



SAFETY DATA SHEET

Revision date: 05-May-2015

Version: 2.0

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

Product Identifier

Material Name: Nifedipine Extended Release Tablets (Greenstone LLC)

Trade Name: Not established

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

Signal Word: Not required

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)	11
Ferric oxide red	1309-37-1	215-168-2	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Cellulose Acetate	9004-70-0	Not Listed	E; R3	Expl. 1.1 (H201)	*
Opadry YS-5-7017	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*
Polyethylene oxide NF	25322-68-3	Not Listed	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

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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

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6. ACCIDENTAL RELEASE MEASURES

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 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 collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:

Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Storage Temperature:

Store as directed by product packaging.

Specific end use(s):

Pharmaceutical product

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Nifedipine

Manufacturer OEL: 300ug/m³

Ferric oxide red

ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
10 mg/m³
Austria OEL - MAKs 5 mg/m³
10 mg/m³
Belgium OEL - TWA 2 ppm
5 mg/m³
Bulgaria OEL - TWA 5.0 mg/m³
Denmark OEL - TWA 3.5 mg/m³
Estonia OEL - TWA 3.5 mg/m³
Finland OEL - TWA 5 mg/m³
France OEL - TWA 5 mg/m³
Greece OEL - TWA 10 mg/m³
Hungary OEL - TWA 6 mg/m³
Ireland OEL - TWAs 5 mg/m³
10 mg/m³
4 mg/m³
Lithuania OEL - TWA 3.5 mg/m³
OSHA - Final PELs - TWAs: 10 mg/m³
15 mg/m³
Poland OEL - TWA 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Romania OEL - TWA 5 mg/m³
Slovakia OEL - TWA 1.5 mg/m³
Spain OEL - TWA 5 mg/m³
Sweden OEL - TWAs 3.5 mg/m³

Sodium chloride

Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³

Polyethylene oxide NF

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³

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Magnesium stearate

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

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:

Rose-pink

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)

Polyethylene glycol

No data available

Cellulose Acetate

No data available

Polyethylene oxide NF

No data available

Opadry YS-5-7017

No data available

Hydroxypropyl methylcellulose

No data available

Magnesium stearate

No data available

Ferric oxide red

No data available

Nifedipine

Measured N/A Log P 2.20

Sodium chloride

No data available

Decomposition Temperature (°C):

No data available.

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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: Dust may cause irritation. May be harmful if swallowed. 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. Antihypertensive drug: has blood pressure-lowering properties.

Known Clinical Effects: Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), headache, dizziness, fatigue, drowsiness, constipation, nausea, gastrointestinal perforation, and ulceration.

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

Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

Magnesium stearate

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

Nifedipine

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

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11. TOXICOLOGICAL INFORMATION

Rat IV LD50 15.5mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/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)

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Polyethylene oxide NF

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate
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

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

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11. TOXICOLOGICAL INFORMATION

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

Ferric oxide red

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)

Nifedipine

Brachydanio rerio (Zebra fish) LC50 96 Hours > 5.77 mg/L

Daphnia magna (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

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.

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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

Cellulose Acetate

CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

Not Listed
Not Listed
Present
Present
Not Listed

Opadry YS-5-7017

CERCLA/SARA 313 Emission reporting
California Proposition 65
EU EINECS/ELINCS List

Not Listed
Not Listed
Not Listed

Ferric oxide red

CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

Not Listed
Not Listed
Present
Present
215-168-2

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15. REGULATORY INFORMATION

Sodium chloride

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	231-598-3

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

Hydroxypropyl methylcellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

Polyethylene oxide NF

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

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

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

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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 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date:

05-May-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