

SAFETY DATA SHEET



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

Material	PAXIL ORAL SUSPENSION
Synonym(s)	SEROXAT LIQUID * SEROXAT SUSPENSION * DEROXAT SUSPENSION * FORMULA CODE B046 * NDC NO. 0029-3215-48 * PAROXETINE HYDROCHLORIDE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	110429-35-1	0.2	
Other components below reportable levels		>99	

3. HAZARDS IDENTIFICATION

Fire and Explosion	This product is classified as non-flammable.
Health	Caution - Potent pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. Possible effects of overexposure in the workplace include: dry mouth; nausea; diarrhoea; constipation; drowsiness; dizziness; weakness; insomnia sexual dysfunction;. Health effects information is based on hazards of components. Not expected to be a health hazard during normal handling.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.

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Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of paroxetine. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water is recommended for fires involving packaging.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	40 mcg/m ³ (8 HR TWA)	REPRODUCTIVE HAZARD
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.	

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Orange.
Physical Form	Liquid.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a selective serotonin re-uptake inhibitor. Adverse effects of overexposure might include: drowsiness; diarrhoea; constipation; nausea; irritation; weakness; insomnia; sexual dysfunction; damage to mucosa.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: central nervous system.
Routes of Exposure	
Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Minor irritation might occur following direct contact with eyes.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This material contains an active pharmaceutical ingredient that has been tested, and which may be toxic to aquatic organisms if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.
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Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration	This material contains an active pharmaceutical ingredient that is harmful to activated sludge microorganisms. IC50: 25 mg/L, 3 Hours, Residential sludge
Microtox	Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is harmful to these microorganisms. EC50: 8.2 mg/L, 15 Minutes
Daphnid	This material contains an active pharmaceutical ingredient that is toxic to daphnids. EC50: 2.5 mg/L, 48 Hours, Daphnia magna, Static test NOEC: 0.49 mg/L, 48 Hours, Daphnia magna, Static test
Fish	This material contains an active pharmaceutical ingredient that is toxic to fish.

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Adult Lepomis macrochirus, bluegill sunfish
 EC50: 1.6 mg/L, 96 Hours, Static test
 Adult Lepomis macrochirus, bluegill sunfish
 NOEC: 0.18 mg/L, 96 Hours, Static test

MOBILITY**Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water. This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Henry's Law Constant 3.39E-10 atm m³/mol, Calculated

Adsorption

This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment. This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.

Soil Sediment Sorption (log K_{oc}): 0.8, Estimated

Sludge Biomass Distribution Coefficient (log K_d): 2.94 Measured

Partitioning

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION**Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured, Deionized Water

Photolysis

This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 2.4 Hours, Measured, Deionized Water

UV/Visible Spectrum: 292 nm at pH 5 to 9

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 11

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

Subsections

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.