



# Material Safety Data Sheet

Rx Pharmaceutical Product Regulated by the FDA

**Product Name:** Rx Tretinoin Cream, 0.1%  
Rx Tretinoin Cream, 0.05%  
Rx Tretinoin Cream, 0.025%

**Synonyms:** Generic for Brand Name Retin-A®

**Category:** Topical Acne Gel

**Perrigo Product Number:** Rx Tretinoin Cream, 0.1% 0A4  
Rx Tretinoin Cream, 0.05% 2R6  
Rx Tretinoin Cream, 0.025% 4R9

This is a pharmaceutical product manufactured in accordance with FDA requirements. The information contained on this MSDS is based primarily on a review of the active pharmaceutical ingredient(s). This product has not been tested as a whole.

## SECTION I – MANUFACTURER INFORMATION

**Distributor:**

Perrigo Company  
515 Eastern Avenue  
Allegan, MI 49010  
269-673-8451  
[www.perrigo.com](http://www.perrigo.com)

**Emergency Number:** 269-673-7600

**MSDS Prepared by:** Perrigo Corporate EHS

**MSDS Date:** 03/05/08

**MSDS Version:** 01

## SECTION II – INFORMATION ON PRIMARY INGREDIENTS

Active Ingredients:	Amount	CAS #
Tretinoin	0.1%, 0.05%, 0.025%	302-79-4

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**Inactive Ingredients:**

Stearic Acid	10-20%	57-11-4
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## SECTION III - PERRIGO SAFETY & HEALTH RATINGS (HMIS®)

**Health:** 2                      **Flammability:** 1                      **Reactivity (Physical Hazards):** 0

**HMIS® Ratings:**                      \* = Chronic Health Hazard

0 = Minimal      1 = Slight                      2 = Moderate      3 = Severe                      4 = Extreme

## SECTION IV - EMERGENCY/FIRST AID PROCEDURES:

### **CONTACT A POISON CONTROL CENTER AND/OR PHYSICIAN FOR OVEREXPOSURE**

**Eyes:** Flush immediately with large amounts of water for at least 15 minutes.

**Ingestion:** Contact a doctor if irritation or other symptoms develop. Never give anything by mouth to an unconscious person. Do not induce vomiting unless directed by medical personnel.

**Inhalation:** Remove to fresh air; support breathing (give oxygen or artificial respiration).

**Skin:** If overexposed, remove contaminated clothing; wash skin with mild soap and water.

## SECTION V – HEALTH HAZARD INFORMATION (Occupational Exposure)

**Primary Route(s) of Entry:** Dermal medication. Low or incidental inhalation or ingestion hazard from occupational exposure. Handling this product in its final form presents minimal risk from occupational exposure.

**Overexposure and Adverse Effects:** The skin of certain sensitive individuals may become excessively red, edematous, blistered or crusted. Temporary hyper-or hypopigmentation may occur with overexposure. Central nervous system depression, dizziness, nausea or vomiting may occur.

**Target Organs:** Skin & liver

**Chronic Effects:** Some people may be hypersensitive. Material is a photosensitizer.

**Inhalation:** May cause irritation to the upper respiratory tract. Inhalation of high vapor concentrations can cause CNS-depression and narcosis.

**Eyes:** May cause irritation.

**Skin:** Direct contact may cause redness, dermatitis or skin rashes; skin sensitization or an allergic reaction; material is a photosensitizer- causes sensitization to light.

**Ingestion:** Not anticipated during occupational exposure.

**Medical Conditions Potentially Aggravated:** Avoid direct sun exposure and weather extremes such as wind and cold as much as possible whenever using this product. Avoid sunlamps entirely while using this product. Do not use this product if sunburned or if the individual has eczema or other chronic skin conditions. Product should not be used if inherently sensitive to sunlight, or while taking other drugs that increase sensitivity to sunlight. Product should be kept away from the eyes, the mouth, angles of the nose and mucous membranes.

**Oral LD-50 Rat for API:** 1960 mg/kg

**Typical Adult Therapeutic Dose:** Apply once per day.

**Carcinogenicity:** N/A

**Pregnancy or Reproductive Effects:** Pregnancy Category C. Risk cannot be ruled out.

Fetotoxic in rabbits. Do not use if you are pregnant, attempting to become pregnant or are at a high risk of pregnancy.

## **SECTION VI – PRECAUTIONS FOR SAFE HANDLING & USE**

**Handling & Storage:** Store per labeled instructions. Keep away from heat, spark and open flame. Keep in a well-ventilated place. Store at temperatures not exceeding 86F. Keep container tightly closed and away from sources of ignition. No smoking. Ensure adequate ventilation. Vapors may form explosive mixtures with air.

### **Personal Protective Equipment for Occupational Exposures:**

**Respiratory Protection:** When working with small quantities in well-ventilated area, respiratory protection is generally not required. If engineering controls are not sufficient to control exposure, NIOSH-approved respiratory protection should be worn in accordance with a comprehensive respiratory protection program (OSHA).

**Perrigo OEL for API:** Tretinoin =  $0.5 \mu\text{g}/\text{m}^3$  (8 Hour TWA)

**Skin Protection:** Normal Hygiene & Gloves

**Eye Protection:** Normal Hygiene & Safety Glasses

**Other Protective Clothing:** As needed to prevent repeated/prolonged contact

**Work/Hygiene Practices:** Handling this product in its final form presents minimal risk from occupational exposure. Wash hands after handling this product and before eating, smoking, using the lavatory and at the end of the day.

## **SECTION VII – PHYSICAL/CHEMICAL PROPERTIES**

**Appearance & Odor:** Light yellow cream

**Specific Gravity (H<sub>2</sub>O = 1):** N/A

**Vapor Pressure (mm Hg 20°C):** N/A

**Vapor Density (AIR = 1):** N/A

**Molecular Weight:** N/A

**pH:** 2.7-4.7

**Viscosity @ 25°C:** N/A

**% Volatile by Volume:** N/A

**Flash Point:** NA

**Boiling Point:** N/A

**Evaporation Rate:** N/A

**Solubility in Water:** N/A

**Solubility in Alcohol:** N/A

**Solubility in Oil:** N/A

**Melting Point:** N/A

## **SECTION VIII – FIRE AND EXPLOSION HAZARD DATA**

**Extinguishing Media:** Water Spray or Foam, Dry Chemical, or Carbon Dioxide Fire Extinguisher.

**Special Fire Fighting Procedures:** Wear appropriate equipment, including self-contained breathing apparatus during fire fighting activities.

**Hazardous Combustion Products:** Toxic, corrosive or flammable thermal decomposition products may be encountered when this product is exposed to fire.

**Flash Point (if Liquid):** NA

**LEL:** NA

**UEL:** NA

**Auto-Ignition Temperature:** N/A

**Unusual Fire/Explosion Hazards:** N/A

#### **SECTION IV – REACTIVITY DATA (Physical Hazards)**

**Stable:** YES

**Conditions/Materials to Avoid:** Avoid contact with heat, sparks, flames or other sources of ignition. May form flammable/explosive vapor-air mixtures. Avoid strong oxidizers and strong acids.

**Hazardous Polymerization:** Should Not Occur

#### **SECTION X - SPILLS, RELEASES & DISPOSAL**

**Spills or Releases:** Wipe up or absorb and put in appropriate container. Wash area.

**Neutralizing Agent:** N/A

**Waste Disposal Methods:** Dispose in accordance with applicable local, state and federal regulations. Do not dump into sewers on the ground, or into any body of water. Dispose of contaminated packaging as unused product.

#### **SECTION XI - CONTAINER LABELING**

**Precautionary Labeling:** Federal law prohibits dispensing without a prescription. For dermatologic use only. Not for ophthalmic use.

**IMO Hazard Class#:** Not Available

**UN/NA#:** Not Available

**Hazard Classification:** Not Available

**DOT Name:** Not Available

**Shipping Instructions:** Not Available

#### **SECTION XII - ENVIRONMENTAL RISKS**

**Aquatic Toxicity:** Not Available

**Biodegradability:** Not Available

**Partition Coefficient:** Not Available

#### **SECTION XIII - REGULATORY INFORMATION**

**OSHA Regulations:** 29 CFR 1910 for occupational exposure

**DOT Regulations:** Consult 49 CFR 172.101 and applicable state and local regulations

**EPA Regulations:** Consult 40 CFR and applicable state and local regulations

**FDA Regulations:** Prescription Medication

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