SAFETY DATA SHEET
Lidocaine Hydrochloride Jelly, USP 2%

1. IDENTIFICATION

Product Identifier	Lidocaine Hydrochloride Jelly, USP 2%
Synonyms:	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride
National Drug Code (NDC):	72485-611-10 72485-611-30
Recommended Use:	Lidocaine Hydrochloride Jelly, USP 2% is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).
Company:	Ophtapharm AG Riethofstrasse 1 CH- 8442 Hettlingen, Switzerland
E mail:	quality@sentiss.ch
Emergency Phone Number:	**CHEMTREC** 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classified.
Health Hazards:	Not classified.
Symbol(s):	None.
Signal Word:	None.
Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	None.
Supplementary Information:	While this material is not classifiable as hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage
Lidocaine Hydrochloride	Acetamide, 2-(diethylamino)- N-(2,6-dimethylphenyl)-, monohydrochloride	6108-05-0	$C_{14}H_{22}N_2O$•HCl	270.80	2%

The formula also contains Methylparaben, Propylparaben, Hypromellose, and Sodium Hydroxide and/or Hydrochloric Acid to adjust pH between 6.0 to 7.0.

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
Medical Conditions Aggravated by Exposure:	As with all pharmaceuticals, hypersensitivity is possible.
Notes to Physician:	Treat supportively and symptomatically. Excessive dosage, or short intervals between doses, can result in high plasma levels and serious adverse effects. Patients should be instructed to strictly adhere to the recommended dosage and administration guidelines as set forth in the package insert. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical or foam as necessary.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products:	Oxides of carbon, nitrogen, and sulfur.
Other Specific Hazards:	Not determined.
Special Protective Equipment and Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8
Methods for Cleaning Up:	Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations
Environmental Precautions:	Contain material and prevent release to basements, confined spaces, waterways or soil.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information

7. HANDLING AND STORAGE

Precautions for Safe Handling:	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
Conditions for Safe Storage, Including Any Incompatibilities:	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature.
Specific End Use:	Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Lidocaine Hydrochloride	Not established	Not established

Engineering Controls:	None required for the normal use of this product.
Respiratory Protection:	None required for the normal use of this product.
Eyes Protection:	None required for the normal use of this product.
Hand Protection:	None required for the normal use of this product.
Skin Protection:	None required for the normal use of this product.

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

Physical State/Color:	Clear to opalescent, colorless to slightly colored, colloidal jelly.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	6.0 to 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient	No data available.
(n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Contact with incompatible materials.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	Inhalation of mist may cause slight irritation and transient numbness to nose and throat, dizziness, and drowsiness. While unlikely with this formulation, overexposure may cause toxic effects on the central nervous system and cardiovascular system.
Ingestion:	No data available
Skin Contact:	Lidocaine can be absorbed through broken or diseased skin. Skin reactions after topical administration include transient blanching, paleness, redness, and dermal analgesia.
Eye Contact:	Local anesthetics applied to the cornea may cause transient stinging, then numbness and loss of sensation. Local anesthesia suppresses automatic blinking and allows abnormal drying of the cornea.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available

.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Lidocaine Hydrochloride	Mouse	Oral	LD_{50}	292 mg/kg
	Rat	Oral	LD_{50}	159-324 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Lidocaine Hydrochloride	Ames Test	S. typhimurium and E. coli	Negative
	Chromosomal aberration	Human lymphocytes	Negative
	In *Vivo* micronucleus assay	Mouse	Negative

Aspiration Hazard: None anticipated from normal handling of this product.

Toxicokinetics/ Metabolism: See package insert for more information.

Target Organ Effects: Based on clinical use, possible target organs include the nervous system and cardiovascular system.

Reproductive Effects: Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine.

Carcinogenicity: Studies of Lidocaine in animals to evaluate the carcinogenic potential have not been conducted.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Lidocaine Hydrochloride	Daphnia magna	EC50	112 mg/l	48 hours
	Zebra danio (Danio rerio)	LC50	106 mg/l	96 hours

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Lidocaine Hydrochloride	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Lidocaine Hydrochloride	Listed	Listed	Not Listed

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.

16. OTHER INFORMATION

Revision No.: 01

Revision Date: 07/2024

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.