



# SAFETY DATA SHEET

Revision date: 20-Mar-2014

Version: 1.0

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

### Product Identifier

**Material Name: Amlodipine besylate/Atorvastatin calcium tablets-  
10 mg/10 mg (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), high cholesterol (hyperlipidemia)

### 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

Serious Eye Damage/Eye Irritation: Category 1  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2

#### EU Classification:

EU Indication of danger: Xi - Irritant  
N - Dangerous for the environment

#### EU Risk Phrases:

R41 - Risk of serious damage to eyes.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H318 - Causes serious eye damage  
H401 - Toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects

**Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P310 - Immediately call a POISON CENTRE or doctor/physician  
P273 - Avoid release to the environment  
P391 - Collect spillage  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards**  
**Australian Hazard Classification (NOHSC):**

No data available  
 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	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	13.9
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
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	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	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.

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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

<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.

#### Most Important Symptoms and Effects, Both Acute and Delayed

<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.
<b>Medical Conditions Aggravated by Exposure:</b>	None known

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

<b>Notes to Physician:</b>	None
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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

#### Special Hazards Arising from the Substance or Mixture

<b>Hazardous Combustion Products:</b>	Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds
<b>Fire / Explosion Hazards:</b>	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

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

<b>Measures for Cleaning / Collecting:</b>	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.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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

<b>Storage Conditions:</b>	Store as directed by product packaging.
<b>Specific end use(s):</b>	No data available

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Amlodipine besylate

Manufacturer OEL: 100ug/m<sup>3</sup>

#### Atorvastatin calcium

Manufacturer OEL: 50ug/m<sup>3</sup>

#### Calcium carbonate

Australia TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 6 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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>

#### 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>

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OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf  
Listed  
Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

Starch, pregelatinized  
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>  
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:** Wear impervious gloves to prevent skin contact.  
**Eyes:** Wear safety goggles as minimum protection.  
**Skin:** Wear impervious protective clothing to prevent skin contact.  
**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:** Film-coated tablets  
**Odor:** No data available.  
**Molecular Formula:** Mixture

**Color:** Blue  
**Odor Threshold:** No data available.  
**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)**

**Calcium carbonate**

No data available

**Croscarmellose sodium**

No data available

**Hydroxypropyl cellulose**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Magnesium stearate**

No data available

**Microcrystalline cellulose**

No data available

**Opadry blue**

No data available

**Opadry clear**

No data available

**Polysorbate 80**

No data available

**Silicon dioxide, NF**

No data available

**Starch, pregelatinized**

No data available

**Amlodipine besylate**

Measured 7 Log P 1.33

**Atorvastatin calcium**

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

**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:** None known

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

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

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### 11. TOXICOLOGICAL INFORMATION

**Short Term:** Can cause eye irritation. May be harmful if swallowed. (based on components)  
Antihypertensive drug: has blood pressure-lowering properties

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

##### **Calcium carbonate**

Rat Oral LD50 6450 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Amlodipine besylate**

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686mg/kg

##### **Atorvastatin calcium**

Rat/Mouse Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/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)

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

##### **Amlodipine besylate**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

##### **Atorvastatin calcium**

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Mild



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### 11. TOXICOLOGICAL INFORMATION

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

##### **Amlodipine besylate**

3 Month(s)	Rat	Oral	3 mg/kg/day	NOAEL	Adrenal gland, Heart
1 Month(s)	Rat	Oral	3.5 mg/kg/day	LOEL	Heart
1 Year(s)	Rat	Oral	2 mg/kg/day	NOAEL	Adrenal gland, Heart

##### **Atorvastatin calcium**

104 Week(s)	Dog	Oral	10 mg/kg/day	LOAEL	Liver
13 Week(s)	Mouse	Oral	100 mg/kg/day	LOAEL	Liver
52 Week(s)	Rat	Oral	5 mg/kg/day	NOAEL	Liver
13 Week(s)	Rat	Oral	5 (male); 20 (female) mg/kg/day	NOAEL	Liver

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

##### **Amlodipine besylate**

Fertility and Embryonic Development	Rat	Oral	25 mg/kg/day	NOAEL	Not teratogenic, Maternal toxicity
Peri-/Postnatal Development	Rat	Oral	4 mg/kg/day	NOAEL	Fetotoxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	25 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rabbit	Oral	25 mg/kg/day	NOAEL	Not Teratogenic

##### **Atorvastatin calcium**

Reproductive & Fertility	Rat	Oral	20 mg/kg/day	NOAEL	Negative
Fertility and Embryonic Development	Rat	Oral	100 mg/kg/day	NOAEL	Negative
Embryo / Fetal Development	Rat	Oral	100 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity
Embryo / Fetal Development	Rabbit	Oral	10 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity, Fetotoxicity
Peri-/Postnatal Development	Rat	Oral	20 mg/kg/day	NOAEL	Fetotoxicity

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

##### **Amlodipine besylate**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Cytogenetics	Mouse Bone Marrow	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative

##### **Atorvastatin calcium**

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

##### **Mutagenicity**

Amlodipine showed No evidence of mutagenic activity in bacterial or mammalian cells in vitro, or clastogenic activity in vitro or in vivo. Atorvastatin showed No evidence of mutagenic or clastogenic activity in in vitro or in vivo tests.

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

##### **Amlodipine besylate**

24 Month(s)	Rat	Oral, in feed	2.5 mg/kg/day	NOAEL	Not carcinogenic, No effects at maximum dose
24 Month(s)	Mouse	Oral, in feed	0.5 mg/kg/day	NOAEL	Not carcinogenic

##### **Atorvastatin calcium**

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### 11. TOXICOLOGICAL INFORMATION

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic  
104 Week(s) Rat Oral 100 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.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This formulation has not been tested as a whole, the following apply to component substance(s): Harmful effects to aquatic organisms could occur.

#### Toxicity:

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

##### Amlodipine besylate

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 9.9 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 14 mg/L  
Green algae OECD EbC50 72 Hours 0.28 mg/L  
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

##### Atorvastatin calcium

*Daphnia magna* (Water Flea) EC50 48 Hours 200 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EbC50 72 Hours 75 mg/L  
*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.14 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

##### Amlodipine besylate

*Nostoc sp.* (Freshwater Cyanobacteria) MIC 20 mg/L  
*Aspergillus Niger* MIC > 100 mg/L  
*Trichoderma viride* MIC > 100 mg/L  
*Clostridium perfringens* MIC >100 mg/L  
*Bacillus subtilis* MIC 80 mg/L

##### Atorvastatin calcium

*Aspergillus niger* (Fungus) MIC > 1000 mg/L  
*Trichoderma viride* (Fungus) MIC > 1000 mg/L  
*Clostridium perfringens* (Bacterium) MIC 100 mg/L  
Activated sludge OECD EC50 >1000 mg/L

**Persistence and Degradability:** No data available

##### Amlodipine besylate

OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready

##### Atorvastatin calcium

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TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
**Atorvastatin calcium**  
OECD 7 Half-Life 0.339 Day(s)

**Bio-accumulative Potential:** No data available

**Amlodipine besylate**  
Measured 7 Log P 1.33

**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 B



Amlodipine besylate

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CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Atorvastatin calcium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Calcium carbonate</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	207-439-9
<b>Croscarmellose sodium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Hydroxypropyl cellulose</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>Magnesium stearate</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	209-150-3
<b>Microcrystalline cellulose</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	232-674-9
<b>Opadry blue</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Opadry clear</b>	
CERCLA/SARA 313 Emission reporting	Not Listed

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California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 80

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

#### 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

#### Starch, pregelatinized

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

Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Xi - Irritant  
N - Dangerous for the environment  
Xn - Harmful

R22 - Harmful if swallowed.  
R41 - Risk of serious damage to eyes.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Revision date:** 20-Mar-2014

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/Atorvastatin calcium  
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**Prepared by:** Product Stewardship Hazard Communication  
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**



# SAFETY DATA SHEET

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

### Product Identifier

**Material Name: Amlodipine besylate/Atorvastatin calcium tablets-  
2.5 mg/10 mg, 5 mg/20 mg and 10 mg/40 mg (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), high cholesterol (hyperlipidemia)

### 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

Serious Eye Damage/Eye Irritation: Category 1  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2

#### EU Classification:

EU Indication of danger: Dangerous for the Environment

#### EU Risk Phrases:

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

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H318 - Causes serious eye damage  
H401 - Toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects

**Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P310 - Immediately call a POISON CENTRE or doctor/physician  
P391 - Collect spillage  
P273 - Avoid release to the environment  
P501 - Dispose of contents/container in accordance with all local and national regulations

## SAFETY DATA SHEET

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**Other Hazards**

No data available

**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 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	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	3.47
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
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	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*



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**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:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**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

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**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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Amlodipine besylate

Manufacturer OEL: 100ug/m<sup>3</sup>

#### Atorvastatin calcium

Manufacturer OEL: 50ug/m<sup>3</sup>

#### Calcium carbonate

Australia TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 6 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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>

#### 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>

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OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf  
Listed  
Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

Starch, pregelatinized  
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>  
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:** Wear impervious gloves to prevent skin contact.  
**Eyes:** Wear safety glasses as minimum protection (goggles recommended).  
**Skin:** Wear impervious protective clothing to prevent skin contact.  
**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:** Blue or White  
**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)**

**Calcium carbonate**

No data available

**Croscarmellose sodium**

No data available

**Hydroxypropyl cellulose**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Magnesium stearate**

No data available

**Microcrystalline cellulose**

No data available

**Opadry blue**

No data available

**Opadry clear**

No data available

**Opadry white**

No data available

**Polysorbate 80**

No data available

**Silicon dioxide, NF**

No data available

**Starch, pregelatinized**

No data available

**Amlodipine besylate**

Measured 7 Log P 1.33

**Atorvastatin calcium**

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

**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**

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### 11. TOXICOLOGICAL INFORMATION

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

**Short Term:** May cause eye irritation May be harmful if swallowed. (based on components)  
Antihypertensive drug: has blood pressure-lowering properties

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver

**Known Clinical Effects:** Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

##### Calcium carbonate

Rat Oral LD50 6450 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### Polysorbate 80

Rat Oral LD50 25 g/kg

##### Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686mg/kg

##### Atorvastatin calcium

Rat/Mouse Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

##### Amlodipine besylate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

##### Atorvastatin calcium

Skin Sensitization - Beuhler Guinea Pig Negative

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### 11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Mild

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

##### **Amlodipine besylate**

3 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart  
1 Month(s) Rat Oral 3.5 mg/kg/day LOEL Heart  
1 Year(s) Rat Oral 2 mg/kg/day NOAEL Adrenal gland, Heart

##### **Atorvastatin calcium**

104 Week(s) Dog Oral 10 mg/kg/day LOAEL Liver  
13 Week(s) Mouse Oral 100 mg/kg/day LOAEL Liver  
52 Week(s) Rat Oral 5 mg/kg/day NOAEL Liver  
13 Week(s) Rat Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

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

##### **Amlodipine besylate**

Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity  
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Fetotoxicity, Fetal mortality  
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic  
Prenatal & Postnatal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

##### **Atorvastatin calcium**

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative  
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Negative  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity  
Peri-/Postnatal Development Rat Oral 20 mg/kg/day NOAEL Fetotoxicity

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

##### **Amlodipine besylate**

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Cytogenetics Mouse Bone Marrow Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative

##### **Atorvastatin calcium**

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative

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

##### **Amlodipine besylate**

24 Month(s) Rat Oral, in feed 2.5 mg/kg/day NOAEL Not carcinogenic, No effects at maximum dose  
24 Month(s) Mouse Oral, in feed 0.5 mg/kg/day NOAEL Not carcinogenic

##### **Atorvastatin calcium**

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic  
104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

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### 11. TOXICOLOGICAL INFORMATION

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This formulation has not been tested as a whole, the following apply to component substance(s):

#### Toxicity:

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

##### Amlodipine besylate

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 9.9 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 14 mg/L  
Green algae OECD EbC50 72 Hours 0.28 mg/L  
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

##### Atorvastatin calcium

*Daphnia magna* (Water Flea) EC50 48 Hours 200 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EbC50 72 Hours 75 mg/L  
*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.14 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

##### Amlodipine besylate

*Nostoc sp.* (Freshwater Cyanobacteria) MIC 20 mg/L  
*Aspergillus Niger* MIC > 100 mg/L  
*Trichoderma viride* MIC > 100 mg/L  
*Clostridium perfringens* MIC >100 mg/L  
*Bacillus subtilis* MIC 80 mg/L

##### Atorvastatin calcium

*Aspergillus niger* (Fungus) MIC > 1000 mg/L  
*Trichoderma viride* (Fungus) MIC > 1000 mg/L  
*Clostridium perfringens* (Bacterium) MIC 100 mg/L  
Activated sludge OECD EC50 >1000 mg/L

**Persistence and Degradability:** No data available

##### Amlodipine besylate

OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready

##### Atorvastatin calcium

TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready

OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready



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### Atorvastatin calcium

OECD 7 Half-Life 0.339 Day(s)

**Bio-accumulative Potential:** No data available

### Amlodipine besylate

Measured 7 Log P 1.33

**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 B



### Amlodipine besylate

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
Not Listed

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**15. REGULATORY INFORMATION**

EU EINECS/ELINCS List	Not Listed
<b>Atorvastatin calcium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Calcium carbonate</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	207-439-9
<b>Croscarmellose sodium</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Hydroxypropyl cellulose</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>Magnesium stearate</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	209-150-3
<b>Microcrystalline cellulose</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	232-674-9
<b>Opadry blue</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Opadry clear</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/Atorvastatin calcium tablets-  
2.5 mg/10 mg, 5 mg/20 mg and 10 mg/40 mg (Greenstone LLC)  
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### 15. REGULATORY INFORMATION

#### Opadry white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 80

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

#### 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

#### Starch, pregelatinized

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful  
Xi - Irritant  
N - Dangerous for the environment

R22 - Harmful if swallowed.  
R41 - Risk of serious damage to eyes.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/Atorvastatin calcium  
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**Prepared by:** Product Stewardship Hazard Communication  
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**

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING****Product Identifier**

**Material Name:** Amlodipine besylate/atorvastatin calcium tablets-  
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (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), high cholesterol (hyperlipidemia)

**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**

Serious Eye Damage/Eye Irritation: Category 2A

**EU Classification:**

EU Indication of danger: Dangerous for the Environment

**EU Risk Phrases:**

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

**Label Elements**

**Signal Word:** Warning  
**Hazard Statements:** H319 - Causes serious eye irritation

**Precautionary Statements:** P264 - Wash hands thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P337 + P313 - If eye irritation persists: Get medical advice/attention



**Other Hazards** No data available

## SAFETY DATA SHEET

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**Australian Hazard Classification (NOHSC):** Non-Dangerous Goods. Hazardous Substance.

**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	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	1.74
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
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	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	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 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.

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**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.

### 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 determined

### 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

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### 7. HANDLING AND STORAGE

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. 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.

#### Conditions for Safe Storage, Including any Incompatibilities

<b>Storage Conditions:</b>	Store as directed by product packaging.
<b>Specific end use(s):</b>	No data available



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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Amlodipine besylate

Manufacturer OEL: 100ug/m<sup>3</sup>

#### Atorvastatin calcium

Manufacturer OEL: 50ug/m<sup>3</sup>

#### Calcium carbonate

Australia TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 6 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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>

#### 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>

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OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf  
Listed  
Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

Starch, pregelatinized  
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>  
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:** Film-coated tablets  
**Odor:** No data available.  
**Molecular Formula:** Mixture

**Color:** White or Blue  
**Odor Threshold:** No data available.  
**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)

##### Atorvastatin calcium

No data available

##### Calcium carbonate

No data available

## SAFETY DATA SHEET

Material Name: Amlodipine besylate/atorvastatin calcium  
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Microcrystalline cellulose

No data available

#### Starch, pregelatinized

No data available

#### Croscarmellose sodium

No data available

#### Hydroxypropyl cellulose

No data available

#### Magnesium stearate

No data available

#### Silicon dioxide, NF

No data available

#### Polysorbate 80

No data available

#### Opadry blue

No data available

#### Opadry white

No data available

#### Opadry clear

No data available

#### Amlodipine besylate

Measured 7 Log P 1.33

**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

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/atorvastatin calcium tablets-  
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### 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:

May cause eye irritation May be harmful if swallowed. (based on components)  
Antihypertensive drug: has blood pressure-lowering properties

##### Long Term:

##### Known Clinical Effects:

Repeat-dose studies in animals have shown a potential to cause adverse effects on liver  
Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

##### Atorvastatin calcium

Rat/Mouse Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000mg/kg

##### Calcium carbonate

Rat Oral LD50 6450 mg/kg

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

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

##### Polysorbate 80

Rat Oral LD50 25 g/kg

##### Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg  
Rat (F) Oral LD50 686mg/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)

##### Atorvastatin calcium

Skin Sensitization - Beuhler Guinea Pig Negative  
Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Mild

##### Microcrystalline cellulose

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

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/atorvastatin calcium tablets-  
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### 11. TOXICOLOGICAL INFORMATION

#### Amlodipine besylate

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Negative

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

##### Atorvastatin calcium

104 Week(s) Dog Oral 10 mg/kg/day LOEL Liver  
13 Week(s) Mouse Oral 100 mg/kg/day LOEL Liver  
52 Week(s) Rat Oral 5 mg/kg/day NOAEL Liver  
13 Week(s) Rat Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

##### Amlodipine besylate

3 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart  
1 Month(s) Rat Oral 3.5 mg/kg/day LOEL Heart  
1 Year(s) Rat Oral 2 mg/kg/day NOAEL Adrenal gland, Heart

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

##### Atorvastatin calcium

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative  
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Negative  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity  
Peri-/Postnatal Development Rat Oral 20 mg/kg/day NOAEL Fetotoxicity

##### Amlodipine besylate

Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity  
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Fetotoxicity, Fetal mortality  
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic  
Prenatal & Postnatal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

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

##### Atorvastatin calcium

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative

##### Amlodipine besylate

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Cytogenetics Mouse Bone Marrow Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative

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

##### Atorvastatin calcium

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic  
104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/atorvastatin calcium tablets-  
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### 11. TOXICOLOGICAL INFORMATION

#### Amlodipine besylate

24 Month(s) Rat Oral, in feed 2.5 mg/kg/day NOAEL Not carcinogenic, No effects at maximum dose  
24 Month(s) Mouse Oral, in feed 0.5 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.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This formulation has not been tested as a whole, the following apply to component substance(s):

#### Toxicity:

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

##### Atorvastatin calcium

*Daphnia magna* (Water Flea) EC50 48 Hours 200 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EbC50 72 Hours 75 mg/L  
*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.14 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

##### Amlodipine besylate

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 9.9 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 14 mg/L  
Green algae OECD EbC50 72 Hours 0.28 mg/L  
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

##### Atorvastatin calcium

*Aspergillus niger* (Fungus) MIC > 1000 mg/L  
*Trichoderma viride* (Fungus) MIC > 1000 mg/L  
*Clostridium perfringens* (Bacterium) MIC 100 mg/L  
Activated sludge OECD EC50 >1000 mg/L

##### Amlodipine besylate

*Nostoc sp.* (Freshwater Cyanobacteria) MIC 20 mg/L  
*Aspergillus Niger* MIC > 100 mg/L  
*Trichoderma viride* MIC > 100 mg/L  
*Clostridium perfringens* MIC >100 mg/L  
*Bacillus subtilis* MIC 80 mg/L

**Persistence and Degradability:** No data available

##### Atorvastatin calcium

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TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
**Amlodipine besylate**  
OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready  
**Atorvastatin calcium**  
OECD 7 Half-Life 0.339 Day(s)

**Bio-accumulative Potential:** No data available  
**Amlodipine besylate**  
Measured 7 Log P 1.33

**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 B



## SAFETY DATA SHEET

Material Name: Amlodipine besylate/atorvastatin calcium  
tablets-  
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)  
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### 15. REGULATORY INFORMATION

#### Amlodipine besylate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Atorvastatin calcium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Calcium carbonate

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	207-439-9

#### Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Hydroxypropyl 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	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

#### 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

#### Opadry blue

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed



## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/atorvastatin calcium tablets-  
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)  
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### 15. REGULATORY INFORMATION

#### Opadry clear

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Opadry white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 80

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

#### 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

#### Starch, pregelatinized

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

N - Dangerous for the environment  
Xi - Irritant  
Xn - Harmful

## SAFETY DATA SHEET

**Material Name:** Amlodipine besylate/atorvastatin calcium  
tablets-  
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)  
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R22 - Harmful if swallowed.

R41 - Risk of serious damage to eyes.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Revision date:** 21-Mar-2014  
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**



# SAFETY DATA SHEET

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

### Product Identifier

**Material Name: AMLODIPINE BESYLATE-ATORVASTATIN CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (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) high cholesterol (hyperlipidemia)

### 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: Dangerous for the Environment

### EU Risk Phrases:

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

### Label Elements

### Other Hazards

No data available

### Australian Hazard Classification (NOHSC):

Non-Dangerous Goods. Hazardous Substance.

### 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

PZ02331

## SAFETY DATA SHEET

Material Name: **AMLODIPINE BESYLATE-ATORVASTATIN  
CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone  
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	0.87
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
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	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	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 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**

## SAFETY DATA SHEET

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**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 CO<sub>2</sub>, extinguishing powder, foam, or water.

### 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 determined

### 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 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

## SAFETY DATA SHEET

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Amlodipine besylate

Manufacturer OEL: 100ug/m<sup>3</sup>

#### Atorvastatin calcium

Manufacturer OEL: 50ug/m<sup>3</sup>

#### Calcium carbonate

Australia TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 6 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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>

#### 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>

## SAFETY DATA SHEET

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OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf  
Listed  
Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

Starch, pregelatinized  
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>  
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

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Atorvastatin calcium</b>			
No data available			
<b>Calcium carbonate</b>			
No data available			

## SAFETY DATA SHEET

Material Name: AMLODIPINE BESYLATE-ATORVASTATIN  
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Microcrystalline cellulose**

No data available

**Starch, pregelatinized**

No data available

**Croscarmellose sodium**

No data available

**Hydroxypropyl cellulose**

No data available

**Magnesium stearate**

No data available

**Silicon dioxide, NF**

No data available

**Polysorbate 80**

No data available

**Opadry blue**

No data available

**Opadry white**

No data available

**Opadry clear**

No data available

**Amlodipine besylate**

Measured 7 Log P 1.33

**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



## SAFETY DATA SHEET

Material Name: AMLODIPINE BESYLATE-ATORVASTATIN  
CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone  
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### 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:

May cause eye irritation May be harmful if swallowed. (based on components)  
Antihypertensive drug: has blood pressure-lowering properties

##### Long Term:

##### Known Clinical Effects:

Repeat-dose studies in animals have shown a potential to cause adverse effects on liver  
Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

##### Atorvastatin calcium

Rat/Mouse Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/kg

##### Calcium carbonate

Rat Oral LD50 6450 mg/kg

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Polysorbate 80

Rat Oral LD50 25 g/kg

##### Amlodipine besylate

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686mg/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)

##### Atorvastatin calcium

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Mild

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

## SAFETY DATA SHEET

Material Name: **AMLODIPINE BESYLATE-ATORVASTATIN  
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### 11. TOXICOLOGICAL INFORMATION

#### Amlodipine besylate

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Negative

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

##### Atorvastatin calcium

104 Week(s) Dog Oral 10 mg/kg/day LOAEL Liver  
13 Week(s) Mouse Oral 100 mg/kg/day LOAEL Liver  
52 Week(s) Rat Oral 5 mg/kg/day NOAEL Liver  
13 Week(s) Rat Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

##### Amlodipine besylate

3 Month(s) Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart  
1 Month(s) Rat Oral 3.5 mg/kg/day LOEL Heart  
1 Year(s) Rat Oral 2 mg/kg/day NOAEL Adrenal gland, Heart

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

##### Atorvastatin calcium

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative  
Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Negative  
Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity  
Peri-/Postnatal Development Rat Oral 20 mg/kg/day NOAEL Fetotoxicity

##### Amlodipine besylate

Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity  
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Fetotoxicity, Fetal mortality  
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic  
Prenatal & Postnatal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

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

##### Atorvastatin calcium

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative

##### Amlodipine besylate

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vivo* Cytogenetics Mouse Bone Marrow Negative  
*In Vitro* Chromosome Aberration Human Lymphocytes Negative

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

##### Atorvastatin calcium

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic  
104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

## SAFETY DATA SHEET

Material Name: **AMLODIPINE BESYLATE-ATORVASTATIN  
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### 11. TOXICOLOGICAL INFORMATION

#### Amlodipine besylate

24 Month(s) Rat Oral, in feed 2.5 mg/kg/day NOAEL Not carcinogenic, No effects at maximum dose

24 Month(s) Mouse Oral, in feed 0.5 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.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This formulation has not been tested as a whole, the following apply to component substance(s):

**Toxicity:** No data available

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

##### Atorvastatin calcium

*Daphnia magna* (Water Flea) EC50 48 Hours 200 mg/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EbC50 72 Hours 75 mg/L

*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.14 mg/L

*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

##### Amlodipine besylate

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 9.9 mg/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 14 mg/L

Green algae OECD EbC50 72 Hours 0.28 mg/L

Green Algae OECD ErC50 72 Hours > 0.91 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

##### Atorvastatin calcium

*Aspergillus niger* (Fungus) MIC > 1000 mg/L

*Trichoderma viride* (Fungus) MIC > 1000 mg/L

*Clostridium perfringens* (Bacterium) MIC 100 mg/L

Activated sludge OECD EC50 >1000 mg/L

##### Amlodipine besylate

*Nostoc sp.* (Freshwater Cyanobacteria) MIC 20 mg/L

*Aspergillus Niger* MIC > 100 mg/L

*Trichoderma viride* MIC > 100 mg/L

*Clostridium perfringens* MIC >100 mg/L

*Bacillus subtilis* MIC 80 mg/L

**Persistence and Degradability:** No data available

##### Atorvastatin calcium

## SAFETY DATA SHEET

**Material Name: AMLODIPINE BESYLATE-ATORVASTATIN  
CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone  
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TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
**Amlodipine besylate**  
OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready  
**Atorvastatin calcium**  
OECD 7 Half-Life 0.339 Day(s)

**Bio-accumulative Potential:** No data available

**Amlodipine besylate**  
Measured 7 Log P 1.33

**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:**

Non-controlled

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.

## SAFETY DATA SHEET

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### 15. REGULATORY INFORMATION

**Amlodipine besylate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Atorvastatin calcium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

**Calcium carbonate**

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	207-439-9

**Croscarmellose sodium**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

**Hydroxypropyl 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	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

**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

**Opadry blue**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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### 15. REGULATORY INFORMATION

#### Opadry clear

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Opadry white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 80

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

#### 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

#### Starch, pregelatinized

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

Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

N - Dangerous for the environment  
Xi - Irritant  
Xn - Harmful

## SAFETY DATA SHEET

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R22 - Harmful if swallowed.

R41 - Risk of serious damage to eyes.

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Revision date:** 20-Mar-2014  
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**



# SAFETY DATA SHEET

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

### Product Identifier

**Material Name:** Amlodipine besylate/Atorvastatin calcium tablets- 5 mg/10 mg and 10 mg/20 mg  
(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), high cholesterol (hyperlipidemia)

### 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

Serious Eye Damage/Eye Irritation: Category 1  
Acute aquatic toxicity: Category 2  
Chronic aquatic toxicity: Category 2

#### EU Classification:

EU Indication of danger: Xi - Irritant  
Dangerous for the Environment

#### EU Risk Phrases:

R36 - Irritating to eyes.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

**Signal Word:** Danger  
**Hazard Statements:** H318 - Causes serious eye damage  
H401 - Toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects

**Precautionary Statements:** P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P310 - Immediately call a POISON CENTRE or doctor/physician  
P273 - Avoid release to the environment  
P391 - Collect spillage  
P501 - Dispose of contents/container in accordance with all local and national regulations



## SAFETY DATA SHEET

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**Other Hazards**

**Australian Hazard Classification (NOHSC):**

No data available

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	%
Amlodipine besylate	111470-99-6	Not Listed	N;R50/53 Xn;R22 Xi;R41	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	6.94
Atorvastatin calcium	134523-03-8	Not Listed	R52/53	Aquatic Acute 3; H402 Aquatic Chronic 3; H412	10.85
Calcium carbonate	471-34-1	207-439-9	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
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	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	Not Listed	*
Opadry blue	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry clear	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	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.

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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:** Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds
- 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

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.

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### 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** No data available

## SAFETY DATA SHEET

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Amlodipine besylate

Manufacturer OEL: 100ug/m<sup>3</sup>

#### Atorvastatin calcium

Manufacturer OEL: 50ug/m<sup>3</sup>

#### Calcium carbonate

Australia TWA 10 mg/m<sup>3</sup>  
Bulgaria OEL - TWA 10.0 mg/m<sup>3</sup>  
France OEL - TWA 10 mg/m<sup>3</sup>  
Latvia OEL - TWA 6 mg/m<sup>3</sup>  
Poland OEL - TWA 10 mg/m<sup>3</sup>  
Portugal OEL - TWA 10 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>

#### 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: 20 mppcf  
Listed

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Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
<b>Starch, pregelatinized</b>	
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>
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:

Wear impervious gloves to prevent skin contact.

#### Eyes:

Wear safety glasses as minimum protection (goggles recommended).

#### Skin:

Wear impervious protective clothing to prevent skin contact.

#### 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

<b>Physical State:</b>	Film-coated tablets	<b>Color:</b>	Blue or White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Calcium carbonate

No data available

#### Croscarmellose sodium

No data available

#### Hydroxypropyl cellulose

No data available

#### Magnesium stearate

No data available

#### Microcrystalline cellulose

## SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium  
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### 9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Opadry blue**

No data available

**Opadry clear**

No data available

**Opadry white**

No data available

**Polysorbate 80**

No data available

**Silicon dioxide, NF**

No data available

**Starch, pregelatinized**

No data available

**Amlodipine besylate**

Measured 7 Log P 1.33

**Atorvastatin calcium**

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

**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:** None known

### 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:** May cause eye irritation May be harmful if swallowed. (based on components)  
Antihypertensive drug: has blood pressure-lowering properties

## SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium  
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### 11. TOXICOLOGICAL INFORMATION

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver  
**Known Clinical Effects:** Adverse effects associated with therapeutic use of amlodipine include headache, swelling, dizziness, flushing, and palpitations. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

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

##### **Calcium carbonate**

Rat Oral LD50 6450 mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Amlodipine besylate**

Rat (M) Oral LD50 393 mg/kg

Rat (F) Oral LD50 686mg/kg

##### **Atorvastatin calcium**

Rat/Mouse Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/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)

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

##### **Amlodipine besylate**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

##### **Atorvastatin calcium**

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Mild

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

##### **Amlodipine besylate**

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Material Name: Amlodipine besylate/Atorvastatin calcium  
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### 11. TOXICOLOGICAL INFORMATION

3 Month(s)	Rat	Oral	3 mg/kg/day	NOAEL	Adrenal gland, Heart
1 Month(s)	Rat	Oral	3.5 mg/kg/day	LOEL	Heart
1 Year(s)	Rat	Oral	2 mg/kg/day	NOAEL	Adrenal gland, Heart

#### Atorvastatin calcium

104 Week(s)	Dog	Oral	10 mg/kg/day	LOAEL	Liver
13 Week(s)	Mouse	Oral	100 mg/kg/day	LOAEL	Liver
52 Week(s)	Rat	Oral	5 mg/kg/day	NOAEL	Liver
13 Week(s)	Rat	Oral	5 (male); 20 (female)	mg/kg/day	NOAEL Liver

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

##### Amlodipine besylate

Fertility and Embryonic Development	Rat	Oral	25 mg/kg/day	NOAEL	Not teratogenic, Maternal toxicity
Peri-/Postnatal Development	Rat	Oral	4 mg/kg/day	NOAEL	Fetotoxicity, Fetal mortality
Prenatal & Postnatal Development	Rat	Oral	25 mg/kg/day	NOAEL	Not Teratogenic
Prenatal & Postnatal Development	Rabbit	Oral	25 mg/kg/day	NOAEL	Not Teratogenic

##### Atorvastatin calcium

Reproductive & Fertility	Rat	Oral	20 mg/kg/day	NOAEL	Negative
Fertility and Embryonic Development	Rat	Oral	100 mg/kg/day	NOAEL	Negative
Embryo / Fetal Development	Rat	Oral	100 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity
Embryo / Fetal Development	Rabbit	Oral	10 mg/kg/day	NOAEL	Not Teratogenic, Maternal Toxicity, Fetotoxicity
Peri-/Postnatal Development	Rat	Oral	20 mg/kg/day	NOAEL	Fetotoxicity

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

##### Amlodipine besylate

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Cytogenetics	Mouse Bone Marrow	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative

##### Atorvastatin calcium

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

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

##### Amlodipine besylate

24 Month(s)	Rat	Oral, in feed	2.5 mg/kg/day	NOAEL	Not carcinogenic, No effects at maximum dose
24 Month(s)	Mouse	Oral, in feed	0.5 mg/kg/day	NOAEL	Not carcinogenic

##### Atorvastatin calcium

104 Week(s)	Mouse	Oral	200 mg/kg/day	NOAEL	Not carcinogenic
104 Week(s)	Rat	Oral	100 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.



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### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** This formulation has not been tested as a whole, the following apply to component substance(s): Harmful effects to aquatic organisms could occur.

**Toxicity:**

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

##### **Amlodipine besylate**

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 9.9 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 14 mg/L  
Green algae OECD EbC50 72 Hours 0.28 mg/L  
Green Algae OECD ErC50 72 Hours > 0.91 mg/L

##### **Atorvastatin calcium**

*Daphnia magna* (Water Flea) EC50 48 Hours 200 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L  
*Pseudokirchneriella subcapitata* (Green Alga) OECD EbC50 72 Hours 75 mg/L  
*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.14 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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

##### **Amlodipine besylate**

*Nostoc sp.* (Freshwater Cyanobacteria) MIC 20 mg/L  
*Aspergillus Niger* MIC > 100 mg/L  
*Trichoderma viride* MIC > 100 mg/L  
*Clostridium perfringens* MIC >100 mg/L  
*Bacillus subtilis* MIC 80 mg/L

##### **Atorvastatin calcium**

*Aspergillus niger* (Fungus) MIC > 1000 mg/L  
*Trichoderma viride* (Fungus) MIC > 1000 mg/L  
*Clostridium perfringens* (Bacterium) MIC 100 mg/L  
Activated sludge OECD EC50 >1000 mg/L

**Persistence and Degradability:** No data available

##### **Amlodipine besylate**

OECD Activated sludge Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready

##### **Atorvastatin calcium**

TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready  
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready

##### **Atorvastatin calcium**

OECD 7 Half-Life 0.339 Day(s)

**Bio-accumulative Potential:** No data available

##### **Amlodipine besylate**

Measured 7 Log P 1.33

**Mobility in Soil:** No data available

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### 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 B



#### Amlodipine besylate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Atorvastatin calcium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Calcium carbonate

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<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	207-439-9
<b>Croscarmellose sodium</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Hydroxypropyl cellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Magnesium stearate</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3
<b>Microcrystalline cellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Opadry blue</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Opadry clear</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Opadry white</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Polysorbate 80</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed

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### 15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
<b>Silicon dioxide, NF</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	231-545-4
<b>Starch, pregelatinized</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 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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xi - Irritant  
N - Dangerous for the environment  
Xn - Harmful

R22 - Harmful if swallowed.  
R41 - Risk of serious damage to eyes.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Revision date:** 20-Mar-2014  
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**

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