



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

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

Material Name: Benproperine Phosphate Film-Coated Tablets

Trade Name: Flaveric(R) Tablets; Cofrel(R) Tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antitussive

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Benproperine Phosphate	3563-76-6	222-635-4	20.8
Magnesium stearate	557-04-0	209-150-3	*
Titanium oxide	12137-20-1	235-236-5	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*

Ingredient	CAS Number	EU EINECS List	%
Light Anhydrous Silicic Acid	7699-41-4	231-716-3	*
Lactose	63-42-3	200-559-2	*
Carboxymethylcellulose Calcium	9050-04-8	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Hypromellose	9004-65-3	Not listed	*
Macrogol 6000	Not assigned	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Medium Chain Fatty Acid Triglyceride	Unassigned	Not listed	*
Carnauba wax	8015-86-9	232-399-4	*
Aminoalkyl methacrylate copolymer E	24938-16-7	Not listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	*

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

3. HAZARDS IDENTIFICATION

Appearance: White film-coated tablets

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

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Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal disturbances and abdominal pain. May cause sleepiness, dry mouth, fatigue. May cause mild skin rash.

EU Indication of danger: Not classified

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: If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Consult a physician if necessary

Inhalation: Move to fresh air Consult a physician

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide and oxides of nitrogen.

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

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General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

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

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D: = 20 mppcf TWA
ACGIH Threshold Limit Value (TWA) = 2 mg/m³ TWA
Australia TWA = 2.5 mg/m³ TWA containing no asbestos fibers
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. 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:	Film-coated tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
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)

Benproperine Phosphate

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Mouse Oral LD 50 1100 mg/kg
Mouse Subcutaneous LD 50 710 mg/kg

Lactose

Rat Oral LD50 > 10 g/kg

Magnesium stearate

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

Talc (non-asbestiform)

Rat Oral LD50 > 1600 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 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.

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

**Talc (non-asbestiform)
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

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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.

Benproperine Phosphate

EU EINECS List 222-635-4

Light Anhydrous Silicic Acid

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-716-3

Lactose

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

Carboxymethylcellulose Calcium

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

Hydroxypropyl cellulose

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

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

Titanium oxide

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 235-236-5

Hydroxypropyl cellulose

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

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 238-877-9

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Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4

Aminoalkyl methacrylate copolymer E

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

Calcium phosphate dibasic, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-826-1

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. 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