



MATERIAL SAFETY DATA SHEET

Revision date: 19-Apr-2007

Version: 2.2

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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

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

Material Name: Pirmenol Hydrochloride Capsules

Trade Name: Pirmenol
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of cardiac arrhythmias.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Pirmenol Hydrochloride	61477-94-9	Not listed	50mg/100mg***
Corn Starch	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Sodium lauryl sulfate	151-21-3	205-788-1	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Gelatin	9000-70-8	232-554-6	*

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: White capsules
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, heart, spleen and kidneys.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include taste abnormalities, dizziness, headache, dry mouth, fatigue and chest pain.

EU Indication of danger: Harmful

EU Hazard Symbols:

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EU Risk Phrases:

R22 - Harmful if swallowed.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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 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:

Not available

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Pirmenol Hydrochloride

Pfizer OEL TWA-8 Hr: 200 µg/m³

Corn Starch

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³
Pfizer STEL 0.75 mg/m³

Magnesium stearate

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

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. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection: 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:	Capsule	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Not determined
Incompatible Materials: None identified

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)

Pirmenol Hydrochloride

Rat Oral LD50 360 mg/kg
Rat IV LD50 24 mg/kg
Mouse Oral LD50 216 mg/kg
Mouse IV LD50 21 mg/kg

Microcrystalline cellulose

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

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Magnesium stearate

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

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)

Microcrystalline cellulose

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

Sodium lauryl sulfate

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Pirmenol Hydrochloride

2 Week(s) Mouse Oral 150 mg/kg/day NOAEL No effects at maximum dose
1 Month(s) Rat Intravenous 7.5 mg/kg/day NOAEL No effects at maximum dose
3 Month(s) Rat Oral 50 mg/kg/day NOAEL Liver, Kidney, Heart, Spleen
3 Month(s) Dog Oral 30 mg/kg/day NOAEL No effects at maximum dose
104 Week(s) Rat Oral 10 mg/kg/day LOAEL None identified

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

Pirmenol Hydrochloride

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not teratogenic

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Embryo / Fetal Development	Rat	Oral	150 mg/kg/day	NOAEL	Not Teratogenic
Peri-/Postnatal Development	Rat	Oral	50 mg/kg/day	NOAEL	Not Teratogenic
Peri-/Postnatal Development	Rat	Oral	25 mg/kg/day	NOAEL	Maternal Toxicity
Embryo / Fetal Development	Rabbit	Oral	10 mg/kg/day	NOAEL	Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Pirmenol Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Rat Bone Marrow Negative
In Vitro Chinese Hamster Ovary (CHO) cells Negative

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

Pirmenol Hydrochloride

2 Year(s) Mouse Oral, in feed 50 mg/kg/day NOAEL Not carcinogenic
2 Year(s) Rat Oral, in feed 50 mg/kg/day NOAEL Not carcinogenic

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly 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.

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OSHA Label:

WARNING

Harmful if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class:

D1b toxic materials



Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

Gelatin

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-554-6

Magnesium stearate

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

16. OTHER INFORMATION

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

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

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End of Safety Data Sheet