



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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

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

Material Name: Codeine Poly(styrene-divinylbenzene) Sulfonate Capsules

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Magnesium stearate	557-04-0	209-150-3	*
Titanium dioxide	13463-67-7	236-675-5	*
Iron oxide	1309-37-1	215-168-2	*
Codeine Poly(styrene-divinylbenzene) Sulfonate	Not Assigned	Not listed	30 mg ***

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Gelatin	9000-70-8	232-554-6	*
Macrogol 400	Not assigned	Not listed	*

Additional Information:

* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause gastrointestinal and central nervous systems effects

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: Harmful

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EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.

Additional Information: Note:

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

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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. Avoid generating airborne dust.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Titanium dioxide

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Iron oxide

OSHA - Final PELs - TWAs: = 10 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 5 mg/m³ TWA

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.

Analytical Method: Analytical method available for codeine phosphate. Contact Pfizer Inc for further information.

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. 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:	Tablets	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

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Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

Codeine Poly(styrene-divinylbenzene) Sulfonate

Rat Oral LD50 427 mg/kg
Rat Subcutaneous LD50 229 mg/kg
Mouse Oral LD50 250 mg/kg

Lactose

Rat Oral LD50 > 10 g/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Titanium dioxide

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

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: See below

Iron oxide

IARC: Group 3

Titanium dioxide

IARC: Group 2B

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OSHA: Present

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 Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
Harmful if swallowed.
May cause gastrointestinal and central nervous systems effects

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.

Lactose

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

Present

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Australia (AICS):	Present
EU EINECS List	200-559-2
Magnesium stearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3
Gelatin	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6
Titanium dioxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5
Iron oxide	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-168-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. 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