SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Imiquidmod Cream 5%
Synonym: 2H1

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 treatment of genital and perianal warts.
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not Hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Imiquimod	99011-02-6	5%
Oleic Acid	112-80-1	Proprietary
Glycerin	56-81-5	Proprietary
Oleyl Alcohol	143-28-2	Proprietary
White Petrolatum	8009-03-8	Proprietary
Polysorbate 60	9005-67-8	Proprietary
Water	7732-18-5	Proprietary
Cetyl Alcohol	3653-82-4	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
Benzyl Alcohol	100-51-6	Proprietary
Sorbitan Monostearate	1338-41-6	Proprietary
Xantham Gum	11138-66-2	Proprietary
Methyl paraben	99-76-3	Proprietary
Propyl Paraben	94-13-3	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: This product is intended for use on the skin. For unintended contact, wash skin with soap and water. If irritation develops and persists, get medical attention. Remove contaminated clothing and wash it before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for several minutes. 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: M ay cause mild eye and skin irritation. Ingestion may cause gastrointestinal and nervous system effects such as headache, dizziness, nausea and hypotension.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is generally not 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 after the water have 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. Cool fire exposed containers with water.

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 eye contact. Avoid unintended contact with skin. 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:

Imiquimod	Perrigo OEB4 (1-10 ug/m3)
Oleic Acid	None Established
Glycerin	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Oleyl Alcohol	None Established
White Petrolatum	5 mg/m3 (inhalable) TWA ACGIH TLV 5 mg/m3 TWA OSHA PEL
Polysorbate 60	None Established
Water	None Established
Cetyl Alcohol	None Established
Stearyl Alcohol	None Established
Benzyl Alcohol	10 ppm TWA AIHA WEEL
Sorbitan Monostearate	None Established
Xantham Gum	None Established
Methyl paraben	500 ug/m3 TWA PERRIGO OEL
Propyl Paraben	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: None required for normal use. Impervious gloves recommended for manufacturing operations.
Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Off-white cream.
Odor: Slight odor

Odor threshold: Not determined	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: None	**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:** 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 and nitrogen 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 with nausea and diarrhea and nervous system effects such as headache and dizziness. May cause hypotension.
Skin contact: Minor irritation is possible.
Eye contact: Contact may cause irritation.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens. Imiquimod revealed no evidence of mutagenic or clastogenic potential based on the results of five in vitro genotoxicity tests (Ames assay, mouse lymphoma L5178Y assay, Chinese hamster ovary cell chromosome aberration assay, human lymphocyte chromosome aberration assay and SHE cell transformation assay) and three in vivo genotoxicity tests (rat and hamster bone marrow cytogenetics assay and a mouse dominant lethal test).

Reproductive Toxicity: No adverse effects are expected. Components are not reproductive toxins. Daily oral administration of imiquimod to rats, throughout mating, gestation, parturition and lactation, demonstrated no effects on growth, fertility or reproduction**.** Systemic embryofetal development studies were conducted in rats and rabbits. Oral doses of 1, 5 and 20 mg/kg/day imiquimod were administered during the period of organogenesis (gestational days 6 – 15) to pregnant female rats. In the presence of maternal toxicity, fetal effects noted at 20 mg/kg/day included increased resorptions, decreased fetal body weights, delays in skeletal ossification, bent limb bones, and two fetuses in one litter (2 of 1567 fetuses) demonstrated exencephaly, protruding tongues and low-set ears. No treatment related effects on embryofetal toxicity or teratogenicity were noted at 5 mg/kg/day. Intravenous doses of 0.5, 1 and 2 mg/kg/day imiquimod were administered during the period of organogenesis (gestational days 6 – 18) to pregnant female rabbits. No treatment related effects on embryofetal toxicity or teratogenicity were noted at 2 mg/kg/day, the highest dose evaluated in this study, or 1 mg/kg/day. A combined fertility and peri- and post-natal development study was conducted in rats. Oral doses of 1, 1.5, 3 and 6 mg/kg/day imiquimod were administered to male rats from 70 days prior to mating through the mating period and to female rats from 14 days prior to mating through parturition and lactation. No effects on growth, fertility, reproduction or post-natal development were noted at doses up to 6 mg/kg/day, the highest dose evaluated in this study. In the absence of maternal toxicity, bent limb bones were noted in the F1 fetuses at a dose of 6 mg/kg/day. This fetal effect was also noted in the oral rat embryofetal development study conducted with imiquimod. No treatment related effects on teratogenicity were noted at 3 mg/kg/day.

Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. In an oral (gavage) rat carcinogenicity study, imiquimod was administered to Wistar rats on a 2X/week (up to 6 mg/kg/day) or daily (3 mg/kg/day) dosing schedule for 24 months. No treatment related tumors were noted in the oral rat carcinogenicity study up to the highest doses tested in this study. In a dermal mouse carcinogenicity study, imiquimod cream (up to 5 mg/kg/application imiquimod or 0.3% imiquimod cream) was applied to the backs of mice 3X/week for 24 months. A statistically significant increase in the incidence of liver adenomas and carcinomas was noted in high dose male mice compared to control male mice.

Acute Toxicity Values: Acute Toxicity Estimate (ATE) oral calculated: 8000 mg/kg
Imiquimod: LD50 oral rat 400-1600 mg/kg, LD50 dermal >5000 mg/kg
Petrolatum: LD50 oral rat >5000 mg/kg
Glycerin: LD50 oral rat 12.6 g/kg
Oleic Acid: LD50 oral rat 74 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): Not Hazardous

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 10, 2015

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).