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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222 

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
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+00 44 (0)1304 616161 

Emergency telephone number:  CHEMTREC (24 hours): 1-800-424-9300  
Emergency telephone number:  ChemSafe (24 hours): +44 (0)208 762 8322 

Materials Name: Sinequan (Doxepin hydrochloride) capsules - 75, 100, and 150 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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxepin hydrochloride</td>
<td>1229-29-4</td>
<td>214-966-8</td>
<td>33.8 - 38.5</td>
</tr>
<tr>
<td>Magnesium stearate/sodium lauryl sulfate blend</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

Appearance: 75 mg - white capsules  100 mg - blue/white capsules  150 mg - blue 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: Harmful
Toxic to Reproduction; Category 3

EU Hazard Symbols: ☒
EU Risk Phrases:
- R22 - Harmful if swallowed.
- 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.

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.


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.

Personal Protective Equipment:

Hands: Rubber gloves 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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Color:</th>
<th>White Blue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Material Name: Sinequan (Doxepin hydrochloride) capsules - 75, 100, and 150 mg
Revision date: 05-Jan-2007

Hazardous Decomposition Products: No data available
Polymerization: Will not occur

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.

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: Individuals taking monoamine oxidase inhibitors (MAO) should avoid exposure to this material.

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: Harmful
Toxic to Reproduction; Category 3

EU Risk Phrases:
R22 - Harmful if swallowed.
R62 - Possible risk of impaired fertility.

EU Safety Phrases:
S22 - Do not breathe dust.
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

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 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