

Lidocaine 10MG Spray LIQ

1 Product and Company Identification

- **Product identifier (Trade Name):** Lidocaine 10MG Spray Liquid
 - **Recommended use:** External use men's genital desensitizer
 - **Synonym:** Lidocaine 8.4% Liquid Spray
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- **Manufacturer / Supplier**
Natureplex, LLC
11085 Airport Road
Olive Branch, MS 38654-0221
662-874-1370 (8AM to 5PM central time; Monday through Friday)
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- **Poison Control Center:** 800-222-1222
 - **Chemtrec:** 800-424-9300 (Transportation Spill Response 24 hours)
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- This SDS is written to provide health and safety information for individuals who will be handling the product during manufacture and packaging. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the product label for handling guidance for the consumer.

2 Hazard(s) Identification

- **Physical hazards:** FLAMMABLE LIQUID – Category 4
- **Health hazards:** EYE IRRITATION – Category 2B
- **OSHA defined hazards:** H227: Combustible liquid; H302: Acute Toxicity, Oral
- **Label elements**

Pictogram:



Signal word Warning!

Hazard statement This pharmaceutical product in stated dosage form is designed for over-the-counter human use. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous. This product is not meant for oral consumption or for ophthalmic use. Should any person while handling or using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention No smoking. Observe good industrial hygiene practices. P210: Keep away from heat, sparks, open flames, and hot surfaces.

Lidocaine 10MG Spray LIQ

<p>Response Wash hands after handling.</p> <p>Storage Store away from incompatible materials. Keep from freezing. Store at a controlled room temperature, 15°- 30° C.</p> <p>Disposal Incineration of waste at an approved USEPA incinerator is recommended.</p> <ul style="list-style-type: none"> • Hazard(s) not otherwise classified (HNOC) None known.
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3 Composition / Information on Ingredients		
Chemical name	CAS number	%
Diethyl Glycol Monoethyl Ether*	111-90-0	Proprietary
Isopropyl Myristate*	110-27-0	Proprietary
Lidocaine	137-58-6	8.4
Stearic Acid*	57-11-4	Proprietary
Vitamin E Acetate*	7695-91-2	Proprietary
Woodlands Fragrance*	N/A	Proprietary

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4 First Aid Measures
<ul style="list-style-type: none"> • Inhalation: Move affected workers to fresh air. If necessary, administer CPR and oxygen. Call a physician if symptoms persist. • Eye contact: Remove contact lenses. Thoroughly flush eyes with water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek medical attention if irritation develops or persists. • Skin contact: Remove contaminated clothing and shoes. Wash skin with soap and water. Cover irritated skin with an emollient. Get medical attention if irritation develops or persists. • Ingestion: Do not induce vomiting, unless directed to do so by medical personnel. Give nothing by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician and/or poison control immediately. Loosen tight clothing. • Most important symptoms/effects, acute and delayed: Side effects may include: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Allergic reactions as a result of sensitivity to lidocaine are extremely rare. • Indication of immediate medical attention and special treatment needed: Supportive measures (including oxygen and vasopressors) should be employed in the management of

Lidocaine 10MG Spray LIQ

circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

- **General information:** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** use water fog, foam, dry chemical, or carbon dioxide.
- **Fire and / or explosion hazards:** as with most organic solids, fire is possible at elevated temperatures. Fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential explosion hazard.
- **Special fire fighting procedures:** for small fires, use a dry chemical powder. For large fires, use a water fog, or foam. Do not use a water jet.

6 Spill or Leak Procedures

- **Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate solvent-resistant personal protective equipment.
- **Methods and materials for containment and cleaning up** Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
- **Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

7 Handling and Storage

- **Handling**

Keep away from heat. Keep away from sources of ignition. Ground the equipment that contains this material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wash thoroughly after handling. 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.
- **Storage**

Keep container tightly closed. Store at cool temperatures, in a well-ventilated area, and out of reach of children. Do not freeze. Store at controlled room temperature at 15-30 °C .

8 Exposure Controls / Personal Protection

- **Occupational exposure limits**
No exposure limits noted for ingredient(s).
- **Biological limit values**
No biological exposure limits noted for the ingredient(s).
- **Appropriate engineering controls**
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels low. If user operations generate dust, fumes, or mist, ventilate to keep exposure to airborne contaminants low.
- **Individual protection measures, such as personal protective equipment**
 - **Eye/face protection**
Avoid contact with eyes. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting.
 - **Skin protection**
Wear a lab coat, rubber gloves, splash goggles, and a dust respirator. Use approved / certified respirator and equivalent gloves. Wash promptly with soap and water if skin becomes contaminated.
 - **Respiratory protection**
None required for consumer use.
 - **Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.
- **General hygiene considerations**
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9 Physical and Chemical Properties

Appearance

Physical state: water-like liquid

Form: liquid

Color: clear colorless to straw-like

Odor: faint woodland scent

Odor threshold: Not Available

pH: 6.5-8.5

Melting point/freezing point: Not Available

Initial boiling point and boiling range: Not Available

Flash point: 91°C

Evaporation rate: Not available

Flammability (solid, gas): Not available

Upper/lower flammability or explosive limits

Lidocaine 10MG Spray LIQ

Flammability limit - lower (%): Not available
Flammability limit - upper (%): Not available
Explosive limit - lower (%): Not available
Explosive limit - upper (%): Not available
Vapor pressure: 0.095 mmHg
Vapor density (Air=1): 4.6
Relative density (specific gravity): 0.989 g/cm³
Solubility: soluble in water
Partition coefficient (n-octanol/water): Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Viscosity: Not available

10 Stability and Reactivity

- Instability information at different temperatures is unavailable. Conditions of instability may include excess heat and incompatible materials.
- The product is non-corrosive in the presence of glass.
- The product is incompatible with strong oxidizing agents.
- Polymerization will not occur.
- Decomposition may yield hazardous products (i.e. carbon dioxide and carbon monoxide).

11 Toxicological Information

- **Information on likely routes of exposure**
 - **Inhalation**
Not expected to be hazardous in final pharmaceutical form.
 - **Skin contact**
Contact will cause localized anesthesia.
 - **Eye contact**
Direct contact with eyes may cause temporary irritation.
 - **Ingestion**
Do not ingest.
- **Symptoms related to the physical, chemical and toxicological characteristics**
Side effects may include: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Allergic reactions as a result of sensitivity to lidocaine are extremely rare.
- **Information on toxicological effects**

Lidocaine 10MG Spray LIQ

- Acute toxicity**

Product/ Ingredient Name	Result	Species	Dose	Exposure
Diethyl Glycol Monoethyl Ether	LD ₅₀ Oral	Rat	6,031 mg/kg	-
	LD ₅₀ Dermal	Rabbit	9,143 mg/kg	
	LC ₅₀ Inhalation	Rat	> 5.24 mg/L	
Isopropyl Myristate	LD ₅₀ Oral	Rat	>16,000 mg/kg	-
	LD ₅₀ Oral	Mouse	49,700 mg/kg	
	LD ₅₀ Dermal	Rabbit	5,000 mg/kg	
	LC ₅₀ Inhalation	Rat	41,000 mg/m ³	
Lidocaine	LD ₅₀ Oral	Rat	317 mg/kg	-

- Skin corrosion/irritation**
 Contact will cause localized anesthesia.
- Serious eye damage/eye irritation**
 Direct contact with eyes may cause temporary irritation.
- Respiratory sensitization**
 Not a respiratory sensitizer.
- Skin sensitization**
 This product is not expected to cause skin sensitization.
- Germ cell mutagenicity**
 No mutagenicity studies have been conducted.
- Carcinogenicity**
 Long-term studies in animals have not been conducted to evaluate carcinogenic potential
- OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**
 Not listed.
- Reproductive toxicity**
 Pregnancy Category B: There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
 It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman
- Specific target organ toxicity - single exposure**
 Not classified.
- Specific target organ toxicity - repeated exposure**
 Not classified.
- Aspiration hazard**
 Not classified.

12 Ecological Information

Lidocaine 10MG Spray LIQ

- Ecotoxicity**

Product/ Ingredient Name	Result	Species	Dose	Exposure
Diethyl Glycol	LC ₅₀	Fish	6,010 mg/L	-
Monoethyl Ether	EC ₅₀	Daphnid	1,982 mg/L	-

- Persistence and degradability**

No data is available on the degradability of this product.

- Bio-accumulative potential**

No data available.

- Mobility in soil**

No data available.

- Other adverse effects**

None.

Uncontrolled Copy

13 Disposal Considerations

This product must be disposed of according to local, state, and federal environmental control regulations.

14 Transport Information

This product is not a Department of Transportation controlled material, and it requires no special provisions for transport.

15 Regulatory Information

- **US federal regulations**

This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&D or drug use. Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

 - **TSCA Section 12(b) Export Notification (40 CFR 707, Sub. D)** Not regulated.
 - **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)** Not listed.
 - **CERCLA Hazardous Substance List (40 CFR 302.4)** Not listed.
- **Superfund Amendments and Reauthorization Act of 1986 (SARA)**
 - Immediate Hazard - No
 - Delayed Hazard - No
 - Fire Hazard - No
 - Pressure Hazard - No
 - Reactivity Hazard - No
- **SARA 302 Extremely hazardous substance** Not listed.
- **SARA 311/312 Hazardous chemical** No
- **SARA 313 (TRI reporting)** Not regulated.
- **Other federal regulations**
 - **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List** Not regulated.
 - **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)** Not regulated.
 - **Safe Drinking Water Act (SDWA)** Not regulated.
- **US state regulations**
 - **Massachusetts RTK - Substance List** Not regulated.
 - **New Jersey Worker and Community Right-to-Know Act** Not listed.
 - **Pennsylvania Worker and Community Right-to-Know Law** Not listed.
 - **Rhode Island RTK** Not regulated.
 - **California Proposition 65** Not Listed.
- **International Inventories**
 - **Australia - Australian Inventory of Chemical Substances (AICS)** Complies with inventory.

Lidocaine 10MG Spray LIQ

- **Canada - Domestic Substances List (DSL)**
Complies with inventory.
- **China - Inventory of Existing Chemical Substances in China (IECSC)**
Complies with inventory.
- **Europe - European Inventory of Existing Commercial Chemical Substances (EINECS)**
Complies with inventory.
- **Japan - Inventory of Existing and New Chemical Substances (ENCS)**
Complies with inventory.
- **Korea - Existing Chemicals List (ECL)**
Complies with inventory.
- **New Zealand - New Zealand Inventory (NZI)**
Complies with inventory.
- **Philippines - Philippine Inventory of Chemicals and Chemical Substances (PICCS)**
Complies with inventory.
- **United States and Puerto Rico - Toxic Substances Control Act (TSCA) Inventory**
Complies with inventory.

16 Additional Information

Revision Date: N/A

Supersedes Date: 2018 April 11

Disclaimer

The information herein is based on data considered to be accurate as of the date of preparation of this safety data sheet. However, no warranty or representation, expressed or implied, is made as to the accuracy or completeness of the foregoing data and safety information. All conditions under which this information and its product, or the products of other manufacturers in combination with this product, may be used cannot be anticipated. The user assumes all liability for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices, or from any hazards inherent in the product.