

Trade Name: Hemorrhoidal Cooling Gel

1. Product and Company Identification
<p>Product Name: Hemorrhoidal Cooling Gel Recommended Use: External use medicinal product Synonyms: Hemorrhoidal Gel</p>
<p>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)</p>
<p>Emergency Telephone Number: 1-866-323-0107 CHEMTREC: 1-800-424-9300 (Transportation Spill Response 24 hours)</p>
2. Hazard Identification
<p>Classification of the product</p> <p>GHS Classification: Acute Toxicity - 4 Acute Toxicity (Oral) Skin Sensitization – 1 Skin Sensitization Acute - 2 Hazardous to the aquatic environment – Acute Combustible Dust - 1 Combustible Dust</p> <div style="text-align: center;">  </div> <p>Pictogram:</p> <p>Signal Word: Warning</p> <p>Hazard Statement: H302 May form combustible dust concentration in air. H317 Harmful if swallowed. H317 May cause an allergic skin reaction. H401 Toxic to aquatic life.</p> <p>Precautionary Statements: Precautionary Statements (Prevention): P280 Wear protective gloves. P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P273 Avoid release to the environment. P272 Contaminated work clothing should not be allowed out of the workplace.</p>



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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):

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):

P501 Dispose of contents/container to hazardous or special waste collection point.

Hazards not otherwise classified

Avoid dust development and deposition - dust explosion risk. Take precautionary measures against static discharges.

According to Regulation 1994 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Emergency overview

DANGER:

HARMFUL IF SWALLOWED.

Product may present a nuisance dust hazard.

Avoid inhalation of dusts.

Avoid contact with the skin, eyes and clothing.

Ensure adequate ventilation.

Wear NIOSH-certified chemical goggles.

Wear a NIOSH-certified (or equivalent) particulate respirator.

Wear chemical resistant protective gloves.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Percent
Purified Water	7732-18-5	Trade Secret
Disodium EDTA	6381-92-6	Trade Secret
Sodium Citrate Anhydrous	68-04-2	Trade Secret
Benzophenone – 4	4065-45-6	Trade Secret
Witch Hazel	84696-19-5	Trade Secret
Aloe Vera Leaf Juice (55)	85507-69-3	Trade Secret
Phenylephrine HCL	61-76-7	Trade Secret
Methylparaben USP (110)	99-76-3	Trade Secret
Propylparaben USP (55)	94-13-3	Trade Secret
Propylene Glycol	57-55-6	Trade Secret
Natrasol 250 H-Pharma (HEC)	9004-62-0	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: water spray, foam, dry powder, carbon dioxide. Do not use water jet. Fire Fighting: Wear self-contained breathing apparatus for firefighting if necessary. Special hazards arising from the substance or mixture Hazards during firefighting: Hydrogen chloride, nitrogen oxides. The substances/groups of substances mentioned can be released in case of fire. Evolution of fumes/fog. Dusty conditions may ignite explosively in the presence of an ignition source causing flash fire.
6. Accidental Release Measures
Personal Precautions: Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with the skin, eyes and clothing. Avoid dust formation. Use personal protective clothing. Information regarding personal protective measures see, section 8. Environmental Precautions: Do not discharge into drains/surface waters/groundwater. Methods and materials 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. For residues: Sweep/shovel up. Dispose of contaminated material as prescribed. Avoid raising dust. Cleaning operations should be carried out only while wearing breathing apparatus. Non-sparking tools should be used.
7. Handling and Storage
Handling: Handle in accordance with good industrial hygiene and safety practice. Avoid dust formation. Provide exhaust ventilation if dust is formed. 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. Respiratory protection:

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Wear a NIOSH-certified (or equivalent) particulate respirator.
 Hand protection: Chemical resistant protective gloves
 Eye protection: Tightly fitting safety goggles (chemical goggles).
 Body protection: Body protection must be chosen based on level of activity and exposure.

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

9. Physical and Chemical Properties

Appearance

Physical state: Clear, viscous gel

Form: Gel

Color: Clear

Odor: Characteristic Witch Hazel scent

Odor threshold: NDA

pH: 4.5 to 6.5

Viscosity: ≥50,000 cps

Specific Gravity: 0.96 to 1.03

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 (water): NDA

Partition coefficient (n-octanol/water): NDA

Auto-ignition temperature: NDA

Decomposition temperature: NDA

10. Stability and Reactivity

Reactivity: NDA

Chemical Stability: Stable under recommended storage conditions.

Conditions to Avoid: See SDS section 7 -Handling and storage. Avoid dust formation.

Materials to Avoid: Strong oxidizing agents.

Hazardous Decomposition Products: None under normal use.

Possibility of Hazardous Reactions: Dust explosion hazard.

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11. Toxicological Information

Acute and Chronic Toxicity:

Phenylephrine Hydrochloride

Primary routes of exposure: Routes of entry for solids and liquids are ingestion and inhalation but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Of moderate toxicity after single ingestion.

Oral

Type of value: LD50

Species: rat

Value: 350 mg/kg

Inhalation

No applicable information available.

Dermal: No applicable information available.

Assessment other acute effects: No data available.

Irritation / corrosion

Assessment of irritating effects: Not irritating to the eyes. Not irritating to the skin. The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

Sensitization

Assessment of sensitization: Human data do not fully exclude a skin sensitizing potential.

Mouse Local Lymph Node Assay (LLNA)

Species: guinea pig

Result: sensitizing

Method: similar to OECD guideline 429

Aspiration Hazard: No data available.

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: No adverse effects were observed after repeated exposure in animal studies.

Genetic toxicity

Assessment of mutagenicity: The substance was not mutagenic in bacteria. No mutagenic

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effect was found in various tests with mammalian cell culture and mammals.

Carcinogenicity

Assessment of carcinogenicity: In long-term studies in rats and mice in which the substance was given by feed, a carcinogenic effect was not observed.

Reproductive toxicity Assessment of reproduction toxicity: No data available.

Teratogenicity

Assessment of teratogenicity: The substance did not cause malformations in animal studies. When given in high doses fetotoxicity was observed.

Symptoms of Exposure: increased pulse rate

Eye Contact: Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Skin contact: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Mutagenicity: Health injuries are not known or expected under normal use.

Chronic effects/carcinogenicity: Health injuries are not known or expected under normal use.

Reproductive effects: Health injuries are not known or expected under normal use.

Witch Hazel

Acute oral toxicity (rat): >5 g/kg

Acute dermal toxicity (rabbit): No skin irritation, no eye irritation, no sensitization.

Acute inhalation toxicity: Alcohol (Ethanol-Standard USP) (64-17-5) 7060 mg/kg (rat) Witch Hazel Distillate (84696-19-5) None specified.

Sub chronic oral toxicity (rat): Alcohol (Ethanol-Standard USP) (64-17-5) 20,000 ppm (10 hours - rat) Witch Hazel Distillate (84696-19-5) None specified

Skin irritation (rabbit): No skin irritation, no eye irritation, no sensitization.

Eye irritation (rabbit): May cause irritation and redness

Sensitization: No skin irritation, no eye irritation, no sensitization.

Phototoxicity (guinea pig): NDA

Chronical toxicity: NDA

12. Ecological Information

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 (48 h) 4.59 mg/l, Daphnia magna (OECD Guideline 202, part 1, static)

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<p>The details of the toxic effect relate to the nominal concentration.</p> <p>Microorganisms/Effect on activated sludge</p> <p><u>Toxicity to microorganisms</u> Screening test aquatic: activated sludge, domestic/EC20 (180 min): > 100 mg/l The details of the toxic effect relate to the nominal concentration.</p> <p>Persistence and degradability Assessment biodegradation and elimination (H2O) Readily biodegradable (according to OECD criteria).</p> <p><u>Elimination information</u> 90 -100 % DOC reduction (21 d) (Screening test (style of OECD 301)) (aerobic, activated sludge, domestic)</p> <p>Mobility in soil <u>Assessment transport between environmental compartments:</u> Adsorption to solid soil phase is not expected.</p>
<p>13. Disposal Considerations</p> <p>Waste Disposal Method: Dispose of in accordance with local and national regulations.</p> <p>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.</p> <p>Packaging Waste: Dispose of as unused product.</p>
<p>14. Transport Information</p> <p>Transport Information This material is not classified as hazardous for transport.</p> <p>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</p>
<p>15. Regulatory Information</p> <p>OSHA Regulatory Status: This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).</p>



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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: 31 July 2017

Preparation Date: 12 July 2019

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