MATERIAL SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION OF THE SUBSTACE/MIXURE AND OF THE COMPANY/UNDERTAKING

Product Name: LIDOCAINE
Synonym: Lignocaine
Chemical Name: 2-(Diethylamino)-N-(2,6-Dimethylphenyl) Acetamide
CAS Number:137-58-6
RTECS Number: AN7525000
Chemical Formula: $C_{14}H_{22}N_2O$
Use: For manufacturing, Process, or Repacking. Used as an anesthetic (topical) in medications
Product Code: LB
Manufacturer: Address; APEX HEALTHCARE LIMITED
Plot no.-4710,4711,4707-A/8, 4707-A/9, GIDC Industrial Estate, Ankleshwar, Dist.-Bharuch-393002, Gujarat, INDIA, Tel.: +91-2646-223525, 227289.

2. HAZARDS IDENTIFICATION

Classification of Substance: Irritant
Physical Hazards: Not classified.
Health Hazards: Acute toxicity (oral)- Category 4. Serious eye damage/eye irritation - Category 2A Label Elements:
Hazard Pictograms:

Signal Word: Warning
Hazard Statement: Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary Statements: Avoid breathing dust/fume/gas/mist/vapors/spray. Wash hand thoroughly after handling. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.
Cross Sensitivity: Persons sensitive to other amide-type anesthetics, flecainide, or tocainide may be sensitive to this material also. Target Organs: Central nervous system and heart.
Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye/face protection.
Response: If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage/Disposal: Dispose of content and/or container in accordance with local, regional, national, and/or international regulations. Store in well-ventilated area. Keep container tightly closed.

3. COMPOSITION/INFORMATION ON INGREDIANTS

Common Name: Lidocaine
CAS Number: 137-58-6
Molecular Weight: 234.3 g/mole
Composition: 100% by Weight

4. FIRST-AID MEASURES

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 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.
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 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 hypersensitization.
Medical Conditions Aggravated by Exposure: Hypersensitivity to material, respiratory depression, existing cardiac conditions,and impaired liver or kidney function.
For additional information on toxicity, see Section 11.
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 a 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 asystole, fluids, dopamine, intubation, epinephrine, atropine, and cardiac pacing may be needed. [USP DI 2002 and HSDB]

5. FIRE-FIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
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 buildup of static electricity.
Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
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 labeled container for disposal. Wash spill site.

7. HANDLING AND STORAGE

Handling: As a general rule, when handling this material, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.
Storage: Store in well-closed, light resistant container. This material should be handled and stored per label instructions to ensure product integrity.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne contaminants below any recommended or statutory limits The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits.
Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Gloves: Chemically compatible
Eye Protection: Safety goggles or glasses Protective Clothing: Protect exposed skin. Exposure Limits: n/f
Biological limit values: No biological exposure limits noted for the ingredient(s).
Individual Protection Measures, such as Personal Protective Equipment:
Eye/face Protection: Safety glasses with side-shields are recommended. Face shields or goggles may be required if splash
potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin and Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory Protection: 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 CFR1910.134).
Thermal hazards: Not available.
General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: White or slightly yellow crystalline powder.
pH: n/f
Melting Range:66-70 °C
Boiling Point: 356-360 F
Flash Point: n/f
Autoignition Temperature: n/f
Vapor Density: n /f
Specific Gravity: n/f
Solubility in Water: Very soluble
Other Solubility: Freely soluble in alcohol.
Partition Coefficient: n-octanol/water: n/f
Percent Volatile: n/f
Reactivity in Water: n/f
Explosive Properties: n/f
Oxidizing Properties: n/f
Formula: $C_{I4}H_{22}N_2O$
Molecular Weight: 234.3 g/mole

10. STABILITY AND REACTIVITY

Conditions to Avoid: Light.
Incompatibilities: Strong oxidizing agents.
Decomposition Products: When heated to decomposition, material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.
Stable: Stable under recommended conditions of use.
Hazardous Polymerization: No

11. TOXILOGICAL PROPERTIES

RTECS No: AN7525000
LD_{50} (Oral-rat): 317 mg/kg Intraperitoneal
LD_{50} (Oral-rat): 133 mg/kg Subcutaneous
LD_{50} (Oral-rat): 335 mg/kg
LD_{50} (Oral-Mouse): 220 mg/kg Intraperitoneal
LD_{50} (Oral-Mouse) : 102 mg/kg Subcutaneous
LD_{50} (Oral-Mouse): 238 mg/kg

Other Toxicity Data: n/f
Irritancy Data: n/f
Corrosive Potential: n/f
Sensitization Data: n/f
Listed as a Carcinogen by:

NTP: No
IARC: No
OSHA: No

Other Carcinogenicity Data: Metabolites of Lidocaine have been shown to be carcinogenic in laboratory animals.
Mutagenicity Data: Lidocaine Base was not shown to be mutagenic in the salmonella/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.
Reproductive and Developmental Effects: Studies in animals have not shown that Lidocaine causes adverse effects on the fetus.
It is used as a local anesthetic during delivery.

12. ECOLOGICAL INFORMATION

Ecotoxicity: No data available.
BOD5 and COD:
Biodegradation: No data available.
Bioaccumulation and mobility: Low potential for bioaccumulation.

13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

14. TRANSPORT INFORMATION

DOT Classification: Not a DOT controlled material (United States).
Identification: Not applicable.
Special Prevision for Transport: Not applicable.
Transportation Regulation: UN Classification: Not applicable
IATAIICAO (air): Not classified
IMDG (sea): Not classified
ADRIRID (road/railway): Not classified

15. REGULATORY INFORMATION

U.S. Regulatory Information: n/f
International Regulatory Information: EINECS # 200-803-8
Hazard code: Xn- Harmful
Risk phrases: R22: Harmful 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
Hazard Statements: H302: Harmful if swallowed.
H317: May cause an allergic skin reaction.
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. OTHER INFORMATION

Reference:

I. United States Department of Labor, A guide to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Issued date: 10/27/2009.
2. EDQM, Lidocaine Base MSDS (revision 07), Issued date: 12/10/2009.
3. Regulation (EC) No. 1272/2008 of the European parliament and of the council, Issued date: 12/31/2008.
4. Hazard & Precautionary Statements of the Regulation (EC) No. 1272/2008 in section 15.
5. Hazardous Materials Identification System (HMIS) (U.S.A.) and National Fire Protection Association (U.S.A.)
classification in section 15.
6. Section II ·**TOXICOLOGICAL PROPERTIES** added LD_{50} (oral-rat): 317 mg/kg based on Lewis, R.J. Saxs Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996, p.1148.

Reasons for revision:

I. Added Hazardous Materials Identification System (HMIS) (U.S.A.) and National Fire Protection Association (U.S. A.) classification in section 15.
2. Revision to conform to Safety Data Sheet format as per OSHA Hazard Communication Standard 29 CFR1910.1200.

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