



# SAFETY DATA SHEET

Printing Date: 18 December 2017

Issued on: 18 December 2017

**Trade name:** Hydrocortisone Cream (BLD 003)

## 1 Product and Company Identification

- **Product Identifier: Hydrocortisone 1% Itch Relief Cream**
  - **Recommended Uses:** External use medicinal product
  - **Trade name:** Monistat Care Hydrocortisone 1% Itch Relief Cream
  - **Synonym:** Monistat Care Intense Itch Relief Cream, Monistat Care Maximum Strength Instant Itch relief Cream Hydrocortisone 1%

- **Manufacturer/Supplier**  
Natureplex, LLC  
11085 Airport Road  
Olive Branch, MS 38654-0221  
(662) 874-1370 (8am – 5pm CT; M-F)

- **Poison Control Center:** 800-222-1222
- **Chemtrec:** 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.

### Precautionary statement

**Prevention** Observe good industrial hygiene practices.

**Response** Wash hands after handling.



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**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>
Ammonium Acryloyldimethyltaurate/ VP Copolymer*	7732-18-5	Proprietary
Carbomer*	9003-01-4	Proprietary
Ceteareth-6*	68439-49-6	Proprietary
Cetyl Alcohol*	57-11-4	Proprietary
Citric Acid*	77-92-9	Proprietary
Dimethicone*	63148-62-9	Proprietary
Edetate Disodium*	6381-92-6	Proprietary
Ethylparaben*	120-47-8	Proprietary
Glycerin*	56-81-5	Proprietary
Hydrocortisone	50-23-7	1.0
Methylparaben*	99-76-3	Proprietary
Mineral Oil*	8042-47-5	Proprietary
Petrolatum*	8009-03-8	Proprietary
Phenoxyethanol*	122-99-6	Proprietary
Propylparaben*	94-13-3	Proprietary
Sodium Citrate*	68-04-2	Proprietary
Stearyl Alcohol*	112-92-5	Proprietary
VP/eicosene Copolymer*	28211-18-9	Proprietary
Water*	7732-18-5	Proprietary

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

### 4 First Aid Measures

- **Inhalation:** Move affected workers to fresh air. If necessary, administer CPR and oxygen. Call a physician if symptoms persist.
- **Eye contact:** Remove contact lenses. Thoroughly flush eyes with water for at least 15 minutes. Do not use an eye ointment as a first aid measure. Seek medical attention if irritation develops or persists.



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- **Skin contact:** Remove contaminated clothing and shoes. Wash skin with soap and water. Get medical attention if irritation develops or persists.
- **Ingestion:** Do not induce vomiting, unless directed to do so by medical personnel. Give nothing by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician and/or poison control immediately. Loosen tight clothing. Seek medical attention.
- **Most important symptoms/effects, acute and delayed:** Direct contact with eyes may cause temporary irritation.
- **Indication of immediate medical attention and special treatment needed:** Treat Symptomatically.
- **General information:** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5 Fire Fighting Measures

- **Suitable extinguishing agents:** use water fog, foam, dry chemical, or carbon dioxide.
- **Fire and / or explosion hazards:** as with most organic solids, fire is possible at elevated temperatures. Fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential explosion hazard.
- **Special fire fighting procedures:** for small fires, use a dry chemical powder. For large fires, use a water fog, or foam.

## 6 Spill or Leak Procedures

- **Personal precautions, protective equipment and emergency procedures** Keep unnecessary personnel away. Wear appropriate solvent-resistant personal protective equipment.
- **Methods and materials for containment and cleaning up** Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
- **Environmental precautions** Avoid discharge into drains, water courses or onto the ground.



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## 7 Handling and Storage

- **Handling**

Keep away from heat. Keep away from sources of ignition. Ground the equipment that contains this material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wash thoroughly after handling. Wear suitable protective clothing. If ingested, seek medical advice immediately, and show the container or the label. Keep away from incompatibles, such as oxidizing agents.

- **Storage**

Keep container tightly closed. Store at cool temperatures, in a well-ventilated area, and out of reach of children. Do not freeze. Store at controlled room temperature at 15-30 °C .

## 8 Exposure Controls / Personal Protection

- **Occupational exposure limits**

No exposure limits noted for ingredient(s).

- **Biological limit values**

No biological exposure limits noted for the ingredient(s).

- **Appropriate engineering controls**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels low. If user operations generate dust, fumes, or mist, ventilate to keep exposure to airborne contaminants low.

- **Individual protection measures, such as personal protective equipment**

- **Eye/face protection**

Avoid contact with eyes. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting.

- **Skin protection**

Wear a lab coat, rubber gloves, splash goggles, and a dust respirator. Use approved / certified respirator and equivalent gloves. Wash promptly with soap and water if skin becomes contaminated.

- **Respiratory protection**

None required for consumer use.

- **Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.



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- **General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9 Physical and Chemical Properties

### Appearance

**Physical state:** semi-solid liquid

**Form:** cream

**Color:** white to off-white

**Odor:** no objectionable odor

**Odor threshold:** Not Available

**pH:** 4.6 ±0.3

**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:** 100-900 kcPs

## 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.



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- 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

- **Information on likely routes of exposure**
  - **Inhalation**  
Not expected to be hazardous in final pharmaceutical form.
  - **Skin contact**  
Not expected to be hazardous in final pharmaceutical form.
  - **Eye contact**  
Direct contact with eyes may cause temporary irritation.
  - **Ingestion**  
Do not ingest. No harmful effects expected in amounts likely to be ingested by accident.
- **Information on toxicological effects**
  - **Acute toxicity**  
No adverse effects are expected.
  - **Skin corrosion/irritation**  
Not classified as a skin corrosive or irritant
  - **Serious eye damage/eye irritation**  
Direct contact with eyes may cause temporary irritation.
  - **Respiratory sensitization**  
Not a respiratory sensitizer.
  - **Skin sensitization**  
This product is not expected to cause skin sensitization.
  - **Germ cell mutagenicity**  
No mutagenicity studies have been conducted.
  - **Carcinogenicity**
    - This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA
  - **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**  
Not listed.
  - **Reproductive toxicity**  
Not expected to cause reproductive effects.
  - **Specific target organ toxicity - single exposure**  
Not classified.



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- **Specific target organ toxicity - repeated exposure**  
Not classified.
- **Aspiration hazard**  
Not classified.

## 12 Ecological Information

- **Ecotoxicity**  
The product is not classified as environmentally hazardous.
- **Persistence and degradability**  
No data is available on the degradability of this product.
- **Bio-accumulative potential**  
No data available.
- **Mobility in soil**  
No data available.
- **Other adverse effects**  
None.

## 13 Disposal Considerations

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

## 14 Transport Information

Product not classified as hazardous for transport.  
Product not regulated by USDOT, IATA, IMDG, or EUADR regulations.

## 15 Regulatory Information

- **US federal regulations**  
This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&D or drug use. Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

- **TSCA Section 12(b) Export Notification (40 CFR 707, Sub. D)** Not regulated.
- **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)** Not listed.



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- **CERCLA Hazardous Substance List (40 CFR 302.4)** Not listed.
- **Superfund Amendments and Reauthorization Act of 1986 (SARA)**
- Immediate Hazard - No
- Delayed Hazard - No
- Fire Hazard - No
- Pressure Hazard - No
- Reactivity Hazard - No
- **SARA 302 Extremely hazardous substance** Not listed.
- **SARA 311/312 Hazardous chemical** No
- **SARA 313 (TRI reporting)** Not regulated.
- **Other federal regulations**
- **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List** Not regulated.
- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

- **Safe Drinking Water Act (SDWA)** Not regulated.
- **US state regulations**
- **Massachusetts RTK - Substance List**
  - Mineral Oil CAS# 8042-47-5
  - Petrolatum CAS# 8009-03-8
- **New Jersey Worker and Community Right-to-Know Act** Not listed.
- **Pennsylvania Worker and Community Right-to-Know Law**
  - Mineral Oil CAS# 8042-47-5
  - Petrolatum CAS# 8009-03-8
- **Rhode Island RTK** Not regulated.
- **California Proposition 65** Not Listed.

#### International Inventories

- **Australia - Australian Inventory of Chemical Substances (AICS)**

Complies with inventory.

- **Canada - Domestic Substances List (DSL)**

Complies with inventory.

- **China - Inventory of Existing Chemical Substances in China (IECSC)**

Complies with inventory.

- **Europe - European Inventory of Existing Commercial Chemical Substances**





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**(EINECS)** Complies with inventory.

- **Japan - Inventory of Existing and New Chemical Substances (ENCS)**

Complies with inventory.

- **Korea - Existing Chemicals List (ECL)**

Complies with inventory.

- **New Zealand - New Zealand Inventory (NZI)**

Complies with inventory.

- **Philippines - Philippine Inventory of Chemicals and Chemical Substances (PICCS)** Complies with inventory.

**United States and Puerto Rico - Toxic Substances Control Act (TSCA) Inventory**

Complies with inventory.

## 16 Additional Information

**Issue Date:** 2017 Dec 18

### 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.