SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: **Hydrocortisone Cream 1% with Aloe** **PRODUCT No.:** 51672-2013

Distributor:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: Temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
• eczema • psoriasis • poison ivy, oak, sumac
• insect bites • detergents • jewelry
• cosmetics • soaps • seborrheic dermatitis
• temporarily relieves external anal and genital itching
• other uses of this product should be only under the advice and supervision of a doctor

Restrictions on Use: **Warnings: For external use only**

Do not use
• in the genital area if you have a vaginal discharge. Consult a doctor.
• for the treatment of diaper rash. Consult a doctor.

When using this product
• avoid contact with eyes
• do not use more than directed unless told to do so by a doctor
• do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if
• condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
• rectal bleeding occurs

SUBSTANCE CLASS: Corticosteroid

FORMULA: $C_{21}H_{30}O_5$

SECTION 2: HAZARD(S) IDENTIFICATION

ADVERSE EFFECTS: May cause irritation to eyes and may cause irritation of the digestive tract when ingested.

OVERDOSE EFFECTS: Seek medical attention for all cases of overexposure.

Acute:

Chronic:

Eyes: Flush eyes with clear running water for a minimum of fifteen (15) minutes while holding eyelids open; if irritation persists, seek medical attention.
Skin: No adverse conditions expected.
Inhalation: Unlikely route of exposure.
Ingestion: Rinse out mouth and drink lots of water. In case of unusual symptoms, seek medical attention and show physician the container details.

Eyes: May cause irritation, characterized by a burning sensation, redness, tearing, inflammation, dryness, and possible other effects.

Skin: No adverse conditions expected.

Ingestion: May cause irritation of the digestive tract.

Inhalation: Unlikely route of exposure.

Medical Conditions Aggravated by Exposure: No information available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Hydrocortisone CAS#: 50-23-7

Inactive Ingredients: Aloe powder, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, citric acid, glycerin, glyceryl monostearate, methylparaben, mineral oil, paraffin wax, propylparaben, purified water, sodium lauryl sulfate, stearyl alcohol.

SECTION 4: FIRST-AID MEASURES

GENERAL: Seek medical attention for all cases of overexposure.

Eyes: Flush immediately with large amounts of water. If redness or irritation persists, contact a physician.

Skin: No adverse conditions expected.

Inhalation: Unlikely route of exposure

Ingestion: Contact a physician immediately

Instructions for Physician: Available date does not identify any conditions.

SECTION 5: FIRE-FIGHTING MEASURES

FLASH POINT:	N/A
FLAMMABLE LIMITS:	N/A
Upper Explosion Limit (UEL%):	N/A
Lower Explosion Limit (LEL%):	N/A
AUTO-IGNITION TEMPERATURE:	N/A
EXTINGUISHING MEDIA:	Use extinguishing media appropriate for the surrounding fire. Use water spray, foam or dry chemical.
FIRE FIGHTING PROCEDURES:	Use self-contained breathing apparatus when fighting fires that involve this material.
FIRE AND EXPLOSION HAZARDS:	Carbon monoxide and carbon dioxide may be generated.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Large spill: Spills should be collected with approved absorbent for disposal.

Small spill: Spills should be collected with approved inert absorbent for disposal.

SECTION 7: HANDLING AND STORAGE

HANDLING: Keep this and other chemicals out of reach of children.

STORAGE: Do not store or mix with strong acids or oxiders. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Ventilation:	N/A
Respiratory Protection:	None required under normal conditions.
Eye:	Eye protection, as necessary to prevent excessive contact.
Gloves:	N/A
Clothing:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT:	135˚C (275˚F)
MELTING POINT:	60˚C (140˚F)
PHYSICAL STATE (liquid/solid/gas):	Semi-solid
SPECIFIC GRAVITY (H_2O=1):	0.81
EVAPORATION RATE:	0.07
SOLUBILITY IN WATER:	Miscible
APPEARANCE:	White homogeneous cream
ODOR DESCRIPTION:	Slightly fatty odor

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: This material is stable under normal conditions.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Extreme heat

INCOMPATIBILITY WITH OTHER MATERIALS: Strong oxidants, Strong Acids

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon Monoxide, Carbon Dioxide

SECTION 11: TOXICOLOGICAL INFORMATION

LISTED as a CARCINOGEN:

NTP: No
IARC: No
OSHA: No
OTHER: No

Acute Toxicity

Product Information: May cause eye and skin irritation.

Component Information:

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrocortisone USP micronized	=5000 mg/kg (Rat)	-	-

Chronic Toxicity: Prolonged or repeated contact may dry skin and cause irritation.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk.
Systematically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Carcinogenicity: Contains no ingredients above reportable quantities listed as a carcinogen.

Teratogenic: **Pregnancy:** Teratogenic Effects: Pregnancy Category C:
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. There are no adequate and well-controlled studies in

pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Target Organ Effects: Skin: Endocrine system. Reproductive System: Contains material that may adversely affect the developing fetus. Immune system.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: The environmental impact of this product has not been fully investigated. Ecotoxicity effects of component substances.

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose of in accordance with Local, State, and Federal regulations.

SECTION 14: TRANSPORT INFORMATION

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes

DOT:	Not regulated.
TDG:	Not regulated.
MEX:	Not regulated.
IATA:	Not regulated.
IMDG/IMO:	Not regulated.

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard:	Exempt
Chronic Health Hazard:	Exempt
Fire Hazard:	Exempt
Sudden Release of Pressure Hazard:	Exempt
Reactive Hazard:	Exempt

This is a FDA regulated product and as such is exempted from SARA Tier II reporting.

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

California Proposition 65

This product does not contain any Proposition 65 chemicals.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: June 2015

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.