



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** AMOXIL VIALS  
**Other means of identification** Not available.  
**Synonym(s)** AMOXIL INJECTION 250 MG \* AMOXIL INJECTION 500 MG \* AMOXIL INJECTION 1 GRAM \* CLAMOXYL INJECTION \* MOXACIN INJECTION \* AMOXYCILLIN SODIUM, FORMULATED PRODUCT  
**Recommended use** Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

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

### Label elements

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

### Hazard(s) not otherwise classified (HNOC)

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

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
AMOXYCILLIN SODIUM	AMOXICILLIN SODIUM SODIUM AMOXYCILLIN SODIUM [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABIC MATERIALS [2S-[2.ALPHA.,5.ALPHA.,6.BETA.(S*)]]-6-[[AMINO(4-HYDROXYPHENYL)ACETYL]AMINO]-3,3-DIMETHYL-7-OXO-4-THIA-1-AZABICYCLO[3.2.0]HEPTAN-2-CARBOXYLA TE	34642-77-8	100

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. 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 CENTER or doctor/physician.

<b>Skin contact</b>	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.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Call a POISON CENTER or doctor/physician if you feel unwell.
<b>Most important symptoms/effects, acute and delayed</b>	Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing), nausea, vomiting, diarrhoea.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. 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.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Wash contaminated clothing before reuse.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	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. Minimize dust generation and accumulation. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes. In case of insufficient ventilation, wear suitable respiratory equipment. Practice good housekeeping.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

#### Components

Components	Type	Value	Note
AMOXYCILLIN SODIUM (CAS 34642-77-8)	15 MIN STEL	100 mcg/m <sup>3</sup>	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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<b>Appropriate engineering controls</b>	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. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. 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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Use tight fitting goggles if dust is generated.
<b>Hand protection</b>	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
<b>Other</b>	Not normally needed.
<b>Respiratory protection</b>	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

<b>Appearance</b>	
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).



Components	Species	Test Results
NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	858 mg/l, 96 hours Static test
	Rainbow trout (Adult Oncorhynchus mykiss)	923 mg/l, 96 hours Static test

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

### Persistence and degradability

#### Hydrolysis

##### Half-life (Hydrolysis-neutral)

AMOXYCILLIN SODIUM 50 - 113 Days Measured

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

#### Adsorption

##### Sludge/biomass distribution coefficient - log Kd

AMOXYCILLIN SODIUM -0.17 Estimated

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

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

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a dangerous good.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

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

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

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations****US. Massachusetts RTK - Substance List**

Not regulated.

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

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	06-12-2014
<b>Revision date</b>	06-12-2014
<b>Version #</b>	16
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 0 Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 0 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision Information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Ecological Information: GSK Environmental Hazard Assessment Concentration  
GHS: Classification