

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**Product Identifier****Material Name:** Triazolam Tablets (Greenstone LLC)**Trade Name:** Not applicable**Chemical Family:** Mixture**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against****Intended Use:** Pharmaceutical product used for insomnia**Details of the Supplier of the Safety Data Sheet**Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095**Emergency telephone number:**
CHEMTREC (24 hours): 1-800-424-9300**2. HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****GHS - Classification**

Reproductive Toxicity: Category 1B : Effects on or via lactation

Label Elements**Signal Word:** Danger**Hazard Statements:** H360D - May damage the unborn child
H362 - May cause harm to breast-fed children**Precautionary Statements:** P201 - Obtain special instructions before use
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up**Other Hazards**

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

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|----------------------------|------------|-----------------------|---------------------------------|---------|
| Triazolam | 28911-01-5 | 249-307-3 | Lact. (H362) Repr.1B (H360D) | 0.1 - 1 |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | * |
| Corn Starch | 9005-25-8 | 232-679-6 | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | * |
| Silicon dioxide, NF | 7631-86-9 | 231-545-4 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|-----------------|------------|-----------------------|--------------------|---|
| Lactose | 63-42-3 | 200-559-2 | Not Listed | * |
| Docusate Sodium | 577-11-7 | 209-406-4 | Not Listed | * |
| Sodium benzoate | 532-32-1 | 208-534-8 | 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 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

5. FIRE FIGHTING MEASURES

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

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Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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. 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 at controlled room temperature.

Specific end use(s): Pharmaceutical product used for insomnia

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Triazolam

Manufacturer OEL: 0.8ug/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³

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| | |
|--|-----------------------|
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf Listed |
| Slovakia OEL - TWA | 4.0 mg/m ³ |
| Slovenia OEL - TWA | 0.3 mg/m ³ |

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). 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.

Hands:

Impervious disposable gloves (e.g. Nitrile, etc.) (double 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.)

Eyes:

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.)

Skin:

Impervious disposable 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.)

Respiratory protection:

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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|---------------------------|--------------------|--------------------------|--------------------|
| Physical State: | Tablet | Color: | White blue |
| 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)

Triazolam

Predicted 7.4 Log D 8.175

Lactose

No data available

Microcrystalline cellulose

No data available

Silicon dioxide, NF

No data available

Docosate Sodium

No data available

Sodium benzoate

No data available

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9. PHYSICAL AND CHEMICAL PROPERTIES

Magnesium stearate

No data available

Corn Starch

No data available

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

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

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.

Long Term: Animal studies indicate that this material may cause adverse effects on the heart liver, lungs, central nervous system.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include fatigue, clumsy motion of limbs/trunk (ataxia), state of intense good feeling (euphoria), incoordination. Other less common effects include hallucinations, delirium, amnesia, addiction, impairment of motor and cognitive skills. The effects are reversible in nature. All observed adverse effects were consistent with the sedative action of this compound. Secreted in human breast milk.

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

Triazolam

Rat Oral LD 50 >5000 mg/kg

Mouse Oral LD 50 > 5,000mg/kg

Rat Intraperitoneal LD 50 >5,000mg/kg

Mouse Intraperitoneal LD 50 1,625mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

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11. TOXICOLOGICAL INFORMATION

Rabbit Dermal LD50 > 2000 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

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)

Triazolam

Eye Irritation Rabbit Mild
Skin Irritation Rabbit No effect

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

Triazolam

1 Year(s) Dog Oral 3 mg/kg/day LOAEL Central nervous system, Liver
1 Year(s) Rat Oral 1 mg/kg/day NOAEL Liver, Lungs, Heart
2 Year(s) Rat Oral 0.5 mg/kg/day NOAEL None identified
3 Month(s) Dog Oral 100 mg/kg/day LOAEL Central Nervous System, Liver
3 Month(s) Rat Oral 300 mg/kg/day LOAEL Central Nervous System

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

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

Triazolam

Embryo / Fetal Development Rat Oral 30 mg/kg/day NOAEL Not teratogenic
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 5 mg/kg/day LOAEL Not Teratogenic, Fetotoxicity

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

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

Triazolam

Bacterial Mutagenicity (Ames) Bacteria Negative
Direct DNA Damage Not specified Negative

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11. TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Triazolam

| | | | | | |
|-----------|-------|---------------|-----|-------|------------------|
| 2 Year(s) | Mouse | Oral, in feed | 80 | NOAEL | Not carcinogenic |
| 2 Year(s) | Rat | Oral, in feed | 100 | NOAEL | Not carcinogenic |

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Silicon dioxide, NF

IARC: Group 3 (Not Classifiable)
NTP: Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation 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)

Triazolam

Predicted 7.4 Log D 8.175

Mobility in Soil: No data available

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.

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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

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.



Triazolam

| | |
|---|--|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | developmental toxicity 4/1/1990 |
| U.S. Drug Enforcement Administration: Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule IV Controlled Substance Schedule 4 |
| EU EINECS/ELINCS List | 249-307-3 |

Lactose

| | |
|--|------------|
| 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 | 200-559-2 |

Microcrystalline cellulose

| | |
|--|------------|
| 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 | 232-674-9 |

Docusate Sodium

| | |
|--|------------|
| 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 | 209-406-4 |

Sodium benzoate

| | |
|--|------------|
| 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 |
| EU EINECS/ELINCS List | 208-534-8 |
| Corn Starch | |
| 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 | 232-679-6 |
| Magnesium 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 | 209-150-3 |
| Silicon dioxide, NF | |
| 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 | 231-545-4 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 10-Jan-2017
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