

# Ketamine hydrochloride

## Safety Data Sheet

**900070**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU)

2015/830

Date of issue: 09/01/2015 Revision date 30/03/2020

Supersedes 15/02/2017

Version: 3.0

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

### 1.1. Product identifier

Product form	: Substance
Substance name	: Ketamine hydrochloride
IUPAC name	: 2-(2-chlorophenyl)-2-(methylamino)cyclohexanone hydrochloride
EC-No.	: 217-484-6
CAS-No.	: 1867-66-9
Product code	: 900070
Formula	: C13H17CL2NO
Product group	: Raw material

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

#### 1.2.1. Relevant identified uses

Main use category	: Pharmaceutical industry
Use of the substance/mixture	: Active Pharmaceutical Ingredient for the preparation of

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

#### Supplier

Duchefa Farma BV  
 A. Hofmanweg 71  
 2031BH Haarlem - The Netherlands  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

### 1.4. Emergency telephone number

Emergency number	: Supplier contact information: +31(0)23-5319093 (M-F 09:00-17:00) +31(0)6-30109355 (outside office hours)
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Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272/2008 [CLP]** show CLP information only

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Serious eye damage/eye irritation, Category 2H319

Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritationH335

Full text of H statements : see section 16


Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP):



GHS07

Signal word (CLP): Warning

Hazard statements (CLP):

H302 - Harmful if swallowed.

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Precautionary statements (CLP):

P261 - Avoid breathing dust.

P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ketamine hydrochloride	(CAS-No.) 1867-66-9 (EC-No.) 217-484-6	99 - 101	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : If possible show this sheet, if not available show packaging or label.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Wash skin with mild soap and water.
- First-aid measures after eye contact : Immediately rinse with plenty of water.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person  
Rinse mouth.  
If you feel unwell, seek medical advice.

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

- Symptoms/effects : Nervous system disorder.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Water spray  
dry chemical powder, alcohol-resistant foam, carbon dioxide (CO<sub>2</sub>).

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

- Hazardous decomposition products in case of fire : Carbon oxides (CO, CO<sub>2</sub>)  
Nitrogen oxides  
Hydrogen chloride gas.

### 5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

- Protective equipment : Protective clothing.
- Emergency procedures : Ensure adequate air ventilation.
- Measures in case of dust release : Avoid dust to spread.

#### 6.1.2. For emergency responders

No additional information available

## 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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

Methods for cleaning up : Sweep up, shovel or vacuum. Small quantities of liquid spill: take up in non-combustible absorbent material and shovel into container for disposal.

## 6.4. Reference to other sections

See Heading 13.

# SECTION 7: Handling and storage

## 7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice.

Hygiene measures : Do not eat, drink or smoke when using this product.

## 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations.

Incompatible products : oxidising substances.

Incompatible materials : Protect from light.

Storage temperature : 15 - 25 °C

Storage area : Keep container tightly closed and dry.

## 7.3. Specific end use(s)

Pharmaceutical industry.

# SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

No additional information available

## 8.2. Exposure controls

### Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

### Personal protective equipment:

Safety glasses. Dust/aerosol mask with filter type P3. Gloves.

### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN ISO 374

### Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

### Skin and body protection:

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Protective clothing (with elasticated cuffs and closed neck). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection:**

Dustmask with filtertype P3

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 274.19 g/mol
Colour	: White.
Odour	: Neutral.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water Soluble in ethanol.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

**9.2. Other information**

No additional information available

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

Stable under normal conditions.

**10.2. Chemical stability**

No additional information available

**10.3. Possibility of hazardous reactions**

No additional information available

**10.4. Conditions to avoid**

No additional information available

**10.5. Incompatible materials**

No additional information available

**10.6. Hazardous decomposition products**

Chlorine

Carbon oxides (CO, CO<sub>2</sub>)

Nitrogen oxides.

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

Acute toxicity : Harmful if swallowed.

**Ketamine hydrochloride (1867-66-9)**

LD50 oral rat	447 mg/kg
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Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

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

No additional information available

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

No additional information available

**12.4. Mobility in soil**

No additional information available

**12.5. Results of PBT and vPvB assessment**

No additional information available

**12.6. Other adverse effects**

No additional information available

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

Product/Packaging disposal recommendations : Dispose of this material and its container at hazardous or special waste collection point.

**SECTION 14: Transport information**

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

**14.6. Special precautions for user****. Overland transport**

No data available

**- Air transport**

No data available

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

Not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Ketamine hydrochloride is not on the REACH Candidate List

Ketamine hydrochloride is not on the REACH Annex XIV List

**15.1.2. National regulations**

No additional information available

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

## SECTION 16: Other information

Indication of changes:

1		Modified	Change of logo
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : REACH Disclaimer:  
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number). DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II) ducheffa nieuwe logo

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*