SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	AUGMENTIN 7:1 ORAL SUSPENSION
Registration number	-
Synonyms	AUGMENTIN DUO 200/28.5 MG/5 ML * AUGMENTIN DUO 400/57 MG/5 ML * AUGMENTIN 200 MG/5 ML * AUGMENTIN 400 MG/5 ML * AUGMENTIN 400 SUSPENSION * AUGMENTIN BD PAEDIATRIC SUSPENSION 400/57 MG/5 ML * AUGMENTIN PAEDIATRIC SUSPENSION 200/28.5 MG/5 ML * AUGMENTIN PAEDIATRIC SUSPENSION 400/57 MG/5 ML * AUGMENTIN DUO SUSPENSION * AUGMENTIN DUO B/D SUSPENSION * AUGMENTAN PAEDIATRIC ORAL SUSPENSION 400 MG/57 MG/5 ML * AUGMENTAN KINDERSAFT * AUGMENTIN 7:1 SF SUSPENSION * CLAVULIN BID ORAL SUSPENSION * CLAVULIN SUSPENSION 200 MG * CLAVULIN SUSPENSION 400 MG * CLAVULOX DUO * NDC NO. 0029-6092-51 * AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT
Issue date	11-September-2014
Version number	20
Revision date	11-September-2014
Supersedes date	04-August-2014

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information None.

2.3. Other hazards

Assume that this material is capable of sustaining combustion.
Assume that this material is capable of producing a dust explosion if ignited as a dust cloud.
Assume that this material is capable of being ignited by an electrostatic discharge.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
AMOXICILLIN TRIHYDRATE	62.01	61336-70-7 2480038	-	-	
Classification: **DSD:** R42/43 **CLP:** Skin Sens. 1;H317, Resp. Sens. 1;H334					
POTASSIUM CLAVULANATE	9.64	61177-45-5 262-640-9	-	-	
Classification: **DSD:** F;R11-R17 **CLP:** Flam. Sol. 1;H228, Self-heat. 1;H251					
ASPARTAME	1 - < 3	22839-47-0 245-261-3	-	-	
Classification: **DSD:** - **CLP:** -					
POLYVINYLPOLYPYRROLIDONE	1 - < 3	25249-54-1 -	-	-	
Classification: **DSD:** R52/53 **CLP:** Aquatic Chronic 3;H412					
SODIUM BENZOATE	1 - < 3	532-32-1 208-534-8	-	-	
Classification: **DSD:** Xi;R36 **CLP:** Eye Irrit. 2;H319					
Silicon dioxide	< 1	7631-86-9 231-545-4	-	-	
Classification: **DSD:** - **CLP:** -					
XANTHAN GUM	< 1	11138-66-2 234-394-2	-	-	
Classification: **DSD:** - **CLP:** -					
MAGNESIUM STEARATE	< 0.3	557-04-0 209-150-3	-	-	
Classification: **DSD:** - **CLP:** -					

Other components below reportable levels 20 - < 30

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse. 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.

4.1. Description of first aid measures

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

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both acute and delayed Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.

4.3. Indication of any immediate medical attention and special treatment needed Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of penicillin antibiotic. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. This material may cause or aggravate allergy to penicillin antibiotics. The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting respiratory symptoms and including respiratory function testing.
In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting respiratory conditions and other allergy symptoms. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma.

SECTION 5: Firefighting measures

General fire hazards Assume that this material is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO_2).

5.2. Special hazards arising from the substance or mixture Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.

5.3. Advice for firefighters

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

Special fire fighting procedures Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Wear a dust mask if dust is generated above exposure limits. 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.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimise dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Keep cool. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure.

7.2. Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in original tightly closed container. Keep away from moisture. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from other materials. Maintain air gap between stacks/pallets.

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)	15 MIN STEL	100 mcg/m3	
	OHC	3	RESPIRATORY SENSITISER
		3	SKIN SENSITISER
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
POTASSIUM CLAVULANATE (CAS 61177-45-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
Silicon dioxide (CAS 7631-86-9)	OHC	1	
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM CARBOXYMETHYL CELLULOSE (CAS 9004-32-4)	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.

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

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the 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

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Wear eye/face protection. If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection	
- Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)
Respiratory protection	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). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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.

Environmental exposure controls

Hazard guidance and control recommendations	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Form	Powder.Bottle.
Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Not available.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions. The purity of this material will be affected by exposure to moisture. This material can become unstable if subjected to heat, high levels of moisture or storage in large masses.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Keep away from heat, sparks and open flame. Contact with incompatible materials. Avoid dispersion as a dust cloud. Moisture.
10.5. Incompatible materials	Water, moisture. Fluorine. Chlorine.
10.6. Hazardous decomposition products	Thermal decomposition of this material can produce toxic, dense smoke containing oxides of carbon, sulphur and nitrogen together with acetaldehyde. Ash remaining after thermal decomposition may contain cyanide compounds and should not come into contact with acidic conditions which may result in the production of hydrogen cyanide gas.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
Inhalation	Health injuries are not known or expected under normal use. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.

11.1. Information on toxicological effects

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

Components	Species	Test results
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
POTASSIUM CLAVULANATE (CAS 61177-45-5)		
Acute		
Oral		
LD	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 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

AMOXICILLIN TRIHYDRATE	Acute dermal irritation Result: negative Species: Rabbit
POTASSIUM CLAVULANATE	OECD 404 Result: Non-irritant

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

POTASSIUM CLAVULANATE	OECD 405 Result: Non-Irritating

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days
AMOXICILLIN TRIHYDRATE	Result: Minimal irritant Species: Rabbit Recovery Period: 2 days

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

AMOXICILLIN TRIHYDRATE	Epidemiology Result: positive Species: Human
POTASSIUM CLAVULANATE	Maximisation assay (Magnusson and Kligman) Result: negative Species: Guinea pig SAR Result: No structural alerts identified.

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

Mutagenicity

POTASSIUM CLAVULANATE	Ames Result: negative
AMOXICILLIN TRIHYDRATE	GreenScreen Result: negative Mouse Lymphoma Cell Assay Result: negative
POTASSIUM CLAVULANATE	Mouse Lymphoma Cell Assay Result: negative SAR Result: No structural alerts identified.

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

POTASSIUM CLAVULANATE	SAR Result: No structual alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

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

Reproductivity

POTASSIUM CLAVULANATE	Fertility (IV) Result: Reproductive and developmental NOAEL 75 mg/kg/day Species: Rat
AMOXICILLIN TRIHYDRATE	Fertility/foetal development, Rat and Mouse Result: No effect
POTASSIUM CLAVULANATE	Reproduction/Fertility Study (IV) Result: Reproductive performance NOAEL 150 mg/kg/day Species: Rabbit Reproduction/Fertility Study (IV) Result: Teratogenic and embryotoxic NOAEL 150 mg/kg/day Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard	Not an aspiration hazard.
Mixture versus substance information	No information available.
Other information	Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	630 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	530 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 2300 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	2300 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 930 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 1000 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	930 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	1000 mg/l, 96 hours Static test
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
POLYVINYLPOLYPYRROLIDONE (CAS 25249-54-1)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test
POTASSIUM CLAVULANATE (CAS 61177-45-5)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	56 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	9.4 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	1610 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	530 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 790 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 960 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	790 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	960 mg/l, 96 hours Static test

Components		Species	Test results
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes
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
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-acidic)

POTASSIUM CLAVULANATE	11.9 Hours Measured

Half-life (Hydrolysis-basic)

ASPARTAME	< 1 Days Measured
POTASSIUM CLAVULANATE	9.92 Hours Measured

Half-life (Hydrolysis-neutral)

AMOXICILLIN TRIHYDRATE	50 - 113 Days Measured
POTASSIUM CLAVULANATE	28.3 Hours Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

AMOXICILLIN TRIHYDRATE	88 %, 28 days Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
POLYVINYLPOLYPYRROLIDONE	0 %, 28 days Modified MITI test, Activated sludge
POTASSIUM CLAVULANATE	90 %, 28 days Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
MAGNESIUM STEARATE	95 %, 22 days Sturm test
SODIUM BENZOATE	100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water 90 %, 7 days Modified Sturm test., Activated sludge

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Percent degradation (Anaerobic biodegradation)

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

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

AMOXICILLIN TRIHYDRATE	-1.56

POTASSIUM CLAVULANATE	-5.8 (Estimated).
SODIUM BENZOATE	1.89

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

AMOXICILLIN TRIHYDRATE	-0.17 Estimated

Soil/sediment sorption - log Koc

ASPARTAME	1.78 Estimated
MAGNESIUM STEARATE	5.86 Estimated
SODIUM BENZOATE	1.16 Calculated

Mobility in general

Volatility

Henry's law

AMOXICILLIN TRIHYDRATE	0 atm m^3/mol Calculated
ASPARTAME	< 0 atm m^3/mol Estimated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Consult authorities before disposal. Dispose in accordance with all applicable regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General REGULATED IN TRANSPORT for packages of greater than 3 cubic metres volume. EXEMPT if transported in packages of not more than 3 cubic metres volume per UN Manual of Tests and Criteria (33.3.1.3.3.1).

ADR

14.1. UN number	UN3088
14.2. UN proper shipping name	Self-heating solid, organic, n.o.s. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	4.2
Subsidiary risk	-
Label(s)	4.2
Hazard No. (ADR)	Not available.
Tunnel code	Not available.
14.4. Packing group	II
14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.

IATA

14.1. UN number	UN3088
14.2. UN proper shipping name	Self-heating solid, organic, n.o.s. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	4.2
Subsidiary class(es)	-
14.4. Packing group	II
Labels required	4.2

14.5. Environmental hazards	No.
14.6. Special precautions for user	Not available.
Other information	
Cargo aircraft only	Forbidden.

IMDG

14.1. UN number	UN3088
14.2. UN proper shipping name	SELF-HEATING SOLID, ORGANIC, N.O.S. (AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	
Class	4.2
Subsidiary risk	-
Label(s)	4.2
14.4. Packing group	II
14.5. Environmental hazards	
Marine pollutant	No.
EmS	F-A, S-J
14.6. Special precautions for user	Not available.
14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

ADR; IATA; IMDG

General information	REGULATED IN TRANSPORT for packages of greater than 3 cubic metres volume. EXEMPT if transported in packages of not more than 3 cubic metres volume per UN Manual of Tests and Criteria (33.3.1.3.3.1).

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Young people under 18 years old are not allowed to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R11 Highly flammable. R17 Spontaneously flammable in air. R36 Irritating to eyes. R42/43 May cause sensitization by inhalation and skin contact. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. H228 Flammable solid. H251 Self-heating: may catch fire. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H412 Harmful to aquatic life with long lasting effects.
Revision information	SECTION 2: Hazards identification: 2.3. Other hazards SECTION 5: Firefighting measures: 5.2. Special hazards arising from the substance or mixture SECTION 5: Firefighting measures: General fire hazards SECTION 7: Handling and storage: 7.1. Precautions for safe handling SECTION 7: Handling and storage: 7.2. Conditions for safe storage, including any incompatibilities SECTION 10: Stability and reactivity: 10.4. Conditions to avoid SECTION 10: Stability and reactivity: 10.6. Hazardous decomposition products SECTION 10: Stability and reactivity: 10.5. Incompatible materials SECTION 10: Stability and reactivity: 10.2. Chemical stability SECTION 14: Transport information: General information GHS: Classification
Training information	Follow training instructions when handling this material.
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.