



SAFETY DATA SHEET

Printing Date: 21 November 2017

Revised on: 21 November 2017

Trade name: Anti-Itch Cream

1 Product and Company Identification

- **Product Identifier**
 - **Recommended Uses:** External use
 - **Trade name:** Anti-Itch Cream
 - **Synonym:** Anti-Itch Cream
- **Manufacturer/Supplier**

Natureplex, LLC
11085 Airport Road
Olive Branch, MS 38654-0221
(662) 874-1370 (8am – 5pm CT; M-F)
- **Emergency Telephone Number:**

1-866-323-0107
Chemtrec: 1-800-424-9300 (Transportation Spill Response 24 hours)
- This SDS is written to provide health and safety information for individuals who will be handling the product during manufacture and packaging. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the product label for handling guidance for the consumer.

2 Hazard(s) Identification

- **Physical hazards** Not classified.
- **Health hazards** Not classified.
- **OSHA defined hazards** Not classified.
- **Label elements**

Hazard symbol None

Signal word Warning

Hazard statement This pharmaceutical product in stated dosage form is designed for over-the-counter human use. Under normal handling and use, and in a manner consistent with the labeled instructions, this product is not chemically hazardous. This product is not meant for oral consumption or for ophthalmic use. Should any person while handling or using this product observe any adverse health effects, they should seek medical treatment.



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Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials. Keep from freezing. Store at a controlled room temperature, 15°- 30° C.

Disposal Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC) None known.

3 Composition / Information on Ingredients

<u>Chemical Name</u>	<u>CAS #</u>	<u>%</u>
Water*	7732-18-5	Proprietary
Carbomer*	9003-01-4	Proprietary
Cetearyl Alcohol*	8005-44-5	Proprietary
Polysorbate 60*	9005-67-8	Proprietary
Menthol	2216-51-5	1%
Glycerin*	56-81-5	Proprietary
Aloe Barbadosensis Leaf Juice*	85507-69-3	Proprietary
DMDM Hydantoin*	6440-58-0	Proprietary
Propylene Glycol*	57-55-6	Proprietary
Pramoxine Hydrochloride	637-58-1	1%
Triethanolamine*	102-71-6	Proprietary

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4 First Aid Measures

- **Emergency and First Aid Procedures**
 - **Inhalation:** Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.
 - **Eye Contact:** Do not rub eyes. Flush eyes thoroughly with water for 15 minutes. If irritation occurs or persists, get medical attention.
 - **Skin Contact:** Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs
 - **Ingestion:** In the event of swallowing this material, dilute with large quantities of water or milk. Medical treatment should be supportive and symptomatic.



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5 Fire Fighting Measures

- **Extinguishing media**
 - **Suitable extinguishing agents:**
Use carbon dioxide, dry chemical, or water spray.
- **Fire and/or Explosion Hazards:** No data available.
- **Special Fire Fighting Procedures:** Wear approved positive pressure, self-contained breathing apparatus and full protective gear.

6 Spill or Leak Procedures

- **Steps to Take in Case Product Is Released or Spilled:**
- **Small spill:** use absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.
- **Large spill:** contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly.

7 Handling and Storage

- **Handling:**
 - No special technical protective measures required.
- **Storage:**
 - Store according to labeled instructions.
 - No special restrictions on storage with other products.



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8 Exposure Controls / Personal Protection

- **Engineering controls:** Ensure adequate ventilation.
- **Personal Protective Equipment:** No special measures required under normal usage.

9 Physical and Chemical Properties

Appearance

Physical state: semi-solid liquid

Form: cream

Color: white to off white

Odor: characteristic

Odor threshold: Not Available

pH: 5.5-7.0

Melting point/freezing point: Not Available

Initial boiling point and boiling range: Not Available

Flash point: Not available

Evaporation rate: Not available

Flammability (solid, gas): Not available

Upper/lower flammability or explosive limits

Flammability limit - lower (%): Not available

Flammability limit - upper (%): Not available

Explosive limit - lower (%): Not available

Explosive limit - upper (%): Not available

Vapor pressure: Not available

Vapor density: Not available

Relative density: Not available

Solubility

Solubility (water): Not available

Partition coefficient (n-octanol/water): Not available

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Viscosity: Not available



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10 Stability and Reactivity

- Instability information at different temperatures is unavailable. Conditions of instability may include excess heat and incompatible materials. For example, it reacts with oxidizing agents and strong mineral acids.
- The product is non-corrosive in the presence of glass.
- The product is incompatible with strong mineral acids.
- Polymerization will not occur.

11 Toxicological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

- **Pramoxine Hydrochloride**
 - **LD50:** Oral 1050 mg/kg mice, IP 300 mg/kg mice
 - **Acute Dermal Irritation** 750 mg/kg mice
 - **Primary Eye Irritation** Not available
 - **Sensitization** Not available
- **Menthol**
 - **LD50:** Oral 3200 mg/kg rat
 - **Acute Dermal Irritation** irritating to skin rabbit
 - **Primary Eye Irritation** mild to moderate rabbit
 - **Sensitization** Not available

12 Ecological Information

- **Ecotoxicity effects:** No data is available on the product itself.
- **Aquatic toxicity effects:** No data is available on the product itself.



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13 Disposal Considerations

- Waste disposal must be in accordance with appropriate US, Federal, State, and international regulations. 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.

14 Transport Information

Transport Information This material is not classified as hazardous for transport.

- **U.S. Department of Transport (DOT)** Not regulated
- **Canadian Transport of Dangerous Goods (TDG)** Not regulated
- **International Civil Aviation Organization (ICAO)** Not regulated
- **International Air Transport Association (IATA)** Not regulated
- **International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)** Not regulated
- **Transport of Dangerous Goods by Rail (RID)** Not regulated
- **Transport of Dangerous Goods by Road (ADR)** Not regulated
- **Transportation of Dangerous Goods via Inland Waterways (ADN)** Not regulated

15 Regulatory Information

USA

- **Federal Regulations**

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.



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SARA 311/312 Hazardous Categorization

Acute Health Hazard No

Chronic Health Hazard No

Fire Hazard No

Sudden Release of Pressure Hazard No

Reactive Hazard No

This product does not contain any HAPs.

- **State Regulations**

California Proposition 65

This product does not contain any Proposition 65 chemicals.

- **Canada**

Not classified

WHMIS Hazard Class

Non-controlled

- **European Union**

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16 Additional Information

Revision Date: 2017 Nov 21

Supersedes Date: 2014 Nov 13

Disclaimer

The information herein is based on data considered to be accurate as of the date of preparation of this safety data sheet. However, no warranty or representation, expressed or implied, is made as to the accuracy or completeness of the foregoing data and safety information. All conditions under which this information and its product, or the products of other manufacturers in combination with this product, may be used cannot be anticipated. The user assumes all liability for any damage or injury resulting from abnormal use, from any failure to adhere to recommended practices, or from any hazards inherent in the product.