



# SAFETY DATA SHEET

Revision date: 05-May-2015

Version: 2.0

Page 1 of 10

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

### Product Identifier

**Material Name:** Nifedipine Capsules (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 for the treatment of high blood pressure (hypertension) angina

### 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** Not classified as hazardous

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

No data available

### Australian Hazard Classification (NOHSC):

Non-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 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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Nifedipine	21829-25-4	244-598-3	Xn;R22	Acute tox.4 (H302)	2.6
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 2 of 10  
Version: 2.0

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Polyethylene glycol 400	25322-68-3	Not Listed	Not Listed	Not Listed	*
Sodium saccharin USP	128-44-9	204-886-1	Not Listed	Not Listed	**
Peppermint oil	8006-90-4	Not Listed	Not Listed	Not Listed	*

### Additional Information:

\* Proprietary

\*\*Sodium saccharin is contained in solution for 10 mg capsules only.

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

None known

#### Aggravated by Exposure:

### Indication of the Immediate Medical Attention and Special Treatment Needed

#### Notes to Physician:

None

## 5. FIRE FIGHTING MEASURES

### Extinguishing Media:

Use carbon dioxide, dry chemical, or water spray.

### Special Hazards Arising from the Substance or Mixture

#### Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire.

#### Fire / Explosion Hazards:

Not applicable

### 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

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 3 of 10  
Version: 2.0

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). 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 product

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 4 of 10  
Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Nifedipine

Manufacturer OEL: 300ug/m<sup>3</sup>

#### Polyethylene glycol 400

Austria OEL - MAKs 1000 mg/m<sup>3</sup>  
Germany - TRGS 900 - TWAs 1000 mg/m<sup>3</sup>  
Germany (DFG) - MAK 1000 mg/m<sup>3</sup> average molecular weight 200-600  
Slovakia OEL - TWA 1000 mg/m<sup>3</sup>  
Slovenia OEL - TWA 1000 mg/m<sup>3</sup>

#### Glycerin, USP

Australia TWA 10 mg/m<sup>3</sup>  
Belgium OEL - TWA 10 mg/m<sup>3</sup>  
Czech Republic OEL - TWA 10 mg/m<sup>3</sup>  
Estonia OEL - TWA 10 mg/m<sup>3</sup>  
Finland OEL - TWA 20 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Germany (DFG) - MAK 50 mg/m<sup>3</sup>  
Greece OEL - TWA 10 mg/m<sup>3</sup>  
Ireland OEL - TWAs 10 mg/m<sup>3</sup>  
OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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: Soft gelatin capsule

Color: 10 mg: Orange  
20 mg: Light brown

Odor: No data available.

Odor Threshold: No data available.

Molecular Formula: Mixture

Molecular Weight: Mixture

Solvent Solubility: No data available

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 5 of 10  
Version: 2.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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)**

**Glycerin, USP**

No data available

**Peppermint oil**

No data available

**Polyethylene glycol 400**

No data available

**Sodium saccharin USP**

No data available

**Nifedipine**

Measured N/A Log P 2.20

**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

**Polymerization:** Will not occur

### 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.

**Short Term:** Antihypertensive drug: has blood pressure-lowering properties  
May cause eye and skin irritation. May be harmful if swallowed. (based on components) .  
Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Exposure to sunlight following contact may result in skin reactions.

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 6 of 10  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

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

##### Glycerin, USP

Mouse Oral LD50 4090 mg/kg  
Rat Oral LD50 12.6 g/kg  
Rabbit Dermal LD50 > 10 g/kg  
Rat Inhalation LC50 1hr > 570 mg/m<sup>3</sup>  
Rat Dermal LD 50 > 21.9 g/kg

##### Peppermint oil

Rat Oral LD 50 2426 mg/kg  
Mouse Oral LD 50 2490mg/kg

##### Sodium saccharin USP

Mouse Oral LD50 17.5 g/kg  
Rat Oral LD50 14.2 - 17g/kg

##### Nifedipine

Mouse Oral LD50 454 mg/kg  
Rat Oral LD50 1022mg/kg  
Mouse IV LD50 4.2mg/kg  
Rat IV LD50 15.5mg/kg

#### 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)

##### Glycerin, USP

Eye Irritation Rabbit Mild

##### Polyethylene glycol 400

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

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

##### Nifedipine

13 Week(s) Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose  
13 Week(s) Dog Oral 50 mg/kg/day NOAEL No effects at maximum dose  
4 Week(s) Dog Oral 125 mg/kg/day NOAEL No effects at maximum dose  
4 Week(s) Dog Intravenous 0.6 mg/kg/day NOAEL No effects at maximum dose  
1 Year(s) Dog Oral 100 mg/kg/day NOAEL No effects at maximum dose

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

##### Nifedipine

Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Reproductive toxicity, Embryotoxicity, Postnatal mortality, Maternal toxicity  
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Reproductive toxicity, Fetotoxicity, Maternal Toxicity  
Peri-/Postnatal Development Rat Oral 3 mg/kg/day NOAEL Embryotoxicity  
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity, Developmental toxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Developmental toxicity

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 7 of 10  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

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

##### Nifedipine

<i>In Vivo</i> Dominant Lethal Assay	Mouse	Negative
<i>In Vivo</i> Cytogenetics	Hamster	Negative
<i>In Vivo</i> Micronucleus	Mouse	Negative
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative

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

##### Nifedipine

2 Year(s) Rat Oral 156-210 mg/kg/day NOAEL Not carcinogenic

#### Carcinogen Status:

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

##### Sodium saccharin USP

#### IARC:

Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

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

#### Toxicity:

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

##### Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
<i>Daphnia magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L

##### Nifedipine

<i>Brachydanio rerio</i> (Zebra fish)	LC50	96 Hours	> 5.77 mg/L
<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	> 3.88 mg/L

#### Aquatic Toxicity Comments:

A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Nifedipine

Activated sludge EC50 > 10000 mg/L

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

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

##### Nifedipine

Measured N/A Log P 2.20

#### Mobility in Soil:

No data available

## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 8 of 10  
Version: 2.0

### 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:

None required

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

#### Nifedipine

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
developmental toxicity initial date 1/29/99  
female reproductive toxicity 1/29/99  
male reproductive toxicity initial date 1/29/99

Australia (AICS):  
Standard for the Uniform Scheduling  
for Drugs and Poisons:  
EU EINECS/ELINCS List

Present  
Schedule 4  
244-598-3

#### Polyethylene glycol 400

CERCLA/SARA 313 Emission reporting  
California Proposition 65  
Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
Standard for the Uniform Scheduling  
for Drugs and Poisons:

Not Listed  
Not Listed  
Present  
Present  
Schedule 3



## SAFETY DATA SHEET

Material Name: Nifedipine Capsules (Greenstone LLC)  
Revision date: 05-May-2015

Page 9 of 10  
Version: 2.0

### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
<b>Sodium saccharin USP</b>	
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	204-886-1
<b>Peppermint oil</b>	
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	Not Listed
<b>Glycerin, USP</b>	
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 V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xn - Harmful

R22 - Harmful if swallowed.

**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 7 - Handling and Storage. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date:**

05-May-2015

**Prepared by:**

Product Stewardship Hazard Communication  
Global Environment, Health, and Safety Operations

## SAFETY DATA SHEET

**Material Name: Nifedipine Capsules (Greenstone LLC)**  
**Revision date: 05-May-2015**

**Page 10 of 10**  
**Version: 2.0**

---

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**