

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

### 1.1. Product identifier

Trade name or designation of the mixture	AMOXIL CAPSULES
Registration number	-
Synonyms	AMOXIL 250 MG CAPSULES * AMOXIL 500 MG CAPSULES * MOXACIN CAPSULES 250 MG * MOXACIN CAPSULES 500 MG * CLAMOXYL CAPSULES * NOVABRITINE CAPSULES * AMOXAL CAPSULES * VELAMOX CAPSULES * PENAMOX CAPSULES * AMOXYCILLIN TRIHYDRATE, FORMULATED PRODUCT
Issue date	11-August-2014
Version number	15
Revision date	11-August-2014

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

**Identified uses** Medicinal Product

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

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

### 1.3. Details of the supplier of the safety data sheet

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

#### 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** Not applicable.

**2.3. Other hazards** 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
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AMOXICILLIN TRIHYDRATE	98	61336-70-7 2480038	-	-	
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**Classification:** **DSD:** R42/43  
**CLP:** Skin Sens. 1;H317, Resp. Sens. 1;H334

MAGNESIUM STEARATE	2	557-04-0 209-150-3	-	-	
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**Classification:** **DSD:** -  
**CLP:** -

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** No unusual fire or explosion hazards noted.

### 5.1. Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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. 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. 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. 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 skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing. 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/m <sup>3</sup>	
	OHC	3	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
MAGNESIUM STEARATE (CAS 557-04-0)	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. 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** Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

**Eye/face protection** Not normally needed.

**Skin protection**

**- Hand protection** 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
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	Hard gelatin capsule.
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.
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.
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**Information on likely routes of exposure**

<b>Ingestion</b>	Expected to be a low ingestion hazard. Health injuries are not known or expected under normal use.
<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	May cause an allergic skin reaction. Health injuries are not known or expected under normal use.
<b>Eye contact</b>	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)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

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

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Corrosivity**

AMOXICILLIN TRIHYDRATE Acute dermal irritation  
Result: negative  
Species: Rabbit

**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 / Kay and Calandra class - Intact**

MAGNESIUM STEARATE 4  
Recovery Period: 2 days

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

**Respiratory sensitisation** May cause allergy or asthma symptoms or breathing difficulties if inhaled. 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  
Result: positive  
Species: Human

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

**Mutagenicity**

AMOXICILLIN TRIHYDRATE GreenScreen  
Result: negative  
Mouse Lymphoma Cell Assay  
Result: negative

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

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

**Reproductivity**

AMOXICILLIN TRIHYDRATE Fertility/foetal development, Rat and Mouse  
Result: No effect

**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.

<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	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)			
<b>Aquatic</b>			
<i>Acute</i>			
Algae	EC50	Green algae ( <i>Selenastrum capricornutum</i> )	630 mg/l, 72 hours
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	530 mg/l, 72 hours
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	> 2300 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	2300 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	> 930 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	> 1000 mg/l, 96 hours Static test
	NOEC	Bluegill sunfish (Adult <i>Lepomis macrochirus</i> )	930 mg/l, 96 hours Static test
		Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	1000 mg/l, 96 hours Static test
MAGNESIUM STEARATE (CAS 557-04-0)			
<b>Aquatic</b>			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i> )	130 mg/l, 96 hours
Microtox	EC50	Microtox	12,5 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-neutral)

AMOXICILLIN TRIHYDRATE 50 - 113 Days Measured

#### Biodegradability

##### Percent degradation (Aerobic biodegradation-inherent)

AMOXICILLIN TRIHYDRATE 88 %, 28 days Zahn-Wellens, Activated sludge

MAGNESIUM STEARATE 77 %, 28 days BOD

##### 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

#### Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

### 12.4. Mobility in soil

#### Adsorption

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

AMOXICILLIN TRIHYDRATE -0,17 Estimated

## Adsorption

### Soil/sediment sorption - log K<sub>oc</sub>

MAGNESIUM STEARATE 5,86 Estimated

## Mobility in general

### Volatility

#### Henry's law

AMOXICILLIN TRIHYDRATE 0 atm m<sup>3</sup>/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

<b>Residual waste</b>	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).
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Special precautions</b>	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** Not applicable.

## 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

R42/43 May cause sensitization by inhalation and skin contact.  
H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Revision information

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Ecological Information: Mobility  
Regulatory Information: United States  
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. The information in the sheet was written based on the best knowledge and experience currently available.