Aspiro Pharma Limited
H.N0.8-3-166/7/1,3rd floor, Erragadda,
Hyderabad 500018, Telangana State, India
Tel: +91-40-23704925,Fax:+91-04023704926
Web: www.aspiropharma.com
CIN No.:U24100TG2014PLC092771

SAFETY DATA SHEET

Section 1: Identification	
Material	Lidocaine Hydrochloride Injection USP
Recommended use	Pharmaceutical product
Strengths	**Preservative free: (single dose vial)** 1% (10 mg/mL) 20 mg/2mL, 50 mg/5mL, 300 mg/30mL& 2% (20 mg/mL) 40 mg/2mL, 100 mg/5mL **Multi Dose vial:** 1% (10 mg/mL) and 2% (20 mg/mL)
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**, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statement	No known significant effects or critical hazards
Precautionary Statements **Prevention** **Response** **Storage** **Disposal** **Hazards not otherwise classified**	 Not applicable Not applicable Not applicable Not applicable None known
This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.	

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Lidocaine Hydrochloride	6108-05-0
Sodium chloride (adjust tonicity)	7647-14-5
Sodium hydroxide (adjust pH)	1310-73-2

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Hydrochloric acid (adjust pH)	7647-01-0
Methylparaben (preservative)	99-76-3
Water for injection	7732-18-5

Section 4: First-Aid Measures

Eye Contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Skin Contact	Flush contaminated skin with plenty of water. Get medical attention if symptoms occur
Ingestion	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
Notes to physician	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Section 5: Fire-Fighting Measures

Extinguishing Media (Suitable)	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable Extinguishing Media	None known.
Specific hazards arising from the chemical	No specific fire or explosion hazard.
Hazardous thermal decomposition products	Decomposition products may include the following materials: carbon dioxide carbon monoxide nitrogen oxides halogenated compounds metal oxide/oxides
Special protective actions for fire-fighters	No special measures are required.

Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures **For non-emergency personnel**	No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
Methods and materials for containment and cleaning up	
Small spill	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.
Section 7: Handling and Storage	
Precautions for Safe Handling **Protective measures**	Put on appropriate personal protective equipment
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.
Conditions for safe storage, including any	Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and

incompatibilities	well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination

Section 8: Exposure Controls/Personal Protection

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.
Individual protection measures **Hygiene measures**	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

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Section 9: Physical and Chemical Properties	
Physical State	Injection
Colour	A clear, colorless solution
Odor	No data available
Description	Lidocaine Hydrochloride Injection USP, 1% (10 mg/mL) 10 x 2 mL Single-Dose Carton NDC 31722-117-34 25 x 2 mL Single-Dose Carton NDC 31722-117-31 10 x 5 mL Single-Dose Carton NDC 31722-117-35 25 x 5 mL Single-Dose Carton NDC 31722-117-32 25 x 30 mL Single-Dose Carton NDC 31722-117-33 Lidocaine Hydrochloride Injection USP, 2% (20 mg/mL) 10 x 2 mL Single-Dose Carton NDC 31722-118-33 25 x 2 mL Single-Dose Carton NDC 31722-118-31 10 x 5 mL Single-Dose Carton NDC 31722-118-34 25 x 5 mL Single-Dose Carton NDC 31722-118-32 Lidocaine Hydrochloride Injection USP, 1% (10 mg/mL) 10x 20 mL Multiple-Dose Vials NDC 31722-116-32 25x 20 ml Multiple-Dose Vials NDC 31722-116-31 10x 50 mL Multiple-Dose Vials NDC 31722-116-34 25 x50 mL Multiple-Dose Vials NDC 31722-116-33 Lidocaine Hydrochloride Injection USP, 2% (20 mg/mL) 25 x 20 mL Multiple-Dose Vials NDC 31722-217-31 10 x 50 mL Multiple-Dose Vials NDC 31722-217-33 25 x 50 mL Multiple-Dose Vials NDC 31722-217-32 Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical stability	The product is stable at normal handling and storage conditions
Possibility of hazardous reactions	Will not occur

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Conditions to avoid	Excessive heat. Freezing.
Incompatible materials	None known
Hazardous decomposition Products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Section 11: Toxicological Information	
Information on Toxicological Effects	
General Information	The information included in this section describes the potential hazards of the individual ingredients.
Known Clinical Effects	The most common adverse effects seen during clinical use of this drug include increase in blood pressure (hypertension), decrease in blood pressure (hypotension), respiratory arrest, troubled breathing, irregular heartbeat (cardiac arrhythmia), slow heart rate (bradycardia), increased heart rate (tachycardia),
Acute Toxicity: (Species, Route, End Point, Dose)	
SODIUM CHLORIDE Rat Inhalation LC50/1hr > 42 g/m^3 Rat Oral LD 50 3g/kg	
Methylparaben ATE US (oral) 2100 mg/kg	
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 contents/container in accordance with local/regional/national/international regulations.

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Section 14: Transport Information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	--	--	--
Transport hazard class(es)	--	--	--
Packing group	--	--	--
Environmental hazards	No.	No.	No.
Additional information	--	--	--

Special precautions for user: Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage

Section 15: Regulatory Information

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

FDA : Lidocaine Hydrochloride Injection, USP is an approved prescription medication.

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined United States inventory (TSCA 8b): All components are listed or exempted

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs): Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances: Not listed

DEA List I Chemicals (Precursor Chemicals): Not listed

DEA List II Chemicals (Essential Chemicals): Not listed

Composition/information on ingredients
No products were found.
SARA 304 RQ : Not applicable.
SARA 311/312
Classification: Not applicable.

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Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) Health hazard	Delayed(chronic) Health hazard
Lidocaine hydrochloride	≥1 - ≤3	No.	No.	No.	Yes.	No

SARA 313

There is no data available.
State regulations
Massachusetts : None of the components are listed.
New York : None of the components are listed
New Jersey: None of the components are listed
Pennsylvania: None of the components are listed
California Prop. 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.

Drug products are considered exempt from hazard communication labeling under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

Section 16: Other Information

Issue Date : 18-12-2024
Version : 01
Further information
Revision date: 18-12-2024
Revision note: 1. Included both SDV & MDV details in single SDS, accordingly updated the applicable sections

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.

Aspiro Pharma Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Aspiro Pharma Limited reserves the right to revise this SDS.