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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: NORVASC® (Amlodipine besylate) tablets - 2.5, 5, and 10 mg

Trade Name: NORVASC
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antianginal; antihypertensive

2. HAZARDS IDENTIFICATION

Appearance: White tablet
Signal Word: WARNING

Statement of Hazard: Toxic to aquatic life.

Additional Hazard Information:

Short Term: May be harmful if swallowed. May cause eye irritation (based on components).
Antihypertensive drug: has blood pressure-lowering properties

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including abdominal pain, dizziness, flushing, heart palpitations, and swelling.

EU Indication of danger: Dangerous for the Environment

EU Hazard Symbols: N

EU Risk Phrases: R51 - Toxic to aquatic organisms.

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

#### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine besylate</td>
<td>111470-99-6</td>
<td>Not listed</td>
<td>N;R51</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R22</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Xi;R41</td>
<td></td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</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.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. 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.

#### 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.

### 5. FIRE FIGHTING MEASURES

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

#### Hazardous Combustion Products:
Emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

#### Fire Fighting Procedures:
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

#### Fire / Explosion Hazards:
Not determined

### 6. ACCIDENTAL RELEASE MEASURES

#### Health and Safety Precautions:
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

Microcrystalline cellulose
   ACGIH Threshold Limit Value (TWA)
   Australia TWA = 10 mg/m³ TWA
   Belgium OEL - TWA Listed
   Estonia OEL - TWA Listed
   France OEL - TWA Listed
   Ireland OEL - TWAs = 10 mg/m³ TWA
                        = 4 mg/m³ TWA
   Latvia OEL - TWA Listed
   OSHA - Final PELS - TWAs: = 15 mg/m³ TWA total
                              = 5 mg/m³ TWA
   Portugal OEL - TWA Listed
   Romania OEL - TWA Listed
   Spain OEL - TWA Listed

Calcium phosphate dibasic, anhydrous
   Latvia OEL - TWA Listed

Magnesium stearate
   ACGIH Threshold Limit Value (TWA)
   Australia TWA = 10 mg/m³ TWA except stearates of toxic metals
   Belgium OEL - TWA Listed
   Ireland OEL - TWAs = 10 mg/m³ TWA except lead stearate
   Lithuania OEL - TWA Listed
   Portugal OEL - TWA Listed
   Spain OEL - TWA Listed
   Sweden OEL - TWAs = 5 mg/m³ LLV
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablet
Color: White
Odor: Odorless
Molecular Formula: Mixture
Molecular Weight: Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: None known
11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000mg/m³

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000mg/kg

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

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

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

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)

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 & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Amlodipine besylate
Fertility and Embryonic Development Rat Oral 25 mg/kg/day NOAEL Not teratogenic, Maternal toxicity
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Fetotoxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic
Prenatal & Postnatal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

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

Amlodipine besylate
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vivo Cytogenetics Mouse Bone Marrow Negative
In Vitro Cytogenetics Mouse Bone Marrow Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
11. TOXICOLOGICAL INFORMATION

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

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated.  The active ingredient in this formulation may be harmful to aquatic organisms.  Releases to the environment should be avoided.  See aquatic toxicity data, below:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Amlodipine besylate
\begin{itemize}
  \item \textit{Daphnia Magna} \textit{OECD} \textit{EC50} 48 Hours 9.9 mg/L
  \item \textit{Rainbow Trout} \textit{OECD} \textit{LC50} 96 Hours 14 mg/L
  \item \textit{Green algae} \textit{OECD} \textit{EbC50} 72 Hours 0.28 mg/L
  \item \textit{Green Algae} \textit{OECD} \textit{ErC50} 72 Hours > 0.91 mg/L
\end{itemize}

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: (Species, Method, End Point, Duration, Result)

Amlodipine besylate
\begin{itemize}
  \item \textit{Nostoc sp.} (Freshwater Cyanobacteria)  MIC 20 mg/L
  \item \textit{Aspergillus Niger}  MIC > 100 mg/L
  \item \textit{Trichoderma viride}  MIC > 100 mg/L
  \item \textit{Clostridium perfringens}  MIC >100 mg/L
    \begin{itemize}
      \item \textit{Bacillus subtilis}  MIC 80 mg/L
    \end{itemize}
\end{itemize}
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: 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

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

EU Symbol: N
EU Indication of danger: Dangerous for the Environment

EU Risk Phrases:
R51 - Toxic to aquatic organisms.

EU Safety Phrases:
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
Toxic to aquatic life.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision B

Sodium starch glycolate
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS/ELINCS List 232-674-9

Calcium phosphate dibasic, anhydrous
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-826-1

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
MATERIAL SAFETY DATA SHEET

Material Name: NORVASC® (Amlodipine besylate) tablets - 2.5, 5, and 10 mg
Revision date: 11-Dec-2008

R22 - Harmful if swallowed.
R41 - Risk of serious damage to eyes.
R50 - Very toxic to aquatic organisms.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

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. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet