

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING**Product Identifier****Material Name: Hydrocortisone Tablets (Greenstone LLC)**

| | |
|-------------------------|------------------------|
| Trade Name: | Not established |
| Synonyms: | Hydrocortisone Tablets |
| Chemical Family: | Glucocorticoid |

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**Intended Use:** Pharmaceutical product used as anti-inflammatory**Details of the Supplier of the Safety Data Sheet**

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION**Classification of the Substance or Mixture****GHS - Classification**

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Not classified

Label Elements

| | |
|---------------------------|--|
| Signal Word: | Warning |
| Hazard Statements: | H361d - Suspected of damaging the unborn child |

Precautionary Statements: P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

**Other Hazards**

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Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|------------------|------------|-----------------------|-------------------|--------------------|---|
| Hydrocortisone | 50-23-7 | 200-020-1 | Repr.Cat.3;R63 | Repr. 2 (H361d) | 4 |
| Corn Starch | 9005-25-8 | 232-679-6 | Not Listed | Not Listed | * |
| Mineral oil | 8012-95-1 | 232-384-2 | Not Listed | Not Listed | * |
| Calcium stearate | 1592-23-0 | 216-472-8 | Not Listed | Not Listed | * |
| Sucrose | 57-50-1 | 200-334-9 | Not Listed | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|---------------------|------------|-----------------------|-------------------|--------------------|---|
| Sorbic acid | 110-44-1 | 203-768-7 | Not Listed | Not Listed | * |
| Lactose Monohydrate | 64044-51-5 | Not Listed | Not Listed | Not Listed | * |

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Hydrocortisone

Pfizer OEL TWA-8 Hr: 100 µg/m³, Skin

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³

Australia TWA 10 mg/m³

Belgium OEL - TWA 10 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|---------------------------|------------------------|
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Czech Republic OEL - TWA | 4.0 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| | 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 4 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |

Mineral oil

| | |
|-----------------------------------|-----------------------|
| ACGIH Threshold Limit Value (TWA) | 5 mg/m ³ |
| Australia TWA | 5 mg/m ³ |
| Belgium OEL - TWA | 5 mg/m ³ |
| Bulgaria OEL - TWA | 5.0 mg/m ³ |
| Czech Republic OEL - TWA | 5 mg/m ³ |
| Denmark OEL - TWA | 1 mg/m ³ |
| Finland OEL - TWA | 5 mg/m ³ |
| Greece OEL - TWA | 5 mg/m ³ |
| Lithuania OEL - TWA | 1 mg/m ³ |
| Netherlands OEL - TWA | 5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 5 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Portugal OEL - TWA | 5 mg/m ³ |
| Romania OEL - TWA | 5 mg/m ³ |
| Slovakia OEL - TWA | 5 ppm |
| | 1 mg/m ³ |
| | 5 mg/m ³ |
| Spain OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 1 mg/m ³ |
| Vietnam OEL - TWAs | 5 mg/m ³ |

Calcium stearate

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

Sucrose

| | |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| Latvia OEL - TWA | 5 mg/m ³ |
| Lithuania OEL - TWA | 10 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Slovakia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Tablets | Color: | White |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Mineral oil

No data available

Sorbic acid

No data available

Calcium stearate

No data available

Corn Starch

No data available

Sucrose

No data available

Lactose Monohydrate

No data available

Hydrocortisone

Predicted 7.4 Log D 1.43

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

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Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable at normal conditions
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause minimal eye irritation (based on animal data). May be harmful if swallowed. May be harmful if absorbed through the skin. (based on components) Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, muscle cramps, weakness, nervousness, restlessness, trouble sleeping. 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).

Acute Toxicity: (Species, Route, End Point, Dose)

Sorbic acid

Rat Oral LD50 7360 mg/kg
Mouse Oral LD50 3200mg/kg

Sucrose

Rat Oral LD50 29.7 g/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Hydrocortisone

Rat Oral LD 50 5000 mg/kg
Mouse Oral LD 50 5000mg/kg
Rat Subcutaneous LD 50 449mg/kg
Rat Intraperitoneal LD 50 150mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Mineral oil

Eye Irritation Rabbit Moderate

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11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Mild

Hydrocortisone

Eye Irritation Rabbit Minimal

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Hydrocortisone

| | | | | | |
|-----------|-------|--------------|---------------|-------|--------------------|
| 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 |

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Hydrocortisone

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Lactose Monohydrate

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Hydrocortisone

| | | |
|-------------------------------|-------------------|----------|
| Bacterial Mutagenicity (Ames) | <i>Salmonella</i> | Negative |
| Unscheduled DNA Synthesis | Rat | Negative |

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Hydrocortisone

Predicted 7.4 Log D 1.43

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Hydrocortisone

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling | Schedule 2 |
| for Drugs and Poisons: | Schedule 3 |
| | Schedule 4 |
| EU EINECS/ELINCS List | 200-020-1 |

Corn Starch

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |

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15. REGULATORY INFORMATION

| | |
|---|-----------|
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 232-679-6 |

Sorbic acid

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 203-768-7 |

Lactose Monohydrate

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | Not Listed |

Mineral oil

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-384-2 |

Calcium stearate

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 216-472-8 |

Sucrose

| | |
|---|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 200-334-9 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Xn - Harmful

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R63 - Possible risk of harm to the unborn child.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 14-May-2015
Product Stewardship Hazard Communication

Prepared by: Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

End of Safety Data Sheet