according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# **Ketamine (5%) Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 1.12
 28.09.2024
 3983605-00013
 Date of first issue: 14.02.2019

# 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 Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

# 1.4 Emergency telephone number

+1-908-423-6000

# **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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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P280 Wear protective gloves/ protective clothing/ eye protective clothing/

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

# **Additional Labelling**

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.

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
	Registration number		
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.

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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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

First Aid responders should pay attention to self-protection. Protection of first-aiders

> 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 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

Suspected of damaging the unborn child. Risks

4.3 Indication of any immediate medical attention and special treatment needed

**Treatment** : Treat symptomatically and supportively.

# **SECTION 5: Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Hazardous combustion prod: :

ucts

Carbon oxides Chlorine compounds Nitrogen oxides (NOx)

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

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

SO.

Evacuate area.

#### **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 pro-

tective 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 absor-

bent.

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 deter-

mine 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 : 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 as-

sessment

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-

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

# **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/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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### 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

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

# **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flammability (solid, gas) : Not applicable

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Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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.

## **SECTION 11: Toxicological information**

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure 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

#### **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

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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.

#### Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

### Ketamine hydrochloride:

Effects on foetal develop-

Species: Rat

ment

Application Route: Intramuscular

Developmental Toxicity: NOAEL: 120 mg/kg body weight

Target Organs: Kidney, Liver, Heart Result: No teratogenic effects

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Test Type: Development

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 - As-

sessment

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.

#### 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

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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 Monkhs

Target Organs : Brain

Remarks : Significant toxicity observed in testing

#### **Aspiration toxicity**

Not classified based on available information.

### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

## Experience with human exposure

### **Components:**

### Ketamine hydrochloride:

Ingestion : Symptoms: The most common side effects are:, central nerv-

ous system effects, hypertension, Dizziness, Headache, Nau-

sea, Drowsiness

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

# 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 Endocrine disrupting properties

### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

### 12.7 Other adverse effects

No data available

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number or ID number

ADR : 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

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#### 14.5 Environmental hazards

Not regulated as a dangerous good

## 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast) Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

### 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**

H302 Harmful if swallowed. H315 Causes skin irritation.

Causes serious eye irritation. H319

Suspected of damaging the unborn child. H361d 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; 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 Re-

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striction 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 Agen-

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

Classification of the mixture: Classification procedure:

Repr. 2 H361d 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.

NO / EN