Hydrocortisone USP (Micronized)

SDS Preparation Date 06/01/2017

SAFETY DATA SHEET

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier:
Identification on the label/ Tradename: HYDROCORTISONE, USP (Micronized)
Identification of the Product: CAS#50-23-7
Formula: C₂₁H₃₀O₅
Cl No.: Not Available
Synonyms: 11-beta-Hydrocortisone, 11-beta-Hydroxycortisone, Dihydrocortisone

Relevant identified uses of the substance and uses advised against:
Identified Uses: Glucocorticoid; anti-inflammatory (Hormone)
Uses Advised Against: No information available

Name, address, and telephone number of the manufacturer:
Refer to Supplier
Name, address, and telephone number of the supplier:
Encore Scientific 801 West New Orleans Street Broken Arrow, OK, USA 74011
Supplier’s Telephone #: 800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel #: INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards Identification

Classification according to Regulation 29 CFR 1910 (OSHA HCS)
Toxic to Reproduction (Category 2)
Specific Target Organ Toxicity - Repeated Exposure (Category 2)
Sensitization - Respiratory (Category 1)
Sensitization - Skin (Category 1)
Adverse physicochemical, human health and environmental effects
Reproductive toxicity (Category 2), H361

Label elements
Labelling according to Regulation 29 CFR 1910 (OSHA HCS)

SIGNAL WORD: Danger
Hazard Statements: Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
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Section 2 Hazards Identification (continued)

PRECAUTIONARY STATEMENT(S)

Symptoms: Not expected to present a significant hazard under anticipated conditions of normal use. May cause systemic effects when applied to large areas when the skin is broken or under occlusive dressings; can cause raised intra-ocular pressure and reduced visual function. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension). When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.

Potential Health Effects:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed. Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, muscle cramps, weakness, nervousness, restlessness, trouble sleeping.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Other hazards

Other hazards not contributing to the classification:

Repeated exposure may cause skin dryness or cracking.

Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCORTISONE</td>
<td>50-23-7</td>
<td>100</td>
</tr>
</tbody>
</table>

Section 4 First aid measures

General Advice: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Skin Contact: Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

Eye Contact: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

Ingestion: No available information.
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Section 4 First aid measures (continued)

Most important symptoms and effects, both acute and delayed
Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use. Dust may cause mechanical irritation to eyes, nose, throat, and lungs.
Symptoms/injuries Inhalation: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries Skin Contact: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries Eye Contact: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries Ingestion: No available information
Chronic Symptoms: None expected under normal conditions of use.

Indication of any immediate medical attention and special treatment needed
If you feel unwell, seek medical advice (show the label where possible).

Section 5 Fire-Fighting measures

Extinguishing media
Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media: Do not get water inside containers.

Special hazards arising from the substance or mixture
Fire hazard: May be combustible at high temperature
Explosion hazard: No data available
Reactivity: Under fire conditions, hazardous fumes will be present.

Advice for firefighters
Precautionary measures fire: Exercise caution when fighting any chemical fire. Do not get water inside containers.
Firefighting instructions: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Protection during firefighting: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Other information: No data available

Section 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures
General measures: Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For non-emergency personnel
Protective equipment: Use appropriate personal protection equipment (PPE). Wear respiratory protection.
Emergency procedures: Evacuate unnecessary personnel.
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For emergency responders
Protective equipment: Equip cleanup crew with proper protection. Wear respiratory protection.
Emergency procedures: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and material for containment and cleaning up
For containment: On land, sweep or shovel into suitable containers. Minimize generation of dust.
Methods for cleaning up: Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

Reference to other sections
For disposal see section 13

Section 7 Handling and storage

Precautions for safe handling
Additional hazards when processed: Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.
Precautions for safe handling: Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.
Hygiene measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Conditions for safe storage, including any incompatibilities
Technical measures: Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials.
Storage conditions: Store in original container, tightly sealed container, protected from direct sunlight, in a dry, cool and well-ventilated area, away from incompatible materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.
Incompatible products: Strong oxidizers.

Specific end use(s)
Glucocorticoid; anti-inflammatory (Hormone)
Section 8 Exposure Controls/Personal Protection

Control parameters
Contains no substances with occupational exposure limit values. Hazardous components without workplace control parameters.

Exposure controls
Appropriate engineering controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment:

Materials for protective clothing:
Chemically resistant materials and fabrics.

Hand protection:
Protective gloves. Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection:
Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection:
Impervious clothing, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection:
Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Environmental exposure controls: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Consumer exposure controls: Do not eat, drink or smoke during use.

Section 9 Physical and chemical properties

Information on basic physical and chemical properties:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Crystalline Solid</td>
</tr>
<tr>
<td>Color</td>
<td>White</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.5 - 8.5</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>211 - 214 °C (412 - 417 °F) - lit.</td>
</tr>
<tr>
<td>Freezing point</td>
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</tr>
</tbody>
</table>
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Section 9 Physical and chemical properties (continued)

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>1.35E-13 mm Hg (25°C)</td>
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<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
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<tr>
<td>Relative density</td>
<td>1.6 g/cm³</td>
</tr>
<tr>
<td>Solubility</td>
<td>200 g/100mL @20°C (68°F)</td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
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<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Other information
No additional information available

Section 10 Stability and reactivity

Reactivity
Hazardous reactions will not occur under normal conditions.

Chemical stability
Stable under recommended handling and storage conditions

Possibility of hazardous reactions
Hazardous polymerization will not occur.

Conditions to avoid
Moisture, sunlight and extreme temperatures. Protect from light.

Incompatible materials: Strong oxidizers.

Hazardous decomposition products: Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur.

Section 11 Toxicological information

Information on toxicological effects

Acute toxicity
Not classified
Oral: Rat: LD50: (mg/kg): 5000
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L): Not available
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Section 11 Toxicological information (continued)

**Skin corrosion/irritation:** Not classified

**Serious eye damage/irritation:** Eye Irritation Rabbit Minimal

**Respiratory or skin sensitization:** Sensitization of the skin; decrease in the formation of antibodies and immunocompetent lymphocytes, inhibition of inflammatory response. There have been occasional reports of hypersensitivity reactions, and sometimes anaphylaxis, caused by corticosteroids. Reactions have occurred with any route, although the topical route is mainly involved.

**Germ cell mutagenicity:**
- Bacterial Mutagenicity (Ames) Salmonella Negative
- Unscheduled DNA Synthesis Rat Negative

**Carcinogenicity:**
- OSHA HYDROCORTISONE is not listed.
- NTP HYDROCORTISONE is not listed.
- IARC HYDROCORTISONE is not evaluated.

**This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.**

**Reproductive toxicity:** Animal studies with some corticosteroids have shown cleft palate and inhibited fetal growth.

- Embryo / Fetal Development Mouse Oral 10 mg/kg/day LOAEL Teratogenic
- Reproductive & Fertility Rat Oral 210 mg/kg/day LOAEL Maternal Toxicity

**Specific target organ toxicity (single exposure):** Not classified

**Specific target organ toxicity (repeated exposure):** May cause damage to organs through prolonged or repeated exposure.

- 7 Day(s) Mouse Oral 140 mg/kg/day LOAEL Thymus
- 4 Day(s) Mouse Subcutaneous 100 mg/kg/day LOAEL Liver
- 2 Week(s) Mouse Subcutaneous 560 mg/kg/day LOAEL Liver, Bone Marrow
- 85 Day(s) Rat Subcutaneous 175 mg/kg/day LOAEL Adrenal gland

**Aspiration hazard:** Not classified

Section 12 Ecological information

**Toxicity:**
- EC50: 48 Hr: Daphnia magna: (mg/L): Not available
- LC50: 96 Hr: Fish: (mg/L): > 100
- IC50: 72 Hr: Algae: (mg/L/4hr): Not available

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

**Bio-accumulative potential:** Biodegradable

**Mobility in soil:**
- Water solubility: 320 mg/L (25°C)
- Henry's Law Constant: 5.77E-08 atm-m3/mole (25°C)

**Results of PBT and vPvB assessment:** No additional information available

**Other adverse effects**

Toxicity to aquatic organisms cannot be excluded.

**Other information:**
This product is not intended to be released into the environment
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Section 13 Disposal considerations

Waste treatment methods
Waste disposal recommendations
Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Ecology - waste materials: Avoid release to the environment.

Section 14 Transport information

In accordance with ADR / RID / IMDG / IATA / ADN
UN number: Not applicable
UN proper shipping name: Not dangerous good
Transport hazard class(es): Not applicable
Packing group: Not applicable

Environmental hazards
Other information: No supplementary information available.

Special precautions for user
Overland transport: No additional information available
Transport by sea: No additional information available
Air transport: No additional information available

Transport in bulk according to Annex II of MARPOL and the IBC Code
Not applicable

Section 15 Regulation information

Safety, health and environmental regulations/legislation specific for the substance or mixture
EU-Regulations
No REACH Annex XVII restrictions

National regulations
SARA 302 Components: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SARA 311/312 Hazards Chronic Health Hazard
California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.
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Section 15 Regulation information (continued)

Chemical safety assessment
No chemical safety assessment has been carried out

Section 16 Other information

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader:
Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.