



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.3

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

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

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

Material Name: Sinequan (Doxepin hydrochloride) capsules - 10, 25, and 50 mg

Trade Name: Sinequan
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antidepressant, antianxiety agent, anti-itch treatment (antipruritus)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Doxepin hydrochloride	1229-29-4	214-966-8	7.24 - 18.2
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not listed	*
Starch	9005-25-8	232-679-6	*

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

3. HAZARDS IDENTIFICATION

Appearance: 10 mg - red/pink capsules 25 mg - blue/pink capsules 50 mg - white/pink capsules
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
May cause reproductive system effects
Antidepressant: may cause central nervous system effects

Additional Hazard Information:

Short Term: Harmful if swallowed (based on animal data).
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, and dilated pupils. Cases of severe overdose may lead to respiratory depression, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

EU Indication of danger: Toxic to Reproduction; Category 3

EU Hazard Symbols:



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EU Risk Phrases:

R62 - Possible risk of impaired fertility.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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:

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact:

Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion:

Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products:

May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

General Handling:

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use only in a well-ventilated area. Minimize dust generation and accumulation.

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Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature: 15 - 30 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Doxepin hydrochloride

Pfizer OEL TWA-8 Hr: 0.6 mg/m³

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

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

Analytical Method: Analytical method available for Doxepin Hydrochloride. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk. For laboratory use, handle in a lab fume hood.

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:	Capsule	Color:	Red Pink Blue White
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available

Polymerization: Will not occur

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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)

Starch

Mouse IP LD50 6600 mg/kg

Doxepin hydrochloride

Mouse (M) Oral LD50 157 mg/kg

Mouse (F) Oral LD50 170 mg/kg

Rat (M) Oral LD50 428 mg/kg

Rat (F) Oral LD50 399 mg/kg

Dog Oral LD50 > 200 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.

Inhalation Acute Toxicity No data available

Ingestion Acute Toxicity See Acute toxicity table

Eye Irritation / Sensitization No data available

Skin Irritation / Sensitization An IM irritation study conducted in rabbits showed that the compound was moderately irritating when injected into muscle.

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

Doxepin hydrochloride

30 Day(s) Dog Oral 25 mg/kg/day LOEL Central nervous system

1 Year(s) Rat Oral 25 mg/kg/day NOEL None identified

18 Month(s) Rat Oral 50 mg/kg/day NOEL Liver

1 Year(s) Dog Oral 5 mg/kg/day NOEL Central Nervous System

Subchronic Effects

Subchronic oral toxicity studies were performed in rats at doses up to 200 mg/kg/day and in dogs at doses up to 50 mg/kg/day for five weeks and one month, respectively. In rats, deaths were seen in all high-dose animals and in 1/3 of the mid-dose animals. No necropsies were performed in this study. No gross, histopathological or hematological changes were observed in dogs. The low dose (25 mg/kg/day) animals showed sedation and mild emesis.

Chronic Toxicity

Chronic toxicity studies were conducted in rats and dogs. Rats treated for 1 year exhibited dose-dependent fatty metamorphosis of the liver, which was moderate to marked at the high dose (200 mg/kg/day). A 1-year study in dogs resulted in ptosis, sedation, tremors, and intermittent emesis at doses of 25 and 50 mg/kg/day.

Chronic Effects/Carcinogenicity

No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material. A similar drug, amitriptylline, was negative when tested for carcinogenicity.

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

Doxepin hydrochloride

Reproductive & Fertility Rat Oral 5 mg/kg/day NOEL Fertility

Embryo / Fetal Development Rat Oral 25 mg/kg/day NOEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 25 mg/kg/day NOEL Not Teratogenic

Embryo / Fetal Development Monkey Oral 18 mg/kg/day NOEL Not Teratogenic

Reproductive Effects

Studies in rats resulted in a reduced conception rate in animals receiving the high dose (25 or 50 mg/kg). No effects on developmental behavior or reproductive performance of the rat offspring were observed in a peri- and post-natal toxicity study.

Teratogenicity

No evidence of teratogenicity was observed in rats, rabbits, or monkeys.

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Mutagenicity No data are available regarding the genetic toxicity of doxepin. However, no evidence of mutagenicity was seen when a similar drug, amitriptyline, was tested in bacterial cells.

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

Additional Information: Doxepin is found in breast milk and the its use by lactating women may cause sleep apnea and drowsiness in breast-fed infants.

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. 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: Toxic to Reproduction; Category 3

EU Risk Phrases: R62 - Possible risk of impaired fertility.

EU Safety Phrases: S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
Harmful if swallowed.
May cause reproductive system effects
Antidepressant: may cause central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

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Doxepin hydrochloride

Australia (AICS):	Present
EU EINECS List	214-966-8

Starch

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

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /
Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 -
Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 -
Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet