

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	PAXIL CR TABLETS
Synonyms	PAXIL CONTROLLED RELEASE TABLET 12.5 MG * PAXIL CONTROLLED RELEASE TABLET 25 MG * PAXIL CONTROLLED RELEASE TABLET 37.5 MG * AROPAX CR TABLETS * SEROXAT CR TABLETS * AROXAT CR TABLETS * PAROXAT CR TABLETS * PAROXETINE CR TABLET * PAROXETINE GEOMATRIX TABLET * NDC NO. 0029-3206-13 * NDC NO. 0029-3207-13 * NDC NO. 0029-3208-13 * 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 RN	Percentage
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	110429-35-1	6 to 22
NON-HAZARDOUS INGREDIENTS	Unassigned	78 to 94

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Potent pharmaceutical agent. Exposure might occur via ingestion; skin; eyes.</p> <p>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.</p>

Environment	Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
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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.
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 or foam extinguishers are recommended. Carbon dioxide or dry powder extinguishers may be ineffective.
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 Avoid breaking or crushing tablets.

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/m³ (8 HR TWA) REPRODUCTIVE HAZARD

Other Equipment or Procedures Wash hands and arms thoroughly after handling. None required for normal handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

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 Irritation is not expected following direct contact with eyes.

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: central nervous system.

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.

Pharmacological Effects This preparation contains ingredient(s) with the following activity: a selective serotonin re-uptake inhibitor. Adverse effects of overexposure might include: drowsiness; dizziness; dry mouth; diarrhoea; constipation; nausea; weakness; insomnia; sexual dysfunction; damage to mucosa.

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.

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

NOEL: 0.49 mg/L, 48 Hours, Daphnia magna, Static test

Fish

This material contains an active pharmaceutical ingredient that is toxic to fish.

Adult Lepomis macrochirus, bluegill sunfish

EC50: 1.6 mg/L, 96 Hours, Static test

Adult Lepomis macrochirus, bluegill sunfish

NOEL: 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 0.8, Estimated
(log Koc):

Sludge Biomass 2.94 Measured
Distribution Coefficient
(log Kd):

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 dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 15-Mar-2007

SDS Version Number 17

SDS Sections Updated

Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

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.