SAFETY DATA SHEET

1. Identification

Product identifier **PAXIL CR TABLETS**

Other means of identification Not available.

Synonym(s) 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 * PAROXETINE HYDROCHLORIDE, FORMULATED PRODUCT

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
LACTOSE	D-LACTOSE 4-O-BETA-D-GLACTOPYRANOSYL-D-GLUC MILK SUGAR SACCHARUM LACTIS LACTOBIOSE LACTIN 4-(BETA-D-GALACTOSIDO)-D-GLUCOSE L-5 BP-680 D-(+)-LACTOSE C12H22O11 OHS12415 RTECS OD9625000	63-42-3	40 - < 50

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M GONIOSOL ISOPRO ALKALINE ISOPTO PLAIN ISOPTO TEARS METHOCEL E,F,K METHOCEL HG METHYL CELLULOSE PROPYLENE GLYCOL ETHER HYPROMELLOSE TEARISOL ULTRA TEARS RTECS NF9125000 CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER METHYLHYDROXYPROPYLCELLULOSE PHARMACOAT 603	9004-65-3	20 - < 30
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	(-)-TRANS-4-(4-FLUOROPHENYL)-3-(3,4-MI HYDROCHLORIDE HEMIHYDRATE BRL-29060A	110429-35-1	10 - < 20
TRIBEHENIN	COMPRITOL 888 DOCOSANOIN, TRI- (7CI,8CI) GLYCERYL BEHENATE GLYCERYL TRIBEHENATE TRIBEHENIN TRIBEHENOYL GLYCEROL TRIDOCOSANOIN	18641-57-1	5 - < 10
EUDRAGIT RL 30 D	OHS09662	33434-24-1	5.8
POLYVINYLPYRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-VINYL-, POLYMERS 1-VINYL-2-PYRROLIDINONE POLYMERS POLY(VINYLPYRROLIDINONE) POLY(N-VINYLPYRROLIDINONE) POLY(1-VINYLPYRROLIDINONE) POLY(VINYLPYRROLIDONE) POLY(N-VINYLPYRROLIDONE) POVIDONE PVP VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDONE HOMOPOLYMER VINYLPYRROLIDONE POLYMER N-VINYLPYRROLIDONE POLYMER RTECS TR8370000 PLASDONE PLASDONE K29/32 POLY-1-VINYL-2-PYRROLIDON POLYVINYL-PYRROLIDONE PROVIDONE	9003-39-8	1 - < 3

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
TALC	TALCUM, NON-ASBESTOS FORM AGALITE ASBESTINE TALCUM TALC FINNTALC EMTAL SOAPSTONE STEATITE NYTAL HYDROUS MAGNESIUM SILICATE MISTRON BEAVER WHITE FRENCH CHALK MUSSOLINITE STEAWHITE TALCRON- MONTANA TALC H2Mg3O12Si4 OHS22400 RTECS WW2710000	14807-96-6	1.5
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS WI4390000 MAGNESIUMDISTEARAT	557-04-0	1
TRIETHYL CITRATE	2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID, TRIETHYL ESTER CITRIC ACID, TRIETHYL ESTER ETHYL CITRATE 1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRIETHYL ESTER C12H20O7 OHS84216 RTECS GE8050000 TRIETHYLCITRAT	77-93-0	0.6
SILICON DIOXIDE	SILICA SILICA GEL AMORPHOUS SILICA DIATOMACEOUS EARTH INFUSORIAL EARTH CAB-O-SIL M-5	7631-86-9	< 1
FERRIC OXIDE RED	IRON OXIDE (Fe2O3) C.I. 77491 C.I. PIGMENT RED 101 CROCUS(IRON OXIDE) DIIRON TRIOXIDE FERRIC OXIDE IRON(III) OXIDE IRON OXIDE IRON(3+) OXIDE IRON OXIDE RED IRON SESQUIOXIDE IRON TRIOXIDE JEWELER'S ROUGE RED IRON OXIDE HEMATITE TURKEY RED ALPHA-FERRIC OXIDE ALPHA-IRON OXIDE GAMMA-FERRIC OXIDE GAMMA-IRON OXIDE (Fe2O3) Fe2O3 RTECS NO7400000	1309-37-1	< 0.1

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

Indication of immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

General information 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.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire-fighting equipment/instructions In the event of fire, cool tanks with water spray.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.

Methods and materials for containment and cleaning up Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.

Environmental precautions Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Do not get this material in contact with eyes. Do not get this material in contact with skin. Avoid prolonged exposure. Do not get this material on clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
FERRIC OXIDE RED (CAS 1309-37-1)	OHC	1	
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)	8 HR TWA	40 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD

GSK

Components	Type	Value	Note
SILICON DIOXIDE (CAS 7631-86-9)	OHC	1	
TRIBEHENIN (CAS 18641-57-1)	OHC	1	
TRIETHYL CITRATE (CAS 77-93-0)	OHC	2	PROVISIONAL

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	PEL	10 mg/m3	Fume.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3	
		20 mppcf	
TALC (CAS 14807-96-6)	TWA	0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
		20 millions of particle	
		2.4 millions of particle	Respirable.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Respirable fraction.
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
FERRIC OXIDE RED (CAS 1309-37-1)	TWA	5 mg/m3	Dust and fume.
SILICON DIOXIDE (CAS 7631-86-9)	REL	6 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Eye/face protection Use tight fitting goggles if dust is generated. Eye wash fountains are required.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other Wear appropriate chemical resistant clothing.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Irritation can occur following direct contact with this material.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: nausea; diarrhoea; constipation; dry mouth; drowsiness; dizziness; weakness; insomnia; sexual dysfunction; tremor; palpitations.

Information on toxicological effects

Acute toxicity	May be harmful if swallowed. May irritate eyes and skin.

Components	Species	Test Results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
LACTOSE (CAS 63-42-3)		
Acute		
Oral		
LD50	Rat	> 10 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)		
Acute		
Oral		
LD50	Rat	374 mg/kg
Chronic		
Oral		
NOAEL	Monkey	3.5 mg/kg/day, 52 weeks
	Rat	5 mg/kg/day, 52 weeks
TD	Monkey	6 mg/kg/day, 52 weeks
	Rat	25 mg/kg/day, 52 weeks
POLYVINYLPYRROLIDONE (CAS 9003-39-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
TRIETHYL CITRATE (CAS 77-93-0)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Oral		
LD50	Rat	5.9 g/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Irritation Corrosion - Skin

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — Acute dermal irritation; OECD 404, Primary Irritation Index: 0
Result: Non-irritating to intact skin
Species: Rabbit
Acute dermal irritation; OECD 404, Primary Irritation Index: 3
Result: Irritating to damaged skin.
Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE — 0

Serious eye damage/eye irritation

Eye

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — OECD 405, Kay and Calndra - Grade 8.
Result: Very severe irritant
Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE — 4
Recovery Period: 2 days

Respiratory sensitization None known.

Skin sensitization This product is not expected to cause skin sensitization.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE — Result: Negative
Species: Guinea pig

Sensitization

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	OECD 406, 0 % Response rate. Result: Negative Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Ames - Screen Result: Negative Chromosomal Aberration Assay In Vitro Result: Negative GreenScreen mammalian cell mutation assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay, GLP Result: Negative Micronucleus Assay, GLP Result: Negative Species: Mouse Mutation in Drosophila melanogaster Result: Negative Sister Chromatid Exchange Result: Negative Unscheduled DNA Synthesis, in vivo - in vitro Result: Negative Species: Rat

Carcinogenicity Not classifiable as to carcinogenicity to humans.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	Result: Negative Species: Mouse Test Duration: 18 months Result: Negative Species: Rat Test Duration: 2 years

IARC Monographs. Overall Evaluation of Carcinogenicity

FERRIC OXIDE RED (CAS 1309-37-1)	3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPYRROLIDONE (CAS 9003-39-8)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Epidemiology studies have identified the ingredient paroxetine hydrochloride hemihydrate as a possible cause of developmental toxicity in humans.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE	13 mg/kg/day Fertility, Female Result: Maternal toxicity; adverse effects on offspring. Species: Rat 13 mg/kg/day Fertility, Male Result: Parental toxicity, no adverse effects on fertility. Species: Rat 3 mg/kg/day Embryo-foetal development Result: Maternal NOAEL Species: Rabbit 4.3 mg/kg/day Fertility, Female Result: NOAEL Species: Rat 5 mg/kg/day Embryo-foetal development Result: NOAEL Species: Rat 6 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rabbit >= 50 mg/kg/day Embryo-foetal development Result: Maternal toxicity; adverse foetal effects Species: Rat Embryo-foetal development, Possible association with clinical use reported in epidemiology studies. Species: Human Organ: Cardiovascular malformations Fertility, Male, Possible association with clinical use reported in epidemiology studies. Result: Reversible effects on sperm quality. Species: Human

Specific target organ toxicity - single exposure Central nervous system.

Specific target organ toxicity - single exposure

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — Organ: Central Nervous System.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure.

PAROXETINE HYDROCHLORIDE HEMIHYDRATE — Epidemiology
Organ: Bone; Testes (reversible).

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test Results
FERRIC OXIDE RED (CAS 1309-37-1)			
Aquatic			
Acute			
Fish	EC50	Golden ide/orfe (Adult Leuciscus idus)	> 1000 mg/l, 48 hours, Static test
Chronic			
Other	EC50	Bacteria	> 5000 mg/l, 24 hours
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/L, 96 hours
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	25 mg/L, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	2.5 mg/L, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	0.49 mg/L, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1.6 mg/L, 96 hours, Static test, OECD 203
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	0.18 mg/L, 96 hours, Static test
Microtox	EC50	Microtox	8.2 mg/L, 15 minutes
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	0.5 mg/l, 7 days, Static renewal test, EPA 2002
	NOEC	Water flea (Ceriodaphnia dubia)	0.25 mg/L, 7 days
POLYVINYLPYRROLIDONE (CAS 9003-39-8)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours, Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours, Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours, Static test

Components		Species	Test Results
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours, Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours, Static renewal test

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.4 Hours Measured, Deionized Water

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 292 nm, pH 5-9

Hydrolysis

Half-life (Hydrolysis-neutral)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE > 1 Years Measured, Deionized Water

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE -5

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 1.3

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.94 Measured

Soil/sediment sorption - log Koc

LACTOSE 1 Calculated

MAGNESIUM STEARATE 5.86 Estimated

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0.8 Estimated

Mobility in general

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE 0 atm m3/mol Estimated

LACTOSE < 0 atm m3/mol Calculated

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0 atm m3/mol Calculated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No
NFPA ratings	Health: 3 Flammability: 1 Instability: 0
HMIS® ratings	Health: 3* Flammability: 1 Physical hazard: 0

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

FERRIC OXIDE RED (CAS 1309-37-1)
SILICON DIOXIDE (CAS 7631-86-9)
TALC (CAS 14807-96-6)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

FERRIC OXIDE RED (CAS 1309-37-1)
SILICON DIOXIDE (CAS 7631-86-9)
TALC (CAS 14807-96-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-19-2013

Revision date 11-19-2013

Version # 19

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 3*
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 3
Flammability: 1
Instability: 0

References GSK Hazard Determination

Disclaimer 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.

Revision Information
Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Ecological Information: GSK Environmental Hazard Assessment Concentration
GHS: Classification