

## Safety Data Sheet

according to Regulation (EC) No 1907/2006 (REACH)  
Classifications according to Regulation (EC) No 1272/2008.  
Printdate 02 Jun 2023

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product name:

Bupivacaine hydrochloride

### 1.1. Catalog No.:

683869

### 1.2. Relevant identified uses of the substance or mixture

Identified: Laboratory chemical  
uses: R&D

### 1.3. Uses advised against:

HPC Standards GmbH  
Am Wieseneck 7

04451 Cunnersdorf  
Deutschland

Tel. +49 34291 3372-36  
Fax. +49 34291 3372-39  
contact@hpc-standards.com

### 1.4. Emergency telephone number

HPC Standards Tel. +49 34291 3372-36  
This number is only available during office hours.

## 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture  
Regulation (EC) No 1272/2008  
Acute toxicity - Oral Category 2 - (H300)  
Reproductive toxicity Category 2 - (H361)  
Effects on or via lactation Yes - (H362)  
Specific target organ toxicity -- single exposure Category 1

### 2.2. Label elements

#### 2.2.1. Pictogram



#### 2.2.2.

241-917-8 Contains Bupivacaine hydrochloride  
Signal word  
Danger

**Hazard statements**

H300 - Fatal if swallowed

H361 - Suspected of damaging fertility or the unborn child

H362 - May cause harm to breast-fed children

H370 - Causes damage to organs

Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P263 - Avoid contact during pregnancy and while nursing

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

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor

**2.3. Other hazards**

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Chemical name Bupivacaine hydrochloride

EU - REACH (1907/2006) - Article 59(1)

- Candidate List of Substances of Very High Concern (SVHC) for Authorisation:-

EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances: -

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name Bupivacaine hydrochloride 18010-40-7

Weight-% 100

REACH registrationnumber

EC No 241-917-8

Classification according to Regulation (EC) No. 1272/2008 [CLP] : Acute Tox. 2 (H300) Repr. 2 (H361) Lact. (H362) STOT

SE 1 (H370)STOT SE 3 (H336)

Specificconcentrationlimit (SCL) :-

M-Factor M-Factor(long-term) :-

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

Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

#### 3.1.1. Formula

C<sub>18</sub>H<sub>29</sub>ClN<sub>2</sub>O

#### 3.1.2. Molecular Weight (g/mol)

324.89

### 3.1.3. CAS-No.

18010-40-7

## 4. FIRST AID MEASURES

### 4.1. Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. IF exposed or concerned: Get medical advice/attention.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a doctor.

Skin contact Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a doctor.

Ingestion Get immediate medical advice/attention. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person.

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

Symptoms No information available.

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

Note to doctors Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

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

Specific hazards arising from the chemical

No information available.

### 5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## 6. ACCIDENTAL RELEASE MEASURES

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

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

Other information Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

## 7. HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

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

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up. Please refer to the manufacturers certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

### 7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC)

No information available.

### 8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. The protective gloves to be used must comply with the specifications

Gloves PPE - Glove material Wear protective Viton gloves

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Physical state Solid

Appearance Solid

Colour off-white

Odour No data available.  
Odour threshold No information available  
Property Values Remarks o Method  
Melting point / freezing point 250 - 253 °C None known  
Boiling point / boiling range No data available None known  
Flammability (solid, gas) No data available None known  
Flammability Limit in Air None known  
Upper flammability or explosive limits  
No data available  
Lower flammability or explosive limits  
No data available  
Flash point No data available None known  
Autoignition temperature No data available None known  
Decomposition temperature None known  
pH No data available None known  
pH (as aqueous solution) No data available No information available  
Kinematic viscosity No data available None known  
Dynamic viscosity No data available None known  
Water solubility No data available None known  
Solubility(ies) DMSO, Methanol, slightly soluble  
Partition coefficient No data available None known  
Vapour pressure No data available None known  
Relative density No data available None known  
Bulk density No data available  
Liquid Density No data available  
Relative vapour density No data available None known  
Particle characteristics  
Particle Size No information available  
Particle Size Distribution No information available  
9.2. Other information  
Molecular weight 324.94  
Molecular formula C<sub>18</sub>H<sub>28</sub>N<sub>2</sub>O.CIH  
9.2.1. Information with regards to physical hazard classes  
Not applicable  
9.2.2. Other safety characteristics  
No information available

## 10. STABILITY AND REACTIVITY

10.1. Reactivity  
Reactivity No information available.  
10.2. Chemical stability  
Stability Stable under normal conditions.  
Explosion data  
Sensitivity to mechanical impact None.  
Sensitivity to static discharge None.  
10.3. Possibility of hazardous reactions  
Possibility of hazardous reactions None under normal processing.  
10.4. Conditions to avoid  
Conditions to avoid None known based on information supplied.  
10.5. Incompatible materials  
Incompatible materials None known based on information supplied.  
Hazardous decomposition products None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008  
Information on likely routes of exposure

#### Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name Bupivacaine hydrochloride

Oral LD50 18 mg/kg (Rabbit)

Dermal LD50

Inhalation LC50

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May cause harm to breast-fed children. Suspected of damaging fertility or the unborn child.

STOT - single exposure Based on the classification criteria of the Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE).

Causes damage to organs if swallowed.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

## 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

## 14. TRANSPORT INFORMATION

IATA

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride)

14.3 Transport hazard class(es) 6.1

14.4 Packing group II

Description UN2811, Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride), 6.1, II

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions A3, A5

ERG Code 6L

IMDG

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride)

14.3 Transport hazard class(es) 6.1

14.4 Packing group II

Description UN2811, Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride), 6.1, II

14.5 Marine pollutant NP

14.6 Special precautions for user

Special Provisions 274

EmS-No F-A, S-A No information available

14.7 Maritime transport in bulk

according to IMO instruments

No information available

RID

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride)

14.3 Transport hazard class(es) 6.1

14.4 Packing group II

Description UN2811, Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride), 6.1, II

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions 274, 614

Classification code T2

ADR

14.1 UN number or ID number UN2811

14.2 UN proper shipping name Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride)

14.3 Transport hazard class(es) 6.1

14.4 Packing group II

Description UN2811, Toxic solid, organic, n.o.s. (Bupivacaine hydrochloride), 6.1, II, (D/E)

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions 274, 614

Classification code T2

Tunnel restriction code (D/E)

## 15. REGULATORY INFORMATION

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

Water hazard class (WGK) strongly hazardous to water (WGK 3)

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV)

This

product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)  
DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

H2 - ACUTE TOXIC

H3 - STOT SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

TSCA Contact supplier for inventory compliance status

DSL/NDSL Contact supplier for inventory compliance status

EINECS/ELINCS Contact supplier for inventory compliance status

ENCS Contact supplier for inventory compliance status

IECSC Contact supplier for inventory compliance status

KECL Contact supplier for inventory compliance status

PICCS Contact supplier for inventory compliance status

AICS Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment has been carried out for this substance

## 16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. For lab use only!