SAFETY DATA SHEET

Section 1: Identification	
Material	Bupivacaine HCl Injection USP 0.25%-25 mg/ 10 mL and 75 mg/30 mL (2.5 mg/mL), 0.5%-50 mg/ 10 mL and 150 mg/30 mL (5 mg/mL) and 0.75%-75 mg/ 10 mL and 225 mg/30 mL (7.5 mg/mL)
Recommended use	Pharmaceutical product
Manufacturer	**Aspiro Pharma Limited,** Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the Substance or Mixture GHS - Classification	Acute Oral Toxicity: Category 4
Label elements **Signal Word:** **Hazard Statements:**	 Warning H302 - Harmful if swallowed
Precautionary Statements	P270 - Do not eat, drink or smoke when using this product P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell P330 - Rinse mouth P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Bupivacaine Hydrochloride	18010-40-7

Hydrochloric acid	7647-01-0
Nitrogen NF,	7727-37-9
Sodium Chloride	7647-14-5
Sodium Hydroxide	1310-73-2
Water for Injection	7732-18-5
Section 4: First-Aid Measures	
Description of First Aid Measures **Eye Contact:**	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
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 known
Indication of the Immediate Medical Attention and Special Treatment Needed Notes to Physician:	None
Section 5: Fire-Fighting Measures	
Extinguishing Media:	Extinguish fires with CO2, extinguishing powder, foam, or water.
Special Hazards Arising from the Substance or Mixture Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards:	Not flammable.
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up	
Measures for Cleaning / Collecting: **Additional Consideration for Large Spills:**	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.
Section 7: Handling and Storage	
Precautions for Safe Handling	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe Storage, Including any Incompatibilities **Storage Conditions:** **Specific end use(s):**	Store as directed by product packaging. Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Exposure Controls	
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Physical Form	Solution
Colour	Clear, colorless

Presentation

Product	Type	Vial Count	NDC
Bupivacaine HCl USP, SDV PF	25 mg / 10 mL (2.5 mg/mL)	10 mLx10	31722-275-31
	25 mg / 10 mL (2.5 mg/mL)	10 mLx25	31722-275-32
	75 mg / 30 mL (2.5 mg/mL)	30 mLx10	31722-275-33
	75 mg / 30 mL (2.5 mg/mL)	30 mLx25	31722-275-34
	50 mg / 10 mL (5mg/mL)	10 mLx10	31722-276-31

	Bupivacaine HCl USP, SDV PF	50 mg / 10 mL (5mg/mL)	10 mLx25	31722-276-32
		150 mg / 30 mL (5mg/mL)	30 mLx25	31722-276-34
		75 mg / 10 mL (7.5mg/mL)	10 mLx10	31722-277-31
		75 mg / 10 mL (7.5mg/mL)	10 mLx25	31722-277-32
		225 mg / 30 mL (7.5mg/mL)	30 mLx25	31722-277-34

Section 10: Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

Section 11: Toxicological Information

Information on Toxicological Effects	
General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	May cause mild eye irritation. May cause slight skin irritation. (based on components). Anesthetic drug: may cause central nervous system and cardiovascular system effects
Known Clinical Effects:	Adverse effects associated with therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.

Acute Toxicity: (Species, Route, End Point, Dose)
Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Bupivacaine Hydrochloride

Rabbit	Oral	LD50	18 mg/kg
Rat	Para-periosteal	LD50	6mg/kg
Rat	Subcutaneous	LD50	43mg/kg
Mouse	Intravenous	LD50	6.1mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg
Irritation / Sensitization: (Study Type, Species, Severity)
Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
Bupivacaine Hydrochloride
Prenatal & Postnatal Development Intravenous 0.6 mg/kg LOAEL Neonatal toxicity

Section 12: Ecological Information

Environmental Overview:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

Section 13: Disposal Considerations

Waste Treatment Methods:	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater

Section 14: Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Bupivacaine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Section 16: Other Information

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Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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