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

Product Identifier

Material Name: Caduet® (amlodipine besylate/atorvastatin calcium) Tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg

Trade Name: CADUET
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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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
**SAFETY DATA SHEET**

**Material Name:** Caduet® (amlodipine besylate/atorvastatin calcium) Tablets - 2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg  
**Revision date:** 21-Mar-2014

**Other Hazards**

<table>
<thead>
<tr>
<th>Australian Hazard Classification (NOHSC):</th>
</tr>
</thead>
</table>

**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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine besylate</td>
<td>11470-99-6</td>
<td>Not Listed</td>
<td>N;R50/53 Xn;R22</td>
<td>Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
<td>1.74</td>
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<tr>
<td>Atorvastatin calcium</td>
<td>134523-03-8</td>
<td>Not Listed</td>
<td>R52/53</td>
<td>Aquatic Acute 3; H402 Aquatic Chronic 3; H412</td>
<td>10.85</td>
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<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<td>Not Listed</td>
<td></td>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Hydroxypropyl cellulose</td>
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<td>Not Listed</td>
<td></td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Opadry clear</td>
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<td>Opadry white</td>
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<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
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: 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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Amlodipine besylate
Pfizer OEL TWA-8 Hr: 100µg/m³

Atorvastatin calcium
Pfizer OEL TWA-8 Hr: 50 µg/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
Vietnam OEL - TWAs 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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Vietnam OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Silicon dioxide, NF</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
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</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment:

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
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

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: 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)

**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
# 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Route</th>
<th>Dose/Level</th>
<th>Duration</th>
<th>Species</th>
<th>Effect</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin calcium</td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>LOAEL</td>
<td>Dog</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td>Amlodipine besylate</td>
<td>Oral</td>
<td>5 mg/kg/day</td>
<td>NOAEL</td>
<td>Rat</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>5 (male); 20 (female) mg/kg/day</td>
<td>NOAEL</td>
<td>Rat (M)</td>
<td>Heart</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Rat (F)</td>
<td>Adrenal gland</td>
<td>Heart</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>3.5 mg/kg/day</td>
<td>LOEL</td>
<td>Rat</td>
<td>Heart</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>2 mg/kg/day</td>
<td>NOAEL</td>
<td>Rat</td>
<td>Adrenal gland</td>
<td>Heart</td>
</tr>
</tbody>
</table>

**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

- **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 100 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
SAFETY DATA SHEET

Material Name:  Caduet® (amlodipine besylate/atorvastatin calcium) Tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg
Revision date: 21-Mar-2014

11. TOXICOLOGICAL INFORMATION

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

Amlodipine besylate

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

In Vivo Cytogenetics Mouse Bone Marrow 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

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
SAFETY DATA SHEET

Material Name: Caduet® (amlodipine besylate/atorvastatin calcium) Tablets-
2.5 mg/20 mg, 5 mg/40 mg, and 10 mg/80 mg
Revision date: 21-Mar-2014

Amlodipine besylate

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

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

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
15. REGULATORY INFORMATION

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
   REACH - Annex XVII - Restrictions on Certain Dangerous Substances:
   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

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
15. REGULATORY INFORMATION

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<td>EU EINECS/ELINCS List</td>
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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 |

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

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: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

Revision date: 21-Mar-2014

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without 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