

## SAFETY DATA SHEET

### 1. IDENTIFICATION

**Product identifier:** Hydrocortisone Lotion USP 2.5%

**Synonym:** 3X1

**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:** May 4, 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
Mineral Oil	8042-47-5	Proprietary
Lactic Acid	50-21-5	Proprietary
Isopropyl Palmitate	142-91-6	Proprietary
Sodium PCA	28874-51-3	Proprietary

Sodium Hydroxide	1310-73-2	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
PEG 100 Stearate	9004-99-3	Proprietary
Glyceryl Stearate	31566-31-1	Proprietary
Myristyl Lactate	1323-03-1	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Cetareth-20	68439-49-6	Proprietary
Carbomer Homopolymer Type C	9007-17-4	Proprietary
DMDM Hydantoin	6440-58-0	Proprietary
Myristyl Alcohol	112-72-1	Proprietary
Dehydroacetic Acid	520-45-6	Proprietary
Fragrance	Mixture	<0.1%

**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 eye irritation. 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.

<b>8. EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
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**Exposure guidelines:**

Hydrocortisone	100 ug/m <sup>3</sup> TWA PERRIGO OEL
Water	None Established
Mineral Oil	5 mg/m <sup>3</sup> (inhalable) TWA ACGIH TLV 5 mg/m <sup>3</sup> TWA OSHA PEL
Lactic Acid	None Established
Isopropyl Palmitate	None Established
Sodium PCA	None Established
Sodium Hydroxide	2 mg/m <sup>3</sup> TWA OSHA PEL 2 mg/m <sup>3</sup> Ceiling ACGIH TLV
Stearyl Alcohol	None Established
PEG 100 Stearate	None Established
Glyceryl Stearate	None Established
Myristyl Lactate	None Established
Cetyl Alcohol	None Established
Ceteareth-20	None Established
Carbomer Homopolymer Type C	None Established
DMDM Hydantoin	None Established
Myristyl Alcohol	None Established
Dehydroacetic Acid	None Established
Fragrance	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.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Appearance (physical state, color, etc.):** White to cream lotion

**Odor:** No odor

<b>Odor threshold:</b> Not determined	<b>pH:</b> 3.5
<b>Melting point/freezing point:</b> Not determined	<b>Boiling Point:</b> Not determined

<b>Flash point:</b> None	<b>Evaporation rate:</b> Not determined
<b>Flammability (solid, gas):</b> Not applicable	<b>VOC:</b> Not determined
<b>Flammable limits: LEL:</b> Not determined	<b>UEL:</b> Not determined
<b>Vapor pressure:</b> Not determined	<b>Vapor density:</b> Not determined
<b>Relative density:</b> Not determined	<b>Solubility(ies):</b> Soluble in water
<b>Partition coefficient: n-octanol/water:</b> Not available	<b>Auto-ignition temperature:</b> Not available
<b>Decomposition temperature:</b> Not available	<b>Viscosity:</b> 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 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
<b>DOT</b>		Not Regulated			
<b>TDG</b>		Not Regulated			
<b>IMDG</b>		Not Regulated			
<b>IATA</b>		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:** May 4, 2014

**Date of last revision:** March 21, 2012

**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).