# 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 TABLETS |
| **Registration number** | - |
| **Synonyms** | AUGMENTIN 156.25 MG TABLETS * AUGMENTIN 250 MG TABLETS * AUGMENTIN 500 MG TABLETS * AUGMENTIN 187.5 MG TABLETS * AUGMENTIN 375 MG TABLETS * AUGMENTIN 625 MG TABLETS * AUGMENTAN TABLETS * AUGMENTIN 2:1 TABLETS * AUGMENTIN 4:1 TABLETS * CLAVULIN 250 TABLETS * CLAVULIN 500F TABLETS * AMOCLAV 375 MG TABLETS * AMOCLAV 625 MG TABLETS * CLAMOXYL TABLETS 250 MG * SPEKTRAMOX 375 MG FINAL TABLETS * NDC NO. 0029-6075-27 * NDC NO. 0029-6075-31 * NDC NO. 0029-6080-12 * NDC NO. 0029-6080-31 * AMOXICILLIN TRIHYDRATE AND POTASSIUM CLAVULANATE, FORMULATED PRODUCT |
| **Issue date** | 11-July-2014 |
| **Version number** | 20 |
| **Revision date** | 11-July-2014 |

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

| | |
|---|---|
| **Identified uses** | Medicinal Product<br><br>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 product is capable of sustaining combustion.
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 | 35 - < 60 | 61336-70-7<br>2480038 | - | - | |
| **Classification:** **DSD:** R42/43<br>**CLP:** Skin Sens. 1;H317, Resp. Sens. 1;H334 | | | | | |
| POTASSIUM CLAVULANATE | 6 - < 24 | 61177-45-5<br>262-640-9 | - | - | |
| **Classification:** **DSD:** F;R11-R17<br>**CLP:** Flam. Sol. 1;H228, Self-heat. 1;H251 | | | | | |
| MICROCRYSTALLINE CELLULOSE | 5 - < 10 | 9004-34-6<br>232-674-9 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| MAGNESIUM STEARATE | 1 - < 3 | 557-04-0<br>209-150-3 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| Silicon dioxide | 1 - < 3 | 7631-86-9<br>231-545-4 | - | - | |
| **Classification:** **DSD:** -<br>**CLP:** - | | | | | |
| Other components below reportable levels | 30 - < 40 | | | | |

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** Wash contaminated clothing before reuse.

**4.1. Description of first aid measures**

**Inhalation** If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician.

**Skin contact** Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. For minor skin contact, avoid spreading material on unaffected skin.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. Get medical attention if symptoms occur.

**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 product is capable of sustaining combustion.

**5.1. Extinguishing media**

**Suitable extinguishing media** Foam. Dry chemical powder. Carbon dioxide (CO2). Water.

**Unsuitable extinguishing media** None known.

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

**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.

**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. 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. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

**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** Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

**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 | SKIN SENSITISER |
| | | 3 | RESPIRATORY SENSITISER |

**GSK**

| Components | Type | Value | Note |
|---|---|---|---|
| MAGNESIUM STEARATE (CAS 557-04-0) | OHC | 1 | |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | 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 STARCH GLYCOLATE (CAS 9063-38-1) | OHC | 1 | |

**UK. EH40 Workplace Exposure Limits (WELs)**

| Components | Type | Value | Form |
|---|---|---|---|
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | STEL | 20 mg/m3 | Inhalable dust. |
| | TWA | 4 mg/m3 | Respirable dust. |
| | | 10 mg/m3 | Inhalable dust. |
| Silicon dioxide (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** Not available.

**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** Not normally needed. 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** Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust)

**Respiratory protection** No personal respiratory protective equipment normally required. 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.

**Hygiene measures** 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.

**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** | Tablet. |
| **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. |
| **10.3. Possibility of hazardous reactions** | No dangerous reaction known under conditions of normal use. |
| **10.4. Conditions to avoid** | Contact with incompatible materials. |
| **10.5. Incompatible materials** | Strong oxidising agents. Fluorine. |
| **10.6. Hazardous decomposition products** | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition. |

## 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. |
| **Skin contact** | May cause an allergic skin reaction. Health injuries are not known or expected under normal use. |
| **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 |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) | | |
| **Acute** | | |
| *Dermal* | | |
| LD50 | Rabbit | > 2000 mg/kg |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |
| POTASSIUM CLAVULANATE (CAS 61177-45-5) | | |
| **Acute** | | |
| *Oral* | | |
| LD | 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. Health injuries are not known or expected under normal use.

**Skin sensitisation** May cause an allergic skin reaction. Health injuries are not known or expected under normal use.

**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 |

**Mutagenicity**

| | |
|---|---|
| POTASSIUM CLAVULANATE | 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 likely, due to the form of the product.

**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 |
| Microtox | EC50 | Microtox | 12.5 mg/l, 15 minutes |

| Components | | Species | Test results |
|---|---|---|---|
| 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 |
| Microtox | EC50 | Microtox | 8700 mg/l, 15 minutes |

* 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)**

| | |
|---|---|
| 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 |
| POTASSIUM CLAVULANATE | 90 %, 28 days Zahn-Wellens, Activated sludge |

**Percent degradation (Aerobic biodegradation-ready)**

| | |
|---|---|
| MAGNESIUM STEARATE | 95 %, 22 days Sturm test |

**Percent degradation (Aerobic biodegradation-soil)**

| | |
|---|---|
| MAGNESIUM STEARATE | 50 %, 13 days |

**12.3. Bioaccumulative potential**

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

| | |
|---|---|
| AMOXICILLIN TRIHYDRATE | -1.56 |
| POTASSIUM CLAVULANATE | -5.8 (Estimated). |

**Bioconcentration factor (BCF)**

| | |
|---|---|
| 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**

| | |
|---|---|
| MAGNESIUM STEARATE | 5.86 Estimated |

**Mobility in general**

**Volatility**

**Henry's law**

| | |
|---|---|
| AMOXICILLIN TRIHYDRATE | 0 atm m^3/mol Calculated |

**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** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations.

**Special precautions** Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

**ADR**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**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.

## 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

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|---|---|
| **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>R42/43 May cause sensitization by inhalation and skin contact.<br>H228 Flammable solid.<br>H251 Self-heating: may catch fire.<br>H317 May cause an allergic skin reaction.<br>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| **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>HazReg Data: Transportation<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. |