

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 03/04/2023 Revision date: 28/01/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Oxybuprocaine hydrochloride
Chemical name	: Oxybuprocaine hydrochloride
EC-No.	: 227-808-8
CAS-No.	: 5987-82-6
Product code	: 201600674

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

##### Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

##### Uses advised against

Restrictions on use	: Not for food, drug or home use
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#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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### 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
Skin sensitisation, Category 1	H317
Specific target organ toxicity – Single exposure, Category 3,	H335
Respiratory tract irritation	
Full text of H- and EUH-statements: see section 16	

##### Adverse physicochemical, human health and environmental effects

Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. Causes serious eye irritation. May cause an allergic skin reaction. Causes skin irritation. May cause respiratory irritation.

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 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+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Precautionary statements (CLP)

: P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P301+P312 - IF SWALLOWED: Call a POISON CENTRE or 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+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 - Call a POISON CENTRE or doctor if you feel unwell.

P321 - Specific treatment (see supplemental first aid instruction on this label).

P330 - Rinse mouth.

P332+P313 - If skin irritation occurs: Get medical advice/attention.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

No labelling required

### 2.3. Other hazards

Other information

: Active substance (in pharmaceutical products).

Warning - substance not yet tested completely.

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Oxybuprocaine hydrochloride	CAS-No.: 5987-82-6 EC-No.: 227-808-8	≤ 100	Acute Tox. 4 (Oral), H302 (ATE=300 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Inhalation:dust,mist), H332 (ATE=1 mg/l/4h) Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. Immediately call a POISON CENTER/doctor.
First-aid measures after skin contact	: Wash skin thoroughly with mild soap and water. Get immediate medical advice/attention. Take off contaminated clothing. Gently wash with plenty of soap and water. If symptoms persist, call a physician. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: May cause an allergic skin reaction. Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

#### 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	: Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
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	: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.
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#### 5.3. Advice for firefighters

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

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

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

General measures : Avoid contact with skin, eyes and clothing.

#### For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

#### For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

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

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

### 6.4. Reference to other sections

See Section 13 for disposal information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

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

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.

Packaging materials : Keep in original containers.

### 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

##### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

#### Personal protection equipment

##### Eye and face protection

##### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Skin protection

#### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

#### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

### Respiratory protection

#### Respiratory protection:

In case of dust formation use respirator with filter: P3

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: white. almost white.
Appearance	: Crystalline powder. Crystals.
Molecular mass	: 344.9 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 158 – 162 °C
Freezing point	: Not available
Boiling point	: 446.9 °C
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 224.1 °C
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 5 – 6
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: > 1000 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not 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

No additional information available

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

No additional information available

## SECTION 11: Toxicological information

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

Acute toxicity (oral) : Harmful if swallowed.  
Acute toxicity (dermal) : Harmful in contact with skin.  
Acute toxicity (inhalation) : Inhalation:dust,mist: Harmful if inhaled.

#### Oxybuprocaine hydrochloride (5987-82-6)

LD50 oral rat	> 300 – < 2000 mg/kg
LD50 dermal	> 1000 – < 2000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 1 – < 5 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.  
pH: 5 – 6  
Serious eye damage/irritation : Causes serious eye irritation.  
pH: 5 – 6  
Respiratory or skin sensitisation : May cause an allergic skin reaction.  
Germ cell mutagenicity : Not classified (Lack of data)  
Carcinogenicity : Not classified (Lack of data)  
Reproductive toxicity : Not classified (Lack of data)  
STOT-single exposure : May cause respiratory irritation.  
STOT-repeated exposure : Not classified (Lack of data)  
Aspiration hazard : Not classified (Lack of data)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)  
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

### 12.2. Persistence and degradability

#### Oxybuprocaine hydrochloride (5987-82-6)

Persistence and degradability	Not rapidly degradable
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### 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

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

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

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

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

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### EU-Regulations

#### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

### Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

## 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Revision date	Added
	Supersedes version of	Added
1.1	Synonyms	Removed
1.1	EC-No.	Added
1.1	CAS-No.	Added
1.1	Name	Modified
1.2	Main use category	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Precautionary statements (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures after eye contact	Modified
4.1	First-aid measures after ingestion	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after inhalation	Added
4.1	First-aid measures after skin contact	Modified
4.2	Symptoms/effects after inhalation	Added
4.2	Symptoms/effects after eye contact	Added



# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
4.2	Symptoms/effects after skin contact	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	General measures	<b>Added</b>
6.1	Protective equipment	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Hand protection	<b>Modified</b>
8.2	Appropriate engineering controls	<b>Modified</b>
8.2	Skin and body protection	<b>Modified</b>
8.2	Eye protection	<b>Added</b>
8.2	Respiratory protection	<b>Added</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Modified</b>
9	Melting point	<b>Added</b>
9	Flash point	<b>Added</b>
9	Boiling point	<b>Added</b>
9	pH	<b>Added</b>
9	Molecular mass	<b>Added</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
11.1	ATE CLP (dermal)	<b>Added</b>
11.1	LD50 dermal	<b>Added</b>

# Oxybuprocaine hydrochloride

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
11.1	LD50 oral rat	Added
11.1	ATE CLP (oral)	Modified
11.1	ATE CLP (dust,mist)	Added
12.1	LC50 Inhalation - Rat (Dust/Mist)	Added
12.1	Ecology - general	Removed
14.1	UN-No. (ADR)	Removed
14.1	UN-No. (IMDG)	Removed
14.1	UN-No. (IATA)	Removed

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
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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