



MATERIAL SAFETY DATA SHEET

Revision date: 27-Sep-2007

Version: 3.4

Page 1 of 7

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
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Trade Name:	Sinequan
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antidepressant, antianxiety agent

2. HAZARDS IDENTIFICATION

Appearance:	Clear, colorless liquid
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
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.
Australian Hazard Classification (NOHSC):	Non-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 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

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Revision date: 27-Sep-2007

Page 2 of 7

Version: 3.4

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Doxepin hydrochloride	1229-29-4	214-966-8	N;R50 R64 Repr. Cat.3;R62 Xn;R22	<1.0
Glycerin, USP	56-81-5	200-289-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Peppermint oil	8006-90-4	Not listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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.

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.

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 available

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 spill with absorbent material. Clean spill area thoroughly.

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Revision date: 27-Sep-2007

Page 3 of 7

Version: 3.4

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:

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Storage Conditions:

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

Storage Temperature:

Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Doxepin hydrochloride

Pfizer OEL TWA-8 Hr:

600µg/m³

Glycerin, USP

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA

Australia TWA

= 10 mg/m³ TWA

Belgium OEL - TWA

= 10 mg/m³ TWA

Estonia OEL - TWA

= 10 mg/m³ TWA

Finland OEL - TWA

= 20 mg/m³ TWA

France OEL - TWA

= 10 mg/m³ VME

Greece OEL - TWA

= 10 mg/m³ TWA

Ireland OEL - TWAs

= 10 mg/m³ TWA

Netherlands OEL - TWA

= 10 mg/m³ MAC

OSHA - Final PELs - TWAs:

= 15 mg/m³ TWA total

= 5 mg/m³ TWA

Poland OEL - TWA

= 10 mg/m³ NDS

Portugal OEL - TWA

= 10 mg/m³ TWA

Spain OEL - TWA

= 10 mg/m³ VLA-ED

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. 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.

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Page 4 of 7

Revision date: 27-Sep-2007

Version: 3.4

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:	Liquid	Color:	Colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None known

Incompatible Materials: Strong oxidizers

Hazardous Decomposition Products: No data available

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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

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

Peppermint oil

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

Methylparaben

Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 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

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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Revision date: 27-Sep-2007

Page 5 of 7

Version: 3.4

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	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

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

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.

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

Doxepin hydrochloride

<i>Daphnia magna</i> (Water Flea)	EC50	48 Hours	11.1 mg/L
<i>Scenedesmus subspicatus</i> (Green Alga)	EC50	72 Hours	0.5-0.73 mg/L

Glycerin, USP

<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LD50	96 Hours	50 mg/L
<i>Daphnia magna</i> (Water Flea)	EC50	24 Hours	>500 mg/L

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Page 6 of 7

Revision date: 27-Sep-2007

Version: 3.4

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Doxepin hydrochloride

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

Peppermint oil

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

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Glycerin, USP

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-289-5

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
---	---------

MATERIAL SAFETY DATA SHEET

Material Name: Sinequan (Doxepin hydrochloride) oral concentrate

Page 7 of 7

Revision date: 27-Sep-2007

Version: 3.4

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 mentioned in Section 3

R22 - Harmful if swallowed.

R50 - Very toxic to aquatic organisms.

R64 - May cause harm to breastfed babies.

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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

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