MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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1-212-573-2222

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CT13 9NJ
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Verapamil Hydrochloride Tablets, Controlled-Onset Extended-Release (Can)

Trade Name: Covera-HS
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Verapamil Hydrochloride	152-11-4	205-800-5	31-33
Butylated hydroxytoluene	128-37-0	204-881-4	*
Titanium dioxide	13463-67-7	236-675-5	*
Black Iron Oxide	1317-61-9	215-277-5	*
Magnesium Stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Cellulose Acetate	9004-70-0	Not listed	*
Lactose	63-42-3	200-559-2	*
Hydroxyethyl cellulose	9004-62-0	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Polyethylene glycol	25322-68-3	Not listed	*
Polyethylene oxide NF	25322-68-3	Not listed	*
Polysorbate 80	9005-65-6	Not listed	*
Povidone	9003-39-8	Not listed	*
SODIUM CHLORIDE	7647-14-5	231-598-3	*
Hypromellose	9004-65-3	Not listed	*

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

3. HAZARDS IDENTIFICATION

Appearance: Purple or yellow film-coated tablets.
Signal Word: DANGER

Statement of Hazard: Toxic if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:
Short Term: Not expected to cause skin irritation , eye irritation (based on components) .
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, kidneys, ureter bladder (based on components) .

Known Clinical Effects: May cause low blood pressure and dizziness. Occasional, transient changes reported in liver function tests, but no liver damage seen. This material has been shown to be secreted in low concentrations in human breast milk.

EU Indication of danger: Toxic
Toxic to Reproduction; Category 3

EU Hazard Symbols:

EU Risk Phrases:
R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May emit toxic fumes such as oxides of nitrogen and chlorine gas.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.
Storage Conditions:	Store at controlled room temperature. Protect from light.
Storage Temperature:	(15-25°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Titanium dioxide

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Black Iron Oxide

ACGIH Threshold Limit Value (TWA)	= 1 mg/m^3 TWA	
Australia TWA	= 1 mg/m^3 TWA	

Magnesium Stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

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

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Verapamil Hydrochloride

Pfizer Occupational Exposure Band (OEB):	OEB3 (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. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear impervious gloves if skin contact is possible.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	None required for normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material.
Respiratory protection:	Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Film-coated tablets .	**Color:**	Purple or yellow.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Exposure to light.
Incompatible Materials:	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)

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Lactose
Rat Oral LD50 > 10 g/kg

Polysorbate 80
Rat Oral LD50 25 g/kg

SODIUM CHLORIDE
Rat Inhalation LC50/1hr > 42 g/m^3
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Butylated hydroxytoluene
Rat Oral LD50 1700 mg/kg
Mouse Oral LD50 650 mg/kg
Rat Oral LD50 890 mg/kg

Mouse Intraperitoneal LD 50 138 mg/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg

Verapamil Hydrochloride
Rat Oral LD 50 108 mg/kg
Mouse Oral LD 50 163 mg/kg
Rat Intravenous LD 50 16 mg/kg
Mouse Intravenous LD 50 5795 mg/kg
Rat Subcutaneous LD 50 107 mg/kg

Black Iron Oxide
Rat Oral LD50 >1000 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)

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

SODIUM CHLORIDE
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Butylated hydroxytoluene
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

Polyethylene oxide NF
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Verapamil Hydrochloride
Skin Irritation Rabbit Mild

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

Magnesium Stearate
13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Butylated hydroxytoluene
4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver
4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

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

Butylated hydroxytoluene
Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic

Verapamil Hydrochloride
Reproductive & Fertility Rat Oral 55 mg/kg/day NOAEL Fertility
Embryo / Fetal Development Rat Oral 60 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rat Oral 60 mg/kg/day LOAEL Fetotoxicity
Embryo / Fetal Development Rabbit Oral 15 mg/kg/day NOAEL Not Teratogenic

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

Verapamil Hydrochloride
Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

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

Verapamil Hydrochloride
18 Month(s) Rat Oral 58 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Rat Oral 120 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: See below

Titanium dioxide
IARC: Group 2B
OSHA: Present

Povidone
IARC: Group 3

Butylated hydroxytoluene
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T

EU Indication of danger:
Toxic
Toxic to Reproduction; Category 3

EU Risk Phrases:
R25 - Toxic if swallowed.
R63 - Possible risk of harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S28 - After contact with skin, wash immediately with plenty of water.
S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
Toxic if swallowed.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision B
Class D, Division 2, Subdivision A

Verapamil Hydrochloride

Australia (AICS):	Present
EU EINECS List	205-800-5

Butylated hydroxytoluene

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-881-4

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Black Iron Oxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-277-5

Cellulose Acetate

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2

Hydroxyethyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Polyethylene oxide NF

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

SODIUM CHLORIDE

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-598-3

Magnesium Stearate

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

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet