

1. Identification

Product identifier

SEPTRIN PAEDIATRIC SUSPENSION

Other means of identification

Synonyms

SEPTRIN PAEDIATRIC SUSPENSION 200 MG/40 MG/5 ML * SEPTRIN PEDIATRIC SUSPENSION * SEPTRIN PEDIATRICO SUSPENSION * SEPTRIN SUSPENSÃO PEDIATRICA * SEPTRIN SUSPENSION PEDIATRICA * SEPTRIN ZAWIESINA 240 MG/5 ML * EUSAPRIM K SUSPENSION FUR KINDER * EUSAPRIM PAEDIATRIC ORAL SUSPENSION * SULPHAMETHOXAZOLE AND TRIMETHOPRIM, 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	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	< 15

Chemical name	Common name and synonyms	CAS number	%
SULFAMETHOXAZOLE	CCI11971 N-(5-METHYLISOXAZOL-3-YL) SULPHANILAMIDE 4-AMINO-N-(5-METHYL-3-ISOXAZOLYL) BENZENESULPHONAMIDE SULPHAMETHOXAZOLE 1689 (GW ACN) GW296858X CCI11974	723-46-6	< 3.5
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	< 2
TRIMETHOPRIM	CCI 2095 5-((3,4,5-TRIMETHOXYPHENYL)METHYL)- 2,4-PYRIMIDINEDIAMINE TRIMETHOXYPRIM TMP 1690 (GW ACN)	738-70-5	< 1
ETHYL ALCOHOL, 90-99%	ETHANOL (ALCOHOL BP 96%) PLAIN BRITISH SPIRIT (95%) DOUBLY RECTIFIED SPIRIT (96%) ETHANOL (95% GL) U 2273 RM 20 ETHYL ALCOHOL, 96% V/V HUNGARIAN ALCOHOL 96% V/V U 1139 ETHANOL B.P., DRS U 1109 ETHANOL DRAA ETHANOL DRS	64-17-5	< 0.25
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODIUM BENZOIC ACID	532-32-1	< 0.1
Other components below reportable levels			81.93

*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. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. 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. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Accidental exposure or contact might produce: nausea, fever, diarrhoea.
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 In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). 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. 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 will support combustion at elevated temperatures.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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. Use water spray to reduce vapors or divert vapor cloud drift. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Prevent product from entering drains. 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 to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling No special control measures required for the normal handling of this product.

Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Keep container tightly closed.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m ³
SULFAMETHOXAZOLE (CAS 723-46-6)	8 HR TWA	2000 mcg/m ³
TRIMETHOPRIM (CAS 738-70-5)	OHC	1
	8 HR TWA	500 mcg/m ³
	OHC	2

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

Components	Type	Value	Form
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	PEL	1900 mg/m ³	
GLYCERIN (CAS 56-81-5)	PEL	1000 ppm	
		5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

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

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	STEL	1000 ppm
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)	TWA	1900 mg/m3	
		1000 ppm	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

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

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties**Appearance**

Physical state Liquid.

Form Suspension.

Color Not available.

Odor Not available.

Odor threshold Not available.

pH 5 - 6.5

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point > 239 °F (> 115 °C) Closed Cup

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

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. Heat, flames and sparks.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of 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.

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

Symptoms related to the physical, chemical and toxicological characteristics Accidental exposure or contact might produce: nausea, fever, diarrhoea.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
ETHYL ALCOHOL, 90-99% (CAS 64-17-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
GLYCERIN (CAS 56-81-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Oral		
LD50	Rat	> 2000 mg/kg
SULFAMETHOXAZOLE (CAS 723-46-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
TRIMETHOPRIM (CAS 738-70-5)		
Acute		
Oral		
LD50	Rat	1360 mg/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.

Corrosivity

SULFAMETHOXAZOLE	Acute dermal irritation Result: Negative Species: Rabbit
ETHYL ALCOHOL, 90-99%	Literature search Result: Negative

Irritation Corrosion - Skin

TRIMETHOPRIM	Acute dermal irritation Result: Negative Species: Rabbit
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Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

SULFAMETHOXAZOLE	Acute ocular irritation Result: Negative Species: Rabbit
ETHYL ALCOHOL, 90-99%	Literature search Result: May cause irritation

Respiratory or skin sensitization

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

Skin sensitization Health injuries are not known or expected under normal use.

Sensitization

ETHYL ALCOHOL, 90-99%	Literature search Result: Negative
SULFAMETHOXAZOLE	Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig
TRIMETHOPRIM	Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig

Germ cell mutagenicity Health injuries are not known or expected under normal use.

Mutagenicity

SULFAMETHOXAZOLE	Ames Assay, GLP assay Result: Negative
TRIMETHOPRIM	Ames Assay, GLP assay; Literature data Result: Negative Chromosomal Aberration Assay In Vitro, CHO cells, Literature data Result: Equivocal (chromosome damage)
SULFAMETHOXAZOLE	Chromosomal Aberration Assay In Vitro, human peripheral lymphocytes Result: Negative
TRIMETHOPRIM	Chromosomal Aberration Assay In Vitro, human peripheral lymphocytes, Literature data Result: Negative

Mutagenicity

SULFAMETHOXAZOLE

Micronucleus Assay in vitro, cultured human peripheral lymphocytes

Result: Positive

TRIMETHOPRIM

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: Positive

SULFAMETHOXAZOLE

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Positive

Carcinogenicity

Carcinogenic effects are not expected as a result of occupational exposure. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

SULFAMETHOXAZOLE

2 year bioassay, Effects considered to be species specific.

Result: Positive (thyroid tumours)

Species: Rat

TRIMETHOPRIM

SAR / QSAR, DEREK, Lhasa, UK

Result: No structural alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

SULFAMETHOXAZOLE (CAS 723-46-6)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Health injuries are not known or expected under normal use. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

TRIMETHOPRIM

Embryo-foetal development - Oral, Literature data

Result: Teratogenic and embryotoxic; folic acid antagonist; adverse effects noted at oral doses 40X equivalent of therapeutic dose

Species: Rat

Embryo-foetal development - Oral, Literature data

Result: Teratogenic and embryotoxic; folic acid antagonist; adverse effects noted at oral doses 6X equivalent of therapeutic dose

Species: Rabbit

Fertility, Literature data

Result: NOAEL / fertility = 70 mg/kg/day (male) and 14 mg/kg/day (female) (maximum doses)

Species: Rat

Specific target organ toxicity - single exposure

Not assigned.

Specific target organ toxicity - repeated exposure

Not assigned.

Aspiration hazard

No studies have been conducted.

Further information

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information**Ecotoxicity**

Contains a substance which causes risk of hazardous effects to the environment.

Components**Species****Test Results**

SODIUM BENZOATE (CAS 532-32-1)

Aquatic*Acute*

Crustacea

EC50

Water flea (*Daphnia magna*)

> 100 mg/L, 96 hours Static test

Fish

EC50

Fathead minnow (Juvenile *Pimephales promelas*)

484 mg/L, 96 hours Flow-through test

SULFAMETHOXAZOLE (CAS 723-46-6)

Aquatic*Acute*

Activated Sludge Respiration

IC50

Residential sludge

> 100 mg/l, 3 hours Nominal, OECD 209

Algae

EC50

Blue-green algae (*S. leopolensis*)

0.0268 mg/l, 96 hours Measured

Components		Species	Test Results
	NOEC	Blue-green algae (S. leopolensis)	0.0059 mg/l
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	15.51 mg/l, 48 hours OECD 202
		Water flea (Daphnia magna)	> 100 mg/l, 48 hours , OECD 202
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 1000 mg/l
	NOEC	Zebra fish (Adult Brachydanio rerio)	> 8 mg/l, 10 days
<i>Chronic</i>			
Crustacea	NOEC	Water flea (Ceriodaphnia dubia)	0.25 mg/l, 7 days 7 day static renewal, EPA 1002 Method
TRIMETHOPRIM (CAS 738-70-5)			
<i>Acute</i>			
	IC50	Activated sludge	17.8 mg/l
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Selenastrum capricornutum)	110 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	123 mg/l, 48 hours
Fish	NOEC	Zebra fish (Adult Brachydanio rerio)	100 mg/l, 72 hours
<i>Chronic</i>			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days 7 day static renewal
	NOEC	Water flea (Ceriodaphnia dubia)	5.6 mg/l, 7 days

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

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

SULFAMETHOXAZOLE 2.4 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SULFAMETHOXAZOLE 0 %, 28 days Zahn-Wellens
44 %, 13 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

TRIMETHOPRIM 50 %, 42 days, Activated sludge
50 %, 75 days, Sediment

Percent degradation (Aerobic biodegradation-ready)

SODIUM BENZOATE 100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water
90 %, 7 days Modified Sturm test., Activated sludge

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

TRIMETHOPRIM 50 %, 100 days, Sediment

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ETHYL ALCOHOL, 90-99% -0.31
GLYCERIN -1.76
SODIUM BENZOATE 1.89
SULFAMETHOXAZOLE 0.68
TRIMETHOPRIM 0.91
0.96

Bioconcentration factor (BCF)

TRIMETHOPRIM 3 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

SULFAMETHOXAZOLE 0.01 Measured, pH 7

Adsorption

Sludge/biomass distribution coefficient - log Kd

TRIMETHOPRIM 1.88 Measured

Soil/sediment sorption - log Koc

SODIUM BENZOATE 1.16 Calculated

TRIMETHOPRIM 1.88 Estimated

Mobility in general

Volatility

Henry's law

SULFAMETHOXAZOLE 0 atm m³/mol, 25 C Estimated

TRIMETHOPRIM 0 atm m³/mol Estimated

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 discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

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 Not established.

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)

ETHYL ALCOHOL, 90-99% (CAS 64-17-5) 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 - Yes

Delayed Hazard - No

Fire Hazard - Yes

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. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

GLYCERIN (CAS 56-81-5)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

GLYCERIN (CAS 56-81-5)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

GLYCERIN (CAS 56-81-5)

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

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 and birth defects or other reproductive harm.

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

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

Listed: April 29, 2011

Listed: July 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

ETHYL ALCOHOL, 90-99% (CAS 64-17-5)

Listed: October 1, 1987

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** 06-18-2015**Revision date** 06-18-2015

Version #	07
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: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Ecological Information: Ecotoxicity Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States