

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Hydroxyzine Pamoate Capsules (Greenstone LLC)  
**Product Code(s)** PZ03936  
**Trade Name:** Not established  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antianxiety agent nausea and vomiting (antiemetic) antihistamine sedative

### 1.3. Details of the supplier of the safety data sheet

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

### 1.4. Emergency telephone number

Emergency Telephone CHEMTREC (24 hours): 1-800-424-9300

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

**Reproductive toxicity** Category 2

### 2.2. Label elements

**Signal word** Warning

**Hazard statements** H361d - Suspected of damaging the unborn child

**Precautionary Statements** P201 - Obtain special instructions before use  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up



### 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

### 3.2 Mixtures

#### Hazardous

| Chemical Name         | EC No     | CAS No     | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|-----------------------|-----------|------------|----------|---|---------------------------|
| Hydroxyzine pamoate   | 233-582-1 | 10246-75-0 | 1-10     | Acute Tox.4 (H302)<br>Repr.2 (H361d)                            |                           |
| Sucrose               | 200-334-9 | 57-50-1    | *        | Not Listed  |                           |
| Starch                | 232-679-6 | 9005-25-8  | *        | Not Listed  |                           |
| Sodium lauryl sulfate | 205-788-1 | 151-21-3   | *        | Not Listed  |                           |
| Magnesium Stearate    | 209-150-3 | 557-04-0   | *        | Not Listed  |                           |

#### NonHazardous

| Chemical Name         | EC No      | CAS No  | Weight-% | Classification according to Regulation (EC) No. 1272/2008 [CLP] | REACH Registration Number |
|-----------------------|------------|---------|----------|---|---------------------------|
| Hard gelatin capsules | Not Listed | MIXTURE | *        | Not Listed  |                           |

**Full text of H- and EUH-phrases: see section 16**

#### 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | Remove to fresh air. Seek immediate medical attention/advice.  |
| <b>Eye contact</b>  | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.   |
| <b>Skin contact</b> | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.  |
| <b>Ingestion</b>    | 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. |

### 4.2. Most important symptoms and effects, both acute and delayed

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**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## **Section 5: FIRE-FIGHTING MEASURES**

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Dry chemical, CO2, alcohol-resistant foam or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Formation of toxic gases is possible during heating or fire.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### 6.1. Personal precautions, protective equipment and emergency procedures

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

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

#### **Advice on safe handling**

Minimize dust generation and accumulation. Use appropriate ventilation. 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 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

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collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

## 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Hydroxyzine pamoate**

Manufacturer OEL: 300  $\mu\text{g}/\text{m}^3$

#### **Magnesium Stearate**

|                |   |
|----------------|---|
| ACGIH TLV      | 10 $\text{mg}/\text{m}^3$                                   |
|                | 3 $\text{mg}/\text{m}^3$                                    |
| Ireland        | 10 $\text{mg}/\text{m}^3$                                   |
|                | STEL: 30 $\text{mg}/\text{m}^3$                             |
| Spain          | 10 $\text{mg}/\text{m}^3$                                   |
| <b>Sucrose</b> |   |
| ACGIH TLV      | 10 $\text{mg}/\text{m}^3$                                   |
| Bulgaria       | 10.0 $\text{mg}/\text{m}^3$                                 |
| Estonia        | 10 $\text{mg}/\text{m}^3$                                   |
| France         | 10 $\text{mg}/\text{m}^3$                                   |
| Ireland        | 10 $\text{mg}/\text{m}^3$                                   |
|                | STEL: 20 $\text{mg}/\text{m}^3$                             |
| Latvia         | 5 $\text{mg}/\text{m}^3$                                    |
| Spain          | 10 $\text{mg}/\text{m}^3$                                   |
| OSHA PEL       | 15 $\text{mg}/\text{m}^3$                                   |
|                | 5 $\text{mg}/\text{m}^3$                                    |
|                | (vacated) TWA: 15 $\text{mg}/\text{m}^3$ total dust         |
|                | (vacated) TWA: 5 $\text{mg}/\text{m}^3$ respirable fraction |
| United Kingdom | TWA: 10 $\text{mg}/\text{m}^3$                              |
|                | STEL: 20 $\text{mg}/\text{m}^3$                             |

#### **Starch**

|                |   |
|----------------|---|
| ACGIH TLV      | 10 $\text{mg}/\text{m}^3$                                   |
| Bulgaria       | 10.0 $\text{mg}/\text{m}^3$                                 |
| Czech Republic | 4.0 $\text{mg}/\text{m}^3$                                  |
| Ireland        | 10 $\text{mg}/\text{m}^3$                                   |
|                | 4 $\text{mg}/\text{m}^3$                                    |
|                | STEL: 30 $\text{mg}/\text{m}^3$                             |
|                | STEL: 12 $\text{mg}/\text{m}^3$                             |
|                | MAC: 10 $\text{mg}/\text{m}^3$                              |
| Russia         | 10 $\text{mg}/\text{m}^3$                                   |
| Spain          | 10 $\text{mg}/\text{m}^3$                                   |
| Switzerland    | 3 $\text{mg}/\text{m}^3$                                    |
| OSHA PEL       | 15 $\text{mg}/\text{m}^3$                                   |
|                | 5 $\text{mg}/\text{m}^3$                                    |
|                | (vacated) TWA: 15 $\text{mg}/\text{m}^3$ total dust         |
|                | (vacated) TWA: 5 $\text{mg}/\text{m}^3$ respirable fraction |
| United Kingdom | TWA: 10 $\text{mg}/\text{m}^3$                              |
|                | TWA: 4 $\text{mg}/\text{m}^3$                               |
|                | STEL: 30 $\text{mg}/\text{m}^3$                             |
|                | STEL: 12 $\text{mg}/\text{m}^3$                             |

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## 8.2. Exposure controls

|  |   |
|--|---|
| <b>Engineering controls</b>            | Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.   |
| <b>Environmental exposure controls</b> | No information available.   |
| <b>Personal protective equipment</b>   | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. |
| <b>Eye/face protection</b>             | Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).  |
| <b>Hand protection</b>                 | Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).   |
| <b>Skin and body protection</b>        | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).  |
| <b>Respiratory protection</b>          | Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).                         |
| <b>General hygiene considerations</b>  | Handle in accordance with good industrial hygiene and safety practice.  |

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

|                                       |   |
|---------------------------------------|---|
| <b>Physical state</b>                 | Capsule   |
| <b>Color</b>                          | Dark green/light green; green/white; green/gray |
| <b>Molecular formula (MF):</b>        | Mixture   |
| <b>Molecular weight</b>               | Mixture   |
| <b>Odor</b>                           | No data available.                              |
| <b>Odor threshold</b>                 | No data available                               |
| <b>Property</b>                       | <b>Values</b>                                   |
| <b>pH</b>                             |   |
| <b>Melting point / freezing point</b> | No data available                               |
| <b>Boiling point / boiling range</b>  | No data available                               |
| <b>Flash point</b>                    | No data available                               |
| <b>Evaporation rate</b>               | No data available                               |
| <b>Flammability (solid, gas)</b>      | No data available                               |
| <b>Flammability Limit in Air</b>      |   |
| <b>Upper flammability limit:</b>      | No data available                               |
| <b>Lower flammability limit:</b>      | No data available                               |
| <b>Vapor pressure</b>                 | No data available                               |
| <b>Vapor density</b>                  | No data available                               |

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|                                  |                   |
|----------------------------------|-------------------|
| <b>Relative density</b>          | No data available |
| <b>Water solubility</b>          | No data available |
| <b>Solubility(ies)</b>           | No data available |
| <b>Autoignition temperature</b>  | No data available |
| <b>Decomposition temperature</b> | No data available |
| <b>Kinematic viscosity</b>       | No data available |
| <b>Dynamic viscosity</b>         | No data available |
| <b>Explosive properties</b>      | No data available |
| <b>Oxidizing properties</b>      | No data available |

## 9.2. Other information

|                       |                   |
|-----------------------|-------------------|
| <b>Liquid Density</b> | No data available |
| <b>Bulk density</b>   | No data available |

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

**Reactivity** No data available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

### Explosion data

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

**Hazardous polymerization** Will not occur.

### 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on toxicological effects

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

**Short term** May be harmful if swallowed 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:** The most commonly reported adverse effects seen with the use of hydroxyzine include drowsiness, somnolence, headache, weakness, depression, and irritability.

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

#### Hydroxyzine pamoate

Rat Oral LD50 1740 mg/kg

#### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

#### Magnesium Stearate

Rat Oral LD50 > 2000 mg/kg

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Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

## Sucrose

Rat Oral LD 50 29,700 mg/kg

| Chemical Name         | Oral LD50             | Dermal LD50            | Inhalation LC50                      |
|-----------------------|-----------------------|------------------------|--------------------------------------|
| Sucrose               | = 29700 mg/kg ( Rat ) | -                      | -                                    |
| Sodium lauryl sulfate | = 1288 mg/kg ( Rat )  | = 200 mg/kg ( Rabbit ) | > 3900 mg/m <sup>3</sup> ( Rat ) 1 h |

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

### Sodium lauryl sulfate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild Moderate

Skin Sensitization - GPMT Guinea Pig Negative

Skin Sensitization - LLNA Mouse Negative

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

### Magnesium Stearate

13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

## Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Teratogenicity

Hydroxyzine when administered to the pregnant mouse, rat, and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic range. Hydroxyzine has been associated with teratogenesis in beagle puppies. In pregnant monkeys (one per dose group), oral doses of 6, 8, and 12 mg/kg resulted in abortion in all three pregnancies. However, dosing at 5 or 10 mg/kg did not produce abortions, nor were any gross malformations seen in offspring.

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

### Sodium lauryl sulfate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

### Carcinogenicity

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

### 12.1. Toxicity

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Sodium lauryl sulfate

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 hours 3.6 mg/l

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

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## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

| Chemical Name         | PBT and vPvB assessment         |
|-----------------------|---------------------------------|
| Sodium lauryl sulfate | The substance is not PBT / vPvB |

## 12.6. Other adverse effects

**Other adverse effects** No information available.

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. 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.

## **Section 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.

## **Section 15: REGULATORY INFORMATION**

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

|   |  |            |
|---|--|------------|
| Hydroxyzine pamoate                         |  |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> |  | Not Listed |
| <b>California Proposition 65</b>            |  | Not Listed |
| <b>EINECS</b>                               |  | 233-582-1  |
| <b>AICS</b>                                 |  | Present    |
| Sucrose                                     |  |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> |  | Not Listed |
| <b>California Proposition 65</b>            |  | Not Listed |
| <b>TSCA</b>                                 |  | Present    |
| <b>EINECS</b>                               |  | 200-334-9  |
| <b>AICS</b>                                 |  | Present    |
| Starch                                      |  |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> |  | Not Listed |



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|   |            |
|---|------------|
| <b>California Proposition 65</b>            | Not Listed |
| <b>TSCA</b>                                 | Present    |
| <b>EINECS</b>                               | 232-679-6  |
| <b>AICS</b>                                 | Present    |
| Sodium lauryl sulfate                       |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>TSCA</b>                                 | Present    |
| <b>EINECS</b>                               | 205-788-1  |
| <b>AICS</b>                                 | Present    |
| Magnesium Stearate                          |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>TSCA</b>                                 | Present    |
| <b>EINECS</b>                               | 209-150-3  |
| <b>AICS</b>                                 | Present    |
| Hard gelatin capsules                       |            |
| <b>CERCLA/SARA Section 313 de minimus %</b> | Not Listed |
| <b>California Proposition 65</b>            | Not Listed |
| <b>EINECS</b>                               | Not Listed |

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under section 3**

Acute toxicity, oral-Cat.4;  
H302 - Harmful if swallowed  
Reproductive toxicity-Cat.2;  
H361d - Suspected of damaging the unborn child

**Prepared By** Product Stewardship Hazard Communication  
Global Environment, Health, and Safety Operations

**Revision date** 01-Jul-2020

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

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