

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Hydrocortisone Cream USP 2.5%

Synonym: 1F3

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
 Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number:: 888-464-2986

Recommended use: Human drug – topical corticosteroid

Restrictions on use: Use only as directed.

Date of Preparation: April 26, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

Label Elements:
Warning!



Hazard statement(s)

Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wear protective clothing and gloves.
 IF exposed or concerned: Get medical attention.
 Store locked up.
 Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Hydrocortisone	50-23-7	2.5%
Water	7732-18-5	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
Propylene Glycol	57-55-6	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Sodium Lauryl Sulfate	151-21-3	Proprietary

Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops and persists, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Ingestion may cause gastrointestinal distress.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not flammable or combustible but may burn in a fire.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Hydrocortisone	100 ug/m ³ TWA PERRIGO OEL
Water	None Established
Stearyl Alcohol	None Established
Propylene Glycol	10 mg/m ³ TWA AIHA WEEL
Cetyl Alcohol	None Established
Sodium Lauryl Sulfate	None Established
Methylparaben	None Established
Propylparaben	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved organic vapor/particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended if contact with the drug product is possible.

Eye protection: Chemical safety goggles recommended if contact with the drug product is possible.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White cream

Odor: No odor

Odor threshold: Not determined	pH: Not determined
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: None	Evaporation rate: Not determined
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not determined	Vapor density: Not determined
Relative density: Not determined	Solubility(ies): Soluble in water
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing may cause gastrointestinal distress.

Skin contact: No adverse effects are expected. Minor irritation is possible. Therapeutic use has resulted in itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

Eye contact: Contact may cause slight irritation with redness and tearing.

Chronic Effects: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.

Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

Germ Cell Mutagenicity: Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Reproductive Toxicity: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Hydrocortisone Sodium Succinate (similar compound): Oral rat LD50 5,000 mg/kg; LD50 oral mouse 5,000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: Hydrocortisone: EC50 daphnia magna >100 mg/L/48 hr.

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Chronic Health

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0

HMIS Rating: Health = 1* Flammability = 0 Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: April 26, 2014

Date of last revision: New SDS

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).