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

Product Identifier

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

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>
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</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>
<td>13.9</td>
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<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>
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<td>Calcium carbonate</td>
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<td>207-439-9</td>
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<td>Magnesium stearate</td>
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<td>209-150-3</td>
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<td>Not Listed</td>
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<td>Microcrystalline cellulose</td>
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<td>232-674-9</td>
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<tr>
<td>Silicon dioxide, NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
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<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>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
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<td>Not Listed</td>
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<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</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:** 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. 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

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
Belgium OEL - TWA: 10 mg/m³
### Exposure Controls / Personal Protection

<table>
<thead>
<tr>
<th>Material Name</th>
<th>TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Ireland OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 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>
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<tr>
<td>Russia OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Vietnam OEL - TWAs</td>
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**Silicon dioxide, NF**

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<td>Australia TWA</td>
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<td>Austria OEL - MAKs</td>
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<td>Finland OEL - TWA</td>
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<tr>
<td>Germany - TRGS 900 - TWAs</td>
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<td>Germany (DFG) - MAK</td>
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<td>Ireland OEL - TWAs</td>
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<td>Slovakia OEL - TWA</td>
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<td>0.3 mg/m³</td>
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**Starch, pregelatinized**

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<td>ACGIH Threshold Limit Value (TWA)</td>
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<td>Australia TWA</td>
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<td>Bulgaria OEL - TWA</td>
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<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
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<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td></td>
<td>5 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</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 OEL - TWA</td>
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<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>
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</table>

**Exposure Controls**
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 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

<table>
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<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
<th>Color:</th>
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<td>Melting/Freezing Point (°C):</td>
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<td>Boiling Point (°C):</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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<tr>
<td></td>
<td>Hydroxypropyl cellulose</td>
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<td>Magnesium stearate</td>
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<td>Opadry clear</td>
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<td>Polysorbate 80</td>
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<td></td>
<td>Amlodipine besylate</td>
<td>Measured 7</td>
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<td>Atorvastatin calcium</td>
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<td>Decomposition Temperature (°C):</td>
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<td>Vapor Pressure (kPa):</td>
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</tbody>
</table>
SAFETY DATA SHEET

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

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: 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
11. TOXICOLOGICAL INFORMATION

Eye Irritation

**Rabbit**
Mild

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

**Skin Sensitization - GPMT**
Guinea Pig Negative

**Amlodipine besylate**
Eye Irritation Rabbit Non-irritating
Skin Sensitization - Beuhler Guinea Pig Negative

**Atorvastatin calcium**
Skin Sensitization - Beuhler Guinea Pig Negative

**Microcrystalline cellulose**
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

**Eye Irritation**

**Rabbit**
Severe

**Rat** Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

**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 Fetal toxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic
11. TOXICOLOGICAL INFORMATION

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

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 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
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
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., LC50/EC50) is not achievable.

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

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<tr>
<th>Bacterial Inhibition</th>
<th>Inoculum</th>
<th>Method</th>
<th>End Point</th>
<th>Result</th>
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<tbody>
<tr>
<td>Aspergillus niger</td>
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<td>&gt; 1000 mg/L</td>
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<tr>
<td>Trichoderma viride</td>
<td>MIC</td>
<td>&gt; 1000 mg/L</td>
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<tr>
<td>Clostridium perfringens</td>
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<tr>
<td>Bacillus subtilis</td>
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Persistence and Degradability:

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<tr>
<td>Activated sludge</td>
<td>Ultimate (CO2 Evolution) 8.11% After 28 Day(s) Not Ready</td>
<td></td>
</tr>
</tbody>
</table>

Bio-accumulative Potential:

- No data available

<table>
<thead>
<tr>
<th>Bio-accumulative Potential</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated sludge OECD</td>
<td>EC50 1000 mg/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mobility in Soil</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated sludge OECD</td>
<td>Ultimate (CO2 Evolution) 10% After 28 Day(s) Not Ready</td>
</tr>
</tbody>
</table>

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

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**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: carcinogen initial date 12/18/09
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f], powder
- 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

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:
- EU EINECS/ELINCS List: 232-679-6

Polysorbate 80
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 | Not Listed |

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: 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 15 - Regulatory Information. Updated Section 11 - Toxicology Information. Updated Section 10 - Stability and Reactivity. Updated Section 8 - Exposure Controls / Personal Protection.

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