



MATERIAL SAFETY DATA SHEET

Revision date: 07-Apr-2010

Version: 1.3

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

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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. 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 Classification

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.

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2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Verapamil Hydrochloride	152-11-4	205-800-5	T; R25, R62, R63	31-33
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	OEL	*

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

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

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.

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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: avoid breathing dust and avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, 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 at controlled room temperature. Protect from light.

Storage Temperature: (15-25°C)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m ³ TWA
Australia TWA	10 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	20 mg/m ³ MAK
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Portugal OEL - TWA	Listed
Slovenia OEL - TWA	Listed

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Black Iron Oxide

ACGIH Threshold Limit Value (TWA)	1 mg/m ³ TWA
Australia TWA	1 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Finland OEL - TWA	Listed
Greece OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Polyethylene oxide NF

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

SODIUM CHLORIDE

Latvia OEL - TWA	Listed
Lithuania 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

Polyethylene glycol

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ MAK
Slovenia OEL - TWA	Listed

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 $>10\mu\text{g}/\text{m}^3$ to $<100\mu\text{g}/\text{m}^3$)

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.
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:	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

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

Titanium dioxide

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11. TOXICOLOGICAL INFORMATION

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 Sub-tenon injection (eye) LC50/1hr > 42 g/m³
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

Hydroxypropyl methylcellulose

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

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11. TOXICOLOGICAL INFORMATION

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 LOEL Liver

Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOEL 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 3 (Not Classifiable)

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.

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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 Symbol:

EU Indication of danger:

T
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



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15. REGULATORY INFORMATION

Verapamil Hydrochloride

Australia (AICS):	Listed
EU EINECS/ELINCS List	205-800-5

Butylated hydroxytoluene

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

Titanium dioxide

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

Black Iron Oxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-277-5

Cellulose Acetate

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

Lactose

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

Hydroxypropyl cellulose

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

Polyethylene oxide NF

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

Polysorbate 80

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

Povidone

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

SODIUM CHLORIDE

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

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EU EINECS/ELINCS List	231-598-3
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Hydroxypropyl methylcellulose

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

Magnesium Stearate

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

Hydroxyethyl cellulose

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

Polyethylene glycol

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R25 - Toxic if swallowed.

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by:

Toxicology and Hazard Communication
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