



SWATI SPENTOSE PVT. LTD. UNIT-I

Manufacturing Site: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396 195, Gujarat. India

Safety Data Sheet

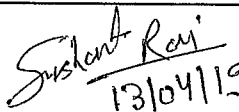
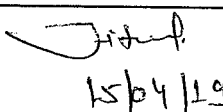
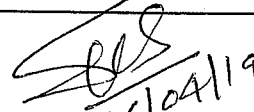
Document No.: FP/LDH/SDS/002/00	Revision No.: 00
Effective Date : 17/04/2019	Supersede No.: Nil
Product Name: Lidocaine Hydrochloride	Page No.:1 of 13

1.0 Product Information & Company Identification

GHS Product Identifier	Lidocaine Hydrochloride
Other means of Identification	2-(Dimethyl amino)-N-(2,6-Dimethylphenyl) acetamide Mon hydrochloride, Monohydrate
Recommended use of the chemical and restrictions on use.	Local Aesthetics
CAS No.	6108-05-0
EC number	200-803-8
RTECS Number	AN7700000
Cat log Codes	SLL1060
Chemical Formula	$C_{14}H_{22}N_2O.HCL.H_2O$
Use	For Pharmaceutical manufacturing, process, or repacking. Used as an anaesthetic (topical) in medications.
Product Code	812
Supplier Details Including name, address, phone number etc.)	Swati Spentose Pvt. Ltd. Corporate Office: 114, Marine Chambers, 11 New Marine Lines, Mumbai-400020, India Manufacturing Unit: A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396195, Gujarat, India
Emergency Phone Number	0260-2433133

2.0 HAZARDS IDENTIFICATION

Hazards effects	Adverse Effects: Adverse effects may include numbness, burning, stinging or swelling of skin, drowsiness or excitement, nervousness, dizziness, blurred vision, tremors, convulsions, unconsciousness, and possible cardiac arrest. When taken orally, Lidocaine may cause
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Activity	Prepared By	Checked By	Approved By
Sign & Date	 13/04/19	 15/04/19	 16/04/19
Name & Designation	Mr. Sushant Rai Officer - EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head - QA &

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nausea, vomiting, or abdominal discomfort. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Symptoms of overdose include low blood pressure; blurred or double vision; nausea or vomiting; ringing in ears; tremors or twitching; difficult breathing; increased sweating; change in heart rate with possible cardiac arrest; pale skin; vision or hearing disturbances; feeling hot, cold, or numb; confusion; convulsions; dizziness; drowsiness; trembling; anxiety or nervousness; headache; weakness; coma; and death.

Acute:

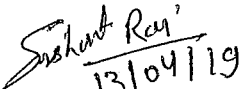

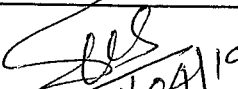
Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitisation.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, respiratory depression, existing cardiac conditions, and impaired liver or kidney function. **Cross Sensitivity:** Persons sensitive to other amide-type anaesthetics, flecainide, or tocainide may be sensitive to this material also.

Target Organs:

Central nervous system and heart. For additional information on toxicity, see Section 11.

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Lidocaine Hydrochloride

HAZARDOUS IDENTIFICATION

Acute Toxicity (Poison): Oral, Dermal, Inhalation
Category-3



Label elements:

Labelling according to Regulation (EC) No. 1272/2008

The substance is classified and labelled according to the CLP regulation.

Hazard pictograms GHS06

Signal word Danger

Hazard statements

H301: Toxic if swallowed.

Precautionary statements

P264: Wash thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

P301+P310: If swallowed: Immediately call a poison centre/doctor.

P330: Rinse mouth.

P405: Store locked up.

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

· NFPA ratings (scale 0 - 4)

· HMIS-ratings (scale 0 - 4)

Other hazards

Results of PBT and vPvB assessment

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Name & Designation	Mr. Sushant Rai Officer - EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head - QA &

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· PBT: Not applicable.

· vPvB: Not applicable.

Toxic if Swallowed

Very Hazardous in case of ingestion. Hazardous in case of skin contact(irritant), of eye contact(irritant),
Keep away from heat. Keep away from source of ignition.
Avoid contact with skin and eyes keep away from incompatibles such as oxidizing agents.

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3.0 Composition/Information on Ingredients

Name	CAS #	% by Weight
Lidocaine Hydrochloride	6108-05-0	100%
Molecular Weight	288.8g/mole	

4.0 First-Aid-Measures

Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact and ingestion.

Inhalation:

May cause irritation and numbness. Avoid inhalation. Remove to fresh air.

Eye:

May cause irritation and numbness. Flush with copious quantities of water for 15 minutes.

Skin:

May cause irritation and numbness. Avoid contact with

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skin. Absorption through intact skin is poor, but absorption may be increase through broken or inflamed skin. Flush with copious quantities of water.

Ingestion:

May cause irritation, numbness, and toxicity. Avoid ingestion. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract.

Swallowing:

Call a doctor immediately.

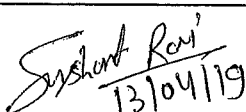
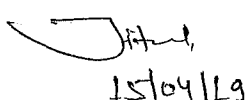
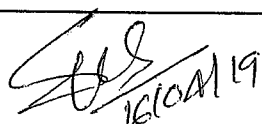
General First Aid Procedures:

Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Overdose treatment is symptomatic and may consist of the following: 1. Administer activated charcoal or cathartics as soon as possible after ingestion. 2. For circulatory depression, administer vasopressor and intravenous fluids. 3. For convulsions, consider slow intravenous administration of a diazepam or an ultra-short-acting barbiturate. Maintain caution in case of additive circulatory depression. 4. A cardiac pacing wire may be necessary for heart block. 5. For a systole, fluids, dopamine, intubation, epinephrine, atropine, and cardiac pacing may be needed. [USP DI 2002 and H

Indication of immediate medical attention and special treatment needed, if necessary

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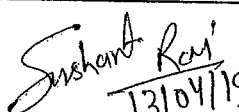
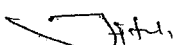
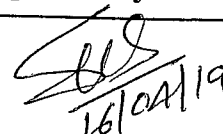
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5.0 Fire Fighting Measures

Suitable and unsuitable extinguishing media and Fire fighting Procedure.	<p>Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.</p> <p>Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.</p> <p>Fire fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire-fighters should use self-contained breathing equipment and protective clothing.</p>
Specific hazardous arising from the chemical	Information not available

6.0 Accidental Release Measures

Personal Precautions, Protective Equipment and emergency procedures.	<p>Spill response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.</p>
Environmental Precautions. Methods and materials for containment and cleaning up.	Information not available
Methods and material for containment for and cleaning up.	<p>Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose</p>

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of according to local & regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

7.0 Handling & Storage

Precautions for safe handling	Precautions: Keep locked up. Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.
Conditions for safe storage, including any incompatibilities	Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 30°C (as per USP pharmacopoeia) (104°F). (Preferably store at temperature between 15°C and 30°C).

8.0 Exposure Controls/Personal Protection

Control parameter (e.g. Occasional exposure limit)	Exposure Limits: Not available
Appropriate engineering controls	Engineering Controls: Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to

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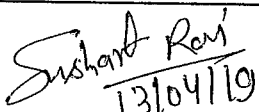
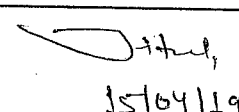
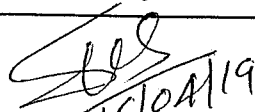
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	airborne contaminants below the exposure limit.
Individual Protection measures, Such as personal protective equipment	<p>Personal Protection: Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.</p> <p>Personal Protection in Case of a Large Spill: Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.</p>

9.0 Physical and Chemical Properties

Appearance (Physical state, colour, etc.)	Crystalline Solid
Odour	Odourless.
Odour Threshold	Not available
pH (1% soln./water)	4.0 to 5.5
Melting range	74-79°C
Initial boiling point and boiling range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	Not available
Upper / Lower Flammability or Explosive Limits	Not available
Vapour Pressure	Not applicable
Vapour Density	Not available
Relative Density	Not available
Other Solubility	Freely soluble in alcohol
Partition Coefficient	Not available

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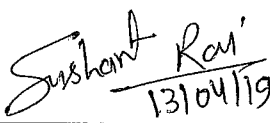
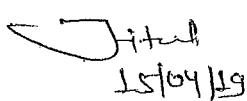
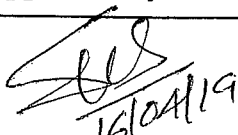
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Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Solubility in water	Very soluble
Colour	White to yellowish.
10.0 Stability & Reactivity Data	
Chemical Stability	The product is stable.
Reactivity and Possibility of Hazardous Reactions	Reacts with strong oxidising agents.
Conditions to Avoid	No further relevant information available.
Incompatibilities	Strong oxidizing agents
Hazardous Polymerization	No
Stable	Stable under recommended condition of use.
Decomposition Products	Carbon monoxide and carbon dioxide. Nitrogen oxides (NOx), Hydrogen chloride (HCL)

11.0 Toxicological Information

Chronic Effects on Humans:	The substance is toxic to the nervous system.
Other Toxic Effects on Humans	Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant), of inhalation. Slightly hazardous in case of skin contact (permeator).
Special Remarks on Toxicity to Animals	Not available.
Special Remarks on Chronic Effects on Humans	May cause adverse reproductive effects and birth defects based on animal data.
Special Remarks on other Toxic Effects on Humans:	Acute Potential Health Effects: Skin: May cause skin irritation and numbness Eyes: May cause eye irritation and numbness Ingestion: Harmful if swallowed. May cause irritation and numbness of the gastrointestinal tract with nausea, vomiting, or abdominal discomfort. May cause blurred vision. May affect behaviour (hallucinations, euphoria, convulsions, spasticity, drowsiness, somnolence,

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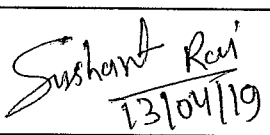
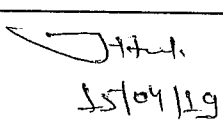
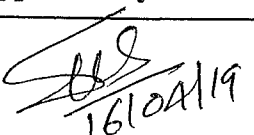
	excitement, nervousness, dizziness, tremors, unconsciousness) , cardiovascular system (low blood pressure, possible cardiac arrest), respiration, and metabolism Inhalation: May cause respiratory tract irritation and numbness
Toxicity to Animals	Acute oral toxicity (LD50): 292 mg/kg [Mouse], (LD50): 317mg/kg (Rat). Inhalation LC50: Not available. Dermal LD50: Not available.
Routes of Entry	Eye contact. Inhalation. Ingestion.

12.0 Ecological Information

Eco toxicity (aquatic and terrestrial, where available).	Eco toxicity: Aquatic toxicity: EC50 (48h)- 112mg/l (Fish), LC50 (96h)- 106mg/l (Fish). BOD5 and COD: Not available. Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.
Bioaccumulation and mobility	No further relevant information available.

13.0 Disposal Consideration

Description of waste residues and information on their safe handling and methods of disposal, including any contaminated packing.	Information not available
Waste Disposal:	Waste must be disposed of in accordance with federal, state and local environmental control regulations.

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14.0 Transport Information

UN Number	UN2811
UN Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S. (Lidocaine hydrochloride)
DOT Classification	Toxic Solid, Organic, N.O.S. (Lidocaine Hydrochloride)
Identification	Not applicable
Transport regulation /UN Classification	Not applicable
Transport Hazard Class (es).	Class 6.1
IATA/ICAO(air)	Toxic Solid, Organic, N.O.S. (Lidocaine Hydrochloride)
ADR / RID (road/Railway)	PG III
IMDG (sea)	Toxic Solid, Organic, N.O.S. (Lidocaine Hydrochloride)

15.0 Regulatory Information

Safety, Health and environmental regulations specific for the product on question.

Regulatory Information: n/f

International Regulatory Information: EINECS # 200-803-8

Hazard code: Xn.- Harmful

R and S Phrases:

Risk phrases: R25- Toxic if swallowed.

Safety phrases: S22- Do not breathe dust. S36/37- Wear suitable protective clothing and gloves. S46- If swallowed, seek medical advice immediately and show this container or label.

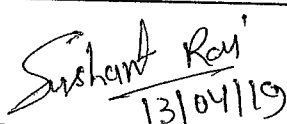
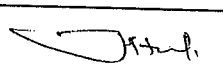
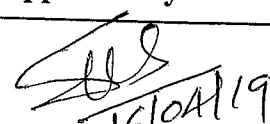
European Regulatory Information: 1272/2008

H and P Phrases:

Hazard Statements:

H301 – Toxic if swallowed.

H317 – May cause an allergic skin reaction.

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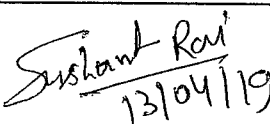
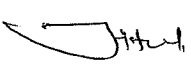
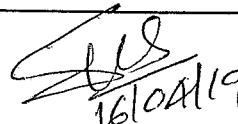
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H319 – Causes serious eye irritation.
H335 – May cause respiratory irritation.
H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary Statements:
P261– Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 – Wash hand thoroughly after handling.
P271 – Use only outdoors or in a well-ventilated area.
P280 – Wear protective gloves/protective clothing/eye protection/face protection..
P285 – In case of inadequate ventilation wear respiratory protection.
HMIS (U.S.A.): Health Hazard: 2
Fire Hazard: 1
Reactivity: 0
Personal Protection: E
National Fire Protection Association (U. S. A.):
Health: 2
Flammability: 1
Reactivity: 0

16.0 Other Information

References and Other information including information on preparation and revision of SDS

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Activity	Prepared By	Checked By	Approved By
Sign & Date	 13/04/19	 15/04/19	 16/04/19
Name & Designation	Mr. Sushant Rai Officer - EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head - QA &

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Safety Data Sheet

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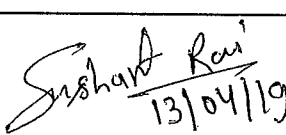
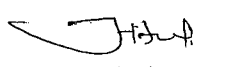
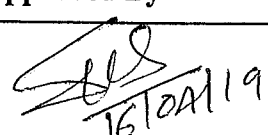
working with or exposed such products of the information contained herein.

Revision Of SDS: Section 1 - EC number & Use of the chemical and restriction on use added. In Section 10 - Reactivity and possibility of Hazardous Reaction & Condition to Avoid added. In Section 11 - Chronic Effects On Human, Other Toxic Effects on Human, Toxicity to Animals & Routes of Entry added. Some editorial change in Section 12.

Abbreviation:

CAS	Chemical Abstract service Number
RTECS	Registry of Toxic Effects of Chemical Substances
DOT	Department of Transportation
UN	United Nations
LD	Lethal dose
NTR	Neutralizing Textile Rinse
HSDB	Hazardous Substances Data Bank

-----*End of Document*-----

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