

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015) Issue date: 2022-11-30

SECTION 1: Identification	
1.1. Product identifier	
Product form Product name	: Mixture : Bupivacaine hydrochloride in Dextrose Injection USP
1.2. Recommended use and restrictions of	on use
Recommended use Restrictions on use	: Injection : No data available
1.3. Supplier	
Omega Laboratories, Ltd. 11177 Hamon St. Montreal, Quebec H3M 3E4 Canada T (514) 335-0310	
1.4. Emergency telephone number	
Emergency number	: (514) 335-0310
SECTION 2: Hazard identification	xture
2.1. Classification of the substance or mix	xture
Classification (GHS CA) Not classified	
2.2. GHS Label elements, including preca	utionary statements
GHS CA labeling	
No labeling applicable	
2.3. Other hazards	
No additional information available	
2.4. Unknown acute toxicity (GHS CA)	
No data available	
SECTION 3: Composition/Information	on ingredients
3.1. Substances	

Not applicable

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

3.2. Mixtures			
Name	Chemical name / Synonyms		Conc. (% w/w)
	2-Piperidinecarboxamide, - 1-butyl- N-(2,6-dimethylphenyl)-, monohydrochloride; Bupivacaine HCI	CAS-No.: 14252-80-3	0.73

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures	
4.1. Description of first aid measures	
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Get medical advice/attention. Rinse mouth out with water. Never give anything by mouth to an unconscious person.
First-aid measures general	: IF exposed or concerned: Get medical advice/attention.
4.2. Most important symptoms and effe	ects (acute and delayed)
Symptoms/effects	: Anesthetic effects. Depression of the central nervous system, headaches, dizziness, drowsiness, loss of coordination.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Repeated or prolonged contact may cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May cause irritation to the digestive tract.
4.3. Immediate medical attention and s	special treatment, if necessary
Other medical advice or treatment	: Treat symptomatically.

SECTION 5: Fire-fighting measures	
5.1. Suitable extinguishing media	
Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
5.2. Unsuitable extinguishing media	
Unsuitable extinguishing media	: No data available.
5.3. Specific hazards arising from the hazard	lous product
	: No fire hazard. : Toxic fumes may be released.
5.4. Special protective equipment and preca	utions for fire-fighters
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

SECTION 6: Accidental release	measures		
6.1. Personal precautions, protection	ve equipment and emergency procedures		
General measures	: Ensure adequate ventilation. Wear personal protective equipment. Avoid breathing dust, mist or spray. Mark out the contaminated area with signs and prevent access to unauthorized personne		
6.2. Methods and materials for containment and cleaning up			
For containment Methods for cleaning up Other information	 Stop leak, if possible without risk. Take up liquid spill into absorbent material. Collect all waste in suitable and labeled containers and dispose according to local legislation. Dispose of materials or solid residues at an authorized site. 		
6.3. Reference to other sections			
For further information refer to section 8:	Exposure controls/personal protection"		
SECTION 7: Handling and stora	age		
7.1. Precautions for safe handling			
Precautions for safe handling Hygiene measures	 Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe gas, fumes, vapor or spray. Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. 		
7.2. Conditions for safe storage, in	cluding any incompatibilities		

Storage conditions

: Store in a well-ventilated place. Keep container tightly closed. Store at room temperature.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters		
No additional information available		
8.2. Appropriate engineering controls		
Appropriate engineering controls Environmental exposure controls	Ensure good ventilation of the work station.Avoid release to the environment.	
8.3. Individual protection measures/Per	sonal protective equipment	
Hand protection:		
Protective gloves		
Eye protection:		
Safety glasses		
Skin and body protection:		

Wear suitable protective clothing

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

Respiratory protection:

Wear respiratory protection.

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Liquid.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
рН	: 4-6.5
Relative evaporation rate (butyl acetate=1)	: No data available
Relative evaporation rate (ether=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.031 g/ml
Solubility	: Miscible with water.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Explosion limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactiv	ity
Reactivity	: No additional information available
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reactions known under normal conditions of use.
Conditions to avoid	: No additional information available
Incompatible materials	: Strong acids. Strong bases. Strong oxidizing agents.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Hardening time:	: No additional information available

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

SECTION 11: Toxicological inform	nation
11.1. Information on toxicological effe	ects
Acute toxicity (oral) Acute toxicity (dermal) Acute toxicity (inhalation)	 Not classified Not classified Not classified
Bupivacaine hydrochloride (14252-8	D-3)
LD50 oral rat	18 mg/kg
ATE CA (oral)	18 mg/kg body weight
Skin corrosion/irritation	: Not classified pH: 4 – 6.5
Serious eye damage/irritation	: Not classified pH: 4 – 6.5
Respiratory or skin sensitization	: 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
Likely routes of exposure	: Dermal. Ingestion. Inhalation.
Symptoms/effects	: Anesthetic effects. Depression of the central nervous system, headaches, dizziness, drowsiness loss of coordination.
Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Repeated or prolonged contact may cause skin irritation.
Symptoms/effects after eye contact	: May cause eye irritation.
Symptoms/effects after ingestion	: May cause irritation to the digestive tract.

SECTION 12: Ecological information

12.1. Toxicity	
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified
12.2. Persistence and degradability	
No additional information available	
12.3. Bioaccumulative potential	
No additional information available	
12.4. Mobility in soil	
No additional information available	
12.5. Other adverse effects	
Ozone	: Not classified

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

SECTION 13: Disposal considerations 13.1. Disposal methods Waste treatment methods Additional information : Dispose of contents/container in accordance with licensed collector's sorting instructions. : Flammable vapors may accumulate in the container.

SECTION 14: Transport information

In accordance with TDG / DOT / IMDG / IATA

TDG	DOT	IMDG	ΙΑΤΑ
14.1. UN number			
Not regulated for transport			
14.2. Proper Shipping Name			
Not applicable	Not applicable	Not applicable	Not applicable
Transport document description			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards	14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information availab	ble		

14.6. Special precautions for user

TDG

No data available

DOT

No data available

IMDG

No data available

ΙΑΤΑ

No data available

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

Not applicable

Safety Data Sheet

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SECTION 15: Regulatory information	
15.1. National regulations	
Bupivacaine hydrochloride (14252-80-3)	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	

SECTION 16: Other information

Issue date

: 11-30-2022

Safety Data Sheet (SDS), Canada

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.