



SAFETY DATA SHEET

Revision date: 20-Mar-2014

Version: 1.0

Page 1 of 14

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 2 of 14

Version: 1.0



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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 3 of 14

Version: 1.0

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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 4 of 14

Version: 1.0

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

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 5 of 14

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Manufacturer OEL: 100ug/m³

Atorvastatin calcium

Manufacturer OEL: 50ug/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 6 of 14

Version: 1.0

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 7 of 14

Version: 1.0

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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 8 of 14

Version: 1.0

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/m³

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 9 of 14

Version: 1.0

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 10 of 14

Version: 1.0

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 11 of 14

Version: 1.0

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 12 of 14

Version: 1.0

15. REGULATORY INFORMATION

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
Opadry clear	
CERCLA/SARA 313 Emission reporting	Not Listed

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 13 of 14

Version: 1.0

15. REGULATORY INFORMATION

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
tablets-
10 mg/10 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 14 of 14

Version: 1.0

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

Revision date: 21-Mar-2014

Version: 1.0

Page 1 of 14

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

Material Name: Amlodipine besylate/Atorvastatin calcium tablets-
2.5 mg/10 mg, 5 mg/20 mg and 10 mg/40 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 2 of 14

Version: 1.0



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	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	*

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)
Revision date: 21-Mar-2014

Page 3 of 14

Version: 1.0

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 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: 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

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)
Revision date: 21-Mar-2014

Page 4 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 5 of 14

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Manufacturer OEL: 100ug/m³

Atorvastatin calcium

Manufacturer OEL: 50ug/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³

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)
Revision date: 21-Mar-2014

Page 6 of 14

Version: 1.0

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

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

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)
Revision date: 21-Mar-2014

Page 7 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 8 of 14

Version: 1.0

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/m³

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

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)
Revision date: 21-Mar-2014

Page 9 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 10 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 11 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 12 of 14

Version: 1.0

15. REGULATORY INFORMATION

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
Opadry clear	
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)
Revision date: 21-Mar-2014

Page 13 of 14

Version: 1.0

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.

Revision date: 21-Mar-2014

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)
Revision date: 21-Mar-2014

Page 14 of 14

Version: 1.0

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

Material Name: Amlodipine besylate/atorvastatin calcium tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 2 of 14

Version: 1.0

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.

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)
Revision date: 21-Mar-2014

Page 3 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 4 of 14

Version: 1.0

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

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

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)
Revision date: 21-Mar-2014

Page 5 of 14

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Manufacturer OEL: 100ug/m³

Atorvastatin calcium

Manufacturer OEL: 50ug/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³

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)
Revision date: 21-Mar-2014

Page 6 of 14

Version: 1.0

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

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
tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 7 of 14

Version: 1.0

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/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 8 of 14

Version: 1.0

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/m³

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-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 9 of 14

Version: 1.0

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 calcium tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg (Greenstone LLC)
Revision date: 21-Mar-2014

Page 10 of 14

Version: 1.0

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

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)
Revision date: 21-Mar-2014

Page 11 of 14

Version: 1.0

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)
Revision date: 21-Mar-2014

Page 12 of 14

Version: 1.0

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)
Revision date: 21-Mar-2014

Page 13 of 14

Version: 1.0

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)
Revision date: 21-Mar-2014

Page 14 of 14

Version: 1.0

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

Revision date: 20-Mar-2014

Version: 1.0

Page 1 of 13

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

Page 2 of 13

Version: 1.0

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

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

Page 3 of 13

Revision date: 20-Mar-2014

Version: 1.0

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

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

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

Revision date: 20-Mar-2014

Page 4 of 13

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Manufacturer OEL: 100ug/m³

Atorvastatin calcium

Manufacturer OEL: 50ug/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³

SAFETY DATA SHEET

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

Page 5 of 13

Revision date: 20-Mar-2014

Version: 1.0

OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed
Slovakia OEL - TWA 4.0 mg/m³

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Slovakia OEL - TWA 4 mg/m³
Spain OEL - TWA 10 mg/m³

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
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 TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone
LLC)
Revision date: 20-Mar-2014

Page 6 of 13

Version: 1.0

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
LLC)

Page 7 of 13

Revision date: 20-Mar-2014

Version: 1.0

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/m³

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: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone
LLC)**

Page 8 of 13

Revision date: 20-Mar-2014

Version: 1.0

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
CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone
LLC)**

Page 9 of 13

Revision date: 20-Mar-2014

Version: 1.0

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
LLC)**

Page 10 of 13

Revision date: 20-Mar-2014

Version: 1.0

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

Material Name: AMLODIPINE BESYLATE-ATORVASTATIN
 CALCIUM TABLETS: 2.5 MG-40 MG; 5 MG-80 MG (Greenstone
 LLC)
 Revision date: 20-Mar-2014

Page 11 of 13

Version: 1.0

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-40 MG; 5 MG-80 MG (Greenstone
LLC)

Page 12 of 13

Revision date: 20-Mar-2014

Version: 1.0

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

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

Page 13 of 13

Revision date: 20-Mar-2014

Version: 1.0

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

Revision date: 20-Mar-2014

Version: 1.0

Page 1 of 14

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

Material Name: Amlodipine besylate/Atorvastatin calcium tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 2 of 14

Version: 1.0



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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 3 of 14

Version: 1.0

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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 4 of 14

Version: 1.0

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

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 5 of 14

Version: 1.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Amlodipine besylate

Manufacturer OEL: 100ug/m³

Atorvastatin calcium

Manufacturer OEL: 50ug/m³

Calcium carbonate

Australia TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
France OEL - TWA 10 mg/m³
Latvia OEL - TWA 6 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Silicon dioxide, NF

Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
0.3 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³
4.0 mg/m³
Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³
2.4 mg/m³
Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
Listed

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 6 of 14

Version: 1.0

Slovakia OEL - TWA	4.0 mg/m ³
Starch, pregelatinized	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Czech Republic OEL - TWA	4.0 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	4 mg/m ³
Spain OEL - TWA	10 mg/m ³

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

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:	Film-coated tablets	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

Magnesium stearate

No data available

Microcrystalline cellulose

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 7 of 14

Version: 1.0

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
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 8 of 14

Version: 1.0

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/m³

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 9 of 14

Version: 1.0

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.

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 10 of 14

Version: 1.0

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 11 of 14

Version: 1.0

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 12 of 14

Version: 1.0

15. REGULATORY INFORMATION

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
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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 13 of 14

Version: 1.0

15. REGULATORY INFORMATION

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

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

SAFETY DATA SHEET

Material Name: Amlodipine besylate/Atorvastatin calcium
tablets- 5 mg/10 mg and 10 mg/20 mg (Greenstone LLC)
Revision date: 20-Mar-2014

Page 14 of 14

Version: 1.0
