


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>LIDOCAINE, USP</b>
<b>PRODUCT CODE</b>	<b>0081</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 4) Sensitization - Skin (Category 1) Sensitization - Respiratory (Category 1) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 2)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed Toxic to aquatic life. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Wash hands thoroughly after handling. Do not touch eyes.  
 Do not eat, drink or smoke when using this product.  
 Avoid breathing dust, fume, gas, mist, vapors, spray.  
 In case of inadequate ventilation wear respiratory protection.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wear eye and face protection.  
 Wear protective gloves.  
 Avoid release to the environment.

**Response**

IF SWALLOWED: Immediately call a poison center. Get medical help. 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 help.  
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional.  
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse.

**Storage**

Not applicable

**Disposal**

Dispose of contents and container in accordance with local regulations.

**HMIS CLASSIFICATION**
**Health Hazard**

2

**Flammability**

1

**Reactivity**

0

**Personal Protection**

G

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**CHEMICAL NAME**

2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Lignocaine

**CHEMICAL FORMULA**

C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O

**CHEMICAL FAMILY**

Aniline derivative; amino amide.

**CAS NUMBER**

137-58-6

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

234.3408

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
LIDOCAINE	137-58-6	205-302-8	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**SECTION 4: FIRST-AID MEASURES**
**IN CASE OF EYE CONTACT**

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED**

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED**

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND SPECIAL TREATMENT**

Get emergency medical help.

## SYMPTOMS CAUSED BY EXPOSURE

May cause irritation and numbness.

## SECTION 5: FIREFIGHTING MEASURES

## SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

## FLAMMABLE PROPERTIES

This material is assumed to be combustible.

## HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

## SUITABLE &amp; UNSUITABLE EXTINGUISHING MEDIA

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

## PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. As with all fires, evacuate personnel to a safe area.

## NOTES

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.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

## PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

## METHODS &amp; MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

## CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

## REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

## SECTION 7: HANDLING AND STORAGE

## PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

## CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

## STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name:** LIDOCAINE **CAS #:** 137-58-6

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>
**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

The substance is a powerful local anaesthetic and should be considered as potentially harmful through exposure by dust inhalation and by ingestion.

USP: ELV: Industrial use:

 STEL 5 mg/m<sup>3</sup>

 TWA 0.05 mg/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or slightly yellow, crystalline powder. Has a characteristic odor and is stable in air.

**SOLUBILITY**

Practically insoluble in water; very soluble in alcohol and in chloroform; freely soluble in benzene and in ether. Dissolves in oils.

**ODOR**

Characteristic odor

**FLAMMABILITY**

This material is assumed to be combustible

**AUTO-IGNITION TEMPERATURE**

Not available

**BOILING POINT**

 (146)°C,  
(294.8)°F, 1  
mmHg

**DECOMPOSITION TEMPERATURE**

Not available

<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	> 93.3 °C, > 199.94 °F
<b>log P (OCTANOL-WATER)</b>	2.26 (pH 7.4)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(66-70)°C, (150.8-158)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	Not available
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	0.000009 kPa (25°C)	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidizing agents. Strong mineral acids. Ammonia.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	When heated to decomposition, material emits toxic fumes of NO <sub>x</sub> . Emits toxic fumes under fire conditions.
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, Sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 317 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Based on available data, the classification criteria are not met. Local effects: 5 % Irritancy test; Result: Non-irritant.; Species: Rabbit; Organ: Skin; Test Duration: 24 hours
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes serious eye irritation.
<b>RESPIRATORY SENSITIZATION</b>	Suspected sensitizer.
<b>SKIN SENSITIZATION</b>	Suspected sensitizer. Local anaesthetics may provoke types I and IV hypersensitivity reactions. Type I reactions (e.g. anaphylaxis) to local anaesthetics are generally rare. Nevertheless, severe or fatal reactions have been associated. Suspected skin sensitizer: CAESAR skin sensitisation model in VEGA (Q)SAR platform predicts that the chemical is Sensitizer (moderate reliability)

**GERM CELL MUTAGENICITY**

Based on available data, the classification criteria are not met.  
 Suspected mutagen: The Toolbox profiler 'Protein binding alerts for Chromosomal aberration by OASIS v1.1' gives an alert for mutagenicity

**CARCINOGENICITY**

**OSHA** LIDOCAINE is not listed.

**NTP** LIDOCAINE is not listed.

**IARC** LIDOCAINE is not evaluated.

**California Proposition 65** This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**ADDITIONAL CARCINOGENICITY INFORMATION**

Based on available data, the classification criteria are not met.  
 Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals.

**REPRODUCTIVE TOXICITY**

Based on available data, the classification criteria are not met.  
 Suspected toxic for reproduction: The Toolbox profiler 'DART scheme v.1.0' gives an alert for toxicity to reproduction.  
 Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects. Studies in animals have not shown that lidocaine causes adverse effects on the fetus. It is used as a local anesthetic during delivery. Serious adverse effects of epidural anaesthesia are rare but lidocaine may have transient effects on the neonatal auditory system.  
 No adverse effects have been seen in breastfed infants whose mothers were receiving lidocaine, and the American Academy of Pediatrics considers that it is therefore usually compatible with breast feeding.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Due to lack of data, the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Due to lack of data, the classification is not possible.

**ASPIRATION HAZARDS**

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF EXPOSURE**

**ROUTES OF EXPOSURE:**  
 Oral, Dermal, Inhalation, Eye contact  
**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**  
 Not available  
**DELAYED HEALTH EFFECT FROM EXPOSURE:**  
 For local anesthetics: Change in blood pressure. Slow or irregular heartbeat. Cessation of breathing. Circulatory depression. Shock. Cardiac arrest. Coma. Death.

Symptoms related to the physical, chemical, and toxicological characteristics:  
 Local anesthetics: Headache. Numbness. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Drowsiness. Weakness. Feeling hot or cold. Ringing in ears. Anxiety. Nervousness. Excitement. Confusion. Difficulty in breathing. Gastrointestinal disturbances.

**Cross sensitivity:**  
 Persons sensitive to one amide-type anesthetics, flecainide, or tocainide may be sensitive to this material also.

**Medical conditions aggravated by exposure:**  
 Hearing disorders. Epilepsy. Liver impairment. Kidney impairment.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** Harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** Harmful if swallowed.

**Skin** Harmful if absorbed through skin. Causes skin irritation. May cause allergic skin reaction. May cause erythema or pigmentation.

**Eyes** Causes eye irritation.

**SECTION 12: ECOLOGICAL INFORMATION**

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 5.05* LC50: 96 Hr: Fish: Fathead Minnow (mg/L): 19.53** EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): 3.59***
<b>PERSISTENCE AND DEGRADABILITY</b>	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable
<b>BIOACCUMULATIVE POTENTIAL</b>	Low bioaccumulative potential: Log Pow 2.26
<b>MOBILITY IN SOIL</b>	Practically insoluble in water Water Solubility: 4100 mg/L (30°C) Henry's Law Constant: 1.31E-10 atm-m <sup>3</sup> /mole (25°C)
<b>OTHER ADVERSE EFFECTS</b>	Not available
<b>NOTES</b>	This product is not intended to be released into the environment *DEMETRA Daphnia Magna toxicity model in VEGA (Q)SAR platform prediction (good reliability) **(EPA) in VEGA (Q)SAR platform prediction (moderate reliability) ***The Danish QSAR database

### SECTION 13: DISPOSAL CONSIDERATIONS

<b>DISPOSAL METHODS</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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### SECTION 14: TRANSPORT INFORMATION

<b>UN PROPER SHIPPING NAME</b>	Not dangerous good
<b>UN NUMBER</b>	Not applicable
<b>CLASS</b>	Not applicable
<b>PACKING GROUP</b>	Not applicable
<b>AUSTRALIA</b>	
<b>HAZCHEM</b>	Not applicable
<b>EU</b>	
<b>TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not Listed
<b>ENVIRONMENTAL HAZARDS</b>	Not available
<b>SPECIAL SHIPPING INFORMATION</b>	Not applicable

### SECTION 15: REGULATORY INFORMATION

#### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
LIDOCAINE 137-58-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
LIDOCAINE 137-58-6	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
LIDOCAINE 137-58-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

**SECTION 16: OTHER INFORMATION**
**REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

**LAST REVISION**

01/2025

**SUPERSEDES**

03/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

**DISCLAIMER**

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

**SUPPLEMENTARY INFORMATION**

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.