

1. Identification

Product identifier	PAXIL ORAL SUSPENSION
Other means of identification	Not available.
Synonym(s)	SEROXAT LIQUID * SEROXAT SUSPENSION * DEROXAT SUSPENSION * FORMULA CODE B046 * 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	%
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	(-)-TRANS-4-(4-FLUOROPHENYL)-3-(3,4-ME HYDROCHLORIDE HEMIHYDRATE BRL-29060A	110429-35-1	< 1

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
TITANIUM DIOXIDE	ANATASE BROOKITE RUTILE TITANIUM OXIDE TITANIUM DIOXIDE (TiO ₂) C.I. PIGMENT WHITE 6 C.I. 77891 TITANIUM(IV) OXIDE TITANIUM(4+) OXIDE TITANIUM PEROXIDE (TiO ₂) TITANIA (TiO ₂) PIGMENT WHITE 6 TITANIA KRONOS TITANIC OXIDE O2Ti OHS23510 RTECS XR2275000 DIOXIDO DE TITANIO TITANOKSIID	13463-67-7	< 1
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID CITIRIC ACID	77-92-9	< 0.3

Other components below reportable levels >98.0

*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. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
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 ingestion of a large amount does occur, call a poison control center immediately.
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 (CO ₂).
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	Move containers from fire area if you can do so without risk.

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.
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Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills in original containers for re-use. 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

Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

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

CITRIC ACID ANHYDROUS (CAS 77-92-9)

8 HR TWA

5000 mcg/m3

PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)

OHC
8 HR TWA

1
40 mcg/m3

OHC

3

REPRODUCTIVE HAZARD

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

Components

Type

Value

Form

TITANIUM DIOXIDE (CAS 13463-67-7)

PEL

15 mg/m3

Total dust.

US. ACGIH Threshold Limit Values

Components

Type

Value

TITANIUM DIOXIDE (CAS 13463-67-7)

TWA

10 mg/m3

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

Chemical goggles are recommended. 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

In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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	Liquid.
Form	Suspension.
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. Fluorine.
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	May be irritating to the skin.
Eye contact	Irritation can occur following direct contact with this material. Risk of serious damage to eyes.

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.
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Components	Species	Test Results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)		
Acute		
<i>Oral</i>		
LD50	Rat	374 mg/kg
Chronic		
<i>Oral</i>		
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
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose 5 mg/m3, 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.
Subchronic		
<i>Inhalation</i>		
LOEC	Rat	3.2 - 20 mg/m3, 8 min, Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

TITANIUM DIOXIDE	Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
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
TITANIUM DIOXIDE	Literature data Result: Non-irritant Species: Guinea pig

Irritation Corrosion - Skin

TITANIUM DIOXIDE

Literature data
Result: Non-irritant
Species: Human**Serious eye damage/eye irritation****Eye**

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

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

TITANIUM DIOXIDE

OECD 405, Literature data
Result: Mild irritant
Species: Rabbit**Respiratory sensitization**

Not available.

Skin sensitization

This product is not expected to cause skin sensitization.

Sensitization

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum
Result: Negative
Species: Guinea pig

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

Test Duration: 48 hour exposure
OECD 406, 0 % Response rate.
Result: Negative

TITANIUM DIOXIDE

Species: Guinea pig
Patch test, Literature data
Result: Negative
Species: Human**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

TITANIUM DIOXIDE

Ames, Literature data
Result: Negative

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

Chromosomal Aberration Assay In Vitro
Result: Negative

TITANIUM DIOXIDE

GreenScreen mammalian cell mutation assay
Result: Negative

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

L5178Y mouse lymphoma thymidine kinase locus assay, GLP
Result: Negative

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data
Result: Negative

PAROXETINE HYDROCHLORIDE HEMIHYDRATE

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data
Result: Positive

TITANIUM DIOXIDE

Micronucleus Assay, GLP
Result: NegativeSpecies: Mouse
Mutation in Drosophila melanogasterResult: Negative
Sister Chromatid ExchangeResult: Negative
Syrian Hamster Embryo (SHE) cell transformation assayResult: Negative
Unscheduled DNA Synthesis, in vivo - in vitroResult: Negative
Species: Rat

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data

Result: Positive

Carcinogenicity

Titanium dioxide is listed as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE

0.5 mg/m³, Literature data
Result: NegativeSpecies: Rat
Test Duration: 24 months0.72 - 14.8 mg/m³, Literature data
Result: Negative

Species: Mouse

Carcinogenicity

TITANIUM DIOXIDE

10 - 250 mg/m³, Dietary study - Literature data.
Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.

Species: Rat

Test Duration: 24 months

25000 - 50000 ppm, Dietary study

Result: Negative

Species: Mouse

25000 - 50000 ppm, Dietary study - Literature data.

Result: Negative

Species: Rat

7.2 - 14.8 mg/m³, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

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

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic 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.

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
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours, Static test
		Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	14 mg/l, 15 minutes
PAROXETINE HYDROCHLORIDE HEMIHYDRATE (CAS 110429-35-1)			
Aquatic			
<i>Acute</i>			
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
<i>Chronic</i>			
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
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static 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

UV/visible spectrum wavelength

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 292 nm, pH 5-9

Hydrolysis

Half-life (Hydrolysis-neutral)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE > 1 Years Measured, Deionized Water

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 1.3

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 2.94 Measured

Soil/sediment sorption - log Koc

PAROXETINE HYDROCHLORIDE HEMIHYDRATE 0.8 Estimated

Mobility in general

Volatility

Henry's law

CITRIC ACID ANHYDROUS < 0 atm m³/mol Calculated, 25 °C

Volatility

Henry's law

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	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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: 1 Flammability: 1 Instability: 0
HMIS® ratings	Health: 1* 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**

TITANIUM DIOXIDE (CAS 13463-67-7)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

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** 11-25-2013**Revision date** 11-25-2013**Version #** 13**Further information** Not available.**HMIS® ratings** Health: 1*
Flammability: 1
Physical hazard: 0**NFPA ratings** Health: 1
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: Physical States
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection