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MATERIAL SAFETY DATA SHEET

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: **LIDOCAINE HYDROCHLORIDE**

Manufacturer: Delta Synthetic Co., Ltd. **Tel:** +886-2-2268-5604

Address: 15, Minsheng St., Tucheng Dist., New Taipei City 23679, Taiwan (R.O.C.) **Fax:** +886-2-2268-0895

Synonym: Lignocaine Hydrochloride

Chemical Name: 2-(Diethylamino)-*N*-(2, 6-dimethylphenyl) acetamide, monohydrochloride, monohydrate

CAS Number: 6108-05-0

RTECS Number: AN7700000

Chemical Formula: $C_{14}H_{22}N_2O \bullet HCl \bullet H_2O$

Use: For **pharmaceuticals** manufacturing, Process, or Repacking. Used as an anesthetic (topical) in medications

Product Code: 812

SECTION 2 - HAZARDS IDENTIFICATION

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.

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.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Common Name: Lidocaine Hydrochloride

CAS Number: 6108-05-0

Molecular Weight: 288.8 g/mole

Composition: 100% by Weight

SECTION 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.

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]

SECTION 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.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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.

SECTION 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.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. If the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety goggles or glasses

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: White or slightly yellow crystalline powder; odorless.

pH: 4.0–5.5 (5 g/L, water)

Melting Range: 74–79 °C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Very soluble

n/f = not found

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: $C_{14}H_{22}N_2O \bullet HCl \bullet H_2O$

Molecular Weight: 288.8 g/mole

SECTION 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

SECTION 11 - TOXICOLOGICAL PROPERTIES

RTECS No: AN7700000

LD_{50} (oral-rat): 317 mg/kg

LD_{50} (oral-mouse): 292 mg/kg

LD_{50} (oral-rat): non-fasted females 459 mg/kg

LD_{50} (oral-rat): fasted females 214 mg/kg

Other Toxity Data: n/f

Irritancy Data: n/f

Corrosivity: 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 hydrochloride 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.

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity: No data available.

Biodegradation: No data available.

Bioaccumulation and mobility: Low potential for bioaccumulation.

SECTION 13 - DISPOSAL CONSIDERATIONS

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

SECTION 14 - TRANSPORT INFORMATION

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Prevision for Transport: Not applicable.

Transport regulation	**UN Classification:** n/f
IATA/ICAO (air)	Not classified
ADR/RID (road/railway)	Not classified
IMDG (sea)	Not classified

n/f = not found

SECTION 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

SECTION 16 - OTHER INFORMATION

Reference:

1. 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 Hydrochloride 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.

Reasons for revision:

Section 11 **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

Revision Date: September 20, 2013

Previous Revision Date: January 31, 2013

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n/f = not found