

SAFETY DATA SHEET

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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product name: Bupivacaine Hydrochloride Injection

1.2. Relevant identified uses of the substance or mixture

Product Use: Pharmaceutical product used for the production of local or regional anesthesia or analgesia for surgery and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures

1.3. Details of the responsible party of the safety data sheet

Manufacturer

Steliscience Specialties Private Limited Sterile Product Division
Bengaluru
Karnataka, 560076
India
+91 80678 40444

Distributor

Xellia Pharmaceuticals
2150 East Lake Cook Road
Buffalo Grove, IL 60089
USA
+1 833 657 3519

Email address for the competent person responsible for the safety data sheet: sales@xellia.com

1.4. Emergency telephone number

Poison Control Center (USA): +1 877 800 5553
CHEMTREC (USA Transportation): +1 800 424 9300
CANUTREC (Canadian Transportation): +1 613 996 6666
<http://apps.who.int/poisoncentres/>

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Not classified according to the CLP regulation.

2.2. Label elements

Not labelled according to the CLP regulation.

2.3. Other hazards:

The active ingredient is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

SECTION 3: Composition/Information on Ingredients

3.1. Substances:

Active component	CAS #	EC/List #
Bupivacaine Hydrochloride 2.5 – 7.5 mg/mL	14252-80-3	627-065-3

REACH: not registered, exempted.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

- Eye contact:** Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.
- Skin contact:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.
- Ingestion:** Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.
- Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

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

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None

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

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives. The product is not flammable.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride.
- Unsuitable extinguishing media:** None
- Specific methods:** Not available

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment, and emergency response

Wear personal protective equipment to avoid exposure – see section 8.

6.2. Environmental precautions

Water spill: Do not empty into drains.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities.

6.3. Methods and materials for containment and cleaning up

Pump up large amount of spilled product. Smaller amount can be absorbed in sand or similar absorbing material. Decontamination can be performed by burning.

6.4. References to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

For large quantities: Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. Adequate eye protection is always required.

Work hygienic practices: Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2. Conditions for safe storage, including any incompatibilities

Store securely, inaccessible for unauthorized persons. Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C to 30°C (59°F - 86°F) in original, unopened or securely sealed package or container. Protect from light. This product is clear and colorless. Do not use the solution if it is discolored or if it contains a precipitate.

7.3. Specific end uses

See section 1.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	ppm	mg/ m ³	ppm	mg/ m ³	ppm	mg/ m ³
Bupivacaine (CAS #: 14252-80-3)	N/A	N/A	N/A	N/A	N/A	0.02

Other country exposure limits: Not listed.

8.2. Exposure controls

PERSONAL PROTECTIVE EQUIPMENT:

Eyes and face: Wear safety glasses with side shields or goggles as appropriate when handling this material.

Skin: Chemical resistant gloves (nitrile or latex) and body covering.

Respiratory: Use an approved respirator suitable to provide level of protection required.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

- (a) **Physical state:** Liquid
- (b) **Color:** Colorless
- (c) **Odor:** Not available
- (d) **Melting point/freezing point:** 0°C (32°F) for product, 107-108 °C for bupivacaine
- (e) **Boiling point or initial boiling point and boiling range:** 100°C (212°F)
- (f) **Flammability:** Not flammable
- (g) **Lower and upper explosion limit:** Not applicable
- (h) **Flash point:** Not applicable
- (i) **Auto-ignition temperature:** Not applicable
- (j) **Decomposition temperature:** 287°C (549°F) for bupivacaine hydrochloride
- (k) **pH:** 4 – 6.5
- (l) **Kinematic viscosity:** like water
- (m) **Solubility:** Miscible with water. The solubility of bupivacaine in water is 2.4 g/L
- (n) **Partition coefficient n-octanol/water (log value):** 3.41 for bupivacaine
- (o) **Vapor pressure:** 2.3 at 20°C (68°F) for the product. Bupivacaine has a vapor pressure of 1,49 E-08 Hgmm, calculated for 25°C
- (p) **Density and/or relative density:** 1.0 (Relative, Water = 1)
- (q) **Relative vapor density:** like water
- (r) **Particle characteristics:** Solution

9.2. Other information:

Not available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not been reported.

10.4. Conditions to avoid

Excess heat.

10.5. Incompatible materials

Strong oxidants, alkaline materials.

10.6. Hazardous decomposition products

Nitrogen oxides, carbon monoxide, and carbon dioxide, hydrochloric acid.

SECTION 11: Toxicological Information

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

Acute dermal LD50:	No dermal information available for the active ingredient. Subcutaneous LD50 in rats is 43 mg/kg, in mouse 59 mg/kg		
Acute oral LD50:	18 mg/kg (rabbit) for the active ingredient.		
Acute inhalation LC50:	No information available		
Chronic toxicity:	After 4 weeks subcutaneous dose of 0, 9, 18 and 30 mg/kg of active ingredient, a systemic NOAEL of 30 mg/kg can be established.		
Eye effects:	Slight irritant		
Skin effects:	Slight irritant		
Sensitization:	No immediate or delayed allergic responses were observed in the guinea pig after sensitivity testing.		
Target organ:	No information available		
Carcinogenicity:	Not available		
	Listed by IARC:	No	Listed by NTP: No Listed by OSHA: No
Mutagenicity:	Negative Results		
Reproductive effects:	Negative Results		
Teratogenic effects:	Negative Results		

11.2 Information on other hazard

Not available

SECTION 12: Ecological Information

12.1. Toxicity

No applicable information found. Because of the amphipathic character of the bupivacaine molecule, acute toxicity can be measured and classified accordingly.

12.2. Persistence and degradability

No applicable information found.

12.3. Bio-accumulative potential

No applicable information found.

12.4. Mobility in soil

No applicable information found.

12.5. Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6. Endocrine disrupting properties

No such properties are known to the substance.

12.7. Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods: Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport Information

14.1. UN Number or ID number

Not Regulated.

14.2. UN proper shipping name

Not Regulated.

14.3. Transport hazard class(es)

Not Regulated.

14.4. Packing group

Not Regulated.

14.5. Environmental hazards

Not Regulated.

14.6. Special precautions for user

Not Regulated.

14.7. Maritime transport in bulk according to IMO instruments

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated.

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not Regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

SECTION 15: Regulatory Information

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

EUROPEAN UNION

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients: Not Listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

National Response Center: US Coast Guard National Center Response Telephone
+1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed

15.2. Chemical safety assessment

No CSR is compiled because the substance is exempted.

SECTION 16: Other Information

Reason for issue: General update because of the diluted solution which is not classified.

Contact Information: See Section 1.

Revision summary: Third issue which should be considered as new.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.
