

Trade Name: Hydrocortisone Intensive Healing Cream REVISION DATE: 10/8/2021

1. Product and Company Identification

Product Identifier: Hydrocortisone Intensive Healing Cream **Recommended Use:** External use. Temporary relief of itching.

Synonym(s): Hydrocortisone Intensive Healing Cream

Manufacturer/Supplier

Natureplex, LLC 11085 Airport Road

Olive Branch, MS 38654-0221

(662) 874-1370 (Monday - Friday, 8:00 a.m. - 5:00 p.m. CST)

Emergency Telephone Number: 1-866-323-0107

CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)

2. Hazard Identification

Classification of the Product

GHS Classification: Reproductive toxicity (Category 2), H361

Pictogram:



Signal Word: Danger

Hazard Statements: Suspected of damaging fertility or the unborn child

Precautionary Statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P281 Use personal protective equipment as required.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	<u>%</u>
PURIFIED WATER	7732-18-5	Trade Secret
HYDROCORTISONE	50-23-7	1%
CARBOPOL ULTREZ 10	195739-91-4	Trade Secret
CETYL ALCOHOL	36653-82-4	Trade Secret
CITRIC ACID	77-92-9	Trade Secret
SODIUM CITRATE	68-04-2	Trade Secret
COLATROPE 555	Proprietary	Trade Secret



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DISODIUM EDTA	6381-92-6	Trade Secret	
DIMETHICONE 100	63148-62-9	Trade Secret	
MINERAL OIL	8042-47-5	Trade Secret	
CETEARETH-6 STE	68439-49-6	Trade Secret	
PROPYLPARABEN	94-13-3	Trade Secret	
PETROLATUM	8009-03-8	Trade Secret	
ALOE BARBADENSIS EXTRACT	85507-69-3	Trade Secret	
GLYCERIN	56-81-5	Trade Secret	
AMMONIUM CR/VP	75-65-0	Trade Secret	
PROPYLENE GLYCOL	57-55-6	Trade Secret	
VITAMIN E	10191-41-0	Trade Secret	
SHEA BUTTER	194043-92-0	Trade Secret	
COCONUT OIL	8001-31-8	Trade Secret	
ISOPROPYL PALMITATE	142-91-6	Trade Secret	
BEESWAX	8012-89-3	Trade Secret	
CORN STARCH	9005-25-8	Trade Secret	
SODIUM LAURYL SULFATE	151-21-3	Trade Secret	
*Specific chemical identity and/or percentage of composition has been withheld as a trade secret			

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4. First Aid Measures

Emergency and First Aid Procedures

Inhalation: Move victim to fresh air. If signs/symptoms continue, get medical attention.

Eye Contact: Do not rub eyes. Flush eyes thoroughly with water for 15 minutes. If condition worsens or irritation persists contact physician.

Skin Contact: Wash with plenty of soap and water. If skin irritation occurs, get medical advice/attention.

Ingestion: Do not induce vomiting. Contact a physician or Poison Control Center.

5. Fire Fighting Measures

Extinguishing media: Suitable extinguishing media. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire Fighting: Wear self-contained breathing apparatus for firefighting if necessary.

Hazard Combustion Products: Carbon oxides

6. Accidental Release Measures

Personal Precautions: Safety glasses or goggles when splash potential exists.

Environmental Precautions: Local authorities should be advised if a significant spill cannot be contained. Do not let product enter drains.

Methods and materials for containment and cleaning up: Pickup and arrange disposal

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without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and Storage

Handling: Handle in accordance with good industrial hygiene and safety practice.

Storage: Keep container tightly closed. Store according to labeled instructions

8. Exposure Controls/Personal Protection

Appropriate Engineering controls: Apply technical measures to comply with the occupational exposure guideline.

Recommended personal protective measures (PPE): No special measures required under normal usage.

Special Requirements for PPE: No special measures required under normal usage.

9. Physical and Chemical Properties

Appearance

Physical state: Smooth, white cream

Form: cream Color: white

Odor: None to slight wax scent

Odor threshold: NDA

pH: 0.96 to 1.02

Melting point/freezing point: NDA

Initial boiling point and boiling range: NDA

Flash point: NDA

Evaporation rate: NDA

Flammability (solid, gas): NDA

Upper/lower flammability or explosive limits

Flammability limit - lower (%): NDA Flammability limit - upper (%): NDA Explosive limit - lower (%): NDA Explosive limit - upper (%): NDA

Vapor pressure: NDA Vapor density: NDA Relative density: NDA

Solubility

Solubility (water): Soluble

Partition coefficient (n-octanol/water): NDA

Auto-ignition temperature: NDA **Decomposition temperature:** NDA

Viscosity: ≥20,000 cps

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Specific Gravity: 0.960 to 1.020

10. Stability and Reactivity

Reactivity: NDA

Chemical Stability: Stable under recommended storage conditions.

Conditions to Avoid: Light.

Materials to Avoid: Strong oxidizing agents.

Hazardous Decomposition Products: None under normal use.

Possibility of Hazardous Reactions: None under normal use

11. Toxicological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Acute toxicity: NDA Inhalation: NDA Dermal: NDA

LOSO intraperitoneal - rat - 150 mg/kg

Remarks: Biochemical: Metabolism (intermediary): Effect on inflammation or mediation of

inflammation.

Skin corrosion/irritation: NDA

Serious eye damage/eye irritation: NDA Respiratory or skin sensitization: NDA

Germ cell mutagenicity: rat

mammary gland DNA inhibition: rat

Unscheduled DNA synthesis: Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1 % is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1 % is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1 % is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1 % is identified as a carcinogen or potential carcinogen by OSHA.



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Possible risk of congenital malformation in the fetus. Suspected human reproductive toxicant: NDA

Specific target organ toxicity - single exposure: NDA

Specific target organ toxicity - repeated exposure: NDA

Aspiration hazard: NDA

Additional Information: RTECS: GM8925000

12. Ecological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information: NDA

Ecotoxicity: NDA

13. Disposal Considerations

Waste Disposal Method: Dispose of in accordance with local and national regulations.

Waste Treatment Methods

Product Waste: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Packaging Waste: Dispose of as unused product.

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



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

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold reporting levels established by SARA Title III, Section 313.

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. Other Information

Last Revision: 30 May 2015 Preparation Date: 8 October 2021

List of References: See Patient Package Insert for more information

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. 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 nature of the product.

Key to abbreviations NDA= No Data Available