MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Torcetrapib/Atorvastatin Calcium Tablets

Trade Name: Not determined
Chemical Family: Not determined
Intended Use: high cholesterol (hyperlipidemia) atherosclerosis

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Torcetrapib (CP-529,414)	NOT ASSIGNED	Not listed	38-83
Atorvastatin calcium	134523-03-8	Not listed	16-60
Calcium carbonate	471-34-1	207-439-9	*
Croscarmellose sodium	74811-65-7	Not listed	*
Starch, pregelatinized	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Dicalcium phosphate	10103-46-5	233-283-6	*
Crospovidone	9003-39-8	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Polysorbate 80	9005-65-6	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Off-white tablet
Signal Word: CAUTION

Statement of Hazard: Possible risk of harm to the unborn child May cause liver effects
Eye Contact: Dust may cause irritation (based on components).
Skin Contact: Not expected to cause skin irritation (based on components).
Inhalation: An Occupational Exposure Limit has been established for this substance; see Section 8.
Ingestion: Accidental ingestion may cause effects similar to those seen in clinical use. See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

Known Clinical Effects: Adverse effects associated with the therapeutic use of torcetrapib include headache, weakness, elevated blood pressure, diarrhea, gastrointestinal discomfort, and dizziness. The most common adverse effects seen with the therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain.

Potential Health Effects: Animal studies have shown a potential to cause adverse effects on the fetus. Therapeutic use of atorvastatin has been associated with changes in liver function and muscle aches or weakness.

EU Indication of danger: Toxic to Reproduction; Category 3
Dangerous for the Environment

EU Hazard Symbols:

R53 - May cause long-term adverse effects in the aquatic environment.
R63 - Possible risk of harm to the unborn child.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

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.

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: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of oxides of carbon and nitrogen.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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: Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly. Prevent discharge to drains.

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: Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust. Transfer all waste to a labeled container and move it to a secure holding area. Prevent discharge to drains.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation.

Storage Conditions: Store in a cool, dry, well-ventilated area.

Storage Temperature: Store at controlled room temperature

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Torcetrapib (CP-529,414)
Pfizer OEL TWA-8 Hr: 0.05 mg/m³

Atorvastatin calcium
Pfizer OEL TWA-8 Hr: 0.05 mg/m³

Calcium carbonate
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

Starch, pregelatinized
OSHA - Final PELS - TWAs: 15 mg/m³ total dust
5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

Microcrystalline cellulose
OSHA - Final PELS - TWAs: 15 mg/m³ total dust
5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

Magnesium stearate
ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Atorvastatin: 03-HXL-021 Torcetrapib (CP-529,414): 03-HXL-002 (Contact Pfizer for additional details)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system. For laboratory use, handle in a lab fume hood.

Personal Protective Equipment:

Hands: Chemical protective gloves
Eyes: Safety glasses or goggles

Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
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:**	Off-white
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

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
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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

Acute Toxicity: (Species, Route, End Point, Dose)

Torcetrapib (CP-529,414)
Rat Oral LD50 1000
Rat Dermal LD50 > 2000

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

Calcium carbonate
Rat Oral LD50 6450 mg/kg

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

Polysorbate 80
Rat Oral LD50 25 g/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Irritation / Sensitization: (Study Type, Species, Severity)

Torcetrapib (CP-529,414)
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

Atorvastatin calcium
Skin Sensitization - Beuhler Guinea Pig Negative
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Mild

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

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

Torcetrapib (CP-529,414)
Six Month(s) Rat Oral 60 mg/kg/day LOAEL Liver
Twelve Month(s) Monkey 240 mg/kg/day NOAEL None identified

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

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

Torcetrapib (CP-529,414)
Fertility and Embryonic Development Rat Oral 60 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rat Oral 60 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 40 mg/kg/day NOAEL Fetotoxicity
Prenatal & Postnatal Development Rat Oral 5 mg/kg/day NOAEL Fetotoxicity

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)

Torcetrapib (CP-529,414)
Bacterial Mutagenicity (Ames) Negative
Mammalian Cell Mutagenicity HGPRT Negative
Chromosome Aberration Human Lymphocytes Negative

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

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.

Crospovidone
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: This formulation has not been tested as a whole, the following apply to component substance(s): Long-term adverse effects to aquatic organisms are possible. Releases to the environment should be avoided.

Mobility, Persistence and Degradability: Torcetrapib has low solubility and can migrate into the sediment

Bioaccumulation and Toxicity: Long-term adverse effects to aquatic organisms are possible.

Torcetrapib (CP-529,414)
Daphnia magna LC50/48 hr (NPDES) > 0.033 mg/L
Sheepshead Minnow LC50/48 hr (NPDES) > 0.05 mg/L
Skeletonema Algae LC50/96 hr (NPDES) > 0.037 mg/L

Atorvastatin calcium
Daphnia magna EC50 48 Hours 200 mg/L
Daphnia magna NOEC 48 Hours 81 mg/L
Aspergillus niger MIC > 1000 mg/L
Trichoderma viride MIC > 1000 mg/L
Clostridium perfringens MIC 100 mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Toxic to Reproduction; Category 3
Dangerous for the Environment

EU Risk Phrases:

R53 - May cause long-term adverse effects in the aquatic environment.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:

S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
CAUTION
Possible risk of harm to the unborn child May cause liver effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Dicalcium phosphate

EU EINECS List	233-283-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Crospovidone

Inventory - United States TSCA - Sect. 8(b)	Listed

Calcium carbonate

EU EINECS List	207-439-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed

Starch, pregelatinized

EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Microcrystalline cellulose

EU EINECS List	232-674-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet