## SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

AUGMENTIN TABLETS BID

of the mixture

Registration number

AUGMENTIN 875 MG TABLETS \* AUGMENTIN 1000 MG TABLETS \* AUGMENTIN 1 GRAM **Synonyms** 

TABLETS \* AUGMENTIN DUO TABLETS \* AUGMENTAN FILMTABLETTEN 875/125 MG \* CLAVULIN 875 TABLETS \* PENILAN 875 MG/125 MG TABLETS \* AUGMENTINE 875 MG/125 MG TABLETS \* CLAMOXYL DUO 1 G TABLETS \* NDC NO. 0029-6086-12 \* NDC NO.

0029-6086-21 \* POTASSIUM CLAVULANATE AND AMOXICILLIN TRIHYDRATE, FORMULATED

**PRODUCT** 

04-November-2014 Issue date

Version number 07

**Revision date** 04-November-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

# 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.

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

Material name: AUGMENTIN TABLETS BID SDS IRELAND **General information** 

CAS-No. / EC No. REACH Registration No. INDEX No. **Chemical name** % **Notes** AMOXICILLIN TRIHYDRATE < 70 61336-70-7

2480038

Classification: **DSD:** R42/43

CLP: Skin Sens. 1;H317, Resp. Sens. 1;H334

MICROCRYSTALLINE CELLULOSE 9004-34-6 < 20

232-674-9

Classification: DSD: -

CLP: -

POTASSIUM CLAVULANATE < 12 61177-45-5

262-640-9

**DSD:** F;R11-R17 Classification:

CLP: Flam. Sol. 1;H228, Self-heat. 1;H251

< 2 557-04-0 MAGNESIUM STEARATE 209-150-3

Classification: DSD: -

CLP: -

Silicon dioxide < 1 7631-86-9

231-545-4

Classification: DSD: -

CLP:

Other components below reportable levels

#### List of abbreviations and symbols that may be used above

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** In the case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible). Ensure that medical personnel are aware of the material(s) involved, and take

precautions to protect themselves.

4.1. Description of first aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if

symptoms develop or persist. Under normal conditions of intended use, this material is not

expected to be an inhalation hazard.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse.

Get medical attention if symptoms occur.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately. Do not induce vomiting without

advice from poison control center.

4.2. Most important symptoms and effects, both acute and

delayed

Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing) nausea, vomiting, diarrhoea, abdominal discomfort.

4.3. Indication of any immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## **SECTION 5: Firefighting measures**

General fire hazards No unusual fire or explosion hazards noted.

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5.1. Extinguishing media

Suitable extinguishing

media

Water. Foam.

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 standard firefighting procedures and consider the hazards of other involved materials. Specific methods

## **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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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

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.

Avoid discharge into drains, water courses or onto the ground.

6.4. Reference to other

For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

sections

## **SECTION 7: Handling and storage**

7.1. Precautions for safe

handling

Avoid prolonged exposure. No special control measures required for the normal handling of this product. Avoid breaking or crushing tablets.

7.2. Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10

of the SDS).

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7.3. Specific end use(s) Medicinal Product.

## **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

GSK

#### Occupational exposure limits

Components	Туре	Value	Note
AMOXICILLIN TRIHYDRATE (CAS 61336-70-7)	15 MIN STEL	100 mcg/m3	
,	OHC	3	RESPIRATORY SENSITISER
		3	SKIN SENSITISER
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	
SODIUM STARCH GLYCOLATE (CAS 9063-38-1)	OHC	1	
Ireland. Occupational Exposure Li	imits		
Components	Туре	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	

Material name: AUGMENTIN TABLETS BID

Ireland. Occupational Exposure Limits Form Value Components **Type MICROCRYSTALLINE** STEL 20 mg/m3 Total inhalable dust. CELLULOSE (CAS 9004-34-6) **TWA** Respirable dust. 4 mg/m3 10 mg/m3 Total inhalable dust. Total inhalable dust. Silicon dioxide (CAS **TWA** 6 mg/m3 7631-86-9) 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.

**Exposure guidelines** 

8.2. Exposure controls

Appropriate engineering

controls

General ventilation normally adequate.

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** If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally

needed.

Skin protection

- Hand protection 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). Not

normally needed.

- Other Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for

splashes, EN ISO 13982 for dust). Not normally needed.

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

**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** 

Solid. Physical state Form Tablet Not available. Colour Not available. Odour **Odour threshold** Not available. Not available. pН Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Flash point Not available.

Evaporation rate Not available.

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Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

(%)

Flammability limit - upper

Flammability limit - lower

(%)

Not available.

Not available.

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water)Not available.Solubility (other)Not available.Partition coefficientNot available.

(n-octanol/water)

Auto-ignition temperature

Decomposition temperature

Viscosity

Explosive properties

Oxidizing properties

Not available.

Not available.

Not available.

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 Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

decomposition products

## **SECTION 11: Toxicological information**

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eve contact Health injuries are not known or expected under normal use.

**Ingestion** Health injuries are not known or expected under normal use. Expected to be a low ingestion

hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms Accidental exposure or contact might produce: symptoms of hypersensitivity (such as skin rash,

hives, itching, and difficulty breathing) nausea, vomiting, diarrhoea, abdominal discomfort.

#### 11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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

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Components Species Test results

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.

**Irritation Corrosion - Skin** 

AMOXICILLIN TRIHYDRATE Acute dermal irritation, Primary Irritation Index: 0

Result: Non-irritant Species: Rabbit

POTASSIUM CLAVULANATE Acute dermal irritation; OECD 404

Result: Non-irritant

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE (

Serious eye damage/eye

Health injuries are not known or expected under normal use.

irritation

Eye

AMOXICILLIN TRIHYDRATE Acute ocular irritation, Kay and Calandra score = 3;

maximum group mean score = 6.7

Result: Minimal Irritant Species: Rabbit

POTASSIUM CLAVULANATE Acute ocular irritation; OECD 405

Result: Non-Irritating

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

Recovery Period: 2 days

**Respiratory sensitisation**Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitisation** This product is not expected to cause skin sensitisation.

Sensitisation

AMOXICILLIN TRIHYDRATE Epidemiology

Result: positive Species: Human

POTASSIUM CLAVULANATE Maximisation assay (Magnusson and Kligman), clavulanic

acid tested Result: negative Species: Guinea pig

SAR

Result: No structural alerts identified.

Germ cell mutagenicity

Mutagenicity

POTASSIUM CLAVULANATE Ames Assay, GLP assay; clavulanic acid tested

Result: negative

AMOXICILLIN TRIHYDRATE GreenScreen, amoxicillin sodium tested

Result: negative

POTASSIUM CLAVULANATE Micronucleus Assay, clavulanic acid tested

Result: negative

AMOXICILLIN TRIHYDRATE Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP

assay; amoxicillin sodium tested

Result: negative

POTASSIUM CLAVULANATE SAR, DEREK, Lhasa, UK

Result: No structural alerts identified.

**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to

carcinogenicity to humans.

POTASSIUM CLAVULANATE SAR, DEREK, Lhasa, UK

Result: No structual alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

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Silicon dioxide (CAS 7631-86-9) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction

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Reproductivity

POTASSIUM CLAVULANATE Fertility (IV)

Result: Reproductive and developmental NOAEL 75

mg/kg/day Species: Rat

Fertility/foetal development, Rat and Mouse AMOXICILLIN TRIHYDRATE

Result: No effect

POTASSIUM CLAVULANATE Reproduction/Fertility Study (IV)

Result: Reproductive performance NOAEL 150 mg/kg/day

Species: Rabbit

Reproduction/Fertility Study (IV)

Result: Teratogenic and embryotoxic NOAEL 150 mg/kg/day

Species: Rat

Specific target organ toxicity -

single exposure

Not assigned.

Specific target organ toxicity -

repeated exposure

Not assigned.

**Aspiration hazard** 

Not likely, due to the form of the product.

Mixture versus substance

information

No information available.

Other information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause

adverse effects.

## **SECTION 12: Ecological information**

12.1. Toxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test results
AMOXICILLIN TRIHYDRAT	E (CAS 61336-70-7	)	
Aquatic			
<i>Acute</i> 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
POTASSIUM CLAVULANA	TE (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

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Components			Species	Test results
			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)			
Aquati	С			
Acute				
Algae		EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
		NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crusta	cea	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
Microto	x	EC50	Microtox	8700 mg/l, 15 minutes

<sup>\*</sup> 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)

9.92 Hours Measured POTASSIUM CLAVULANATE

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

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

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

Material name: AUGMENTIN TABLETS BID

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). Avoid discharge into water courses or onto the ground.

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. Do not

discharge into drains, water courses or onto the ground. 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.

**RID** 

Not regulated as dangerous goods.

**ADN** 

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

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.

MARPOL73/78 and the IBC Code

#### **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(10) 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

Material name: AUGMENTIN TABLETS BID SDS IRELAND

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

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

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Directive 94/33/EC on the protection of young people at work

Not listed.

The product is classified and labelled in accordance with EC directives or respective national laws. Other regulations

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

**National regulations** 15.2. Chemical safety Follow national regulation for work with chemical agents. No Chemical Safety Assessment has been carried out

assessment

## **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.

R17 Spontaneously flammable in air.

R42/43 May cause sensitization by inhalation and skin contact.

H228 Flammable solid.

H251 Self-heating: may catch fire. H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Product and Company Identification: Product and Company Identification **Revision information** 

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Regulatory Information: Risk Phrases - Class.

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.

Material name: AUGMENTIN TABLETS BID

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