

# Ropivacaine hydrochloride monohydrate

## Safety Data Sheet

**900264**

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

2015/830

Date of issue: 12/12/2011 Revision date 14/05/2020

Supersedes 08/03/2017

Version: 3.0

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Ropivacaine hydrochloride monohydrate
IUPAC name	: (-)-(2S)-N-(2,6-Dimethylphenyl)-1-propylpiperidine-2-carboxamide hydrochloride monohydrate
EC-No.	: 663-286-1
CAS-No.	: 132112-35-7
Product code	: 900264
Formula	: C <sub>17</sub> H <sub>27</sub> ClN <sub>2</sub> O · H <sub>2</sub> O
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 ingredient for the preparation of pharmaceuticals
Function or use category	: Raw material

##### 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@ducheffa.nl](mailto:farma@ducheffa.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)
------------------	------------------------------------------------------------------------------------------------------------------

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

Serious eye damage/eye irritation, Category 1 H318

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 (H) to display

Hazard pictograms (CLP)



GHS05

GHS07

Signal word (CLP) : Danger

Hazard statements (CLP) : H302 - Harmful if swallowed.  
H318 - Causes serious eye damage.

Precautionary statements (CLP) : P280 - Wear eye protection, face protection, protective clothing, protective gloves.  
P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.  
P330 - Rinse mouth.  
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.  
P310 - Immediately call a POISON CENTER/doctor.

### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ropivacaine hydrochloride monohydrate	(CAS-No.) 132112-35-7 (EC-No.) 663-286-1	99 - 101	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318

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	: Allow affected person to breathe fresh air Obtain medical attention if breathing difficulty persists.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. Seek medical advice.

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

No additional information available

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

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

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.
Explosion hazard	: Product is not explosive.

#### 5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
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

Emergency procedures	: Ensure adequate air ventilation. Avoid raising dust. Only qualified personnel equipped with suitable protective equipment may intervene.
----------------------	--------------------------------------------------------------------------------------------------------------------------------------------

##### 6.1.2. For emergency responders

Protective equipment	: Wear proper protective equipment.
----------------------	-------------------------------------

#### 6.2. Environmental precautions

Prevent product from entering drains.

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

- For containment : Stop leak without risks if possible. Sweeping or shovelling without dust for disposal.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water.

### 6.4. Reference to other sections

See Heading 8. 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 procedures.

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

- Storage conditions : Store in dry, well-ventilated area  
Keep container tightly closed.  
Protect from heat and direct sunlight.
- Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

No additional information available

## 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 P2. 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:

Protective clothing (with elasticated cuffs and closed neck)

#### Respiratory protection:

Dust production: dust mask with filter type P2



## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 328.9 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.5 - 6
pH solution	: 4.5 - 6 % (2% solution)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 267 - 269 °C
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

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

High temperature

Direct sunlight.

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed.

Ropivacaine hydrochloride monohydrate (132112-35-7)	
LD50 oral rat	1750 mg/kg

Skin corrosion/irritation : Not classified

pH: 4.5 - 6

Serious eye damage/irritation : Causes serious eye damage.

pH: 4.5 - 6

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

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 in a safe manner in accordance with local/national regulations.

**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

Ropivacaine hydrochloride monohydrate is not on the REACH Candidate List

Ropivacaine hydrochloride monohydrate is not on the REACH Annex XIV List

**15.1.2. National regulations**

No additional information available

## Safety Data Sheet

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

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

Indication of changes:

1.1	EC-No.	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	H319 changed into H318
8.2	Appropriate engineering controls	Added	
8.2	Skin and body protection	Modified	

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 : EP. Supplier. ECHA.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.

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.*