

Trade Name: Hemorrhoidal Cream

Prepared Date: February 24, 2021

1. Product and Company Identification

Product Identifier: Hemorrhoidal Cream

Recommended Use: Temporarily relieves pain, soreness, and burning. Helps relieve local

itching and discomfort associated with hemorrhoids.

Synonym(s): Hemorrhoidal 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

OSHA Hazards: Target organ effect, harmful by ingestion, irritant

Target organs: Nerves

GHS Classification:

Skin Sensitization – Category 1 – Skin Sensitization

Aquatic Acute - Category 2 - Hazardous to the aquatic environment - Acute

Acute Toxicity, Oral - Category 4

Skin Irritation - Category 2

Eye Irritation - Category 2A

Specific Target Organ Toxicity – Single Exposure – Category 3

Pictogram:



Signal Word: Warning

Hazard Statement:

H302 Harmful if swallowed

H315 Causes skin irritation

H317 May cause allergic skin reaction

H319 Causes serious eve irritation

H332 Harmful if swallowed

H401 Toxic to aquatic life



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Precautionary Statements (Prevention):

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
- P280 Wear protective gloves
- P273 Avoid release to the environment
- P272 Contaminated work clothing should not be allowed out of the workplace
- P270 Do not eat, drink or smoke when using this product
- P264 Wash with plenty of water and soap thoroughly after handling

Precautionary Statements (Response):

P305 + P351 + P338 IF in eyes: rinse cautiously with water for several minutes. Remove

Contact lenses, if present and easy to do. Continue rinsing.

P303 + P352 IF on skin (or hair): Wash with plenty of soap and water

P333 + P311 If skin irritation or rash occurs: Call a Poison Center or doctor/physician

P301 + P312 IF swallowed: Call a Poison Center or doctor/physician if you feel unwell

P330 Rinse mouth

P362 + P364 Take off contaminated clothing and wash before reuse

Precautionary Statements (Disposal):

Precautionary Statements (Disposal):
P501 Dispose of contents/container to hazardous or special waste collection point

3. Composition/Information on Ingredients

Chemical Name	CAS Number	<u>%</u>
Water	7732-18-5	Trade Secret*
Glycerin	56-81-5	Trade Secret*
Propylene Glycol	57-55-6	Trade Secret*
Disodium EDTA	6381-92-6	Trade Secret*
Cetyl Alcohol	36653-82-4	Trade Secret*
GMS	123-94-4	Trade Secret*
Stearyl Alcohol	112-92-5	Trade Secret*
Laureth-23	9002-92-0	Trade Secret*
Steareth-2	9005-00-9	Trade Secret*
Steareth-20	9005-00-9	Trade Secret*
White Petrolatum	8009-03-8	Trade Secret*
Mineral Oil 350 W	8042-47-5	Trade Secret*
Xanthan Gum	11138-66-2	Trade Secret*
Sodium CMC	9004-32-4	Trade Secret*
Methylparaben	99-76-3	Trade Secret*
Propylparaben	94-13-3	Trade Secret*
ВНА	25013-16-5	Trade Secret*
Panthenol	16485-10-2	Trade Secret*



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Vitamin E	58-95-7	Trade Secret*
Sodium Benzoate	532-32-1	Trade Secret*
Aloe Vera	85507-69-3	Trade Secret*
Citric Acid	77-92-9	Trade Secret*
Propyl Gallate	121-79-9	Trade Secret*
Phenylephrine HCL	61-76-7	Trade Secret*
Pramoxine HCL	637-58-1	Trade Secret*
1.0 1.0 1.1 1.1		

^{*}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 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

Exitinguishing Media:

Suitable extinghuishing media: water spray, foam, dry powder, carbon dioxide

Unsuitable extinghuishing media for safety reasons: water jet

Special hazards arising from the substance mixture:

Hazards during the fire-fighting: Hydrogen chloride, nitrogen oxides

The substances/groups of substances mentioned can be released in case of fire. Evolution of funes/fog.

Advise for firefighters: Protective equipment for firefighting: Wear self-contained breathing apparatus and chemical-protective clothing

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Avoid contact with the skin, eyes and clothing. Use personal protective clothing. Information regarding personal protective clothing.

Environmental precautions: Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up: For large amounts: Sweep/shovel up. Collect waste in suitable containers, which can be labeled and sealed. Dispose of contaminated material as prescribed.



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For residues: Sweep/shovel up. Dispose of contaminated material as prescribed. Cleaning opprations should be carried out only while wearing breathing apparatus. Nonsparking tools should be used.

7. Handling and Storage

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

Storage: Keep container tightly closed.

8. Exposure Controls/Personal Protection

Personal protective equipment

Respiratory protection: Wear a NIOSH certified (or equilient) particulate respirator.

Hand protection: Chemical resistant protective gloves.

Eye protection: Tightly fitting safety goggles (chemical goggles).

Body protection: Body protection must be chosen on level of activity and exposure.

General safety and hydiene measures: Avoid contact with the skin, eyes and clothing. Handle in accordance with good industrial hygience and safety practice. Wearing of closed work clothing is recommended. Remove contaminated clothing. No eating, drinking smoking or tobacco use at the place of work. Store work clothing seperately. Hands and/or face should be washed before breaks and at the end of the shift.

9. Physical and Chemical Properties

Appearance

Physical state: Smooth, white viscous cream

Form: cream

Color: white to off white **Odor**: Characteristic waxy scent

Odor threshold: NDA

pH: 3.5-5.5

Viscosity: $\geq 100,000$ cps

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



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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): NDA

Partition coefficient (n-octanol/water): NDA

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

10. Stability and Reactivity

Chemical Stability: Stable at room temperature.

Conditions to Avoid: Keep medicated wipes away from ignition sources.

Materials to Avoid: No materials to be especially mentioned

Hazardous Decomposition Products: None under normal use.

Possibility of Hazardous Reactions: None under normal use

11. Toxicological Information

Cetyl Alcohol

Acute Toxicity:

LD/LC50 Values releva	nt for classification:	
Oral	LD50	>5000 mg/kg (rat
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50	>0.375 mg/l Rat
	LD50	>0.014 ppm (rat)

Mineral Oil

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
White mineral oil (petroleum)	LC50 Inhalation Dusts and mists	Rat	>5 mg/l	4 hours
	LD50 Dermal	Rabbit	>2000 mg/kg	-
	LD50 Oral	Rat	>5000 mg/kg	-

Xanthan Gum

Acute oral: LOSO Oral Rat: 45,000 mg/kg; LD50 Oral Mouse: 20,000 mg/kg

Acute inhalation:

Rat: 21 mg/I Exposure time: 1 h

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Assessment: The substance or mixture has no acute

inhalation toxicity

Remarks: An LC50/inhalation/4h/rat could not be determined because no mortality of rats was

observed at the maximum achievable concentration.

Acute dermal: No skin irritation

Methylparaben

LD50 Oral Rat >2100 mg/kg

Propylparaben

SL50 Oral Rat: >5000 mg/kg

BHA

ATEmix (oral): 2000 mg/kg

Panthenol

Acute toxicity: LD50(Oral, Rat): >2000 mg/kg by

LD50(Dermal, Rat): >2000 mg/kg bw

LC50(inhalation, Rat): NDA

Vitamin E

	L.Csa(4hr)	LDse		
Chemical name	<u>inh, rat</u>	(Oral, rat)	(Rabbit, dermal)	
DtAlpha-Tocopheryl acetate	NAU	N/Av	N/Av	

Sodium Benzoate

Chemical Name Sodium benzoate Inhalation LC50 Species >12.2 mg/L (4 hours, Rat/ adult based on benzolc Oral LD50 Species
>2000 mg/kg (weight Rat/ adult
of evidence)

Dermai LD50 Species
>2000 mg/kg (based Rabbit/ adult
on benzoic acid)

Citric Acid

Acute oral toxicity: D50 Oral (Mouse): 5.400 mg/kg body weight. Method: OECD Test Guideline 401

LD50 Oral (Rat): 11. 700 mg/kg body weig ht Method: OECD Test Guideline 401

Acute dermal tocicity: LD50 Dermal (Rat):> 2.000 mg/kg body weight

Phenylephrine HCL

Acute toxicity: LD50: 350 mg/kg (oral, rat)

Pramoxine HCL



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Acute toxicity:

LD50 ORAL: MOUSE-1,050 MG/KG

INHALATION: LC50

DERMAL LD50: NO DATA AVAILABLE

Eyes: Irritating to eyes. Risk of serious damage to eyes. Avoid contact with eyes

Skin: Harmful in contact with skin. Irritating to skin. Avoid contact with skin.

Inhalation: Harmful by inhalation. Irritating to mucous membranes. Irritating to respiratory system. **Ingestion**: Harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and

diarrhea. Do not ingest.

Information on toxicological effects

Symptoms: No information available. Delayed and immediate effects as well as chronic effects from short and long-term exposure.

12. Ecological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Toxicity

Aquatic toxicity

Assessment of aquatic toxicity: The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations. Acutely toxic for aquatic organisms.

Aquatic invertebrates:

EC50 (48h) 4.59 mg/l, Daphnia magna (OECD Guidelines 202, part static) The details of the toxic effect relate to the nominal concentration.

Microorganisms/Effect on activated sludge

Toxicity to microorganisms

Screening test aquatic

Activated sludge, domestic/EC20 (180 min): >100 mg/l

The details of the toxic effect relate to the nominal concentration.

Persistence and degradability

Assessment biodegradation and elimination (H20)

Readily biodegradable (according to OECD criteria).

Elimination information

90-100% DOC reduction (21d)(Screening test (style of OECD 301))(aerobic, activated sludge, domestic)

Mobility in Soil



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Assessment transport between environmental compartments Adsorption to solid soil phase is not expected.

13. Disposal Considerations

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

Container disposal: Dispose of in accordance with national, state and local regulations.

14. Transport Information

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

Land Transport

USDOT - Not classified as a dangerous good under transport regulations

Sea Transport

IMDG - Not classified as a dangerous good under transport regulations

Air Transport

IATA/ICAO - Not classified as a dangerous good under transport regulations

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.

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.

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16. Other Information

Last Revision: 21 November 2017 Revised Date: 24 February 2021

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Key to abbreviations NDA= no data available