# 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

**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<br>2480038 | - | - | |
| **Classification:** **DSD:** R42/43<br>**CLP:** Skin Sens. 1;H317, Resp. Sens. 1;H334 | | | | | |
| POTASSIUM CLAVULANATE | 9,64 | 61177-45-5<br>262-640-9 | - | - | |
| **Classification:** **DSD:** F;R11-R17<br>**CLP:** Flam. Sol. 1;H228, Self-heat. 1;H251 | | | | | |
| ASPARTAME | 1 - < 3 | 22839-47-0<br>245-261-3 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| POLYVINYLPOLYPYRROLIDONE | 1 - < 3 | 25249-54-1<br>- | - | - | |
| **Classification:** **DSD:** R52/53<br>**CLP:** Aquatic Chronic 3;H412 | | | | | |
| SODIUM BENZOATE | 1 - < 3 | 532-32-1<br>208-534-8 | - | - | |
| **Classification:** **DSD:** Xi;R36<br>**CLP:** Eye Irrit. 2;H319 | | | | | |
| Silicon dioxide | < 1 | 7631-86-9<br>231-545-4 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| XANTHAN GUM | < 1 | 11138-66-2<br>234-394-2 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| MAGNESIUM STEARATE | < 0,3 | 557-04-0<br>209-150-3 | - | - | |
| **Classification:** **DSD:** -<br>**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 | |

**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<br>Result: negative<br>Species: Rabbit |
| POTASSIUM CLAVULANATE | OECD 404<br>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<br>Result: Non-Irritating |

**Eye / Kay and Calandra class - Intact**

| | |
|---|---|
| MAGNESIUM STEARATE | 4<br>Recovery Period: 2 days |
| AMOXICILLIN TRIHYDRATE | Result: Minimal irritant<br>Species: Rabbit<br>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<br>Result: positive<br>Species: Human |
| POTASSIUM CLAVULANATE | Maximisation assay (Magnusson and Kligman)<br>Result: negative<br>Species: Guinea pig<br>SAR<br>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<br>Result: negative |
| AMOXICILLIN TRIHYDRATE | GreenScreen<br>Result: negative<br>Mouse Lymphoma Cell Assay<br>Result: negative |
| POTASSIUM CLAVULANATE | Mouse Lymphoma Cell Assay<br>Result: negative<br>SAR<br>Result: No structural alerts identified. |

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

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

| Components | | Species | Test results |
|---|---|---|---|
| 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<br>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 |

**Adsorption**

**Soil/sediment sorption - log Koc**

| | |
|---|---|
| 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.<br>R17 Spontaneously flammable in air.<br>R36 Irritating to eyes.<br>R42/43 May cause sensitization by inhalation and skin contact.<br>R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.<br>H228 Flammable solid.<br>H251 Self-heating: may catch fire.<br>H317 May cause an allergic skin reaction.<br>H319 Causes serious eye irritation.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>H412 Harmful to aquatic life with long lasting effects. |
| **Revision information** | Product and Company Identification: Product and Company Identification<br>Composition / Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>Transport Information: Material Transportation Information<br>Regulatory Information: United States<br>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. |