MATERIAL SAFETY DATA SHEET

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

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

Material Name: Codeine Poly(styrene-divinylbenzene) Sulfonate and Phenyltoloxamine Poly(styrene-divinylbenzene) Sulfonate Syrup

Trade Name: Codipront(R) Retard
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as cough medicine

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Phenyltoloxamine Poly(styrene-divinylbenzene) sulfonate	Not Assigned	Not listed	0.2
Codeine Poly(styrene-divinylbenzene) Sulfonate	Not Assigned	Not listed	1.2

Ingredient	CAS Number	EU EINECS List	%
Hydrogel 843T	Not Assigned	Not listed	*
Sodium saccharin	128-44-9	204-886-1	*
Sorbitol	6706-59-8	Not listed	*
Propylparaben	94-13-3	202-307-7	*
Edetate disodium	139-33-3	205-358-3	*
Sodium bicarbonate	144-55-8	205-633-8	*
Flavor	NOT ASSIGNED	Not listed	*
Methylparaben	99-76-3	202-785-7	*
Water, purified	7732-18-5	231-791-2	*
Sodium Citrate, Anhydrous	6132-04-3	Not listed	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	*

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

3. HAZARDS IDENTIFICATION

Appearance: Viscous fluid

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Known Clinical Effects: The most frequently observed adverse reactions to codeine include lightheadedness, dizziness, drowsiness, nausea, vomiting, constipation, and depression of respiration. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Clinical use of this drug has caused addiction, symptoms of dependence/withdrawal.

EU Indication of danger: Not classified

Additional Information: Codeine is classified by the DEA as a Schedule II controlled substance.

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 eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get 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: Not an expected route of exposure. If discomfort occurs, get medical attention.

5. FIRE FIGHTING MEASURES

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

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

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 spill with absorbent material. 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 contact with eyes Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Codeine Poly(styrene-divinylbenzene) Sulfonate

Pfizer OEL TWA-8 Hr: 0.07mg/m³

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Syrupy liquid	**Color:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
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)

Sodium bicarbonate
Rat Oral LD50 4220 mg/kg
Mouse Oral LD50 3360 mg/kg
Rat Inhalation LC50 > 900 mg/m³

Codeine Poly(styrene-divinylbenzene) Sulfonate
Rat Oral LD50 427 mg/kg
Rat Subcutaneous LD50 229 mg/kg
Mouse Oral LD50 250 mg/kg

Phenyltoloxamine Poly(styrene-divinylbenzene) sulfonate
Rat Oral LD50 1400 mg/kg
Mouse Oral LD50 1127 mg/kg

Methylparaben
Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Sodium saccharin
Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg
Rat Intraperitoneal LD50 7100 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.

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

Codeine Poly(styrene-divinylbenzene) Sulfonate
14 Day(s) Mouse Oral 3000 mg/kg NOEL None identified
13 Week(s) Rat Oral 450 mg/kg/day NOEL None identified
13 Week(s) Mouse Oral 1000 mg/kg/day NOEL None identified

Sodium saccharin
36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

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

Codeine Poly(styrene-divinylbenzene) Sulfonate
Embryo / Fetal Development Mouse Oral 150 mg/kg/day NOEL Maternal toxicity, Embryotoxicity, Not teratogenic
Embryo / Fetal Development Hamster Oral 20 mg/kg/day NOEL Embryotoxicity, Not Teratogenic

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

Codeine Poly(styrene-divinylbenzene) Sulfonate
2 Year(s) Rat Oral, in feed 70 NOEL Not carcinogenic
2 Year(s) Mouse Oral, in feed 400 NOEL Not carcinogenic

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

Sodium saccharin
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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 Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium saccharin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	204-886-1

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

Edetate disodium

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-358-3

Sodium bicarbonate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-633-8

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Sodium Citrate, Anhydrous

Australia (AICS):	Present

Sodium phosphate, monobasic

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-449-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

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End of Safety Data Sheet