



HEALTHCARE BEYOND BURN CARE™

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: US OSHA Hazard Communication Standard (29 CFR 1910.1200) and Canada WHMIS 2015 which includes the amended Hazardous Products Act (HPA) and the Hazardous Products Regulation (HPR)

Issuing Date 08-Mar-2019

Revision date 08-Mar-2019

Revision Number 1

1. Identification

Product identifier

Product Name Hydrocortisone Cream 1%

Other means of identification

Product Code(s) HY.00.121

Synonyms Hydrocortisone Cream 1% Maximum Strength Anti-Itch

Recommended use of the chemical and restrictions on use

Recommended use For the temporary relief of itching associated with minor skin irritation and rashes

Restrictions on use For external use only.

Details of the supplier of the safety data sheet

Manufacturer Address

WaterJel Technologies®
50 Broad Street
Carlstadt, NJ 07072
P: 201-507-8300

Emergency telephone number

Emergency Telephone 800-275-3433 (8:00 am-5:00 pm EST Weekdays)

2. Hazard(s) identification

Classification

Not classified.

Label elements

Hazard statements

Not classified.

Other information

No information available.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Synonyms

Hydrocortisone Cream 1% Maximum Strength Anti-Itch.

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Stearic acid	57-11-4	5-10	-	-
Glycerin	56-81-5	1-5	-	-
Propane-1,2-diol	57-55-6	0.5-1.5	-	-

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms	May cause skin irritation in susceptible persons. May cause redness and tearing of the eyes. Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis in sensitive individuals.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Unsuitable extinguishing media	No information available.
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Specific hazards arising from the chemical	No information available.
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Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name		ACGIH TLV	OSHA PEL	NIOSH IDLH
Stearic acid 57-11-4		TWA: 10 mg/m³ inhalable particulate matter TWA: 3 mg/m³ respirable particulate matter	-	-
Glycerin 56-81-5		No data available	TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction	-
Chemical name	Alberta	British Columbia	Ontario	Quebec
Glycerin 56-81-5	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³		TWA: 10 mg/m³
Propane-1,2-diol 57-55-6			TWA: 10 mg/m³ TWA: 50 ppm TWA: 155 mg/m³	

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Hand protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties**Information on basic physical and chemical properties**

Appearance	White cream
Physical state	Solid (compressed)
Color	White
Odor	Odorless
Odor threshold	No information available

Property	Values	Remarks • Method
pH	6.0 - 7.2	
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	0.81	@25°C
Water solubility	Miscible in water	
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	10,000 - 75,000 cP	Spindle #4 (64), 6 RPM, 15 seconds
Other information		
Explosive properties	No information available.	
Oxidizing properties	No information available.	
Softening point	No information available	
Molecular weight	No information available	

VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation.
Eye contact	Specific test data for the substance or mixture is not available. May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis in sensitive individuals.
Ingestion	Specific test data for the substance or mixture is not available. May cause gastrointestinal discomfort if consumed in large amounts.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	May cause skin irritation in susceptible persons. May cause redness and tearing of the eyes. Corticosteroids (such as Hydrocortisone) may cause allergic contact dermatitis in sensitive individuals.
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Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	30,388.30 mg/kg
ATEmix (dermal)	44,356.72 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Stearic acid	= 4600 mg/kg (Rat)	> 5 g/kg (Rabbit)	
Glycerin	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m ³ (Rat) 1 h
Propane-1,2-diol	= 20 g/kg (Rat)	= 20800 mg/kg (Rabbit)	

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause mild to moderate irritation.
Serious eye damage/eye irritation	May cause mild to moderate irritation.
Respiratory or skin sensitization	Repeated or prolonged contact may cause allergic reactions in very susceptible persons.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. Ecological information**Ecotoxicity**

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerin 56-81-5	-	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	-	EC50: >500mg/L (24h, Daphnia magna)
Propane-1,2-diol 57-55-6	EC50: =19000mg/L (96h, Pseudokirchneriella subcapitata)	LC50: 41 - 47mL/L (96h, Oncorhynchus mykiss) LC50: =51600mg/L (96h, Oncorhynchus mykiss) LC50: =51400mg/L (96h, Pimephales promelas) LC50: =710mg/L (96h, Pimephales promelas)	-	EC50: >1000mg/L (48h, Daphnia magna) EC50: >10000mg/L (24h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulation No information available.

Component Information

Chemical name	Partition coefficient
Glycerin 56-81-5	-1.76

Mobility in soil No information available.

Mobility No information available.

Other adverse effects No information available.

13. Disposal considerations**Waste treatment methods**

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

<u>DOT</u>	Not regulated
<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

US Federal Regulations

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 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate

classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations**US State Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Glycerin 56-81-5	X	X	X
Propane-1,2-diol 57-55-6	X	-	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	Health hazards 0	Flammability 0	Instability 0	Physical and chemical properties -
HMIS	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

U.S. Environmental Protection Agency ChemView Database
 European Food Safety Authority (EFSA)
 EPA (Environmental Protection Agency)
 Acute Exposure Guideline Level(s) (AEGL(s))
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
 U.S. Environmental Protection Agency High Production Volume Chemicals
 Food Research Journal
 Hazardous Substance Database
 International Uniform Chemical Information Database (IUCLID)
 Japan GHS Classification
 NIOSH (National Institute for Occupational Safety and Health)
 National Library of Medicine's ChemID Plus (NLM CIP)

National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

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Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. 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 in any process, unless specified in the text.

End of Safety Data Sheet