

**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

**EU Classification:**

EU Indication of danger: Toxic to Reproduction: Category 2

**EU Risk Phrases:**

R61 - May cause harm to the unborn child.

R64 - May cause harm to breastfed babies.

**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**

No data available

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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	%
Triazolam	28911-01-5	249-307-3	R64 Repr. Cat.2;R61	Lact. (H362) Repr.1B (H360D)	0.1 - 1
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Silicon dioxide, NF	7631-86-9	231-545-4	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Corn Starch	9005-25-8	232-679-6	Not Listed	Not Listed	*

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

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### 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.

### 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/m<sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Estonia OEL - TWA 10 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
4 mg/m<sup>3</sup>  
Latvia OEL - TWA 2 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 mg/m<sup>3</sup>  
Romania OEL - TWA 10 mg/m<sup>3</sup>  
Spain OEL - TWA 10 mg/m<sup>3</sup>

#### Silicon dioxide, NF

Australia TWA 2 mg/m<sup>3</sup>  
Austria OEL - MAKs 4 mg/m<sup>3</sup>  
0.3 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 0.1 mg/m<sup>3</sup>  
4.0 mg/m<sup>3</sup>  
Estonia OEL - TWA 2 mg/m<sup>3</sup>  
Finland OEL - TWA 5 mg/m<sup>3</sup>  
Germany - TRGS 900 - TWAs 4 mg/m<sup>3</sup>  
Germany (DFG) - MAK 4 mg/m<sup>3</sup>  
Ireland OEL - TWAs 6 mg/m<sup>3</sup>  
2.4 mg/m<sup>3</sup>  
Latvia OEL - TWA 1 mg/m<sup>3</sup>  
OSHA - Final PELs - Table Z-3 Mineral D:  
Listed  
Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

#### Magnesium stearate

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

#### Corn Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>  
Australia TWA 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 4.0 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
5 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
4 mg/m<sup>3</sup>

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OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

### 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:	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

#### Docusate Sodium

No data available

#### Sodium benzoate

No data available

#### 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

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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
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/m <sup>3</sup>

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### 11. TOXICOLOGICAL INFORMATION

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

##### Triazolam

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

#### 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

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### 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.

### 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.





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### 15. REGULATORY INFORMATION

#### Triazolam

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	developmental toxicity initial date 4/1/90
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
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

#### 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

#### 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
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

#### Magnesium stearate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

#### 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

### 16. OTHER INFORMATION

#### Text of R phrases and 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

Toxic to Reproduction: Category 2

R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.

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

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

**Revision date:** 03-Apr-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**