



SAFETY DATA SHEET

Issue Date: 1/28/2023

Revision Date: N/A

Revision Number: 01

1. IDENTIFICATION

Product identifier: Lidocaine Pain Relief Patch 4%

NDC Number: 0121-0970-01, 0121-0970-05

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

Email Address: SDSRequest@perrigo.com

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

This product consists of an adhesive material containing a 4% lidocaine solution, which is applied to a non-woven polyester backing and covered with a polyethylene terephthalate film release liner. The composition below is for the liquid component.

Chemical name	CAS No.	Amount
Lidocaine Hydrochloride	73-78-9	4.0%
Methyl Paraben	99-76-3	Proprietary
Propyl Paraben	94-13-3	Proprietary
Propylene Glycol	57-77-6	Proprietary
Polyvinyl Alcohol	9002-89-5	Proprietary
Gelatin	9000-70-8	Proprietary
Urea	57-13-6	Proprietary
Disodium EDTA	139-33-3	Proprietary
D-sorbitol	50-70-4	Proprietary
Kaolin	1332-58-7	Proprietary
Tartaric Acid	526-83-0	Proprietary
Sodium Polyacrylate	7446-81-3	Proprietary

Sodium Carboxymethylcellulose	9004-32-4	Proprietary
Glycerin	56-81-5	Proprietary
Dihydroxyaluminum Aminoacetate	41354-48-7	Proprietary
Polyacrylic Acid	9003-01-4	<1%
Water	7732-18-5	Proprietary

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: For unintended contact, remove contaminated clothing. 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.

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

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. Polyester backing will burn after the water has evaporated.

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.

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: Pick up product and place in appropriate container for disposal. Clean area thoroughly if needed to remove residue.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with eyes. Avoid unintentional contact with skin and clothing. Wash hands 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 Hydrochloride	None Established
Methyl Paraben	None Established
Propyl Paraben	None Established
Propylene Glycol	10 mg/m ³ TWA AIHA&OARS WEEL
Polyvinyl Alcohol	None Established
Gelatin	None Established
Urea	None Established
Disodium EDTA	None Established
D-sorbitol	None Established
Kaolin	2 mg/m ³ (respirable) TWA ACGIH TLV 5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
Tartaric Acid	None Established
Sodium Polyacrylate	None Established
Sodium Carboxymethylcellulose	None Established
Glycerin	5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
Dihydroxyaluminum Aminoacetate	None Established
Polyacrylic Acid	None Established

Appropriate engineering controls: No special ventilation is required for normal use.

Individual protection measures:

Respiratory protection: None needed under normal use conditions.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations if contact with the drug product is possible.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations if eye contact is possible.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): This product consists of an adhesive material containing a 4% lidocaine solution, which is applied to a non-woven polyester backing and covered with a polyethylene terephthalate film release liner. White to yellow color.

Odor: Characteristic

Odor threshold: Not applicable	pH: Not determined
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: Not determined	Solubility(ies): Solution is soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined
Particle Characteristics: Not applicable	

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 oxides and chlorine compounds.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation is an unlikely route of exposure due to the product form. Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar ingestion.

Ingestion: Swallowing is unlikely due to product form, but ingestion 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.

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.

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 Hydrochloride: Oral mouse LD50 220 mg/kg

Methyl Paraben: Oral mouse LD50 >8000 mg/kg

Propyl Paraben: LD50 oral rat >5000 mg/kg

Glycerin: LD50 oral rat 12.6 g/kg

12. ECOLOGICAL INFORMATION

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

Ecotoxicity values: Lidocaine Hydrochloride: No data available.

Methyl Paraben: EC50 daphnia magna 11.2 mg/L/48 hr.; LC50 fish 59.5 mg/L/96 hr. EC50 algae 91 mg/L

Propyl Paraben: EC50 daphnia magna 15.4 mg/L/48 hr.; LC50 fish 6.4 mg/L/96 hr. EC50 algae 16 mg/L

Glycerin: LC50 goldfish >5000 mg/L/24 hr; LC50 daphnia magna >10,000 mg/L/24 hr.

Persistence and degradability: Methyl Paraben, propyl paraben and glycerin are readily biodegradable.

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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**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**

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