SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Clobetasol Propionate Shampoo 0.05%
Synonym: 6A9

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

Telephone number: 269-673-8451
Technical Contact: (972)-523-667-422 (Israel)

Global Emergency phone number: 760-476-3962 Code: 333304

Recommended use: Human drug for treatment of scalp psoriasis– prescription only.
Restrictions on use: Use only as directed.

Date of Preparation: March 26, 2014

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Flammable Liquid Category 3	Eye Damage Category 1

Label Elements:
DANGER!



Hazard statement(s)

Flammable liquid and vapor
Causes serious eye damage.

Precautionary statement(s)
Keep away from heat, sparks, open flames and hot surfaces. No smoking.
Keep container tightly closed.
Wash hands thoroughly after handling.
Wear eye protection.

Precautionary statement(s)

IF in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor.
IF on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
In case of fire: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam to extinguish.
Store in a well-ventilated place. Keep cool.
Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Clobetasol Propionate	25122-46-7	0.05%
Sodium Laureth-2-sulfate	9004-82-4	Proprietary
Water	7732-18-5	Proprietary
Ethanol	64-17-5	<11%
Coco-Betaine	68424-94-2	Proprietary
Polyquaternium 10	68610-92-4	Proprietary
Hydrochloric Acid	7647-01-0	<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: This product is intended for use on the skin. If irritation develops and persists, discontinue use and get medical attention. Remove and contaminated clothing and launder it before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for at least 15 minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, and then continue flushing. Get immediate medical attention**.**
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 immediate medical attention.

Most important symptoms/effects, acute and delayed: May cause severe eye irritation and possible damage. Ingestion or inhalation may cause gastrointestinal irritation and effects on the endocrine system as described below. Some users have reported skin irritation, changes in skin pigmentation, dermatitis and infection. Clobetasol propionate is absorbed through the skin. Effects of systemic absorption of clobetasol propionate include tiredness, muscle weakness, loss of appetite, nausea, vomiting, dizziness, weight loss, irritability, depression, high blood sugar and Cushing's syndrome. Clobetasol propionate may cause adverse reproductive effects.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for eye contact or ingestion. For other unintended exposure, seek medical advice.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

Specific hazards arising from the chemical: Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.

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. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Were appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area with explosion-proof equipment.

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: Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid eye contact. Avoid breathing vapors. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep product away from heat, sparks and all other sources of ignition. Do not smoke while using. Do not leave the container in direct sunlight.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging at room temperature. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Store out of direct sunlight. Store away from oxidizers.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Clobetasol Propionate	2 ug/m3 TWA Perrigo OEL
Sodium Laureth-2-sulfate	None Established
Water	None Established
Ethanol	1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV
Coco-Betaine	None Established
Polyquaternium 10	None Established
Hydrochloric Acid	5 ppm Ceiling OSHA PEL 2 ppm Ceiling ACGIH TLV
Coco-Betaine	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, a NIOSH approved organic vapor or supplied air 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: This product is intended for use on the skin. Impervious gloves recommended for handling this product other than for use.
Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Colorless, transparent viscous liquid
Odor: Alcohol odor

Odor threshold: 100 ppm (Ethanol)	**pH:** 5.0 – 7.0
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: 29°C (84°F)	**Evaporation rate:** Not determined
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: 3% (ethanol)	**UEL:** 19% (ethanol)
Vapor pressure: 59.3 mmHg @ 25°C (ethanol)	**Vapor density:** 1.59 (ethanol)
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:** 800-3000 cP

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: Reaction with strong oxidizers will generate heat and cause fire.
Conditions to avoid: Avoid heat, sparks, flames, and all other sources of ignition.
Incompatible materials: Avoid oxidizing agents, acids and bases.
Hazardous decomposition products: Thermal decomposition may yield carbon and sulfur oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of vapors may cause irritation of the mucous membranes and upper respiratory tract and central nervous system effects such as dizziness, drowsiness and headache. Absorption through the respiratory tract may cause adverse effects as described by other routes of exposure.
Ingestion: Swallowing may cause gastrointestinal irritation and nervous system effects such as drowsiness and dizziness. . Absorption through the intestinal tract may cause adverse effects as described by other routes of exposure.
Skin contact: No adverse effects are expected. Some users have reported skin irritation, changes in skin pigmentation, dermatitis and infection. Clobetasol propionate is absorbed through the skin. Effects of systemic absorption of clobetasol propionate include tiredness, muscle weakness, loss of appetite, nausea, vomiting, dizziness, weight loss, irritability, depression, high blood sugar and Cushing's syndrome.
Eye contact: Contact may cause severe irritation with redness, pain and tearing.
Chronic Effects: Corticosteroids suppress the endocrine system. Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.
Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.
Germ Cell Mutagenicity: Clobetasol propionate was non-mutagenic in four different test systems: the Ames test, the mouse lymphoma test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. coli* B WP2 fluctuation test. In the *in vivo* mouse micronucleus test, a positive finding was observed at 24 hours, but not at 48 hours, following oral administration at a dose of 2000 mg/kg.
Reproductive Toxicity: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals. Clobetasol propionate has not been tested for teratogenicity when applied topically; however, it is absorbed percutaneous, and when administered subcutaneously, it was a significant teratogen in both the rabbit and the mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent. Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose

levels tested down to 0.03 mg/kg. These doses are approximately 1.4 and 0.04 times, respectively, the human topical dose of clobetasol propionate foam, 0.05% (emulsion) based on body surface area comparisons. Abnormalities seen included cleft palate and skeletal abnormalities. In rabbits, clobetasol propionate was teratogenic at doses of 0.003 and 0.01 mg/kg. These doses are approximately 0.02 and 0.05 times, respectively, the human topical dose of clobetasol propionate foam, 0.05% (emulsion) based on body surface area comparisons. Abnormalities seen included cleft palate, cranioschisis, and other skeletal abnormalities. Ethanol is known to cause developmental toxicity when intentionally ingested during pregnancy.
Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate foam, 0.05% (emulsion) or clobetasol propionate. In a 90-day repeat-dose toxicity study in rats, topical administration of clobetasol propionate foam, 0.05% (emulsion) at dose concentrations from 0.001 – 0.1% or from 0.03 to 0.3 mg/kg/day of clobetasol propionate resulted in a toxicity profile consistent with long term exposure to corticosteroids including adrenal atrophy, histopathological changes in several organs systems indicative of severe immune suppression and opportunistic fungal and bacterial infections. A NOAEL could not be determined in this study. Although the clinical relevance of the findings in animals to humans is not clear, sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk for carcinogenesis. Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1).

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 3,333 mg/kg
Clobetasol Propionate: LD50 oral rat >3000 mg/kg
Sodium Laureth-2-sulfate: LD50 oral rat 1600 mg/kg
Ethanol: LD50 oral rat 7060 mg/kg; LC50 inhalation rat 20000 ppm/10 hr.

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	UN1170	Ethanol Solution	Combustible liquid(see below)	III	No
TDG	UN1170	Ethanol Solution	3	III	No
IMDG	None	Not regulated per Special Provision A58			No
IATA	UN1170	Not regulated per Special Provision 144			No

Note: This product can be re-classed to a Combustible Liquid per the alcohol exception at 49CFR 173.150. Combustible liquids are not subject to regulation in non-bulk packages. In Canada aqueous solutions of alcohol <=24% are not regulated in a small means of containment – see 1.36.

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): Fire Hazard, Acute 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 = 3	Flammability = 3	Instability = 0
HMIS Rating:	Health = 3	Flammability = 3	Physical Hazard = 0

SDS Revision History: New SDS
Date of preparation: March 14, 2014
Date of last revision: June 6, 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).