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

Product Identifier

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate
Trade Name: Sinequan
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antidepressant, antianxiety agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 2  Effects on or via lactation

EU Classification:
EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:
R62 - Possible risk of impaired fertility.
R64 - May cause harm to breastfed babies.

Label Elements

Signal Word: Warning
Hazard Statements:
H361f - Suspected of damaging fertility
H362 - May cause harm to breast-fed children

Precautionary Statements:
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
SAFETY DATA SHEET

Other Hazards
Australian Hazard Classification (NOHSC): No data available

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxepin hydrochloride</td>
<td>1229-29-4</td>
<td>214-966-8</td>
<td>N;R50 R64</td>
<td>Acute Tox.4 (H302) Repr.2 (H261f) Lact. (H362) Aquatic Acute 1 (H400)</td>
<td>1-5</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Peppermint oil</td>
<td>8006-90-4</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water, purified</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
Fire / Explosion Hazards: Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
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

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

Conditions for Safe Storage, Including any Incompatibilities
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
Specific end use(s): Pharmaceutical product used as antidepressant antianxiety agent anti-itch treatment (antipruritus)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Doxepin hydrochloride
Pfizer OEL TWA-8 Hr: 600μg/m³

Glycerin, USP
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 50 mg/m³
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELs - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL -TWAs 50 mg/m³

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


Exposure Controls
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:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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: 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State:</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available.</td>
</tr>
</tbody>
</table>
9. PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient: (Method, pH, Endpoint, Value)
- Peppermint oil: No data available
- Propylparaben: No data available
- Water, purified: No data available
- Methylparaben: No data available
- Glycerin, USP: No data available
- Doxepin hydrochloride: No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Short Term: Active ingredient may be harmful if swallowed. (based on animal data).
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on central nervous system, liver.

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. Secreted in human breast milk.
11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Peppermint oil
Rat  Oral  LD 50  2426 mg/kg
Mouse  Oral  LD 50  2490mg/kg

Glycerin, USP
Mouse  Oral  LD50  4090 mg/kg
Rat  Oral  LD50  12.6 g/kg
Rabbit  Dermal  LD50  > 10 g/kg
Rat  Inhalation  LC50 1hr  > 570 mg/m³
Rat  Dermal  LD 50  > 21.9 g/kg

Doxepin hydrochloride
Mouse (M)  Oral  LD50  157 mg/kg
Mouse (F)  Oral  LD50  170mg/kg
Rat (M)  Oral  LD50  428mg/kg
Rat (F)  Oral  LD50  399mg/kg
Dog  Oral  LD50  > 200mg/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.

Irritation / Sensitization: (Study Type, Species, Severity)

Glycerin, USP
Eye Irritation  Rabbit  Mild

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

Doxepin hydrochloride
30 Day(s)  Dog  Oral25 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

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

Doxepin hydrochloride
Reproductive & Fertility  Rat  Oral5 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

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

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP
- *Onchorhynchus mykiss* (Rainbow Trout) LD50 96 Hours 50 mg/L
- *Daphnia magna* (Water Flea) EC50 24 Hours >500 mg/L

Doxepin hydrochloride
- *Daphnia magna* (Water Flea) EC50 48 Hours 11.1 mg/L
- *Scenedesmus subspicatus* (Green Alga) EC50 72 Hours 0.5-0.73 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

---

Revision date: 16-Apr-2015

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Version: 4.0
15. REGULATORY INFORMATION

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Doxepin hydrochloride

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Australia (AICS): Present
EU EINECS/ELINCS List 214-966-8

Glycerin, USP

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
REACH - Annex V - Exemptions from the obligations of Register: Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern

EU EINECS/ELINCS List 200-289-5

Methylparaben

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Propylparaben

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-307-7

Peppermint oil

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
15. REGULATORY INFORMATION

| Inventory - United States TSCA - Sect. 8(b) | Present |
| **Australia (AICS):** | Present |
| EU EINECS/ELINCS List | Not Listed |

Water, purified

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| **Australia (AICS):** | Present |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List | 231-791-2 |

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

Xn - Harmful
Toxic to Reproduction: Category 2
N - Dangerous for the environment

R22 - Harmful if swallowed.
R62 - Possible risk of impaired fertility.
R64 - May cause harm to breastfed babies.
R50 - Very toxic to aquatic organisms.

**Data Sources:**

Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:**

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

**Revision date:** 16-Apr-2015

**Prepared by:**

Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet