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

Product Identifier

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

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
3. COMPOSITION / INFORMATION ON INGREDIENTS

<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>111470-99-6</td>
<td>Not Listed</td>
<td>N;R50/53</td>
<td>Acute Tox. 4, H302</td>
<td>0.87</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R22</td>
<td>Eye Dam. 1, H318</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R41</td>
<td>Aquatic Acute 1, H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1, H410</td>
<td></td>
</tr>
<tr>
<td>Atorvastatin calcium</td>
<td>134523-03-8</td>
<td>Not Listed</td>
<td>R52/53</td>
<td>Aquatic Acute 3; H402</td>
<td>10.85</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3; H412</td>
<td></td>
</tr>
<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>
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<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>
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<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>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<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>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry blue</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry clear</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Opadry white</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<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>

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
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
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

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
Ireland OEL - TWAs 10 mg/m³
Russia OEL - TWA 6 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.
SAFETY DATA SHEET

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

Revision date: 19-Mar-2014

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
<th>Color:</th>
<th>White</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Atorvastatin calcium
No data available
Calcium carbonate
No data available
Microcrystalline cellulose
No data available
Starch, pregelatinized
No data available
Crocarmellose 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
SAFETY DATA SHEET

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

Revision date: 19-Mar-2014

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
- 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 > 2000 mg/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**

PZ02329
### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>LD50</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine besylate</td>
<td>Oral</td>
<td>25 g/kg</td>
<td>-</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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>Species</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine besylate</td>
<td>Oral</td>
<td>Rat</td>
<td>Mild</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Oral</td>
<td>Rabbit</td>
<td>Non-irritating</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Target Organ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin calcium</td>
<td>104 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>13 Week(s)</td>
<td>Mouse</td>
<td>Oral</td>
<td>100 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>52 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>5 mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td></td>
<td>13 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>5 (male); 20 (female) mg/kg/day</td>
<td>NOAEL</td>
<td>Liver</td>
</tr>
<tr>
<td>Amlodipine besylate</td>
<td>3 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>3 mg/kg/day</td>
<td>NOAEL</td>
<td>Adrenal gland, Heart</td>
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<tr>
<td></td>
<td>1 Month(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>3.5 mg/kg/day</td>
<td>LOEL</td>
<td>Heart</td>
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<td></td>
<td>1 Year(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>2 mg/kg/day</td>
<td>NOAEL</td>
<td>Adrenal gland, Heart</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin calcium</td>
<td>Oral</td>
<td>20 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>100 mg/kg/day</td>
<td>NOAEL</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic, Maternal Toxicity</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>20 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic, Maternal Toxicity, Fetotoxicity</td>
</tr>
<tr>
<td>Amlodipine besylate</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>NOAEL</td>
<td>Not teratogenic, Maternal toxicity</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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

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
*Onchorhyncus 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
*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)

<table>
<thead>
<tr>
<th>Organism/Strain</th>
<th>MIC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Atorvastatin calcium</strong></td>
<td></td>
</tr>
<tr>
<td><em>Aspergillus niger</em></td>
<td>&gt; 1000 mg/L</td>
</tr>
<tr>
<td><em>Trichoderma viride</em></td>
<td>&gt; 1000 mg/L</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>100 mg/L</td>
</tr>
<tr>
<td>Activated sludge</td>
<td>OECD EC50 &gt;1000 mg/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organism/Strain</th>
<th>MIC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amlodipine besylate</strong></td>
<td></td>
</tr>
<tr>
<td><em>Nostoc sp.</em></td>
<td>20 mg/L</td>
</tr>
<tr>
<td><em>Aspergillus Niger</em></td>
<td>&gt; 100 mg/L</td>
</tr>
<tr>
<td><em>Trichoderma viride</em></td>
<td>&gt; 100 mg/L</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>&gt;100 mg/L</td>
</tr>
<tr>
<td><em>Bacillus subtilis</em></td>
<td>80 mg/L</td>
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Persistence and Degradability: No data available

<table>
<thead>
<tr>
<th>Organism/Strain</th>
<th>Ultimate (CO2 Evolution)</th>
<th>% After 28 Day(s)</th>
<th>Not Ready</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Atorvastatin calcium</strong></td>
<td>OECD Activated sludge</td>
<td>&lt;10%</td>
<td>Not Ready</td>
</tr>
<tr>
<td>TAD Soil (various)</td>
<td>OECD Activated sludge</td>
<td>&lt;10%</td>
<td>Not Ready</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organism/Strain</th>
<th>Ultimate (CO2 Evolution)</th>
<th>% After 28 Day(s)</th>
<th>Not Ready</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amlodipine besylate</strong></td>
<td>OECD Activated sludge</td>
<td>8.11%</td>
<td>Not Ready</td>
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Bio-accumulative Potential: No data available

<table>
<thead>
<tr>
<th>Organism/Strain</th>
<th>Measured 7</th>
<th>Log P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amlodipine besylate</strong></td>
<td></td>
<td>1.33</td>
</tr>
</tbody>
</table>

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.

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

Crosclarmellose 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
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
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<tbody>
<tr>
<td>Magnesium stearate</td>
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<td>Present</td>
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<td>Microcrystalline cellulose</td>
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<tr>
<td>Opadry clear</td>
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<tr>
<td>Opadry white</td>
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<td>Silicon dioxide, NF</td>
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</table>
15. REGULATORY INFORMATION

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.

Revision date: 19-Mar-2014
Prepared by: Product Stewardship Hazard Communication

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End of Safety Data Sheet