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

Product Identifier

Material Name: Caduet (Amlodipine besylate/Atorvastatin calcium) tablets- 5 mg/10 mg and 10 mg/20 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

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

Other Hazards
Australian Hazard Classification (NOHSC):

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

<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 Xn;R22 Xi;R41</td>
<td>Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</td>
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<tr>
<td>Atorvastatin calcium</td>
<td>134523-03-8</td>
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<td>R52/53</td>
<td>Aquatic Acute 3; H402 Aquatic Chronic 3; H412</td>
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<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</td>
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<td>*</td>
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<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>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</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>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Caduet (Amlodipine besylate/Atorvastatin calcium) tablets-
5 mg/10 mg and 10 mg/20 mg
Revision date: 19-Mar-2014

| Ingredient(s) | Not Assigned | Not Listed | Not Listed | Not Listed | *
|---------------|--------------|------------|------------|------------|
| Opadry blue   |              |            |            |            | *
| Opadry clear  |              |            |            |            | *
| Opadry white  |              |            |            |            | *
| Polysorbate 80| 9005-65-6    |            |            |            | *

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures
Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: 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.

---

**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

---

**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: 100 µg/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
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>10 mg/m³</td>
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<tr>
<td>Estonia</td>
<td>10 mg/m³</td>
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<tr>
<td>France</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia</td>
<td>6 mg/m³</td>
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<tr>
<td>Spain</td>
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<tr>
<td>Switzerland</td>
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<td>Vietnam</td>
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Silicon dioxide, NF

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<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>Austria</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Czech Republic</td>
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</tr>
<tr>
<td></td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>2 mg/m³</td>
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<tr>
<td>Finland</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</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>2.4 mg/m³</td>
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<tr>
<td>Latvia</td>
<td>1 mg/m³</td>
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</table>
| OSHA - Final PELs - Table Z-3 Mineral D: | 20 mppcf
|                         | Listed      |
| Slovakia                 | 4.0 mg/m³    |
| Switzerland              | 4 mg/m³      |
|                         | 0.3 mg/m³    |

Starch, pregelatinized

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia</td>
<td>10 mg/m³</td>
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<tr>
<td>Bulgaria</td>
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<tr>
<td>Czech Republic</td>
<td>4.0 mg/m³</td>
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<td>Greece</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
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<tr>
<td>Ireland</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - TWAs :</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

Inhalation Protection
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| 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 |

Color: Blue or White
Odor Threshold: No data available.
Molecular Weight: Mixture

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.

Material Name: Caduet (Amlodipine besylate/Atorvastatin calcium) tablets- 5 mg/10 mg and 10 mg/20 mg
Revision date: 19-Mar-2014
Version: 3.0
SAFETY DATA SHEET

Material Name: Caduet (Amlodipine besylate/Atorvastatin calcium) tablets-
5 mg/10 mg and 10 mg/20 mg
Revision date: 19-Mar-2014

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

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
11. TOXICOLOGICAL INFORMATION

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  686 mg/kg

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

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

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
  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
11. TOXICOLOGICAL INFORMATION

**Atorvastatin calcium**

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)

**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

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:  
No data available

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**

Revision date: 19-Mar-2014
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

Atorvastatin calcium
- *Aspergillus niger* (Fungus) MIC > 1000 mg/L
- *Trichoderma viride* (Fungus) MIC > 1000 mg/L
- *Clostridium perfringens* (Bacterium) MIC 100 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

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

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

Hydroxypropyl cellulose

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15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name: Caduet (Amlodipine besylate/Atorvastatin calcium) tablets- 5 mg/10 mg and 10 mg/20 mg</th>
<th>Revision date: 19-Mar-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td><strong>Silicon dioxide, NF</strong></td>
</tr>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>CERCLA/SARA 313 Emission reporting</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>California Proposition 65</td>
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<tr>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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Revision date: 19-Mar-2014

Version: 3.0
15. REGULATORY INFORMATION

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Polysorbate 80

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

Revision date: 19-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