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

Material Name: Lipitor® (Atorvastatin Calcium) Tablets

Trade Name: Lipitor®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Lipid regulating agent.

2. HAZARDS IDENTIFICATION

Appearance: White film-coated tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
- Short Term: May cause eye irritation (based on components).
- 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 atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Clinical use of this drug has caused changes in liver function, muscle pain, weakness.

EU Indication of danger: Not classified

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>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin calcium</td>
<td>134523-03-8</td>
<td>Not Listed</td>
<td>R52/53</td>
<td>7.0</td>
</tr>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>207-439-9</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>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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. 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.

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.

Atorvastatin calcium

Pfizer OEL TWA-8 Hr: 50 µg/m³

Calculus 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

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
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 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


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).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| 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 |
| Molecular Formula: | Mixture |
| Color: | White |
| Molecular Weight: | Mixture |

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

| Chemical Stability: | Stable under normal conditions of use. |
| 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 |

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)

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

- **Calcium carbonate**
  - Rat Oral LD50 6450 mg/kg

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

- **Polysorbate 80**
  - Rat Oral LD50 25 g/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)
11. TOXICOLOGICAL INFORMATION

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

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)

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))

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)

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

Mutagenicity  No evidence of mutagenic or clastogenic activity in in vitro or in vivo tests.

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview:  In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil. Not readily biodegradable. May have harmful effects on the aquatic environment. May persist in the aquatic environment. Releases to the environment should be avoided.

Mobility, Persistence and Degradability:  <10% biodegraded in 28 days (atorvastatin calcium)

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
12. ECOLOGICAL INFORMATION

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
Aquatic Toxicity Comments: The (21) day (NOEC) study above is a reproductive/survival study. The 32 day study above is an Early Life-Stage Toxicity test. A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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

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

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications
15. REGULATORY INFORMATION

WHMIS hazard class:
None required
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.

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Reasons for Revision:
Updated Section 12 - Ecological Information.

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