



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** PIRITEZE SYRUP

### Other means of identification

**Synonyms** PIRITEZE SYRUP 1 MG/ML (UK) \* CETIRIZINE DIHYDROCHLORIDE, 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

Chemical name	Common name and synonyms	CAS number	%
D-SORBITOL	SORBITOL * L-GULITOL * 1,2,3,4,5,6-HEXANEHEXOL * D-SORBOL	50-70-4	38.0 - 39.0
GLYCERIN	GLYCEROL * GLYCERIN ANHYDROUS * GLYCERINE * GLYCERITOL * GLYCYL ALCOHOL * 1,2,3-PROPANETRIOL * PROPANETRIOL * GLYROL * GLYSANIN * TRIHIDROXYPROPANE * 1,2,3-TRIHIDROXYPROPANE * OSMOGLYN	56-81-5	17.0 - 18.0

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL * 1,2-DIHYDROXYPROPANE * 2-HYDROXYPROPANOL * ISOPROPYLENE GLYCOL * METHYLETHYLENE GLYCOL * METHYLETHYL GLYCOL * MONOPROPYLENE GLYCOL * 2,3-PROPANEDIOL * ALPHA-PROPYLENE GLYCOL * 1,2-PROPYLENE GLYCOL * (RS)-1,2-PROPANEDIOL * 1,2-(RS)-PROPANEDIOL * 1,2-PROPANDIOL * DL-1,2-PROPANEDIOL * DL-PROPYLENE GLYCOL * PROPANE-1,2-DIOL (PROPYLENE GLYCOL) * PROPANE-1-2-DIOL * PROPANEDIOL,1,2-	57-55-6	4.0 - 5.0
METHYL PARABEN	GR30517X * METHYL P-HYDROXYBENZOATE * P-HYDROXYBENZOIC ACID, METHYL ESTER * 4-HYDROXYBENZOIC ACID, METHYL ESTER * METHYL P-OXYBENZOATE * METHYL PARAHYDROXYBENZOATE	99-76-3	<1.0
SODIUM ACETATE ANHYDROUS	ANHYDROUS SODIUM ACETATE * SODIUM ACETATE * ACETIC ACID, SODIUM SALT * SODIUM ETHANOATE	127-09-3	<1.0
ACETIC ACID	GLACIAL ACETIC ACID * ETHANOIC ACID * VINEGAR ACID * ETHYLIC ACID * PYROLIGNEOUS ACID * METHANECARBOXYLIC ACID * ACETIC ACID, GLACIAL * UN 2789 * C2H4O2 * OHS00120 * RTECS AF1225000 * 108 (GW ACN)	64-19-7	<0.1
CETIRIZINE DIHYDROCHLORIDE	ACETIC ACID, (2-(4-((4-CHLOROPHENYL)PHENYLMETH YL)-1-PIPERAZINYLET HOXY)-, DIHYDROCHLORIDE * (2-(4-((4-CHLOROPHENYL)PHENYLMETH YL)-1-PIPERAZINYLET HOXY)ACETIC ACID DIHYDROCHLORIDE	83881-52-1	<0.1
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE * PROTABEN * 4-HYDROXYBENZOIC ACID, PROPYL ESTER * P-HYDROXYBENZOIC ACID, PROPYL ESTER * PASEPTOL * PARASEPT * PROPYL ASEPTOFORM * PROPYL P-OXYBENZOATE	94-13-3	<0.1
Other components below reportable levels			35.0 - 40.0

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

#### 4. First-aid measures

##### Inhalation

Move to fresh air. Call a physician if symptoms develop or persist. If breathing is difficult, trained personnel should give oxygen. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

##### Skin contact

Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water. 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. Do not induce vomiting without advice from poison control center.

##### Most important symptoms/effects, acute and delayed

The following adverse effects have been noted with therapeutic use of this material: irritability; somnolence; abdominal pain; sore throat; nausea.

**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 center.

**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. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**5. Fire-fighting measures**

**Suitable extinguishing media**

Water. Alcohol resistant 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**

Move containers from fire area if you can do so without risk.

**Specific methods**

Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**

This product is non-flammable.

**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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

**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. Use water spray to reduce vapors or divert vapor cloud drift. 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.

**Environmental precautions**

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

**7. Handling and storage**

**Precautions for safe handling**

No special control measures required for the normal handling of this product. Avoid prolonged exposure.

**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection**

**Occupational exposure limits**

**GSK**

**Components**

**Type**

**Value**

CETIRIZINE  
DIHYDROCHLORIDE (CAS  
83881-52-1)

OHC

2

D-SORBITOL (CAS  
50-70-4)

OHC

1

PROPYL PARABEN (CAS  
94-13-3)

8 HR TWA

5000 mcg/m3

SODIUM ACETATE  
ANHYDROUS (CAS  
127-09-3)

OHC

1

OHC

1

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

Components	Type	Value	Form
ACETIC ACID (CAS 64-19-7)	PEL	25 mg/m3	
GLYCERIN (CAS 56-81-5)	PEL	10 ppm	Respirable fraction. Total dust.
		5 mg/m3 15 mg/m3	

**US. ACGIH Threshold Limit Values**

Components	Type	Value
ACETIC ACID (CAS 64-19-7)	STEL	15 ppm
	TWA	10 ppm

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
ACETIC ACID (CAS 64-19-7)	STEL	37 mg/m3
	TWA	15 ppm
		25 mg/m3 10 ppm

**US. AIHA Workplace Environmental Exposure Level (WEEL) Guides**

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	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. General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Skin protection</b>	
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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.

**9. Physical and chemical properties****Appearance**

<b>Physical state</b>	Liquid.
<b>Form</b>	Syrup.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Expected to be non-flammable based on components present.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	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)**

**Solubility (water)** 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** Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

**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** Health injuries are not known or expected under normal use.

**Symptoms related to the physical, chemical and toxicological characteristics** The following adverse effects have been noted with therapeutic use of this material: irritability; somnolence; abdominal pain; sore throat; nausea.

**Information on toxicological effects**

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
ACETIC ACID (CAS 64-19-7)		
<b>Acute</b>		
<i>Inhalation</i>		
LCLo	Rat	39.6 mg/l 4-hour exposure
<i>Oral</i>		
LD50	Rat	3310 mg/kg
CETIRIZINE DIHYDROCHLORIDE (CAS 83881-52-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	365 mg/kg

Components	Species	Test Results
D-SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
GLYCERIN (CAS 56-81-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
METHYL PARABEN (CAS 99-76-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	> 8 g/kg
PROPYL PARABEN (CAS 94-13-3)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use.
<b>Respiratory or skin sensitization</b>	
<b>Respiratory sensitization</b>	Not available.
<b>Skin sensitization</b>	None known.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

#### Mutagenicity

CETIRIZINE DIHYDROCHLORIDE

Ames  
Result: Negative  
Notes: FDA Approval Package  
Chromosomal Aberration Assay In Vitro, human lymphocytes  
Result: Negative  
Notes: FDA Approval Package  
In vivo Micronucleus  
Result: Negative  
Species: Mouse  
Notes: FDA Approval Package  
In vivo Micronucleus  
Result: Negative  
Species: Rat  
Mouse Lymphoma Cell (L5178Y) Mutation Assay  
Result: Negative  
Notes: FDA Approval Package

**Carcinogenicity** Not classifiable as to carcinogenicity to humans.

CETIRIZINE DIHYDROCHLORIDE

16 mg/kg/day, Species-specific  
Result: Increase in benign tumours  
Species: Mouse  
Organ: Liver  
Notes: FDA Approval Package  
20 mg/kg/day  
Result: Negative  
Species: Rat  
Notes: FDA Approval Package

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

**Reproductivity**

CETIRIZINE DIHYDROCHLORIDE

135 mg/kg/day Embryo-foetal development  
 Result: Maternal toxicity; adverse foetal effects  
 Species: Rabbit  
 Notes: FDA Approval Package

25 mg/kg/day Embryo-foetal development  
 Result: Maternal NOAEL, Foetal NOAEL  
 Species: Rat  
 Notes: FDA Approval Package

45 mg/kg/day Embryo-foetal development  
 Result: Maternal NOAEL, Foetal NOAEL  
 Species: Rabbit  
 Notes: FDA Approval Package

64 mg/kg/day Female Fertility / Early Embryonic Development  
 Result: Negative  
 Species: Mouse

75 - 225 mg/kg/day Embryo-foetal development  
 Result: Maternal toxicity; adverse effects on offspring.  
 Species: Rat  
 Notes: FDA Approval Package

96 mg/kg/day Embryo-foetal development  
 Result: Maternal NOAEL, Foetal NOAEL  
 Species: Mouse  
 Notes: FDA Approval Package

**Specific target organ toxicity - single exposure** Not assigned.

**Specific target organ toxicity - repeated exposure** None known.

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

**Further information** Caution - Pharmaceutical agent.

**12. Ecological information**

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
ACETIC ACID (CAS 64-19-7)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	47 mg/L, 24 hours Static test
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	79 mg/L, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	251 mg/L, 96 hours Static test
Microtox	EC50	Microtox	11 mg/L, 15 minutes
METHYL PARABEN (CAS 99-76-3)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	11.2 mg/l, 48 hours
Fish	LC50	Medaka, high-eyes (Oryzias latipes)	59.5 mg/l, 96 hours
<i>Chronic</i>			
Crustacea	NOEC	Water flea (Daphnia magna)	0.2 mg/l, 21 days OECD 211
PROPYLENE GLYCOL (CAS 57-55-6)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days

Components		Species	Test Results
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	51600 mg/l, 96 hours Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhynchus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM ACETATE ANHYDROUS (CAS 127-09-3)			
<i>Chronic</i>			
Other	LC50	Pseudomonas putida	7200 mg/l, 18 hours
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia magna)	7170 mg/l, 24 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	5000 mg/l, 24 hours Static test
		Fathead minnow (Adult Pimephales promelas)	13330 mg/l, 120 hours Static test
Microtox	EC50	Microtox	22500 mg/l, 15 minutes

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

#### Persistence and degradability

##### Photolysis

###### Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL 1.3 - 2.3 Years Estimated

###### Half-life (Photolysis-atmospheric)

ACETIC ACID 22 Days Estimated

PROPYLENE GLYCOL 32 Hours Estimated

##### Biodegradability

###### Percent degradation (Aerobic biodegradation-inherent)

ACETIC ACID 95 %, 5 days Zahn-Wellens, Activated sludge

PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge

79 %, 20 Days BOD20, Activated sludge

SODIUM ACETATE ANHYDROUS 100 %, 5 days Modified Zahn-Wellens, Activated sludge

97.4 % Coupled Unit test (OECD 303A), Activated sludge

###### Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days

##### Bioaccumulative potential

###### Partition coefficient n-octanol / water (log Kow)

ACETIC ACID -0.24

D-SORBITOL -2.2

GLYCERIN -1.76

METHYL PARABEN 1.96

PROPYL PARABEN 3.04

PROPYLENE GLYCOL -1.35

###### Bioconcentration factor (BCF)

D-SORBITOL 1 Estimated

PROPYLENE GLYCOL < 1 Estimated

SODIUM ACETATE ANHYDROUS < 10 Measured, Leuciscus idus, golden ide/orfe

##### Mobility in soil

###### Adsorption

###### Soil/sediment sorption - log Koc

ACETIC ACID 0.81 - 2.36 Measured

## Adsorption

### Soil/sediment sorption - log Koc

D-SORBITOL 0.3 Estimated

## Mobility in general

### Volatility

#### Henry's law

ACETIC ACID 0 atm m<sup>3</sup>/mol Measured, 25 C

D-SORBITOL 0 atm m<sup>3</sup>/mol Estimated

PROPYLENE GLYCOL 0 atm m<sup>3</sup>/mol Estimated

### Distribution

#### Octanol/water distribution coefficient log DOW

PROPYL PARABEN 3.04

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**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 dangerous goods.

### IMDG

Not regulated as dangerous goods.

**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** One or more components are not listed on TSCA. This product is not known to be 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)

ACETIC ACID (CAS 64-19-7) Listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

**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.**US state regulations****US. Massachusetts RTK - Substance List**

ACETIC ACID (CAS 64-19-7)

GLYCERIN (CAS 56-81-5)

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

ACETIC ACID (CAS 64-19-7)

GLYCERIN (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6)

**US. Pennsylvania Worker and Community Right-to-Know Law**

ACETIC ACID (CAS 64-19-7)

GLYCERIN (CAS 56-81-5)

PROPYLENE GLYCOL (CAS 57-55-6)

**US. Rhode Island RTK**

ACETIC ACID (CAS 64-19-7)

**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**

<b>Issue date</b>	09-15-2014
<b>Revision date</b>	09-15-2014
<b>Version #</b>	04
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 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: Undisclosed Ingredient Statement

Physical &amp; Chemical Properties:

Transport Information: Agency Name, Packaging Type, and Transport Mode Selection

GHS: Classification