



# SWATI SPENTOSE PVT. LTD. UNIT-I

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

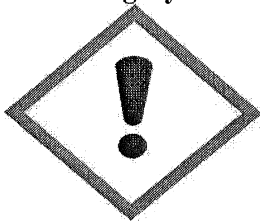
## Safety Data Sheet

Document No.: FP/SDS/003/05	Revision No.: 05
Effective Date: 30/05/2018	Supersede No.: 04
Product Name: Lidocaine	Page No.:1 of 11

### 1.0 Product and company Identification

GHS Product Identifier	Lidocaine
Other means of Identification	2-(Diethyl amino)-N-(-2,6-Dimethylphenyl) acetamide
Recommended use of the chemical and restrictions on use.	Anesthetic
Supplier Details Including name, address, phone number etc.)	Swati Spentose Pvt. Ltd. A-1/2102 & 2103, Phase-III, G.I.D.C, Vapi-396195. Gujarat, India.
Chemical Name:	Lidocaine
Chemical Formula:	C <sub>14</sub> -H <sub>22</sub> -N <sub>2</sub> -O
RTECS:	AN7525000
Catalog Codes:	SLL1648
CAS#:	137-58-6
TSCA: TSCA 8(b) inventory:	Lidocaine
Synonym:	2-(Dimethyl amino)-N-(2,6-Dimethylphenyl) acetamide
Emergency Phone Number:	0260-2433133
Recommended Use:	Inflamed mucous membranes of the mouth and pharynx. It is also useful for reducing gagging during the taking of X-ray pictures and dental impressions.

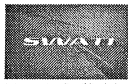
### 2.0 Hazards Identification:

Hazards effects	Lidocaine
	<p><b>HAZARDOUS IDENTIFICATION</b> Acute Toxicity (Poison): Oral, Dermal, Inhalation Category-3</p>  <p>Harmful if swallowed May cause an allergic skin reaction May cause harm to breast-fed children Causes damage to: Blood Nervous System Cardiovascular System Causes damage to organs: Blood Nervous System Cardiovascular System through prolonged or repeated exposure</p>

Activity	Prepared By	Checked By	Approved By
Sign & Date	Sushant Rai 25/05/18	Jitendra 26/05/18	S.K. Srivastava 28/05/18
Name & Designation	Mr. Sushant Rai Officer - EHS	Mr. Jitendra Varma Project & MNT - Head	Mr. S. K. Srivastava Corporate Head - QA & QC

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GHS label elements, including precautionary statements.	<b>Label elements:</b> <b>Labelling according to Regulation (EC) No. 1272/2008</b> The substance is classified and labeled according to the CLP regulation. <b>Hazard pictograms</b> GHS06 <b>Signal word</b> Danger <b>Hazard statement(s)</b> H302 Harmful if swallowed. <b>Precautionary statement(s)</b> P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P330 Rinse mouth. P501 Dispose of contents/container to an approved waste disposal plant.
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### 3.0 Composition/Information On Ingredients

Impurities and Stabilizing additives which are themselves classified and which contribute to the classification of the substance.	<b>Impurity A:</b> 2,6-dimethylaniline <b>Impurity B:</b> 2-(diethylazinoyl)-N(2,6-dimethylphenyl) acetamide (Lidocaine N2-oxide) <b>Impurity C:</b> N-(2,6-dimethylphenyl) acetamide <b>Impurity D:</b> N-(2,6-dimethylphenyl)2-(ethyl amino) acetamide <b>Impurity E:</b> 2-2 <del>6</del> -(azanediyl) bis [N(2,6-dimethylphenyl) acetamide] <b>Impurity F:</b> 2-(diethyl amino)-N-(2,3-dimethylphenyl) acetamide <b>Impurity G:</b> N-(2,6dimethylphenyl)-2-[(1methylethyl) amino] acetamide, <b>Impurity H:</b> 2-chloro-N-(2,6dimethylphenyl) acetamide N <b>Impurity I:</b> 2-(diethyl amino)-N(2,4-dimethylphenyl) acetamide <b>Impurity J:</b>
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	2-(diethyl amino)-N(2,5-dimethylphenyl) acetamide
Concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cut-off levels.	Information not available

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.	<p><b>Eye Contact:</b> Check for and remove any contact lenses. Flush with copious amounts of water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek medical attention.</p> <p><b>Skin Contact:</b> Remove contaminated clothing and shoes. Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.</p> <p><b>Serious Skin Contact:</b> Not available.</p> <p><b>Inhalation:</b> If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.</p> <p><b>Serious Inhalation:</b> Not available.</p> <p><b>Ingestion:</b> Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.</p> <p><b>Serious Ingestion:</b> Not available.</p>
Indication of immediate medical attention and special treatment needed, if necessary	<p><b>Eye Contact:</b> Check for and remove any contact lenses. Flush with copious amounts of water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek medical attention.</p> <p><b>Skin Contact:</b> Remove contaminated clothing and shoes. Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.</p> <p><b>Serious Skin Contact:</b> Not available.</p> <p><b>Inhalation:</b> If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.</p> <p><b>Serious Inhalation:</b> Not available.</p>

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### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

### 5.0 Fire Fighting Measures

Suitable and unsuitable extinguishing media.

**Flammability of the Product:** May be combustible at high temperature.

**Auto-Ignition Temperature:** Not available.

**Flash Points:** CLOSED CUP: Higher than 93.3°C (200°F).

**Flammable Limits:** Not available.

**Products of Combustion:** These products are carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides (NO, NO<sub>2</sub>...).

**Fire Hazards in Presence of Various Substances:**

Slightly flammable to flammable in presence of open flames and sparks, of heat. Non-flammable in presence of shocks.

**Explosion Hazards in Presence of Various Substances:**

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

**Fire Fighting Media and Instructions:**

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

**Special Remarks on Fire Hazards:** Not available.

**Special Remarks on Explosion Hazards:** Not available.

Special Protective Equipment and precautions for fire-fights

**Personal Protection:**

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

**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.

Specific hazardous arising from the chemical

Information not available

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### 6.0 Accidental Release Measures

Personal Precautions, Protective Equipment and emergency procedures.	<b>Personal Protection:</b> Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). Gloves. <b>Personal Protection in Case of a Large Spill:</b> 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.
Methods and material for containment for and cleaning up.	<b>Small Spill:</b> 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 of according to local and regional authority requirements. <b>Large Spill:</b> 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 and Storage

Precautions for safe handling.	<b>Precautions:</b> 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	<b>Storage:</b> Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 30°C (104°F). as per USP pharmacopeia (Preferably store at temperature between 15°C and 30°C). And as per BP Pharmacopoeia protect from light.

### 8.0 Exposure Controls/Personal Protection

Control limit	Exposure Limits: Not available.
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Appropriate engineering controls.	<b>Engineering Controls:</b> 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 airborne contaminants below the exposure limit.
Individual Protection measures, Such as personal protective equipment	<b>Personal Protection:</b> Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). Gloves. <b>Personal Protection in Case of a Large Spill:</b> 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.
<b>9.0 Physical and Chemical Properties</b>	
Appearance (Physical state, color, etc.)	Crystalline Solid
Odor	Characteristic
Odor Threshold	Not available
pH (1% soln./water)	Not applicable
Melting point/Freezing point	66°C to 70°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
Vapor Pressure	Not applicable
Vapor Density	Not available
Relative Density	Not available
Other Solubility	The product is more soluble in Oil. Log (Oil/water) = 2.3 and in soluble in water and very soluble in ethanol (96%) and in methylene chloride as per BP/EP/IH. (ICHQ3C)

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Partition Coefficient	Not available
Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Solubility in water	Very soluble
Color	White to yellowish and A Green color is develops.

### 10.0 Stability and Reactivity Data

Chemical Stability	<b>Stability:</b> The product is stable.
Possibility of Hazardous reactions.	Not Reported
Condition to avoid	Excess heat, incompatible materials
Incompatible materials	<b>Incompatibility with various substances:</b> Reactive with oxidizing agents. <b>Special Remarks on Reactivity:</b> Also incompatible with Strong mineral acids.
Hazards decomposition product	Not available

### 11.0 Toxicological Information

Delayed and immediate effects and also chloric effects from shorts and long term exposure.	<b>Chronic Effects on Humans:</b> <b>MUTAGENIC EFFECTS:</b> Mutagenic for bacteria and/or yeast. <b>TERATOGENIC EFFECTS:</b> Classified POSSIBLE for human. May cause damage to the following organs: cardiovascular system, central nervous system (CNS). <b>Other Toxic Effects on Humans:</b> Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation. <b>Special Remarks on Toxicity to Animals:</b> Not available. <b>Special Remarks on Chronic Effects on Humans:</b> May cause adverse reproductive effects and birth defects based on animal data. <b>Special Remarks on other Toxic Effects on Humans:</b> 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 behavior (hallucinations, euphoria, convulsions,
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	spasticity,drowsiness, somnolence, excitement, nervousness, dizziness, tremors, unconsciousness) , cardiovascular system (low bloodpressure, possible cardiac arrest)), respiration, and metabolism Inhalation: May cause respiratory tract irritation and numbness
Other Toxic Effects on Humans	Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of inhalation
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:	<b>Acute Potential Health Effects:</b> 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 behavior (hallucinations, euphoria, convulsions, spasticity,drowsiness, somnolence, excitement, nervousness, dizziness, tremors, unconsciousness) , cardiovascular system (low bloodpressure, possible cardiac arrest)), respiration, and metabolism Inhalation: May cause respiratory tract irritation and numbness
Toxicity to Animals	Acute oral toxicity (LD50): 220 mg/kg [Mouse]
Routes of Entry	Inhalation. Ingestion
<b>12.0 Ecological information</b>	
Eco toxicity (aquatic and terrestrial, where available).	Eco toxicity: Not available.
Persistence and degradability	<b>Products of Biodegradation:</b> Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. <b>Toxicity of the Products of Biodegradation:</b> The products of degradation are less toxic than the product itself.
<b>13.0 Disposal Consideration</b>	

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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.

### 14.0 Transport Information

DOT Classification	Not a DOT controlled material (United states).
Transport regulation/UN Classification	Not applicable
IATA/ICAO(air)	Not Classified
ADR/RID(road/Railway)	Not Classified
IMDG (sea)	Not Classified

### 15.0 Other Regulatory Information

Safety, Health and environment for the products in question	<p><b>Regulatory Information:</b> Not Applicable</p> <p><b>International Regulatory Information:</b> EINECS # 200-803-8</p> <p><b>Hazard code:</b> Xn- Harmful</p> <p><b>R and S Phrases:</b></p> <p><b>Risk phrases:</b> R25- Toxic if swallowed.</p> <p><b>Safety phrases:</b></p> <p>S22- Do not breathe dust.</p> <p>S36/37- Wear suitable protective clothing and gloves.</p> <p>S46- If swallowed, seek medical advice immediately and show this container or label.</p> <p><b>European Regulatory Information:</b> 1272/2008</p> <p><b>H and P Phrases:</b></p> <p><b>Hazard Statements:</b></p> <p>H301 – Toxic if swallowed.</p> <p>H317 – May cause an allergic skin reaction.</p> <p>H319 – Causes serious eye irritation.</p>
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**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/vapors/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**  
**Personal Protection: E**  
**National Fire Protection Association (U. S.A.): Health: 2**  
**Flammability: 1**  
**Reactivity: 0**  
**Protective Equipment:**  
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles  
**Federal and State Regulations:** TSCA 8(b) inventory: Lidocaine  
**Other Regulations:**  
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.  
**Other Classifications:**  
**WHMIS (Canada):** Not controlled under WHMIS (Canada).  
**DSCL (EEC):** R22- Harmful if swallowed.  
R36- Irritating to eyes.  
R63- Possible risk of harm to the unborn child.  
S2- Keep out of the reach of Children.  
S46- If swallowed, seek medical advice immediately and show this container or label.

### 16.0 Other Information

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

This data is furnished gratuitously independent of any sales of the product and only for your investigation and

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independent verification. While the information is believed to be correct, Swati Spentose Private Limited shall in no event be any responsible for any damage whatever, directly or indirectly resulting in the use of or reliance upon data contained herein. No warranty, either expressed or implied, or merchantability, of fitness, or of any nature with respect to the product, or to the data is made herein. You are urged to obtain data sheet for all Swati Spentose Private limited product you buy, process, use or distribute, and encouraged to advise anyone working with or exposed such products of the information contained herein.

### Abbreviation:

CAS	Chemical Abstract Service Number
RTECS	Registry of Toxic Effects of Chemical Substances
DOT	Department of Transportation
UN	United Nations
LD	Lethal dose
IATA	International Air Transport Association

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