

SAFETY DATA SHEET

Safety Data Sheet according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations.

Mohark Pharmaceuticals urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION AND CONTACT INFORMATION

PRODUCT NAME: LIDOCAINE 4% TOPICAL ANESTHETIC CREAM

NATIONAL DRUG CODE (NDC): 73715-001-01

MANUFACTURER PRODUCT CODE: F24621

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SECTION 2. HAZARD(S) IDENTIFICATION

This is an OTC drug product for topical anesthetic use. Use only as directed

CLASSIFICATION:
NOT CLASSIFIED.

ADDITIONAL INFORMATION: This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Topical Anesthetic

MIXTURE:

CHEMICAL NAME	CAS NUMBER	SYNONYMS	CHEMICAL FORMULA	MOLECULAR WEIGHT	PERCENTAGE
2-(diethylamino)-N-(2,6- dimethyl phenyl)-acetamide	137-58-6	Lignocaine	C ₁₄ H ₂₂ N ₂ O	234.34	4

COMPOSITION COMMENTS: Components not listed are either non-hazardous or are below reportable limits.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air.

SKIN CONTACT: In case of skin contact, wash skin thoroughly with soap and water.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink plenty of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
LARGE FIRE:	CAUTION: Use of water spray when fighting fire may be inefficient.
FLAMMABILITY DATA:	None
HAZARDOUS COMBUSTION PRODUCTS:	Carbon Oxides
SPECIAL FIRE FIGHTING PROCEDURES:	Wear full protective clothing and self-contained breathing apparatus (SCBA).

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:	Avoid contact with eyes.
SPILL RESPONSE / CLEANUP:	Prevent further leakage or spillage if safe to do so. In the case of liquids, use proper inert absorbent material to clean up spill. Collect and dispose of in properly labeled containers.

SECTION 7. HANDLING AND STORAGE

HANDLING:	Handle in accordance with good industrial hygiene and safety practice. Keep containers adequately sealed during material transfer, transport, or when not in use.
STORAGE:	Do not freeze. Store at controlled room temperature at 20–25 °C (68–77°F).

SECTION 8. EXPOSURE CONTROLS AND 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:	Ventilation should be matched to conditions.
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	
Hand protection	Wear protective gloves (i.e. latex, nitrile, neoprene). Wash hands after contact.
Other	Wash promptly with soap and water if skin becomes contaminated. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Cream; Liquid
APPEARANCE:	White Semi-solid
ODOR:	Not Available
COLOR:	Off-White
ODOR THRESHOLD:	Not Applicable
SPECIFIC GRAVITY:	Not Available
pH	6.5 – 7.3
Boiling Point:	Not Available
Freezing Point:	Not Available
Flash Point:	Not available
Vapor Density:	Not available
Vapor Pressure:	Not available
Evaporation Rate:	Not available
Solubility in Water:	Soluble

SECTION 10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute & Chronic Toxicity

Skin Sensitivity:	NA			
Eye Sensitivity:	NA			
Respiratory Sensitization:	None			
Carcinogenicity:	NTP	None	IARC	None
Reproductive Toxicity:	No human data is available for this product.			
Teratogenicity:	No human data is available for this product.			
Embryotoxicity:	No human data is available for this product.			
Mutagenicity:	No human data is available for this product.			

SECTION 12. ECOLOGICAL INFORMATION

The environmental characteristics of this product have not been fully evaluated. Releases to the environment in pure form should be avoided.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of USDOT (transport by land), IATA (transport by sea) or IMDG (transport by air).

SECTION 15. REGULATORY INFORMATION

US Federal Regulations:

The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable). The finished product is labeled in compliance to the appropriate regulatory requirements and must be used in prescribed manner.

Toxic Substance Control Act (TSCA): This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity:

SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Not listed.
Pennsylvania:	Not listed.
California Proposition 65:	Not listed.

OSHA:	Non-regulated
EPA:	Non-regulated

SECTION 16. OTHER INFORMATION**REVISION DATE:** 31 AUG 2020**REVISION NO:** 1.0

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