





TOLMAR Inc.

## Safety Data Sheet

### Section 1. Identification

<b>Domestic Product Name:</b>	Lidocaine 2.5% and Prilocaine 2.5% Cream		
<b>Export Product Name:</b>	Lidocaine 2.5% and Prilocaine 2.5% Cream		
<b>Manufacturer:</b>	TOLMAR, Inc. 701 Centre Avenue Fort Collins, CO 80526		
		Phone: 970.212.4500	970.212.4511
<b>Chemical Use:</b>	Lidocaine and Prilocaine are both local anesthetics. This cream is used to numb skin and prevent pain before treatment.		

### Section 2. Hazard(s) Identification

<b>Appearance:</b>	White homogenous cream	<b>Ratings:</b>	
<b>Classification:</b>	Heath (Acute- Chronic):2-2 Flammability: 0 Reactivity: 0 Environment (Air-Water-Soil): 0-0-0 Special Hazards: No information available	Minimal Slight Moderate Severe Extreme	0 1 2 3 4
<b>Signal Word:</b>	Warning		
<b>Hazard Information:</b>	Hazard Statements: H312- Harmful in contact with skin H317- May cause an allergic skin reaction H320- Causes eye irritation H371- May cause damage to organs H351- Suspected of causing cancer Pictograms:  		
<b>Precautionary Information:</b>	Precautionary statements: P102- Keep out of reach of children P103- Read label before use P233- Keep container tightly closed P281- Use protective equipment as required P301- If swallowed rinse mouth and do not induce vomiting P305- If in eyes rinse with water, contact medical personnel P370- In case of fire extinguish with dry chemical powder, water spray, CO <sub>2</sub> P401- Store at room temperature		
<b>Other Hazards:</b>	No applicable information available		

### Section 3. Composition and Information for Product Ingredients

List of Components and Information for Component 1			
Chemical Name	CAS#	Synonyms	% W/W
Lidocaine, USP	000137-58-6	Xilocaine, Lignocaine, Acetmaide	~2.5
Prilocaine, USP	000721-50-6	Propanamide, Propitocaine	~2.5
Carbomer 5984 EP, NF	9003-01-4	Carbomer Homopolymer Type B, Acrylic polymer, Carboxy polymethylene	>1
PEG-60 Hydrogenated Castor Oil	25322-68-3	Polyethylene Glycol, Polyoxyethylene	>1
Purified Water, USP*	7732-18-5	Deionized ultra-filtered water; Water; Hydrogen oxide	>1
Other constituents <1% w/w each in the formulation	Remainder of formulation is not considered hazardous. Further information can be made available to medical personnel in the event of an emergency		
* This compound is NOT HAZARDOUS in this specific formulation according to the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Please contact TOLMAR, Inc. if you wish further information.			

### Section 4. First Aid Measures

Exposure Scenario	First Aid Measures
Inhalation	Not an expected route of exposure. General precautionary. Remove from source of exposure. If not breathing, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. If signs of toxicity occur, seek medical attention. No specific treatment is necessary since material is not likely to be hazardous by inhalation
Ingestion	If inadvertently swallowed in significant quantities, seek medical advice immediately. General precautionary. Never give anything by mouth to an unconscious person. Remove from source of exposure.
Skin Contact	If not being used therapeutically, remove from source of exposure. Removed contaminated clothing. Flush with copious amounts of water and wash with soap. If irritation persists or signs of toxicity occur, seek medical attention. Wash clothing before reuse.
Eye Contact	Remove from source of exposure. Removed contaminated clothing. Flush with copious amounts of water and wash with soap. If irritation persists or signs of toxicity occur, seek medical attention.
General Precautions	Avoid contact with eyes, skin and clothing. Wash hands and clothing thoroughly after handling. SDS will be provided to medical care provider if medical attention is necessary. In case of exposure to large areas of skin or prolonged exposure, monitor carefully for CNS and CVS symptoms and seek qualified medical attention upon onset of symptoms. Medical attention may need to include maintenance of respiration and heartbeat.

### *Section 5. Fire Fighting Measures*

<b>Characteristic</b>	<b>Details</b>
Flash Point	No applicable information available
Extinguishing Media	Water spray, carbon dioxide, or dry chemical powder as appropriate for surrounding fire.
Unusual Fire/Explosion Hazards	In case of fire, keep containers cool with water and remove from fire area. Toxic fumes may be produced in a fire
Special Protective Equipment	Fire fighters should wear full protective clothing, including self contained breathing apparatus. Wash all protective equipment thoroughly after use.

### *Section 6. Accidental Release Measures*

<b>Measure</b>	<b>Details</b>
Personal Precautionary Measures	Wear appropriate personal protective equipment such as impermeable gloves made of nitrile or latex and eye protection. Additional protective equipment may be necessary depending upon the extent of the spill. Avoid contact with eyes and skin by using appropriate personal protective equipment. Wash thoroughly with soap and water after handling. Remove contaminated clothes immediately.
Cleaning/Absorption Measures	<p>Remove ignition sources. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Contain spill with sand or other inert material. Wash spill area thoroughly with water. Avoid dispersion of dust. Collect spilled material, absorbent, etc. into suitable containers for proper disposal in accordance with applicable waste disposal regulations.</p> <p>In the event of a release of this material, the user should determine if the release qualifies as reportable according to local, state, and federal regulations.</p>

### *Section 7. Handling and Storage*

<b>Action</b>	<b>Details</b>
Handling	Avoid ingestion. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling. Remove contaminated clothes immediately.
Storage	Keep containers tightly closed when not in use. Store at room temperatures of 59°F - 86°F (15°C - 30°C). Do not freeze.

## ***Section 8. Exposure Controls and Personal Protection***

<b>Action</b>	<b>Details</b>
Engineering Controls	Use a local exhaust ventilation system when handling in bulk.
Respiratory Protection	Respirator is not required for routine conditions of use of this product. If respiratory protection is needed, such as in the event of a spill, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02.
Protective Clothing	Health care workers should wear protective gloves if administering product to a patient to avoid acute or repeated skin contact. Wear gloves, lab coat, or other protective over garment if skin contact is likely.
Eye Protection	Wear safety glasses with side shields for manufacturing, or a greater degree of eye protection in case of large spill.
OSHA PEL	No applicable information available
ACGIH TLV	No applicable information available

## ***Section 9. Physical and Chemical Properties of Product***

<b>Characteristic</b>	<b>Details</b>
Physical State	Emulsion – soft, hydrophilic homogenous cream
Color	White
Odor	Mild
pH	~9
Specific gravity	1.0
Boiling point/ Boiling Range	No applicable information available
Melting point/Freezing Point	18°C
Flash Point	No applicable information available
Flammability	No applicable information available
Flammability & Explosive Limits	No applicable information available
Vapor Pressure	No applicable information available
Vapor Density	No applicable information available
Relative Density	No applicable information available
Solubility	Soluble in water

**Section 9 cont. Physical and Chemical Properties of Product**

Characteristic	Details
Odor Threshold	No applicable information available
Evaporation Rate (nBuAc = 1)	No applicable information available
Partition coefficient	No applicable information available
Auto-ignition temperature	No applicable information available
Decomposition temperature	No applicable information available
Viscosity	No applicable information available

**Section 10. Stability and Reactivity of Product**

Characteristic	Details
Reactivity/ Chemical Stability	Stable under normal conditions of handling, use and transport; stability not guaranteed beyond expiration date on package
Hazardous Polymerization	Will not occur
Conditions to Avoid	None
Incompatible Materials	None
Hazardous Decomposition	When heated to decomposition, emits toxic fumes

**Section 11. Health Hazard Information**

Toxicity Category	Details
Acute Oral Toxicity	Lidocaine LD50 Rat – 317 mg/kg
Target Organs	CNS, skin, eyes, liver
Skin Irritation	Irritant, transient skin blanching, erythema, edema, itching or rash
Eye Irritation	Eye contact will most likely cause significant irritation but the irritation is reversible based on ingredients and composition.
Inhalation	Although unlikely route of exposure due to product, may slightly irritate the nose, throat and lungs. Symptoms generally alleviated upon breathing fresh air.
Ingestion	Not a significant route of exposure. Acute ingestion of large quantities of this product or chronic ingestion may cause adverse symptoms.
Injection	Although not likely due to composition of product, contact medical assistance if injection occurs.

### *Section 11 cont. Health Hazard Information*

<b>Toxicity Category</b>	<b>Details</b>
Carcinogenicity	Not listed as a carcinogen, however, a metabolic by-product of prilocaine, ortho-toluidine, has been shown to cause cancer in mice and rats.
Mutagenicity	No applicable information available
Reproductive Toxicity	No applicable information available
Teratogenicity	Pregnancy Category B (No evidence of risk). Human and animal studies have not been completed on the formulation as a whole.
Potential Health Effects	Impaired cardiovascular function; renal and hepatic disorders; hypersensitivity to amid-type local anesthetics; use of antiarrhythmic drugs, stimulants, and depressants; acidosis; early pregnancy; very young patients with glucose-6-phosphate dehydrogenase deficiency and patients taking oxidizing drugs such as antimalarials and sulfonamides are more susceptible to methemoglobinemia; congenital or idiopathic methemoglobinemia.

### *Section 12. Ecological Information*

<b>Characteristic</b>	<b>Details</b>
Toxicity	96 hr. LC50 for zebra fish – 188 mg/L 48hr. EC50 for daphnia magna – 61 mg/L 72hr. EC50 for green algae – 154 mg/L
Degradability	No data on formulation. Lidocaine is not biodegradable
Persistence	No applicable information available.
Bioaccumulation	No data on formulation. Lidocaine has a low potential for bioaccumulation.
Mobility in Soil	No applicable information available

### *Section 13. Disposal of Product*

<b>Measure</b>	<b>Details</b>
Disposal Methods	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. TOLMAR Inc. recommends incineration. Do not send down drain. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Shipment of wastes must be done with appropriately permitted and registered transporters.
Disposal Container	Waste must be placed and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Ensure proper marking and labeling.
Waste Handling	Wear proper protective equipment when handling waste materials.

#### Section 14. Transport Information

##### Land Transportation

DOT (non-bulk)	DOT Shipping Name	Not listed
	UN/NA Number	Not applicable
	Hazard Class	Not applicable
DOT (bulk)	DOT Shipping Name	Not listed
	UN/NA Number	Not applicable
	Hazard Class	Not applicable
	Packing Group	Not applicable

#### Section 15. Regulatory Information

Category	Details
TSCA Inventory	No applicable information available
SARA Hazard Categories	No applicable information available
CERCLA	No applicable information available
California Proposition 65	No applicable information available

#### Section 16. Other Information

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