SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Nystatin and Triamcinolone Acetonide Cream USP
Synonym: 7M9

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

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – topical corticosteroid
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 1B

Label Elements:
Danger!



Hazard statement(s)

May damage 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
Triamcinolone Acetonide	76-25-5	0.1%
Nystatin	1400-61-9	1.5%
White Petrolatum	8009-03-8	Proprietary
Sorbitol	50-70-4	Proprietary
Polyoxyl Stearate 8	9004-99-3	Proprietary
Propylene Glycol	57-55-6	Proprietary
Glyceryl Monostearate	31566-31-1	Proprietary

Cetearyl Alcohol	67762-27-0	Proprietary
Ceteareth-20	68439-49-6	Proprietary
Titanium Dioxide (bound in cream)	13463-67-7	Proprietary
Polysorbate 60	9005-67-8	Proprietary
Simethicone Emulsion	9004-67-5	Proprietary
Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	Proprietary
Aluminum Hydroxide	21645-51-2	Proprietary
Sodium Hydroxide	1310-73-2	<0.1%
Sorbic Acid	110-44-1	Proprietary
Water	7732-18-5	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. Never give anything by mouth to a person who is unconscious or convulsing. Get immediate medical attention.

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

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

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray or fog, CO2, dry chemical or foam.

Specific hazards arising from the chemical: Product is not flammable or combustible but will burn in a fire after the water has evaporated.

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 **c**ollect 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:

Triamcinolone Acetonide	1 ug/m^3 TWA PERRIGO OEL
Nystatin	100 ug/m3 TWA Perrigo OEL
White Petrolatum	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Sorbitol	None Established
Polyoxyl Stearate 8	None Established
Propylene Glycol	10 mg/m3 TWA AHIA WEEL
Glyceryl Monostearate	None Established
Cetearyl Alcohol	None Established
Ceteareth-20	None Established
Titanium Dioxide (bound in cream)	None Established
Polysorbate 60	None Established
Sorbitan Monostearate	None Established
Simethicone Emulsion	None Established
Methylparaben	500 ug/m3 TWA Perrigo OEB2
Propylparaben	None Established
Aluminum Hydroxide (as Al)	5 mg/m3 (respirable) 15 mg/m3 (total dust) TWA OSHA PEL 1 mg/m3 (respirable) ACGIH TLV
Sodium Hydroxide	2 mg/m3 Ceiling ACGIH TLV 2 mg/m3 TWA OSHA PEL
Sorbic Acid	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.): Light yellow to buff cream
Odor: None

Odor threshold: Not applicable	**pH:** 4.5-5.5
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: >93°C (200°F)	**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):** Partially soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** 8,000-40,000 cP

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 with nausea and diarrhea.
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: Triamcinolone Acetonide: Oral mouse LD50 5,000 mg/kg
Nystatin: LD50 oral rat 10 g/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
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.

16. OTHER INFORMATION

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

SDS Revision History: New SDS
Date of preparation: August 28, 2016

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).