MATERIAL SAFETY DATA SHEET

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

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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	*

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.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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

11. TOXICOLOGICAL INFORMATION

Rat Inhalation LC50 > 2000 mg/m^3

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