

# Safety Data Sheet

## Product: HYDROCORTISONE 1% CREAM

### Section 1: Identification

**Product Name:** Hydrocortisone 1% Cream.

**Use:** Active-Anti-pyretic (Anti-Itch)

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

**Distributor:** Akron Pharma INC. Fairfield, NJ-07004

### Section 2: Hazard(s) Identification

#### Classification of the substance or mixture:

**Product description:** This product is a white smooth flowing lotion.

**GHS-Classification** Not Available

**Health Hazard:** Reproductive toxicity Category 2

**Other Hazards:** No data available. It is considered non-hazardous according to OSHA Hazard communication standard 2012(29 CFR 1910,1200)

**Flammability Hazards:** 1. This product is not combustible. This material may decompose and produce irritating vapors and toxic compounds of carbon including carbon oxides.

**Reactivity Hazard:** This product is not reactive. Stable. Conditions to avoid, high temperatures, sparks, open flames, and all other sources of ignition.

**Emergency:** This mixture is a product regulated by the FDA. Within the meaning of the OSHA Hazard Communication Standard [29 CFR 1910.1200]: this mixture is not considered a hazard when used in a manner which is consistent with the label direction

### Section 3: Composition/Information on Ingredients

| Ingredient                     | w/w%        |
|--------------------------------|-------------|
| Hydrocortisone USP Micronized  | 1%          |
| Aloe Vera                      | Proprietary |
| Benzyl Alcohol                 | Proprietary |
| Glyceryl Monostearate          | Proprietary |
| Mineral Oil                    | Proprietary |
| PEG 25 Stearate                | Proprietary |
| PEG-40 Hydrogenated Castor oil | Proprietary |
| Propylene Glycol               | Proprietary |
| Purified water                 | Proprietary |
| Squalane                       | Proprietary |
| Stearic Acid                   | Proprietary |

In accordance with 29CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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### Section 4: First-Aid Measures

**Eye:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Skin:** Itching or burning of skin. Immediately flush with plenty of soap and water. Get medical attention if symptoms occur.

**Inhalation:** Move to fresh Air. Call a Physician if symptoms develop or persist.

**Ingestion:** Rinse mouth. If swallowed: Call a poison center or doctor/physician if you feel unwell.

**Most important symptoms/effects, Acute and Delayed:** Irritation of eyes and mucous membranes. Ingestion may cause gastrointestinal distress.

**Indication of immediate medical attention and special treatment needed:** Immediate Medical attention is not generally required

### Section 5: Firefighting Measures

**Suitable Extinguishing media:** Use dry chemicals, foam or carbon dioxide to extinguish fire. Water can be used to dilute spills and to flush them away from source of ignition.

**Firefighting procedures:** Do not flush down sewers or any other drainage systems. Exposed fire fighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full face mask and full protective clothing.

**Unusual fire and Explosive Hazards:** None known.

**Combustion products:** Irritating or toxic substances may be emitted upon decomposition. Thermal decomposition products may include oxides of carbon

### Section 6: Accidental Release Measures

#### **Personal precautions, protective equipment and emergency procedures**

**Personal precautions;** None under normal use conditions.

**Advice for emergency responders:** Use personal protective equipment as required.

**Environmental precautions Household:** Product is safe to dispose of in household garbage or down the drain.

**Non-household:** Do not discharge product into natural waters without pre-treatment or adequate dilution

**Methods and materials for containment and cleaning up:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dust during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site

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### Section 7: Handling and Storage

**Handling:** Do not get in eyes. Use good personal hygiene practices. Wash hands before eating or drinking. Remove contaminated clothing and clean before re-use.

**Keep away from heat and flame.** Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

**Storage:** Store in tightly closed containers in cool, dry, well ventilated area away from heat and sources of ignition.

**Incompatible products:** Do not mix with nitric acid or other strong acids or bases

### Section 8: Exposure Controls/Personal Protection

#### Exposure Limit Value

Industrial Use

#### Material Type Value

Hydrocortisone (CAS 50-23-7) TWA 100 micrograms/m<sup>3</sup>

#### Exposure controls:

This safety data sheet was developed based on regulations applicable to bulk substances in an industrial/occupational setting.

**For Consumers and Retail personnel** - follow product label directions and warnings when using and/or handling this product.

**For Distribution and Manufacturing sites** - follow the procedure as listed according to your Workplace Safety protocols.

**Engineering Measures:** No information available

#### Personal Protective Equipment (PPE)

**Eye Protection:** Manufacturing Sites: Safety glasses with side-shields Distribution, Workplace and Household Settings: No special protective equipment required.

**Hand Protection:** No special protective equipment required.

**Skin and Body Protection:** No special protective equipment required, Avoid excessive large skin contact. Wear gloves

**Respiratory Protection:** No special protective equipment required; NIOSH approved respiratory protection should be worn

**Carcinogen Status:** None

**Engineering Control:** Local exhaust ventilation may be necessary to control air contaminants. Use of local ventilation is recommended to control emission near the sources.

### Section 9: Physical and Chemical Properties

**Physical State @20°C:** Smooth White to off white cream

**Appearance:** white to off white cream

**Odor:** slight medicinal odor

**Odor threshold:** No information available

**pH Value:** No information available

**Melting and Freezing point:** No information available

**Boiling point:** No information available

**Flash point:** No information available

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**Flammability:** No information available  
**Vapor pressure:** No information available  
**Water solubility:** Insoluble  
**Solubility in other solvents:** Mineral oil  
**Viscosity of Product:** No information available  
**VOC Content (%) :** None  
**Explosive/Oxidizing properties:** None

### Section 10: Stability and Reactivity

**Reactivity:** None  
**Stability:** Stable under normal conditions.  
**Hazardous:** Hazardous polymerization does not occur.  
**Hazardous Reactions:** None under normal processing.  
**Conditions to Avoid:** None under normal processing.  
**Incompatible material:** Strong Oxidizing Agents  
**Hazardous Decomposition Products:** NO<sub>x</sub>, Cl<sup>-</sup>, irritating and/or toxic fumes or gases, emits toxic fumes under fire condition.

### Section 11: Toxicological Information

**Product Information Information on likely routes of exposure**  
**Inhalation:** inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.  
**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.  
**Ingestion:** swallowing may cause gastrointestinal distress.  
**Eye contact:** Avoid contact with eyes. Irritating to eyes.  
**Acute toxicity:** Harmful if swallowed.

| Chemical                                    | Species | Test Results |
|---|---------|--------------|
| <b>Hydrocortisone sodium (CAS# 50-23-7)</b> |         |              |
| Oral<br>LD50                                | Rat     | 5000mg/kg    |
| <b>Acute</b>                                |         |              |
| Oral<br>LD50                                | Mouse   | 5000mg/kg    |
| <b>Benzyl Alcohol(CAS# 100-51-6)</b>        |         |              |
| Oral<br>LD50                                | Rat     | 1230mg/kg    |
| <b>Acute</b>                                |         |              |
| Oral<br>LD50                                | Mouse   | 1360mg/kg    |

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**Skin corrosion/irritation:** No known effect.

**Serious eye damage/eye irritation:** Irritating to eyes.

**Skin sensitization:** Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.

**Respiratory sensitization:** No known effect.

**Germ cell mutagenicity:** No known effect.

**Neurological Effects:** No known effect.

**Reproductive toxicity:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage level. The more potent a corticosteroid have been shown to be teratogenic after dermal application in laboratory animals

**Developmental toxicity** No known effect.

**Teratogenicity** No known effect.

**STOT - single exposure** No known effect.

**STOT - repeated exposure** No known effect.

**Target Organ Effects** No known effect.

**Aspiration hazard** No known effect.

**Carcinogenicity:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids. None of the component are listed as carcinogenic by IARC, NTP or OSHA

### Section 12: Ecological Information

**Ecotoxicity values:** Hydrocortisone: EC50 daphnia magna >100mg/L/48 hr.

**Persistence and degradability:** No information available.

**Bio accumulative potential** No information available.

**Mobility** No information available.

**Other adverse effects** No information available.

### Section 13: Disposal Considerations\*<sup>1</sup>

#### Waste treatment

**Waste from Residues / Unused Products:** Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

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### Section 14: Transport Information\*

**DOT:** Not regulated as a hazardous material by DOT.

**IATA:** Not regulated as a dangerous good.

**Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code:** No information available.

### Section 15: Regulatory Information\*

**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.

**Food and Drug Administration (FDA)** The product described in this Safety Data Sheet is regulated under the Federal Food, Drug, and Cosmetics Act and is safe to use as per directions on container, box or accompanying literature (where applicable)

**Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (see 40 CFR 61)** This product does not contain any substances regulated as hazardous air pollutants (HAPS) under Section 112 of the Clean Air Act Amendments of 1990.

**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)

**California Proposition 65:** This product is not subject to warning labeling under California Proposition 65.

### Section 16: Other Information

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