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

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CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Simvastatin Tablets

Trade Name: Not applicable
Chemical Family: HMG-CoA reductase inhibitor; Statin
Intended Use: Pharmaceutical product for the treatment of high cholesterol (hyperlipidemia)

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 include respiratory infection, abdominal pain, constipation, nausea. Clinical use of this drug has caused changes in liver function, muscle pain, and weakness.

EU Indication of danger: Not classified


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>Simvastatin</td>
<td>79902-63-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>5,10,20,40, or 80mg***</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>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Butylated hydroxyanisole</td>
<td>25013-16-5</td>
<td>246-563-8</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.

Microcrystalline cellulose

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

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed
Greece OEL - TWA Listed
Ireland OEL - TWAs Listed
OSHA - Final PELS - TWAs: 15 mg/m³ total
Portugal OEL - TWA Listed
Spain OEL - TWA Listed

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Ireland OEL - TWAs Listed
Lithuania OEL - TWA Listed
Portugal OEL - TWA Listed
Spain OEL - TWA Listed
Sweden OEL - TWAs Listed

Simvastatin
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.

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
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: 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)

- Ascorbic acid (Vitamin C)
  Rat Oral LD 50 11.9 g/kg

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

- Magnesium stearate
  Rat Oral LD50 > 2000 mg/kg
11. TOXICOLOGICAL INFORMATION

Simvastatin
- Rat Oral LD50 4438 mg/kg

Butylated hydroxyanisole
- Rat Oral LD50 2000 mg/kg
- Mouse Oral LD 50 1100 mg/kg
- Rat Intraperitoneal LD 50 881 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

Citric acid monohydrate
- Eye Irritation Rabbit Mild
- Skin Irritation Rabbit Mild

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

Simvastatin
- 14 Week(s) Dog Oral 180 mg/kg/day LOAEL Eyes, Central nervous system
- 2 Year(s) Rat Oral 50 mg/kg/day LOAEL Eyes
- 3 Month(s) Dog Oral 90 mg/kg/day LOAEL Eyes, Central Nervous System

Butylated hydroxyanisole
- 12 Day(s) Rat Oral 3300 mg/kg LOAEL Liver, Blood

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

Simvastatin
- Reproductive & Fertility Rat Oral 25 mg/kg/day NOAEL Negative
- Embryo / Fetal Development Rat Oral 25 mg/kg/day NOAEL Not Teratogenic
- Embryo / Fetal Development Rabbit Oral 25 mg/kg/day NOAEL Not Teratogenic

Butylated hydroxyanisole
- Embryo / Fetal Development Rat Oral 30 g/kg LOEL Teratogenic

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

Simvastatin
- In Vitro Bacterial Mutagenicity (Ames) Salmonella Negative
- In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
- In Vivo Chromosome Aberration Mouse Bone Marrow Negative

Butylated hydroxyanisole
- In Vivo Micronucleus Bone Marrow Negative
- In Vitro Bacterial Mutagenicity (Ames) Salmonella Negative
11. TOXICOLOGICAL INFORMATION

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Simvastatin
72 Week(s)  Mouse  Oral  25 mg/kg/day  NOAEL  Liver, Lungs, Tumors
2 Year(s)  Rat  Oral  25 mg/kg/day  LOAEL  Thyroid, Tumors
2 Year(s)  Rat  Oral  50 mg/kg/day  LOAEL  Liver, Thyroid, Tumors

Butylated hydroxyanisole
Two Year(s)  Rat  Oral  728 g/kg/day  Gastrointestinal system, Tumors
Two Year(s)  Rat  Oral  874 g/kg/day  Gastrointestinal system, Endocrine system, Tumors

Carcinogen Status: None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA, or ACGIH as a carcinogen.

Butylated hydroxyanisole
IARC: Group 2B
NTP: Listed
OSHA: Present

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

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

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

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.

Ascorbic acid (Vitamin C)

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 200-066-2

Lactose NF, monohydrate

Australia (AICS): Listed

Microcrystalline cellulose

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

Starch, pregelatinized

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 232-679-6

Citric acid monohydrate

Australia (AICS): Listed

Butylated hydroxyanisole

California Proposition 65 carcinogen, initial date 1/1/90
Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): Listed
EU EINECS/ELINCS List 246-563-8

Magnesium stearate

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

16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communications
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