SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Lidocaine and Prilocaine Cream, USP 2.5%/2.5%
Synonyms: None

Manufacturer Name: Padagis US LLC
Address: 3940 Quebec Ave. North
Minneapolis, MN 55427

Telephone number: +1-763-546-4676

Emergency phone number: +1 866 519 4752 (U.S. calls)
+1 760-476-3961 (International calls)
Code 335768

Email Address: EHS@padagis.com

Recommended use: Topical anesthetic
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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

4. FIRST-AID MEASURES

Inhalation: No first aid should be needed. If irritation occurs or symptoms develop, move to fresh air and get medical attention.
Skin contact: First aid is not required for skin contact. This product is intended for use on the skin. If irritation develops, discontinue use and get medical attention. For unintended contact, wash with soap and water.

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

Ingestion: In the case of 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 if any adverse effects occur.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation and numbness. Skin contact causes numbness. If swallowed, may cause gastric upset and nervous system effects including drowsiness; dizziness; disorientation; confusion; lightheadedness; tremulousness; psychosis; nervousness; apprehension; agitation; euphoria; tinnitus; visual disturbances including blurred or double vision; nausea; vomiting; paresthesia; sensations of neat, cold or numbness; difficulty swallowing; dyspnea; and slurred speech. Muscle twitching or tremors, seizures, unconsciousness, coma, and respiratory depression and arrest may also occur. Cardiovascular manifestations may include hypotension, bradycardia, arrhythmia, and cardiovascular collapse.

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

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire. Do not use straight water stream.

Specific hazards arising from the chemical: Not a fire hazard but may burn under fire conditions.

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: Collect liquid with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with eyes. Avoid creating and breathing mists.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Lidocaine	Padagis OEB3 (10-100 ug/m3)
Prilocaine	None Established
PEG-60 Hydrogenated Castor Oil	None Established

Carbopol	None Established
Sodium Hydroxide	2 mg/m3 Ceiling ACGIH TLV 2 mg/m3 TWA OSHA PEL

Appropriate engineering controls: No special ventilation required for normal use. Use with adequate general ventilation to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are excessive, a NIOSH approved supplied air 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 bulk handling.
Eye protection: None required for normal use. Chemical safety goggles recommended for bulk handling.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White cream or emulsion
Odor: Not available

Odor threshold: Not determined	**pH:** 8.7-9.7
Melting point/freezing point: Not available	**Boiling Point:** Not determined
Flash point: >93.3ºC (200ºF)	**Evaporation rate:** Not determined
Flammability (solid, gas): Not applicable	**VOC:** Not available
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not available	**Vapor density:** Not available
Relative density: Not available	**Solubility(ies):** Not available
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: Avoid excessive heat and open flames.
Incompatible materials: Avoid oxidizing and reducing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause numbness of the mucous membranes and upper respiratory tract and possibly symptoms like ingestion.
Ingestion: Swallowing may cause gastric upset and nervous system effects including drowsiness; dizziness; disorientation; confusion; lightheadedness; tremulousness; psychosis; nervousness; apprehension; agitation; euphoria; tinnitus; visual disturbances including blurred or double vision; nausea; vomiting; paresthesia; sensations of neat, cold or numbness; difficulty swallowing; dyspnea; and slurred speech. Muscle twitching or tremors, seizures, unconsciousness, coma, and respiratory depression and arrest may also occur. Cardiovascular manifestations may include hypotension, bradycardia, arrhythmia, and cardiovascular collapse.
Skin contact: This product is intended for use on the skin. Skin contact causes temporary numbness due to anesthetic properties.

Eye contact: Contact may cause slight irritation with redness and tearing and temporary numbness due to anesthetic properties.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. The mutagenic potentials of lidocaine and prilocaine have been tested in the Ames Salmonella reverse mutation assay, an in vitro chromosome aberrations assay in human lymphocytes and in an in vivo mouse micronucleus assay. There was no indication of any mutagenic effects for either compound in these studies.
Reproductive Toxicity: None of the components are reproductive toxins. No significant effects were observed in offspring of rats administered lidocaine at by constant infusion for 2 weeks before mating and throughout pregnancy. There were no effects on fertility in an 8 month study in rats with prilocaine. There were also no adverse effects on the fetus.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Lidocaine was not oncogenic when administered topically weekly to the dorsal skin of mice for 26 weeks. Chronic oral toxicity studies of o-toluidine, a metabolite of prilocaine, have shown that this compound is a carcinogen in both mice and rats.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >2000 mg/kg
Lidocaine: Oral rat LD50 317 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is 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. No specific disposal method is recommended.

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): Refer to Section 2 for the OSHA Hazard Classification.

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**.**

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: New SDS.
Date of preparation: November 5, 2022
Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).