



SAFETY DATA SHEET

Revision date: 23-May-2018

Version: 4.2

Page 1 of 10

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

Product Identifier

Material Name: Verapamil HCl Caplets, Sustained Release

Trade Name: CALAN SR

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as Anti-anginal; anti-hypertensive.

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 3

Reproductive Toxicity: Category 2

Acute aquatic toxicity: Category 2

Chronic aquatic toxicity: Category 2

Label Elements

Signal Word: Danger

Hazard Statements:
H301 - Toxic if swallowed
H361d - Suspected of damaging the unborn child
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 2 of 10
Version: 4.2

Precautionary Statements:

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P273 - Avoid release to the environment
- P281 - Use personal protective equipment as required
- P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P321 - Specific treatment (see supplemental instructions on the administration of antidotes on this label)
- P330 - Rinse mouth
- P391 - Collect spillage
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations



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 requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Verapamil Hydrochloride	152-11-4	205-800-5	Acute Tox. 3, H301 Repr. 2, H361dAcute 2,H401Chronic 2,H411	30-34

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Opadry	Not assigned	Not Listed	Not Listed	*
Opadry Pink	MIXTURE	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Sodium alginate	9005-38-3	Not Listed	Not Listed	*

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 3 of 10
Version: 4.2

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: 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.

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: Not applicable

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.

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 4 of 10
Version: 4.2

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

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

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.

Magnesium Stearate

Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Russia OEL - TWA 6 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 3 mg/m³
Vietnam OEL - TWAs 10 mg/m³
5 mg/m³

Polyethylene glycol

Austria OEL - MAKs 1000 mg/m³
Germany - TRGS 900 - TWAs 1000 mg/m³
Germany (DFG) - MAK 1000 mg/m³ average molecular weight 200-600
Slovakia OEL - TWA 1000 mg/m³
Slovenia OEL - TWA 1000 mg/m³
Switzerland OEL - TWAs 1000 mg/m³

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 5 of 10
Version: 4.2

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): OEB 3 (control exposure to the range of 10ug/m³ to < 100ug/m³)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. General room ventilation is adequate unless the process generates dust, mist or fumes.

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: Film-coated Caplets .

Odor: No data available.

Molecular Formula: Mixture

Color: Pink or green.

Odor Threshold: No data available.

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)

Magnesium Stearate

No data available

Sodium alginate

No data available

Povidone

No data available

Carnauba wax

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 6 of 10
Version: 4.2

9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Opadry

No data available

Polyethylene glycol

No data available

Microcrystalline cellulose

No data available

Verapamil Hydrochloride

Measured Log P 3.79

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

Flammability:

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

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

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: 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 (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.

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

Povidone

Rat Oral LD50 100 g/kg

Microcrystalline cellulose

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 7 of 10
Version: 4.2

11. TOXICOLOGICAL INFORMATION

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

Verapamil Hydrochloride

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

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

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

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

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

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 8 of 10
Version: 4.2

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Povidone
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Toxic to aquatic life with long lasting effects. See Aquatic toxicity data of the active ingredient, below:

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

Verapamil Hydrochloride

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 2.72 mg/L
Daphnia magna (Water Flea) LC50 48 Hours 7.04 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Verapamil Hydrochloride

Pimephales promelas (Fathead Minnow) OECD 28 Day(s) NOEC 0.3 mg/L Growth
Pimephales promelas (Fathead Minnow) OECD 28 Day(s) NOEC 0.6 mg/L Survival

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)

Verapamil Hydrochloride
Measured Log P 3.79

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.

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 9 of 10
Version: 4.2

15. REGULATORY INFORMATION

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

Magnesium Stearate

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

Opadry

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

Opadry Pink

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

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

Povidone

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

Sodium alginate

SAFETY DATA SHEET

Material Name: Verapamil HCl Caplets, Sustained Release
Revision date: 23-May-2018

Page 10 of 10
Version: 4.2

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	Not Listed

Verapamil Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	205-800-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child
Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 23-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