

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078881747

N/A



# MATERIAL SAFETY DATA SHEET

Revision date: 30-Jul-2009

Version: 1.0

Page 1 of 8

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

Emergency telephone number:  
800-435-7095

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-262-8200

### Material Name: Mirtazapine Tablets

Trade Name:	Not applicable
Synonyms:	None
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product used as, antidepressant

## 2. HAZARDS IDENTIFICATION

Appearance: Tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

Short Term:	Active ingredient may be harmful if swallowed.
Long Term:	May be harmful to aquatic organisms. May have long-term effects on the aquatic environment.
Known Clinical Effects:	May cause adverse effects on the developing fetus. Ingestion of this material may cause effects similar to those seen in clinical use including drowsiness, dry mouth, nausea, diarrhea, constipation, weakness, insomnia, suicidal behavior, and sexual disturbances.

EU Indication of danger: Not classified

### EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

### Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

PZ01022

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 2 of 8  
Version: 1.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Mirtazapine	85650-52-8	288-060-6	Xn;R22 N;R51-53	7, 15, 30 or 45 mg***
Maize starch	9005-25-8	232-679-6	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose Monohydrate	64044-51-5	Not listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

#### Additional Information:

\* Proprietary

\*\*\* per tablet/capsule/lozenge/suppository

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<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.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of the spill or leak. Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 3 of 8  
Version: 1.0

**Measures for Environmental  
Protections:**

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

**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

**General Handling:**

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

**Storage Conditions:**

Store as directed by product packaging.

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 4 of 8  
Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

#### Maize starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

#### Colloidal silicon dioxide

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup> MAK
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(% SiO <sub>2</sub> ) mg/m <sup>3</sup> TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### 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.

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 5 of 8  
Version: 1.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Partition Coefficient (Calculated - Log Pow/Log Kow):	3.09 (Mirtazapine)		
Polymerization:	Will not occur		

### 10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
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

### 11. TOXICOLOGICAL INFORMATION

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

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

##### **Magnesium stearate**

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m <sup>3</sup>

##### **Lactose Monohydrate**

Rat	Oral	LD 50	29700 mg/kg
-----	------	-------	-------------

##### **Mirtazapine**

Rat (F)	Oral	LD50	320 mg/kg
Rat (M)	Oral	LD50	490 mg/kg

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

##### **Mirtazapine**

Embryo / Fetal Development mortality	Rat	No route specified	100 mg/kg/day	NOAEL	Not teratogenic, Embryotoxicity, Postnatal
Embryo / Fetal Development mortality	Rabbit	No route specified	40 mg/kg/day	NOAEL	Not Teratogenic, Embryotoxicity, Neonatal

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

##### **Lactose Monohydrate**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Negative
---	----------

##### **Mirtazapine**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Not specified	Negative
---	---------------	----------

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 6 of 8  
Version: 1.0

### 11. TOXICOLOGICAL INFORMATION

*In Vitro* Mammalian Cell Mutagenicity Hamster Negative  
*In Vitro* Sister Chromatid Exchange Rabbit Lymphocytes Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative

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

**Colloidal silicon dioxide**  
**IARC:** Group 3

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The following information is available for the individual ingredients. Releases to the environment should be avoided.

**Mobility, Persistence and Degradability:** Not readily biodegradable (Mirtazapine)

**Partition Coefficient** 3.09 (Mirtazapine)  
**(Calculated - Log Pow/Log Kow):**

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

#### Mirtazapine

*Pimephales promelas* (Fathead Minnow) LC50 96 Hours 6.92 mg/L

*Daphnia magna* (Water Flea) EC50 48 Hours 19.9 mg/L

*Daphnia Magna* (Water Flea) NOEC 21 Days 0.24 mg/L

**Aquatic Toxicity Comments:** The (21) day (Daphnia) study above is a reproductive/survival study.

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** 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

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

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**EU Risk Phrases:**

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EU Safety Phrases:**

S22 - Do not breathe dust.  
S57 - Use appropriate containment to avoid environmental contamination.

## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 7 of 8  
Version: 1.0

### 15. REGULATORY INFORMATION

#### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 1, Subdivision B



#### Mirtazapine

EU EINECS/ELINCS List	288-060-6
-----------------------	-----------

#### Lactose Monohydrate

Australia (AICS):	Listed
-------------------	--------

#### Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Water

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Maize starch

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

#### Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

#### Magnesium stearate

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



## MATERIAL SAFETY DATA SHEET

Material Name: Mirtazapine Tablets  
Revision date: 30-Jul-2009

Page 8 of 8  
Version: 1.0

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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**