

# Prilocaine

## Safety Data Sheet

according to Regulation (EC) No. 453/2010  
Date of issue: 08/06/2015    Revision date:

Version: 1.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Prilocaine  
EC no : 211-957-0  
CAS No : 721-50-6  
Product code : 758418  
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  
Industrial/Professional use spec : For professional use only  
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

##### 1.2.2. Uses advised against

No additional information available

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

Duchefa FARMA BV  
A. Hofmanweg 71  
2031BH Haarlem - Nederland  
T +31(0)23-5319093 - F +31(0)23-5318027  
[info@duchefa.com](mailto:info@duchefa.com) - [www.duchefa.com](http://www.duchefa.com)

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 4 (Oral) H302  
Skin Irrit. 2 H315  
Eye Irrit. 2 H319

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Aquatic Chronic 3

H412

Full text of H-phrases: see section 16

### Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Xi; R41

R52/53

Full text of R-phrases: see section 16

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP)

: P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell  
P302+P352 - IF ON SKIN: Wash with plenty of soap and water  
P305 - IF IN EYES:  
P351 - Rinse cautiously with water for several minutes  
P273 - Avoid release to the environment

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Name : Prilocaine  
CAS No : 721-50-6  
EC no : 211-957-0

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Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Prilocaine	(CAS No) 721-50-6 (EC no) 211-957-0	100	Xi; R41 R52/53	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412

Full text of R- and H-phrases: see section 16

### 3.2. Mixture

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : Allow victim to breathe fresh air. Get medical advice and attention if you feel unwell.
- First-aid measures after skin contact : Wash with plenty of soap and water.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes.
- First-aid measures after ingestion : Get medical advice/attention if you feel unwell.

### 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

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

### 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

General measures : Evacuate unnecessary personnel.

#### 6.1.1. For non-emergency personnel

#### 6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

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

Methods for cleaning up : Recover the product by vacuuming, shovelling or sweeping.

### 6.4. Reference to other sections

Reference to other sections (8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

No additional information available

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

Storage conditions : Protect from light. Store at room temperature. Keep container tightly closed.

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 : Handle in accordance with good industrial hygiene and safety practice.

Hand protection : Wear gloves to EN374 to protect against skin effects from powders

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 : Dustmask with filtertype P1

## SECTION 9: Physical and chemical properties

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

Physical state : Solid

Appearance : Crystalline powder.

Molecular mass : 220,3 g/mol

Colour : white.

Odour : characteristic.

Odour threshold : No data available

pH : No data available

Relative evaporation rate (butylacetate=1) : No data available

Melting point : 36 - 39 °C

Freezing point : No data available

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Boiling point	: 156 - 158
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	: Poorly soluble in water. Soluble in ethanol.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
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

No additional information available

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

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

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

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

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

<b>Prilocaine (721-50-6)</b>	
Additional information	Harmful to aquatic organisms

#### 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

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### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

- Regional legislation (waste) : Disposal must be done according to official regulations.  
Waste disposal recommendations : Dispose of contaminated material at an authorized site.

### SECTION 14: Transport information

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

#### 14.1. UN number

Not regulated for transport

#### 14.2. UN proper shipping name

- Proper Shipping Name (ADR) : Not applicable  
Proper Shipping Name (IMDG) : Not applicable  
Proper Shipping Name (IATA) : Not applicable  
Proper Shipping Name (ADN) : Not applicable  
Proper Shipping Name (RID) : Not applicable

#### 14.3. Transport hazard class(es)

##### ADR

- Transport hazard class(es) (ADR) : Not applicable

##### IMDG

- Transport hazard class(es) (IMDG) : Not applicable

##### IATA

- Transport hazard class(es) (IATA) : Not applicable

##### ADN

- Transport hazard class(es) (ADN) : Not applicable

##### RID

- Transport hazard class(es) (RID) : Not applicable

#### 14.4. Packing group

- Packing group (ADR) : Not applicable  
Packing group (IMDG) : Not applicable  
Packing group (IATA) : Not applicable  
Packing group (ADN) : Not applicable  
Packing group (RID) : Not applicable

#### 14.5. Environmental hazards

- Dangerous for the environment : No  
Marine pollutant : No  
Other information : No supplementary information available

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### 14.6. Special precautions for user

#### - Overland transport

No data available

#### - Transport by sea

No data available

#### - Air transport

No data available

#### - Inland waterway transport

Carriage prohibited (ADN) : No

Not subject to ADN : No

#### - Rail transport

Carriage prohibited (RID) : No

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 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

Prilocaine is not on the REACH Candidate List

Prilocaine 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

## SECTION 16: Other information

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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. Supplier.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H412	Harmful to aquatic life with long lasting effects
R41	Risk of serious damage to eyes
R52/53	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Xi	Irritant

SDS EU (REACH Annex II) Duchefa

*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*