

Safety Data Sheet



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1. Identification

Product Identifier	Bupivacaine Hydrochloride
Other means of identification	
Internal item number	82393-0208
CAS number	73360-54-0
Chemical name	2-Piperidinecarboxamide, 1-butyl-N-(2,6-dimethylphenyl)-, monohydrochloride, monohydrate, (+/-)
Relevant use and restrictions:	No further information available.
Application of substance:	Active pharmaceutical ingredient.
Manufacturer/Supplier information	
Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com
Emergency phone number	Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Acute toxicity, oral	Category 2
Environmental hazards	Not classified	
OSHA defined hazards	Not classified	
Label elements	A red diamond-shaped hazard symbol with a black border, containing a black skull and crossbones.	

Signal word	Danger
Hazard statement	Fatal if swallowed
Precautionary statement	
Prevention	Wash thoroughly after handling.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/ international regulations.
Hazards not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/Information on Ingredients

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Substance

Chemical name	Common name and synonyms	CAS number	%
Bupivacaine Hydrochloride		73360-54-0	100

4. First-aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. Call a physician or poison control center immediately. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Central nervous system effects. Cardiovascular effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically
General Information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling	As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material	Type	Value
Bupivacaine HCl (CAS 73360-54-0)	STEL	0.5 mg/m3
	TWA	0.05 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

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Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Procedures for any use or quantity should be determined after an appropriate assessment.

9. Physical and Chemical Properties

Appearance

Appearance descriptions are general information and not specific to any lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White.

Odor

Faint odor.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

478.4 - 498.2 °F (248 - 259 °C) (decomposes)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)

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Solubility (water)

Freely soluble.

Solubility (other)

Acetone: Slightly soluble.
Chloroform: Slightly soluble.
Ethanol: Freely soluble.
Ether: Slightly soluble.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Piperidine derivative; amino amide.

Molecular formula

C₁₈H₂₈N₂O.HCl.H₂O

Molecular weight

342.9

pH in aqueous solution

4.5 – 6 Solution: 1%

Specific gravity

1.03 – 1.04

10. Stability and Reactivity

Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability

Material is stable under normal conditions.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Contact with incompatible materials.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

HCl. NO_x. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Information on likely routes of exposure

Inhalation

Knowledge about health hazard is incomplete.

Skin contact

Knowledge about health hazard is incomplete.

Eye contact

Knowledge about health hazard is incomplete.

Ingestion

Fatal if swallowed.

Symptoms related to the physical, chemical, and toxicological characteristics

Local anesthetics: Headache. Numbness. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Drowsiness. Weakness. Feeling hot or cold. Ringing in ears. Anxiety. Nervousness. Excitement. Confusion. Difficulty in breathing. Gastrointestinal disturbances.

Information on toxicological effects

Acute toxicity

Fatal if swallowed.

Product

Species

Test Results

Bupivacaine HCl (CAS 73360-54-0)

Oral

LD₅₀

Rabbit

18 mg/kg

Skin corrosion/irritation

Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation

Knowledge about health hazard is incomplete.

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Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Micronucleus test

Result: Negative.

Species: Mouse

Organ: Bone marrow

Carcinogenicity

Based on available data, the classification criteria are not met.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological Information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

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Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Bupivacaine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Bupivacaine Hydrochloride)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II
Other information	

Passenger and cargo aircraft

Allowed with restrictions.

Cargo aircraft only

Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

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US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No

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New Zealand	New Zealand Inventory	No
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substances Inventory (TCSI)	Yes
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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