

Bupivacaine hydrochloride

Safety Data Sheet

537624

Version: 3.0

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 25/07/2012 Revision date 11/12/2019
Supersedes 15/02/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Bupivacaine hydrochloride
IUPAC name : (2RS)-1-Butyl-N-(2,6-dimethylphenyl)piperidine-2-carboxamide hydrochloride monohydrate
EC-No. : 241-917-8
CAS-No. : 14252-80-3
Product code : 537624
Formula : C18H29ClN2O.H2O
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@duchefa.nl - 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]**

Acute toxicity (oral), Category 2	H300
Acute toxicity (dermal), Category 2	H310
Acute toxicity (inhal.), Category 2	H330

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(s) to display

Hazard pictograms (CLP) :



GHS06

Signal word (CLP) :

: Danger

Hazard statements (CLP) :

: H300+H310+H330 - Fatal if swallowed, in contact with skin or if inhaled

Precautionary statements (CLP) :

: P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.**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]
Bupivacaine hydrochloride	(CAS-No.) 14252-80-3 (EC-No.) 241-917-8	98.5 - 101	Acute Tox. 2 (Oral), H300 Acute Tox. 2 (Dermal), H310 Acute Tox. 2 (Inhalation), H330

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 after inhalation	: Remove victim to fresh air If not breathing, give artificial respiration Seek medical attention immediately.
First-aid measures after skin contact	: For even minor contact, immediately remove contaminated clothing. Wash skin thoroughly with mild soap and water Seek medical attention immediately.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical attention immediately.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person Seek medical attention immediately.

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

Symptoms/effects	: Irritation to eyes, skin and respiratory tract Exposure may produce an allergic reaction Causes depression of the respiratory system. Nausea Vomiting Diarrhea Sleepiness. Unconsciousness Reduced blood pressure Nervous system disorder.
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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 : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon dioxide. Carbon monoxide. Nitrogen oxides. Chlorine.

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. Evacuate area.

6.1.2. For emergency responders

Protective equipment : Use self-contained breathing apparatus and chemically protective clothing.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water. Detergent.

6.4. Reference to other sections

No additional information available

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. Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from 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:

Dust/aerosol mask with filter type P3. Safety glasses. Gloves.

Hand protection:

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

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 P3. Respiratory protection according to European standard EN 14387 or equivalent.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 342.9 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 4.5 - 6
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 254 - 258 °C
Freezing point	: No data available
Boiling point	: 423 °C atmospheric pressure
Flash point	: 210 °C
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 Alcohol.
Log Pow	: 2.59
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

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

High temperature

heat

Light (daylight).

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 : Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled.

Bupivacaine hydrochloride (14252-80-3)	
LD50 oral rat	≈ 11 mg/kg Data based on LD50 oral rabbit

Skin corrosion/irritation : Not classified

pH: 4.5 - 6

Serious eye damage/irritation : Not classified

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**

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

Bupivacaine hydrochloride (14252-80-3)	
EC50 Daphnia 1	39 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Bupivacaine hydrochloride (14252-80-3)	
Log Pow	2.59
Bioaccumulative potential	Low bioaccumulation potential.

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**

Regional legislation (waste) : Disposal must be done according to official regulations.
 Waste treatment methods : Avoid release to the environment.
 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
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
II	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No

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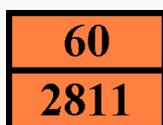
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ADR	IATA
No supplementary information available	

14.6. Special precautions for user

Overland transport

Classification code (ADR) : T2
Special provisions (ADR) : 274, 614
Limited quantities (ADR) : 500g
Excepted quantities (ADR) : E4
Vehicle for tank carriage : AT
Transport category (ADR) : 2
Hazard identification number (Kemler No.) : 60
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : 2X

- 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

Bupivacaine hydrochloride is not on the REACH Candidate List

Bupivacaine hydrochloride 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

Indication of changes:

1.2	Use of the substance/mixture	Added	
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)
8.2	Personal protective equipment	Added	

Abbreviations and acronyms:

Bupivacaine hydrochloride

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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.

Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.

SDS EU (REACH Annex II) ducheafa 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.