



MATERIAL SAFETY DATA SHEET

Revision date: 15-Jul-2010

Version: 1.0

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

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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

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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

| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|----------------------------|------------|-----------------------|-------------------|------------------------|
| Simvastatin | 79902-63-9 | Not Listed | Not Listed | 5,10,20,40, or 80mg*** |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | * |
| Starch, pregelatinized | 9005-25-8 | 232-679-6 | Not Listed | * |
| Butylated hydroxyanisole | 25013-16-5 | 246-563-8 | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | * |

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| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
|---------------------------|------------|-----------------------|-------------------|---|
| Ascorbic acid (Vitamin C) | 50-81-7 | 200-066-2 | Not Listed | * |
| Lactose NF, monohydrate | 64044-51-5 | Not Listed | Not Listed | * |
| Citric acid monohydrate | 5949-29-1 | Not Listed | Not Listed | * |

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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.

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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/m ³ TWA |
| Australia TWA | 10 mg/m ³ |
| 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/m ³ total 5 mg/m ³ |
| Portugal OEL - TWA | Listed |
| Romania OEL - TWA | Listed |
| Spain OEL - TWA | Listed |

Starch, pregelatinized

| | |
|-----------------------------------|---|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ TWA |
| Australia TWA | 10 mg/m ³ |
| 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/m ³ total 5 mg/m ³ |
| Portugal OEL - TWA | Listed |
| Spain OEL - TWA | Listed |

Magnesium stearate

| | |
|-----------------------------------|--------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ TWA |
| Australia TWA | 10 mg/m ³ |
| 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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of >10ug/m³ to < 100ug/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).

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 |
| Molecular Formula: | Mixture | 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

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11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 > 2000 mg/m³

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

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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:

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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

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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