

SAFETY DATA SHEET



GlaxoSmithKline

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

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| Material | AMOXIL ORAL SUSPENSION |
| Synonyms | AMOXIL ORAL SUSPENSION 250 MG/5 ML * AMOXIL ORAL SUSPENSION 125 MG/5 ML * CLAMOXYL SUSPENSION * NDC NO. 0029-6009-22 * NDC NO. 0029-6009-23 * AMOXICILLIN TRIHYDRATE, FORMULATED PRODUCT |
| Company Name | GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response |

2. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS RN | Percentage |
|---------------------------|------------|------------|
| AMOXICILLIN TRIHYDRATE | 61336-70-7 | 2 to 4 |
| NON-HAZARDOUS INGREDIENTS | Unassigned | 96 to 98 |

3. HAZARDS IDENTIFICATION

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| Fire and Explosion | Assume that this product is capable of sustaining combustion. |
| Health | Exposure might occur via skin; eyes; ingestion; inhalation. May produce allergic skin reactions. Respiratory allergen. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); nausea; vomiting; diarrhoea. Health effects information is based on hazards of components. |
| Environment | No information is available about the potential of this product to produce adverse environmental effects. |

4. FIRST-AID MEASURES

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| Ingestion | Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention. |
| Inhalation | Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed. |
| Skin Contact | Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed. |
| Eye Contact | Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention. |

NOTES TO HEALTH PROFESSIONALS

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| Medical Treatment | Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. 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. |
| Medical Conditions Caused or Aggravated by Exposure | Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product. Ocular symptoms may be indicative of allergic reaction. Pulmonary symptoms may indicate allergic reaction or asthma. This material may cause or aggravate allergy to penicillin antibiotics. |
| Antidotes | No specific antidotes are recommended. |

5. FIRE-FIGHTING MEASURES

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| Fire and Explosion Hazards | The combustibility of the product is not known, however the packaging is combustible. |
| Extinguishing Media | Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective. |
| Special Firefighting Procedures | For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal. |
| Hazardous Combustion Products | Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire. |

6. ACCIDENTAL RELEASE MEASURES

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| Personal Precautions | Wear protective clothing and equipment consistent with the degree of hazard. |
| Environmental Precautions | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. |
| Clean-up Methods | Collect and place it in a suitable, properly labelled container for recovery or disposal. |

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| Decontamination Procedures | No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations. |
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7. HANDLING AND STORAGE

HANDLING

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| General Requirements | No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. |
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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| INGREDIENT | AMOXICILLIN TRIHYDRATE |
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| GSK Occupational Hazard Category | 3 |
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| GSK Occupational Exposure Limit | 100 MCG/M3 (15 MIN STEL) | RESPIRATORY SENSITISER, SKIN SENSITISER |
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| * Occupational Hygiene Air Monitoring Methods | For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. |
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ENGINEERING CONTROLS

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| Exposure Controls | 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. |
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PERSONAL PROTECTIVE EQUIPMENT

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| Eye Protection | Wear approved safety glasses with side shields if eye contact is possible. |
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| Respirators | If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present. |
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| Other Equipment or Procedures | Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. |
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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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| Colour | White. |
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| Physical Form | Free flowing powder. |
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10. STABILITY AND REACTIVITY

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| Stability | This product is expected to be stable. |
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| Conditions to Avoid | None for normal handling of this product. |
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11. TOXICOLOGICAL INFORMATION

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| Oral Toxicity | Not expected to be toxic following ingestion. |
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| Inhalation Toxicity | Adverse effects might occur following inhalation. |
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| Skin Effects | Irritation might occur following direct contact. |
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| Eye Effects | Minor irritation might occur following direct contact with eyes. |
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| Target Organ Effects | No specific target organ effects have been identified. |
| Sensitisation | Allergic skin reactions might occur following dermal exposure. Assessment based upon effects of structurally similar substances. |
| Genetic Toxicity | Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances. |
| Carcinogenicity | Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. |
| Reproductive Effects | Not expected to produce adverse effects on fertility or development under occupational exposure conditions. No adverse effects have been reported following extensive use or exposure in humans. |
| Pharmacological Effects | This material is a penicillin; an antibiotic. |
| * Other Adverse Effects | None known for occupational exposure. |

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Algal

This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: 630 mg/l, 72 Hours, Selenastrum capricornutum, green algae

NOEL: 530 mg/l, 72 Hours, Selenastrum capricornutum, green algae

* Daphnid

This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 2300 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 2300 mg/l, 48 Hours, Daphnia magna, Static test

Fish

This material contains an active pharmaceutical ingredient that is not toxic to fish.

Adult Lepomis macrochirus, bluegill sunfish

EC50: > 930 mg/l, 96 Hours, Static test

Adult Lepomis macrochirus, bluegill sunfish

NOEL: 930 mg/l, 96 Hours, Static test

Adult Oncorhynchus mykiss, rainbow trout

EC50: > 1000 mg/l, 96 Hours, Static test

Adult Oncorhynchus mykiss, rainbow trout

NOEL: 1000 mg/l, 96 Hours, Static test

MOBILITY

Solubility

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 2.00E-16 atm m³/mol, Calculated

Adsorption This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Sludge Biomass -0.17 Estimated
Distribution Coefficient
(log Kd):

Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Hydrolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 50 to 113 Days, Measured

Biodegradation This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Inherent

Percent Degradation: 88 %, 28 days, Zahn-Wellens, Activated sludge

BIOACCUMULATION

This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 19-Jan-2006

SDS Version Number 13

SDS Sections Updated

Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND
OF COMPANY

REGULATORY INFORMATION

TOXICOLOGY INFORMATION

Subsections

US Environmental (EPA) Requirements

Other Adverse Effects

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.