CHATTEM_® A SANOFI COMPANY

SAFETY DATA SHEET

1. Identification

Product identifier Maximum Strength Cortizone-10 Ultra Moisturizing Creme

Other means of identification None.

Recommended use Anti Itch

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name Chattem, Inc.

Address 1715 West 38th Street

Chattanooga, TN 37409

Telephone 1-800-366-6077

E-mail consumer.affairs@chattem.com

Emergency phone number (800) 366-6833

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Reproductive toxicity Category 2

Specific target organ toxicity, repeated Category 2 (endocrine system)

exposure

OSHA defined hazards Not classified.

This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner consistent with the labeled directions.

Label elements



Signal word Warning

Hazard statement Suspected of damaging fertility or the unborn child. May cause damage to organs (endocrine

system) through prolonged or repeated exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe mist or vapor. Wear protective gloves/protective clothing/eye

protection/face protection.

Response If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Product is a consumer commodity. Empty containers may be disposed of as refuse.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Hydrocortisone	50-23-7	>1

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

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Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Rinse mouth. Get medical attention if symptoms occur. Ingestion

Most important

symptoms/effects, acute and

Prolonged exposure may cause chronic effects.

delaved Indication of immediate

medical attention and special

treatment needed **General information** Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

IF exposed or concerned: Get medical advice/attention. If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in

attendance.

5. Fire-fighting measures

Suitable extinguishing media Unsuitable extinguishing

media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2). Do not use water jet as an extinguisher, as this will spread the fire.

During fire, gases hazardous to health may be formed. Specific hazards arising from the chemical

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Applies only to the product when used in an industrial setting.

For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Industrial: Wipe up with absorbent material. Collect and place in a suitable disposal container. This material is not known to possess additional hazards when spilled, beyond those of other non-hazardous solids.

Household: Product used in household may be disposed of in refuse or sewer.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Avoid prolonged exposure. Pregnant or breastfeeding women must not handle this product. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Туре	Value	Form
Glycerin (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
Petrolatum (CAS 8009-03-8)	PEL	5 mg/m3	Mist.
White mineral oil (petroleum) (CAS 8042-47-5)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Туре	Value	Form
Petrolatum (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.
White mineral oil (petroleum) (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Туре	Value	Form	
Petrolatum (CAS 8009-03-8)	STEL	10 mg/m3	Mist.	
	TWA	5 mg/m3	Mist.	
White mineral oil (petroleum) (CAS 8042-47-5)	STEL	10 mg/m3	Mist.	
	TWA	5 mg/m3	Mist.	

No biological exposure limits noted for the ingredient(s). **Biological limit values**

Appropriate engineering

controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Applies only to the product when used in an industrial setting. Chemical respirator with organic

vapor cartridge and full facepiece.

Skin protection

Applies only to the product when used in an industrial setting. Wear appropriate chemical resistant Hand protection

gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other Applies only to the product when used in an industrial setting. Use of an impervious apron is

recommended.

Applies only to the product when used in an industrial setting. Chemical respirator with organic Respiratory protection

vapor cartridge and full facepiece.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Semi-solid. Physical state Cream. **Form**

Color White to off-white. Characteristic. Odor **Odor threshold** Not available. 4 - 6.5 pН

Melting point/freezing point Not available. Initial boiling point and boiling 212 °F (100 °C)

range

Flash point > 200.0 °F (> 93.3 °C) Pensky-Martens Closed Cup

Evaporation rate Not available. Flammability (solid, gas) Not applicable. Upper/lower flammability or explosive limits

Flammability limit - lower Not available.

(%)

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(%)

Not available.

Explosive limit - lower (%)

Not available. Explosive limit - upper (%) Not available.

Vapor pressure Not available. Not available. Vapor density Relative density 1.01 g/cm3 @ 25C

Solubility(ies)

Not available. Solubility (water) **Partition coefficient** Not available.

(n-octanol/water)

Auto-ignition temperature 750 °F (398.89 °C) **Decomposition temperature** Not available. **Viscosity** 60000 cSt @ 25C

Other information

Explosive properties Not explosive. **Oxidizing properties** Not oxidizing.

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Material is stable under normal conditions. **Chemical stability**

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Avoid temperatures exceeding the flash point. Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Decomposition may yield acrolein.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause damage to organs through prolonged or repeated exposure by inhalation.

Skin contact No adverse effects due to skin contact are expected. Eye contact Direct contact with eyes may cause temporary irritation.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity Not available.

Components **Species Test Results**

Glycerin (CAS 56-81-5)

Acute Oral

LD50 Rat 12600 mg/kg

Skin corrosion/irritation No adverse effects due to skin contact are expected. Serious eye damage/eye Direct contact with eyes may cause temporary irritation.

irritation

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

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^{*} Estimates for product may be based on additional component data not shown.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are

mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

White mineral oil (petroleum) (CAS 8042-47-5) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Petrolatum (CAS 8009-03-8) Known To Be Human Carcinogen.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Reproductive toxicity Suspected of damaging fertility or the unborn child. Not classified.

Specific target organ toxicity -

single exposure

Specific target organ toxicity repeated exposure

May cause damage to organs (endocrine system) through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects May cause damage to organs through prolonged or repeated exposure. Prolonged inhalation may

be harmful.

12. Ecological information

The product is not classified as environmentally hazardous. However, this does not exclude the **Ecotoxicity**

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

No data is available on the degradability of this product. Persistence and degradability

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Glycerin (CAS 56-81-5) -1.76

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Applies only to the product when used in an industrial setting.

Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Dispose in accordance with all applicable regulations. Local disposal regulations

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company. Material as generated is not a RCRA hazardous waste.

Waste from residues / unused

products

For bulk quantities: Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe

manner (see: Disposal instructions).

Product is a consumer commodity. Empty containers may be disposed of in refuse. Contaminated packaging

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

931790

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not established.

15. Regulatory information

This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard **US** federal regulations

Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used

in a manner consistent with the labeled directions.

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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

US. Massachusetts RTK - Substance List

Glycerin (CAS 56-81-5) Petrolatum (CAS 8009-03-8)

White mineral oil (petroleum) (CAS 8042-47-5)

US. New Jersey Worker and Community Right-to-Know Act

Glycerin (CAS 56-81-5)

US. Pennsylvania Worker and Community Right-to-Know Law

Glycerin (CAS 56-81-5) Petrolatum (CAS 8009-03-8)

White mineral oil (petroleum) (CAS 8042-47-5)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region Inventory name On inventory (yes/no)*

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s). 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(s).

16. Other information, including date of preparation or last revision

29-December-2015 Issue date

Revision date Version # 01

HMIS® ratings Health: 1*

Flammability: 0 Physical hazard: 0

Disclaimer Chattem, Inc. cannot anticipate all conditions under which this information and its product, or the

products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the

sheet was written based on the best knowledge and experience currently available.

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