

This Safety Data Sheet is not intended for consumers and does not address consumer use of the product. For information regarding consumer applications of this product, refer to the product labeling.

1. Identification of the substance / preparation and of the company

Product Name: Pramoxone® Cream 1%

Generic Name: Hydrocortisone acetate 1% and pramoxine hydrochloride 1%

Pharmaceutical Action: Topical corticosteroid and anesthetic

Usage: Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)

Company Name: Sebela Pharmaceuticals Inc.
645 Hembree Parkway, Suite I
Roswell, GA 30076

Emergency Phone Number: For emergency involving spill, leak, fire, exposure or accident, call CHEMTREC day or night at (800) 424-9300

Product Technical and Medical Information: (844) 732-3521

2. Hazards identification

	<u>Health</u>	<u>Flammability</u>	<u>Reactivity</u>
National Fire Protection Association (NFPA) (estimated)	2	1	0

Emergency Overview – Irritant

Substance pharmacologically active at low dose (anti-inflammatory corticosteroid). Harmful! Possible risk of harm to unborn child. Causes numbing effect to skin and respiratory tract. Adverse effects may include numbness, burning, redness, itching, hives, or large hive-like swellings on the skin or in the mouth or throat. May cause allergic reaction if inhaled, ingested, or in contact with skin.

Appearance: White smooth cream

Odor: Characteristic

Potential Health Effects

Eye Contact: May cause irritation.

Skin Contact: Repeated or prolonged contact may cause irritation.

Ingestion: May cause abdominal cramps and diarrhea.

Prolonged Exposure: Danger of serious damage to health by prolonged contact with skin and if swallowed.

3. Composition / information on ingredients			
Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air (8 hr. TWA)
Hydrocortisone Acetate	50-03-3	1%	Not Established
Pramoxine Hydrochloride	637-58-1	1%	Not Established
Stearic Acid	57-11-4	<20%	OSHA PEL: 5 mg/m ³ ACGIH TLV: 3 mg/m ³
Propylene Glycol	57-55-6	<15%	AIHA WEEL: 10 mg/m ³
Polyoxyl 40 Stearate	9004-99-3	<10%	ACGIH: 10 mg/m ³ (total dust)
Cetyl Alcohol	36653-82-4	<10%	Not Established
Isopropyl Palmitate	142-91-6	<5%	Not Established
Aquaphor® Petrolatum Mineral Oil Ceresin Lanolin Alcohol	N/A	<5%	Not Established

Listed carcinogens: The following components, present at concentrations of ~ 0.1% are listed as carcinogens or potential carcinogens by either the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), the Occupational Safety and Health Administration (OSHA) or the American Conference of Industrial Hygienists (ACGIH): None.

4. First aid measures	
Eyes:	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately. Continue to rinse.
Skin:	Flush skin thoroughly with soap and water. Get medical attention if symptoms persist or occur after washing.
Ingestion:	Wash out mouth with water if conscious. Do NOT induce vomiting. Get medical attention.

5. Firefighting measures	
Flammable Properties:	During a fire, gases hazardous to health may be formed.
Flash Point:	>210°F / 99°C
Extinguishing Media:	Do NOT direct a solid stream of water or foam into burning molten material; this may cause spattering and spread the fire. Suitable extinguishing media: Water spray, CO ₂ , foam or dry chemical.
Special Fire Fighting Procedures:	Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

6. Accidental release measures	
Personal Protection:	Use personal protection recommended in section 8 of this Safety Data Sheet.
Spill Cleanup Methods:	Cover with inert, absorbent material and remove to disposal container. Spill area may be slippery. Flush with plenty of water.

7. Handling and storage

Handling: Store at controlled room temperature between 59-86°F (15-30°C).

8. Exposure controls / personal protection

Engineering Controls: Not applicable.

Respiratory Protection: Not applicable; aerosol formation is extremely unlikely.

Eye Protection: None required during normal administration or use of Pramoxone® Cream 1%. When handling large quantities, use approved eye protection to safeguard against potential eye contact.

Protective Clothing: Prolonged skin contact may require protective gloves.

Hygienic Work Practices: Wash hands thoroughly after handling. If working with large quantities of the cream (such as spill clean-up), use chemical resistant gloves and appropriate eye protection. No eating, drinking or smoking in area.

9. Physical and chemical properties

Appearance: White, smooth cream

pH: 3.5 to 5.0

10. Stability and reactivity

Stability: Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

Conditions to Avoid: Avoid high temperatures, moisture and all sources of ignition.

Materials to Avoid: Avoid contact with strong oxidizing agents, strong acids, caustics, aliphatic amines, and isocyanates.

Hazardous Decomposition Products: When heated to decomposition material may emit acrid smoke and fumes. Under fire conditions toxic fumes are emitted. Combustion can yield carbon dioxide, carbon monoxide, and other oxides. Partial combustion also forms carbon monoxide, soot, aldehydes, and ketones.

Hazardous Polymerization: Will not occur.

11. Toxicology information**LD50 / LC50:**

Hydrocortisone Acetate:

- Intraperitoneal (mouse): 2250 mg/kg
- Subcutaneous (mouse): 45 mg/kg

Pramoxine Hydrochloride:

- Oral: LD50 = 1050 mg/kg (mouse)

Stearic Acid:

- Skin Rabbit LD50: > 5000 mg/kg
- Oral: LD50 = 20 g/kg (rat)
- Oral: LD50 = 22 g/kg (mouse)

Polyoxyl 40 Stearate:

- Oral: LD50 >20 g/kg (rat)

Propylene Glycol:

- Skin Rabbit LD50: 10,000 mg/kg

Irritancy Data:

Cetyl Alcohol:

- Rabbit / Skin: mild-PII = 0.79
- Rabbit / Eye: mild

Isopropyl Palmitate:

- Human / Skin: mild
- Rabbit / Skin: moderate

Propylene Glycol:

- Human / Skin: mild, moderate
- Rabbit / Eye: mild

Stearic Acid:

- Standard Draize, human skin, 75 mg/3D-I, mild
- Standard Draize, rabbit skin, 500 mg/24-hr, moderate

Teratogenicity: Corticosteroids are generally teratogenic in laboratory animals when administered systematically but there are no well-controlled studies in humans.

Reproductive Effects: In animals, experiments have shown teratogenic effects, varying with species. In humans, retrospective studies have not shown abnormal effects due to administration of corticoids during the first trimester. An increase in nonviable rat fetuses was seen with the administration of 0.4 mg/kg/day of hydrocortisone acetate between gestational days 6 and 21.

Mutagenicity: Hydrocortisone acetate did not cause observable changes in the DNA damage / alkaline elution tests.

12. Ecological information

There is no ecological information available at this time. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways.

13. Disposable considerations

This product is not hazardous waste when disposed of. For small quantities, discard in a municipal landfill as ordinary trash. For large quantities, any disposal practice must be in compliance with local, state, and federal laws and regulations (contact local or state environmental agency for specific rules). Do not dispose of via sinks, drains, or into immediate environment.

14. Transport information

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

15. Regulatory information

TSCA: Exempt

CERCLA: This product contains no components subject to reporting or notification requirements.

SARA Title III: Exempt

16. Other information

Date Issued: April 10, 2015

Supersedes Date: New

SDS: 716, Pramoxone® Cream 1%

Notice: The preceding information is based on available data compiled by the manufacturer from its own studies and the work of others and is believed to be correct. However, no warranty is expressed or implied as to the accuracy, completeness or adequacy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Sebela Pharmaceuticals Inc. does not assume any responsibility for the results of its use. The information is furnished upon the condition that the persons receiving it shall make their own determination as to the suitability of the product for their particular use.