



SAFETY DATA SHEET

Revision date: 16-Apr-2015

Version: 4.0

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

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

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

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Other Hazards

No data available

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 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Doxepin hydrochloride	1229-29-4	214-966-8	N;R50 R64 Repr. Cat.3;R62 Xn;R22	Acute Tox.4 (H302) Repr.2 (H261f) Lact. (H362) Aquatic Acute 1 (H400)	1-5
Glycerin, USP	56-81-5	200-289-5	Not Listed	Not Listed	*

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

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.

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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, anti-anxiety agent, anti-itch treatment (antipruritus)

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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/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	50 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	50 mg/m ³

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.

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

Physical State:

Liquid

Color:

Colorless

Odor:

No data available.

Odor Threshold:

No data available.

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

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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.

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11. TOXICOLOGICAL INFORMATION

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

Peppermint oil

Rat Oral LD50 2426 mg/kg
Mouse Oral LD50 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 LD50 > 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 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.

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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

Oncorhynchus 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

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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

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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
Product Stewardship Hazard Communication

Prepared by: 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