.04.2025SDS Number:  
3976732-00011Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019**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.

**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 : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe mist or vapours. 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. 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 contami-

**Ketamine (5%) Formulation**

Version 2.0	Revision Date: 14.04.2025	SDS Number: 3976732-00011	Date of last issue: 30.09.2023 Date of first issue: 14.02.2019
----------------	------------------------------	------------------------------	---

nated 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. 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

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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
Ketamine hydro-chloride	1867-66-9	TWA	10 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal

**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.

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

Minimize open handling.

**Personal protective equipment**

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

# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version 2.0      Revision Date: 14.04.2025      SDS Number: 3976732-00011      Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019

---

Remarks	:	Consider double gloving.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
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)

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	:	liquid
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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available

# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version 2.0 Revision Date: 14.04.2025 SDS Number: 3976732-00011 Date of last issue: 30.09.2023 Date of first issue: 14.02.2019

---

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 : Not applicable

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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.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

**Ketamine (5%) Formulation**

Version 2.0      Revision Date: 14.04.2025      SDS Number: 3976732-00011      Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019

---

**Components:****Ketamine hydrochloride:**

Acute oral toxicity	: LD50 (Rat): 447 mg/kg
	LD50 (Mouse): 617 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 59 mg/kg Application Route: Intravenous
	LD50 (Mouse): 59 mg/kg Application Route: Intramuscular
	LD50 (Mouse): 356 mg/kg Application Route: Intramuscular
	LD50 (Guinea pig): 361 mg/kg Application Route: Intramuscular
	LD50 (Rat): 224 mg/kg Application Route: Intraperitoneal

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Ketamine hydrochloride:**

Species	: Rabbit
Result	: irritating

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Ketamine hydrochloride:**

Species	: Rabbit
Result	: irritating

**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.

**Carcinogenicity**

Not classified based on available information.

**Ketamine (5%) Formulation**Version  
2.0Revision Date:  
14.04.2025SDS Number:  
3976732-00011Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019**Reproductive toxicity****|| Suspected of damaging the unborn child.****Components:****Ketamine hydrochloride:**

Effects on foetal development	: Test Type: Development Species: Rat Application Route: Intramuscular Developmental Toxicity: NOAEL: 120 mg/kg body weight Target Organs: Kidney, Liver, Heart Result: No teratogenic effects
	Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 20 mg/kg body weight Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Rat Application Route: Intramuscular Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Rabbit Application Route: Intramuscular Developmental Toxicity: LOAEL: 60 mg/kg body weight Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.
	Test Type: Development Species: Monkey Application Route: Intramuscular Target Organs: Brain Result: Effects on prenatal and postnatal growth.
Reproductive toxicity - Assessment	: Suspected of damaging the unborn child.

**STOT - single exposure****|| Not classified based on available information.****STOT - repeated exposure****|| Not classified based on available information.****Components:****Ketamine hydrochloride:**

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

**Ketamine (5%) Formulation**Version  
2.0Revision Date:  
14.04.2025SDS Number:  
3976732-00011Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019**Repeated dose toxicity****Components:****Ketamine hydrochloride:**

Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	3 Months
Target Organs	:	Kidney, Liver, Bladder
Remarks	:	Significant toxicity observed in testing
Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	6 Months
Target Organs	:	Kidney, Liver, Bladder
Remarks	:	Significant toxicity observed in testing
Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	28 Weeks
Target Organs	:	Kidney
Remarks	:	Significant toxicity observed in testing
Species	:	Mouse
LOAEL	:	30 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	30 Days
Target Organs	:	Brain, Liver
Remarks	:	Significant toxicity observed in testing
Species	:	Monkey
LOAEL	:	1 mg/kg
Application Route	:	Intraperitoneal
Exposure time	:	6 Months
Target Organs	:	Brain
Remarks	:	Significant toxicity observed in testing

**Aspiration toxicity****Not classified based on available information.****Experience with human exposure****Components:****Ketamine hydrochloride:**

Ingestion	:	Symptoms: The most common side effects are:, central nervous system effects, hypertension, Dizziness, Headache, Nausea, Drowsiness
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**Ketamine (5%) Formulation**

Version 2.0 Revision Date: 14.04.2025 SDS Number: 3976732-00011 Date of last issue: 30.09.2023 Date of first issue: 14.02.2019

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**SECTION 12: Ecological information****12.1 Toxicity****Components:****Ketamine hydrochloride:****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:****Ketamine hydrochloride:**

Partition coefficient: n-octanol/water	: log Pow: 2,18
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**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.
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**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.
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**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.
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# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version 2.0	Revision Date: 14.04.2025	SDS Number: 3976732-00011	Date of last issue: 30.09.2023 Date of first issue: 14.02.2019
----------------	------------------------------	------------------------------	---

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

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

Remarks : Not applicable for product as supplied.

# SAFETY DATA SHEET



## Ketamine (5%) Formulation

Version  
2.0

Revision Date:  
14.04.2025

SDS Number:  
3976732-00011

Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019

---

### 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

H302 : Harmful if swallowed.  
H315 : Causes skin irritation.  
H319 : Causes serious eye irritation.  
H361d : Suspected of damaging the unborn child.  
H373 : May cause damage to organs through prolonged or repeated exposure in contact with skin.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Irrit. : Eye irritation  
Repr. : Reproductive toxicity  
Skin Irrit. : Skin irritation  
STOT RE : Specific target organ toxicity - repeated exposure

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



## Ketamine (5%) Formulation

Version  
2.0

Revision Date:  
14.04.2025

SDS Number:  
3976732-00011

Date of last issue: 30.09.2023  
Date of first issue: 14.02.2019

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. 2

H361d

### Classification procedure:

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.

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