

## Safety Data Sheet

473472

Version: 3.0

Issue date: 09/02/2015      Revision date 19/11/2020  
Supersedes 23/02/2017

### 1.1. Product identifier

Product form	: Substance
Substance name	: Oxybuprocaine hydrochloridum
Chemical name	: 2-(diethylamino)ethyl-4-amino-3-butoxybenzoaathydrochloride
EC-No.	: 227-808-8
CAS-No.	: 5987-82-6
Product code	: 473472
Formula	: C17H29CLN2O3
Product group	: Raw material

### 1.2.1. Relevant identified uses

Main use category	: Pharmaceutical
Industrial/Professional use spec	: Industrial For professional use only
Use of the substance/mixture	: Active ingredient for the preparation of pharmaceuticals

No additional information available

## Supplier

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

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]

Acute toxicity (oral), Category 4	H302
Acute toxicity (dermal), Category 4	H312
Acute toxicity (inhalation:dust,mist) Category 4	H332
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335

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 classification (CLP) to display

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled  
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 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

This substance/mixture does not meet the criteria of REACH regulation, annex XIII

This substance/mixture does not meet the criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type

: Pharmaceuticals

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Oxybuprocaine hydrochloridum	(CAS-No.) 5987-82-6 (EC-No.) 227-808-8	98,5 - 101,5	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 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 : Never give anything by mouth to an unconscious person  
If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
Call a POISON CENTER/doctor if you feel unwell.
- First-aid measures after skin contact : Wash skin with mild soap and water  
If skin irritation or rash occurs: Get medical advice/attention.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes.  
Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists:  
Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth  
Drink PLENTY of water  
Call a physician immediately.

### 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 : Alcohol resistant foam  
Dry powder  
Carbon dioxide  
Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

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

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

#### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. 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

- General measures : Do not breathe dust. Avoid dust formation. Reduce/avoid exposure and/or contact. Ensure adequate ventilation.

##### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

##### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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

- Methods for cleaning up : Recover the product by vacuuming, shovelling or sweeping. Avoid raising dust. Store away from other materials.

#### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

### 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 : Protect from sunlight.  
Keep only in original container.  
Store in a dry place.

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Incompatible products : oxidising substances.

Storage temperature : 15 - 25 °C

### 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.

#### 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	: 344,9 g/mol
Colour	: White.
Odour	: No data available
Odour threshold	: No data available
pH	: 4,5 - 6 (10 g/l)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 159 - 161 °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)	: Non flammable.

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Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Highly soluble in water Soluble in ethanol.
Log Pow	: 4,38
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 dangerous reactions known under normal conditions of use.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Possible reaction with strong oxidizers.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

acids

alkalis

Oxidizing agent

Reducing agents

Water.

### 10.6. Hazardous decomposition products

Nitrogen oxides

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

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	: Harmful by inhalation, in contact with skin and if swallowed. Irritating to eyes, respiratory system and skin
Skin corrosion/irritation	: Causes skin irritation. pH: 4,5 - 6 (10 g/l)
Serious eye damage/irritation	: Causes serious eye irritation. pH: 4,5 - 6 (10 g/l)
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met

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Germ cell mutagenicity	: Mutagenicity tests revealed no genotoxic potential. Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled.

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

Ecology - general : There are no available data for a classification.

Oxybuprocaine hydrochloridum (5987-82-6)	
EC50 Daphnia 1	30,2 mg/l (OECD-Directive 202, part 1, static)
EC20 (180 min)	80.2 mg/l activated organic sludge (OECD-Directive 209, static)

**12.2. Persistence and degradability**

Oxybuprocaine hydrochloridum (5987-82-6)	
Persistence and degradability	Not established.

**12.3. Bioaccumulative potential**

Oxybuprocaine hydrochloridum (5987-82-6)	
Log Pow	4,38
Bioaccumulative potential	Not established. Based on the coefficient n-octanol / water (log Pow) a concentration in organisms is possible.

**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**

Additional information : Avoid release to the environment.. Warning - substance not yet tested completely

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

Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations regulations. Dispose of contents/container to Collection point.

Ecology - waste materials : Avoid release to the environment.

**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

Oxybuprocaine hydrochloridum is not on the REACH Candidate List

Oxybuprocaine hydrochloridum is not on the REACH Annex XIV List

**15.1.2. National regulations****Germany**

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

**Netherlands**



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SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	The substance is not listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	The substance is not listed

### Denmark

Recommendations Danish Regulation	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product
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### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

		Added	Change of logo
7.1	Precautions for safe handling	Modified	
9.1	Melting point	Modified	
9.1	Molecular mass	Modified	
9.2	Additional information	Removed	
10.3	Possibility of hazardous reactions	Added	

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 : Supplier. EP.

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2

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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.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II) ducheфа 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.*