SAFETY DATA SHEET

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

Product Identifier

Material Name: Lipitor® (Atorvastatin Calcium) Tablets

Trade Name: Aspavor, Atorvastatin, Atorvastatin Almus, Cardyl, Citalor, Eturion, Lipitor, Liprimar, Sortis, Tahor, Torvast, Xarator, Zarator, Texzor, Atorvastatina, Orbeos, Totalip

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Lipid regulating agent.

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Atorvastatin calcium	134523-03-8	Not Listed	Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	7.0
Calcium carbonate	471-34-1	207-439-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Simethicone emulsion	67762-90-7	Not Listed	Not Listed	*
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Atorvastatin calcium

Pfizer OEL TWA-8 Hr:	50 µg/m^3

Calcium carbonate

Australia TWA	10 mg/m^3
Bulgaria OEL - TWA	10.0 mg/m^3
France OEL - TWA	10 mg/m^3
Latvia OEL - TWA	6 mg/m^3
Poland OEL - TWA	10 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Vietnam OEL - TWAs	10 mg/m^3

Magnesium stearate

Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3 4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Russia OEL - TWA	6 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3
Vietnam OEL - TWAs	10 mg/m^3 5 mg/m^3

Exposure Controls

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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	White
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Microcrystalline cellulose
No data available
Lactose NF, monohydrate
No data available
Calcium carbonate
No data available
Opadry white
No data available
Hydroxypropyl cellulose
No data available
Simethicone emulsion
No data available
Magnesium stearate
No data available
Polysorbate 80
No data available
Atorvastatin calcium
No data available
Croscarmellose sodium
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available

10. STABILITY AND REACTIVITY

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
Hazardous Decomposition Products:	No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

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

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/m^3

Polysorbate 80
Rat Oral LD50 25 g/kg

Atorvastatin calcium
Rat/Mouse Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000mg/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

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)

11. TOXICOLOGICAL INFORMATION

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.

Toxicity:

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

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 perfingens (Bacterium) MIC 100 mg/L
Activated sludge OECD EC50 >1000 mg/L

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Atorvastatin calcium
TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready
Photolysis: (Method, pH, Endpoint, Results)
Atorvastatin calcium
OECD 7 Half-Life 0.339 Day(s)

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

15. REGULATORY INFORMATION

Simethicone emulsion

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Atorvastatin calcium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Croscarmellose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Opadry white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Hydroxypropyl cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Calcium carbonate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	207-439-9

Polysorbate 80

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Lactose NF, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Magnesium stearate

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Data Sources:	Pfizer proprietary drug development information. Publicly available toxicity information.
Reasons for Revision:	Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information.
Revision date:	25-May-2018
	Product Stewardship Hazard Communication
Prepared by:	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