



SAFETY DATA SHEET

Issue Date: 2/28/2024

Revision Date: N/A

Revision Number: 01

1. IDENTIFICATION

Product identifier: Lidocaine and Prilocaine Cream 2.5%/2.5%

NDC Number: 0121-1002-30

Supplier Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – Topical anesthetic

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Lidocaine	137-58-6	2.5%
Prilocaine	721-50-6	2.5%
Water	7732-18-5	Proprietary
PEG 60 Hydrogenated Castor Oil	61788-85-0	Proprietary
Carbomer Homopolymer	9007-20-9	Proprietary
Sodium Hydroxide	1310-73-2	pH Adjustment

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation or symptoms occur, get medical attention.

Skin contact: Wash skin with soap and water. If irritation or symptoms develop and persist, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation or symptoms persist.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

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Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation and numbness. Swallowing may cause lightheadedness, nervousness, confusion, dizziness, drowsiness, ringing in the ears, vision changes, feeling hot cold or numb, slow heartbeat, loss of consciousness or seizures. Inhalation of mists may cause respiratory irritation and symptoms similar to ingestion.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling. For external use only.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Lidocaine	None Established
Prilocaine	None Established
Water	None Established
PEG 60 Hydrogenated Castor Oil	None Established
Carbomer Homopolymer	None Established
Sodium Hydroxide	2 mg/m ³ TWA OSHA PEL, 2 mg/m ³ Ceiling ACGIH TLV

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded or if irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES
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Appearance (physical state, color, etc.): White cream.

Odor: Odorless

Odor threshold: Not applicable	pH: 9
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Evaporation rate: Same as water
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Same as water	Vapor density: Same as water
Relative density: 1.0	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not available

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.

Ingestion: Swallowing may cause lightheadedness, nervousness, confusion, dizziness, drowsiness, ringing in the ears, vision changes, feeling hot cold or numb, slow heartbeat, loss of consciousness or seizures. Inhalation of mists may cause respiratory irritation.

Skin contact: May cause mild irritation and numbness.

Eye contact: May cause mild irritation and numbness.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.

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Reproductive Toxicity: Components are not classified as reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Lidocaine: Oral mouse LD50 220 mg/kg

Prilocaine: ATE oral = 300-2000 mg/kg

PEG 60 Hydrogenated Castor Oil: LD50 oral rat >5000 mg/kg

Carbomer Homopolymer: LD50 oral rat >5000 mg/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: No data available.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

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EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

Issue Date: 02/28/2024

Revision Number: 01

Revision Date: N/A

SDS Revision History: N/A

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.