

SAFETY DATA SHEET

spectrum®



Revision date 05-June-2020

Revision Number 2

1. Identification

Product identifier

Product Name BUPIVACAINE HYDROCHLORIDE, MONOHYDRATE, USP

Other means of identification

Product Code(s) B1391

UN/ID no UN1544

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 1
Acute toxicity - Dermal	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 1

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Fatal if swallowed
Fatal in contact with skin
Fatal if inhaled



Appearance Crystalline powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Do not get in eyes, on skin, or on clothing
Wear protective gloves/protective clothing
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection

Precautionary Statements - Response

IF ON SKIN: Wash with plenty of water and soap
Immediately call a POISON CENTER or doctor
Take off immediately all contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Unknown acute toxicity

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Bupivacaine Hydrochloride, Monohydrate	73360-54-0	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice

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

Inhalation

If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.

Eye contact	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
Skin contact	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Ingestion	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

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.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). hydrogen chloride gas.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak.
Other information	Refer to protective measures listed in Sections 7 and 8.

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	Pick up and transfer to properly labeled containers.

7. Handling and storage

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. Take off contaminated clothing and wash before reuse. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

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

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Crystalline powder
Color white

Odor Odorless
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	255 - 258 °C / 491 - 496.4 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	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	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Partially soluble in acetone Soluble in Methanol Soluble in Methanol Insoluble in Ether Insoluble in Chloroform	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	342.90	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Excessive heat.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

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

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. Fatal in contact with skin. (based on components).

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 Coughing and/ or wheezing. Difficulty in breathing.

Acute toxicity

Numerical measures of toxicity
No information available

Unknown acute toxicity

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 sensitization No information available.
Germ cell mutagenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

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

Persistence and degradability No information available.
Bioaccumulation Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

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

DOT
UN/ID no UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s.
Hazard class 6.1
Packing group: II
Special Provisions IB8, IP2, IP4, T3, TP33
Marine Pollutant Severe Marine Pollutant
Description: UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
Emergency Response Guide Number 151

TDG

UN-No: UN1544
Proper Shipping Name: Alkaloid salts, solid, n.o.s.
Hazard class 6.1
Packing Group: II
Description: UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

MEX

UN-No UN1544
Proper Shipping Name Alkaloids, solid, n.o.s.
Hazard class 6.1
Special Provisions 43, 274
Packing Group II
Description UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

ICAO (air)

UN-No: UN1544
Proper Shipping Name: Alkaloid salts, solid, n.o.s.
Hazard class 6.1
Packing Group: II
Special Provisions A3, A5, A6
Description: UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

IATA

UN number UN1544
Proper Shipping Name: Alkaloid salts, solid, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Description: UN1544, Alkaloid salts, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

IMDG

UN number UN1544
Proper shipping name Alkaloids, solid, n.o.s.
Transport hazard class(es) 6.1
Packing group II
EmS-No F-A, S-A
Special Provisions 43, 274
Marine pollutant NP1
Description UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II

RID

UN number UN1544
Proper Shipping Name: Alkaloids, solid, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Classification code T2
Special Provisions 43, 274
Description: UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
Labels 6.1

ADR

UN number 1544
Proper Shipping Name: Alkaloids, solid, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Classification code T2
Tunnel restriction code (D/E)

Special Provisions 43, 274
Description: 1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II, (D/E)
Labels 6.1

ADN

UN/ID No UN1544
Proper shipping name Alkaloids, solid, n.o.s.
Transport hazard class(es) 6.1
Packing Group II
Classification code T2
Special Provisions 43, 274, 802
Description UN1544, Alkaloids, solid, n.o.s. (Bupivacaine Hydrochloride, Monohydrate), 6.1, II
Hazard label(s) 6.1
Limited quantity (LQ) 500 g
Equipment Requirements PP, EP

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL Does not Comply
EINECS/ELINCS Does not Comply
ENCS This product complies with ENCS:
IECSC This product does not comply with china:
KECL Does not Comply
PICCS Does not Comply
AICS This product does not comply with AICS

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

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level

pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 4

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 4

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 05-June-2020

Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage,

transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet