



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Identifier #009
Product Name Hydrocortisone Cream 1%
Product Use Topical Skin Preparation
Manufacturer Water Jel Technologies LLC
50 Broad Street
Carlstadt, New Jersey 07072
Telephone 201-507-8300
E-mail Address
Emergency Telephone 1-800-275-3433
FAX Number 201-507-8325
Issue Date: 06-01-2015

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

Chemical Name	Common Name and Synonyms	CAS Number	%
Hydrocortisone Acetate	Hydrocortisone	50-23-7	1
Mineral Oil	White Mineral Oil	8042-47-5	Proprietary
Glycerin	1, 2, 3, Propanetriol	56-81-5	Proprietary

SECTION 3: HAZARDS IDENTIFICATION

Emergency Overview:

This product is regulated by the US FDA as an over-the-counter, monograph drug.

For Consumers, consult the Drug Facts on the package for use directions and warnings information.

Warnings: For External Use Only.

When using this product, avoid contact with the eyes.

Do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Stop use and ask a doctor if condition worsens, symptoms persist for more than 7 days or if condition clears up and occurs again within a few days.

If swallowed, get medical help or contact a Poison Control Center immediately.

Physical Hazards: This mixture does not meet the classification criteria according to OSHA Hazcom 2012.
Health Hazards: This mixture does not meet the classification criteria according to OSHA Hazcom 2012.
Environmental Hazards: This mixture does not meet the classification criteria according to OSHA Hazcom 2012.
OSHA Defined Hazards: This mixture does not meet the classification criteria according to OSHA Hazcom 2012.

Label Elements:

Hazard Symbol: None

Signal Word: None

Hazard Statement: The mixture does not meet the criteria for classification.

Precautionary Statement:

Prevention

None required according to OSHA Hazcom 2012.



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Response None required according to OSHA Hazcom 2012.
Storage None required according to OSHA Hazcom 2012.
Disposal None required according to OSHA Hazcom 2012.

Hazards not otherwise
Classified (HNOC): None known.

Supplemental Information: None.

Route of Entry:

Skin Contact: May cause irritation, redness, tearing, inflammation or dryness..
Skin Absorption: No adverse conditions expected.
Eye Contact: Flush eyes with clear running water for a minimum of 15 minutes; if irritation persists, seek medical attention.
Inhalation: Unlikely route of exposure.
Ingestion: May cause irritation of the digestive tract.

SECTION 4: FIRST AID MEASURES

Skin Contact: Wash off with warm water and soap. Get medical attention if symptoms occur.
Skin Absorption: No adverse conditions expected.
Eye Contact: Flush eyes with clear running water for a minimum of 15 minutes; if irritation persists, seek medical attention.
Inhalation: Unlikely route of exposure.
Ingestion: May cause irritation of the digestive tract.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable: No
Means of Extinction: Use extinguishing media appropriate for surrounding fire. Use water spray, foam or dry chemical.
 In fires involving large quantities of this product, the use of large streams of water should be avoided.
 Use self-contained breathing apparatus when fighting fires that involve this material.
Flash Point and Method: NA
Upper Flammable Limit (% by volume): NA
Lower Flammable Limit (% by volume): NA
Autoignition Temperature (°C): NA
Explosion Data – Sensitivity to Impact: No unusual fire or explosion hazards noted.
Explosion Data – Sensitivity to Static Discharge: No unusual fire or explosion hazards noted.
Hazardous Combustion Products: Carbon oxides. Nitrogen Oxides (NOx).

NFPA Health 1 Fire 0 Reactivity 0 Other NA

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions,
Protective equipment and
Emergency procedures: Wear appropriate personal protective equipment.

Methods and materials for containment



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and clean up: Absorb spill with vermiculite or other inert material, then place in a sealed container for chemical waste.

Large Spills: Flush with plenty of water. Prevent entry into waterways, sewer, basements or confined areas. Dike for later disposal.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Environmental Precautions: Avoid discharge into drains and water sources.

SECTION 7: HANDLING AND STORAGE

Handling Procedures and Equipment: Keep this and other chemicals out of the reach of children.

Storage Temperature: Do not store or mix with strong acids or oxidizers. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Components	ACGIH-TLVs	OSHA-PELs	NIOSH	Form
Hydrocortisone Acetate	NE	NE	NE	NE
Mineral Oil (CAS 8042-47-6)	5 mg/m3	5 mg/m3	10 mg/m3	Mist/Inhalable fraction
Glycerin (CAS 57-55-8)	NE	5 mg/m3		Aerosol

Biological Limit Values: No biological Exposure limits noted for the ingredients.

Ventilation and Engineering Controls: Ensure adequate ventilation.

Personal Protective Equipment: None required under normal conditions
Hand Protection: None required under normal conditions.
Eye and Face Protection: Eye protection, as necessary to prevent excessive contact.
Skin Protection: None required under normal conditions.

General Hygiene Considerations: Practice safe work habits.
Other Protective Equipment: Eye wash stations should be nearby and ready to use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Cream.
Physical State: Cream.
Form: Cream.
Color: White.
Odor: Slight fatty odor.

pH: No information available.
Boiling Point: 135°C to 275°C

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Melting Point: 60°C (140°F)
Flash Point: N/A
Explosive Properties: No information available.
Oxidizing Properties: No information available.
Specific Gravity: 0.81
Water Solubility: Miscible
Partition Coefficient: No information available.
Viscosity: No information available.
Vapor Pressure (mm Hg): No information available.
Vapor Density (Air=1): No information available.
Evaporation Rate: 0.07
% Volatile: 65

SECTION 10: STABILITY AND REACTIVITY

Reactivity: The product is stable and non-reactive under normal conditions of use.
Chemical Stability: Stable at normal conditions.
Possibility of Hazardous Reactions: Hazardous polymerization does not occur.
Conditions to Avoid: Extreme heat.
Materials to Avoid: Strong oxidants and strong acids.
Hazardous Decomposition Products: Carbon monoxide, carbon dioxide.
Hazardous Polymerization: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Symptoms of Overexposure by Route of Exposure:
The health hazard information provided is for handling this product in an occupational setting.

Effects of Acute and Chronic Exposure:

Acute: The primary health effect that may be experienced in an occupational setting is mild irritation of contaminated skin. Accidental ingestion may be harmful. Although unlikely, irritation can irritate the respiratory system. Eye contact will cause irritation.

Chronic: Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis.

Target Organs: **Acute:** Occupational exposure: Skin, eyes.
Chronic: Occupational exposure: Skin.

Inhalation:

Although unlikely due to form of product, vapors may slightly irritate the nose, throat and lungs. Symptoms are generally alleviated upon breathing fresh air.

Skin Contact:

Skin contact may cause burning sensation, stinging, itching and tingling. Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis.

Eye Contact:

Eye contact can cause irritation, stinging, redness and tearing.

Ingestion:

Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion may cause adverse symptoms that may include nausea, vomiting and diarrhea.

Irritancy of the Product:

This product may cause mild to moderate irritation on damaged skin.

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Skin Sensitization:

Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis in sensitive individuals.

Respiratory Sensitization:

Not likely due to form of product.

LD50/LC50:

Hydrocortisone acetate:

- Intraperitoneal (rat): 2250 mg/kg
- Subcutaneous (rat): 250 mg/kg

Mineral Oil:

- Oral (rat): 22g/kg
- Subcutaneous (rat): 2g/kg

Glycerin (Mist):

- Oral (rat): 12,600 mg/kg
- Subcutaneous (rat): Not Available

Carcinogenicity: Not classified as a human carcinogen by IARC or ACGIH. Long term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids.

Reproductive Toxicity:

Mutagenic/Embryo Toxicity: The components of this product are not reported to cause mutagenic or embryonic effects in humans.

Teratogenicity: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relative low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Reproductive Toxicity: Long term animal studies have not been performed to evaluate the effect on fertility of topical corticosteroids.

SECTION 12: ECOLOGICAL INFORMATION

No specific information is currently available on the effect of this product on plants or animals in the environment. The product may be harmful to contaminated terrestrial and aquatic plant life in large quantities. The following aquatic toxicity data currently available for components of this product:

Glycerin:

EC0 (Pseudomonas putida bacteria) 16 hours = >10,000 mg/L
EC0 (Microcystis aeruginosa algae) 8 days = 2900 mg/L
EC0 (Scenedesmus quadricauda green algae) 7 days = >10,000 mg/L
EC0 (Entosiphon sulcatum protozoa) 72 hours = 3200 mg/L
EC0 (Uronema parduczi Chatton-Lwoff protozoa) = >10,000 mg/L
LC 50 (Goldfish) 24 hours = > 5000 mg/L

Environmental Exposure Controls: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

No component of this product is known to have ozone depletion potential.

SECTION 13: DISPOSAL CONSIDERATIONS

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Disposal Instructions: Collect or dispose in sealed containers at licensed waste disposal site.
Dispose in accordance with local, state and federal regulations.

SECTION 14: TRANSPORT INFORMATION

DOT Classification: Not regulated for Domestic Transport.
IATA Classification: Not regulated for International Transport.
IMDG Classification: Not regulated for International Water Transport.

SECTION 15: REGULATORY INFORMATION**U.S. FEDERAL REGULATIONS**

TSCA (TOXIC SUBSTANCE CONTROL ACT): Not regulated.

CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT): Not listed.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT) 304: Not regulated.

SARA 311/312 HAZARD CATEGORIES: Not regulated.

SARA 313 REPORTABLE INGREDIENTS: Not listed.

STATE REGULATIONS:**California Prop 65:**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

New Jersey RTK:

Glycerin (CAS 56-81-5)

Massachusetts RTK: Not regulated.

Pennsylvania RTK: Not regulated.

INTERNATIONAL REGULATIONS:

<u>Country or Region</u>	<u>Inventory Name</u>	<u>Listed</u>
Australia	Australia Inventory of Chemical Substances	No
Canada	Domestic Substance List (DSL)	Yes
Canada	Non-Domestic Substance List (NDSL)	No
China:	Inventory of Existing Chemical Substances In China (IECSC)	Yes
Europe	European List of Notified Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substance Control Act (TSCA) Inventory	No

Note: A "Yes" indicates that all components comply with the inventory requirements administered by the governing country.
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country.



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SECTION 16: OTHER INFORMATION

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Disclaimer:

The information provided in this Safety Data Sheet (SDS) is accurate to the best of our knowledge. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or processes.