

1. Identification

Product identifier SEPTRIN TABLETS

Other means of identification

Synonyms

SEPTRIN ADULT TABLETS 400/80MG * SEPTRIN COMPRIMIDOS * EUSAPRIM * SEPTRA TABLETS * SEPTRAN TABLETS * SEPTRIN SS TABLETS * ESPECTIN COMPRIMIDOS * SEPTRIN TABLETKI 480MG * SEPTRIN TABLETS 480MG * SEPTRIN TABLETS SINGLE STRENGTH * SEPTRIN S TABLETS * SEPTRIN TABLETS (CONTAINING SULFAMETHOXAZOLE) * 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	%
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	70 - < 80
TRIMETHOPRIM	CCI 2095 * 5-((3,4,5-TRIMETHOXYPHENYL)METHYL)-2,4-PYRIMIDINEDIAMINE * TRIMETHOXYPRIM * TMP * 1690 (GW ACN)	738-70-5	10 - < 20

Chemical name	Common name and synonyms	CAS number	%
POLYVINYLPIRROLIDONE	1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER * POLY(N-VINYLPYRROLIDONE) * PLASDONE	9003-39-8	1 - < 3
SODIUM STARCH GLYCOLATE	STARCH, CARBOXYMETHYL ETHER, SODIUM SALT * CARBOXYMETHYL STARCH SODIUM SALT * EXPLOTAB * SODIUM CARBOXYMETHYL STARCH * SODIUM CM-STARCH * 738 (GW ACN) * CARBOXYMETHYLSTÄRKE, NATRIUMSALZ * SODIUM STARCH GLYCOLATE	9063-38-1	1 - < 3
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
DIOCTYL SODIUM SULFOSUCCINATE	BUTANEDIOIC ACID, SULFO-, 1,4-BIS(2-ETHYLHEXYL) ESTER, SODIUM SALT * SULFOBUTANEDIOIC ACID 1,4-BIS(2-ETHYLHEXYL) ESTER, SODIUM SALT * SUCCINIC ACID, SULFO-, 1,4-BIS(2-ETHYLHEXYL) ESTER, SODIUM SALT * SULFOSUCCINIC ACID 1,4-BIS(2-ETHYLHEXYL) ESTER, SODIUM SALT * DIOCTYL SULFOSUCCINATE SODIUM * DIOCTYL SULFOSUCCINATE SODIUM SALT * DOCUSATE SODIUM * SODIUM DIOCTYL SULFOSUCCINATE * TRITON GR 5 * TRITON GR 7 * AEROSOL OT * ALPHASOL OT * DIOCTYLAL * DIOCTYL-MEDO FORTE * DIOTILAN * DIOVAC * DISONATE * DOXINATE * DOXOL * C20H38NAO7S * 1,4-BIS(2-ETHYLHEXYL) SODIUM SULFOSUCCINATE * BIS(2-ETHYLHEXYL) S-SODIUM SULFOSUCCINATE * BIS(2-ETHYLHEXYL) SODIOSULFOSUCCINATE * BIS(2-ETHYLHEXYL) SODIUM SULFOSUCCINATE * BIS(2-ETHYLHEXYL) SULFOSUCCINATE SODIUM SALT * BUTANEDIOIC ACID, SULFO-, 1,4-BIS(2-ETHYLHEXYL)ESTER, SODIUM SALT * DI(2-ETHYLHEXYL) SULFOSUCCINATE SODIUM SALT * DI(2-ETHYLHEXYL)SULFOSUCCINIC ACID, SODIUM SALT * DI-2-ETHYLHEXYL SODIUM SULFOSUCCINATE * OHS00406 * RTECS WN0525000 * DI-ISO-OCTYL-SULFOBERNSTEINSÄURE, NATRIUMSALZ * DIETHYLHEXYL SODIUM SULFOSUCCINATE * DIOCTYLSODIUM SULFOSUCCINATE * DIOCTYLSODIUM SULPHOSUCCINATE	577-11-7	< 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

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.

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). Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Possible effects of overexposure in the workplace include: fever; nausea; 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 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	Use water spray to cool unopened containers. 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	Expected to be non-combustible.

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 SDS.
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 SDS.
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 away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
DIOCTYL SODIUM SULFOSUCCINATE (CAS 577-11-7)	OHC	2	PROVISIONAL
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1	
SULFAMETHOXAZOLE (CAS 723-46-6)	8 HR TWA	2000 mcg/m ³	
TRIMETHOPRIM (CAS 738-70-5)	OHC 8 HR TWA	1 500 mcg/m ³	

GSK Components	Type	Value	Note
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	OHC	2	
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US. ACGIH Threshold Limit Values Components	Type	Value
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MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
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Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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	Not normally needed.
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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
Skin protection	
Other	Not normally needed.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).
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.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Tablet.
Color	Not available.

Odor	Not available.
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Odor threshold	Not available.
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pH	Not available.
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Melting point/freezing point	Not available.
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Initial boiling point and boiling range	Not available.
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Flash point	Not available.
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Evaporation rate	Not available.
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Flammability (solid, gas)	Not available.
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Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
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Flammability limit - upper (%)	Not available.
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Explosive limit - lower (%)	Not available.
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Explosive limit - upper (%)	Not available.
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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	Not available.
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	Peroxides. Phenols.
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.
Inhalation	Health injuries are not known or expected under normal use. Prolonged inhalation may be harmful.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics
 Direct contact with eyes may cause temporary irritation. Possible effects of overexposure in the workplace include: fever, nausea, diarrhoea.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components	Species	Test Results
DIOCTYL SODIUM SULFOSUCCINATE (CAS 577-11-7)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 10 g/kg
<i>Oral</i>		
LD50	Rat	1900 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
SULFAMETHOXAZOLE (CAS 723-46-6)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
TRIMETHOPRIM (CAS 738-70-5)		
Acute		
<i>Oral</i>		
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
Irritation Corrosion - Skin		
TRIMETHOPRIM		Acute dermal irritation Result: Negative Species: Rabbit
Irritation Corrosion - Skin: P.I.I. value		
MAGNESIUM STEARATE		0
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.	
Eye		
SULFAMETHOXAZOLE		Acute ocular irritation Result: Negative Species: Rabbit
Eye / Kay and Calandra class - Intact		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory or skin sensitization		
Respiratory sensitization	Health injuries are not known or expected under normal use.	
Skin sensitization	Health injuries are not known or expected under normal use.	
Sensitization		
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	Not available.	
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
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

Carcinogenicity

SULFAMETHOXAZOLE

2 year bioassay
Result: Positive (thyroid tumours)
Species: Rat

TRIMETHOPRIM

SAR / QSAR, DEREK, Lhasa, UK
Result: No structural alerts identified.**IARC Monographs. Overall Evaluation of Carcinogenicity**

POLYVINYLPIRROLIDONE (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

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

Not available.

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**

None known.

**Specific target organ toxicity -
repeated exposure**

None known.

Aspiration hazard

Not likely, due to the form of the product.

Chronic effects

Prolonged inhalation may be harmful.

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
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)
		130 mg/l, 96 hours
Microtox	EC50	Microtox
		12.5 mg/l, 15 minutes
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge
		> 1000 mg/l, 3 hours Static test
Aquatic		
<i>Acute</i>		
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
SULFAMETHOXAZOLE (CAS 723-46-6)		
Aquatic		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Residential sludge
		> 100 mg/l, 3 hours Nominal, OECD 209

Components		Species	Test Results
Algae	EC50	Blue-green algae (S. leopolensis)	0.0268 mg/l, 96 hours Measured
	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

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

POLYVINYLPIRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

SULFAMETHOXAZOLE 0 %, 28 days Zahn-Wellens

TRIMETHOPRIM 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-soil)

MAGNESIUM STEARATE 50 %, 13 days

Percent degradation (Anaerobic biodegradation)

TRIMETHOPRIM 50 %, 100 days, Sediment

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SULFAMETHOXAZOLE 0.68

TRIMETHOPRIM 0.91

0.96

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

TRIMETHOPRIM 3 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

SULFAMETHOXAZOLE 0.01 Measured, pH 7
TRIMETHOPRIM 1.88 Measured

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated
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 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

UN number UN3077
UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (SEPTRIN TABLETS (CONTAINING SULFAMETHOXAZOLE)), MARINE POLLUTANT

Transport hazard class(es)

Class 9
Subsidiary risk -
Label(s) 9
Packing group III

Environmental hazards

Marine pollutant Yes

Special precautions for user Not available.
Special provisions 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33
Packaging exceptions 155
Packaging non bulk 213
Packaging bulk 240
Qty limits cargo No limit
Qty limits passenger No limit

IATA

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (SEPTRIN TABLETS (CONTAINING SULFAMETHOXAZOLE))

Transport hazard class(es) 9
Subsidiary class(es) -
Packaging group III
Labels required 9
Environmental hazards No.
ERG Code 9L
Special precautions for user Not available.
Other information

Cargo aircraft only Allowed.

Passenger & cargo Allowed.
Additional Information:
Packaging Instruction 956
Pkg Inst cargo only 956
Pkg Inst passenger & cargo Y956
SP see 44 A97,A158,A179
Max net qty pkg 400 kg
Max net qty pkg cargo only 400 kg
Max net qty pkg LQ 30 kg G

IMDG

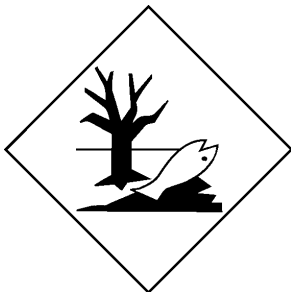
UN number UN3077
UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (SEPTRIN TABLETS (CONTAINING SULFAMETHOXAZOLE))
Transport hazard class(es)
Class 9
Subsidiary risk -
Label(s) 9
Packing group III
Environmental hazards
Marine pollutant Yes
EmS F-A, S-F
Special precautions for user Not available.

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.

DOT; IATA; IMDG



Marine pollutant



General information

Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not 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 - Yes
 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**

Not regulated.

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

Not listed.

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

Not listed.

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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 06-24-2014

Revision date	06-24-2014
Version #	05
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 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: Ingredients Physical & Chemical Properties: Transport Information: Proper Shipping Name/Packing Group Regulatory Information: Risk Phrases - Class. GHS: Classification