

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

### 1.1. Product identifier

Trade name or designation of the mixture	ALBENDAZOLE TABLETS
Registration number	-
Synonyms	ALBEN TABLETS 400 MG * AZENTEL TABLETS 400 MG * ESKAZOLE TABLETS 400 MG * ESKAZOLE 400 MG CHEWABLE TABLETS * NEMATIL TABLETS 400 MG * ZENTEL TABLETS 400 MG * ALBENDAZOLE, FORMULATED PRODUCT
Issue date	18-June-2014
Version number	14
Revision date	18-June-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

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** Not applicable.

### 2.3. Other hazards

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards. Assume that this product is capable of sustaining combustion.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

## General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ALBENDAZOLE	38.94	54965-21-8 259-414-7	-	-	
<b>Classification:</b>	<b>DSD:</b>	Repr. Cat. 2;R61, Xn;R22, N;R50/53			
	<b>CLP:</b>	Acute Tox. 4;H302, Repr. 1B;H360, STOT RE 1;H372, Aquatic Acute 1;H400, Aquatic Chronic 1;H410			
MICROCRYSTALLINE CELLULOSE	20 - < 30	9004-34-6 232-674-9	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
Starch	10 - < 20	9005-25-8 232-679-6	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
Polyvinylpyrrolidone	1 - < 3	9003-39-8	-	-	
<b>Classification:</b>	<b>DSD:</b>	R52/53			
	<b>CLP:</b>	Aquatic Chronic 3;H412			
MAGNESIUM STEARATE	< 1	557-04-0 209-150-3	-	-	
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			

Other components below reportable levels 10 - < 20

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** 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. Call a physician if symptoms develop or persist.

**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.

**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** Direct contact with eyes may cause temporary irritation.

The possible symptoms of overexposure include: nausea; vomiting; abdominal pain; headache.

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

## 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 (CO<sub>2</sub>). Water.

**Unsuitable extinguishing media** None known.

<b>5.2. Special hazards arising from the substance or mixture</b>	During fire, gases hazardous to health may be formed.
<b>5.3. Advice for firefighters</b>	
<b>Special protective equipment for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Special fire fighting procedures</b>	Move containers from fire area if you can do so without risk.

## SECTION 6: Accidental release measures

<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
<b>For non-emergency personnel</b>	Keep unnecessary personnel away. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Following product recovery, flush area with water.
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### GSK

Components	Type	Value	Note
ALBENDAZOLE (CAS 54965-21-8)	8 HR TWA	100 mcg/m <sup>3</sup>	
	OHC	3	Reproductive hazard
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	

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

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m <sup>3</sup>	Inhalable dust.
	TWA	4 mg/m <sup>3</sup>	Respirable dust.
		10 mg/m <sup>3</sup>	Inhalable dust.
Starch (CAS 9005-25-8)	TWA	4 mg/m <sup>3</sup>	Respirable.
		10 mg/m <sup>3</sup>	Inhalable

**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.

### 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.

<b>Eye/face protection</b>	Not normally needed.
<b>Skin protection</b>	
<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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
<b>- Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	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.
<b>Environmental exposure controls</b>	
<b>Hazard guidance and control recommendations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour 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.

#### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.

<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.

#### Solubility(ies)

<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.

<b>Partition coefficient (n-octanol/water)</b>	Not available.
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<b>Auto-ignition temperature</b>	Not available.
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<b>Decomposition temperature</b>	Not available.
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<b>Viscosity</b>	Not available.
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<b>Explosive properties</b>	Not available.
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<b>Oxidizing properties</b>	Not available.
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**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** Health injuries are not known or expected under normal use.
- Inhalation** Health injuries are not known or expected under normal use.
- Skin contact** Health injuries are not known or expected under normal use.
- Eye contact** Direct contact with eyes may cause temporary irritation. Avoid contact with eyes.

**Symptoms** The possible symptoms of overexposure include: nausea, vomiting, abdominal pain, headache.

**11.1. Information on toxicological effects**

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

Components	Species	Test results
ALBENDAZOLE (CAS 54965-21-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1320 - 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
Polyvinylpyrrolidone (CAS 9003-39-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	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**

ALBENDAZOLE Acute dermal irritation  
Result: Non-irritant  
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**

ALBENDAZOLE Acute Ocular irritation  
Result: Non-Irritating  
Species: Rabbit

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

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

**Sensitisation**

ALBENDAZOLE Maximisation assay (Magnusson and Kligman)  
Result: negative  
Species: Guinea pig

**Germ cell mutagenicity** Health injuries are not known or expected under normal use.

**Mutagenicity**

ALBENDAZOLE Ames  
Result: negative  
Chromosomal Aberration Assay In Vitro  
Result: negative

**Mutagenicity**  
ALBENDAZOLE

In vivo Micronucleus  
Result: negative

**Carcinogenicity**  
ALBENDAZOLE

Health injuries are not known or expected under normal use.  
24 Month  
Result: negative  
Species: Mouse  
24 Month  
Result: negative  
Species: Rat

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Polyvinylpyrrolidone (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity**

Possible risk of affecting the quantity or the quality of breast milk in humans. May damage the unborn child.

**Reproductivity**  
ALBENDAZOLE

Embryo-foetal development  
Result: Effects seen at 10 mg/kg/day, NOAEL 5 mg/kg/day  
Species: Rabbit  
Embryo-foetal development  
Result: Effects seen at 10 mg/kg/day, NOAEL 5 mg/kg/day  
Species: Rat  
Fertility, Female  
Result: negative  
Species: Rat  
Fertility, Male  
Result: negative  
Species: Rat  
Milk effects  
Result: Excreted in milk, inconclusive effects.  
Species: Rat

**Specific target organ toxicity - single exposure**

None known.

**Specific target organ toxicity - repeated exposure**

ALBENDAZOLE

30 mg/kg/day Repeat dose non-clinical studies  
Result: Decrease in size, rat, mouse.  
Organ: Testes  
Repeat dose non-clinical studies; clinical observation  
Result: Human, rat, mouse  
Organ: Liver  
Repeat dose non-clinical studies; clinical observation  
Result: Human, rat, mouse  
Organ: bone marrow; blood

**Aspiration hazard**

Not an aspiration hazard.

**Mixture versus substance information**

No information available.

**Other information**

Caution - Pharmaceutical agent.

**SECTION 12: Ecological information**

**12.1. Toxicity**

No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
ALBENDAZOLE (CAS 54965-21-8)			
<i>Chronic</i>			
Fish	NOEC	Danio rerio	0.022 mg/l, 6 days
<b>Aquatic</b>			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 0.27 mg/l, 3 hours
Algae	EC50	Green algae (Selenastrum capricornutum)	> 50 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.024 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	0.017 mg/l, 48 hours Static test

Components		Species	Test results
Microtox	EC50	Microtox	0.36 mg/l, 15 minutes
<b>Terrestrial</b>			
<i>Acute</i>			
Earthworm	EC50	Redworm ( <i>Lumbricus rubellus</i> )	15 mg/kg, 60 days agricultural soil
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
Polyvinylpyrrolidone (CAS 9003-39-8)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Water flea ( <i>Daphnia magna</i> )	84 mg/l, 48 hours Static test
	NOEC	Water flea ( <i>Daphnia magna</i> )	32 mg/l, 48 hours Static test

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

## 12.2. Persistence and degradability

### Photolysis

#### Half-life (Photolysis-aqueous)

ALBENDAZOLE 0.1 - 1.65 Days Measured

#### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

#### UV/visible spectrum wavelength

ALBENDAZOLE 295 nm, pH 7

MAGNESIUM STEARATE 210 nm

### Biodegradability

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

MAGNESIUM STEARATE 77 %, 28 days BOD

Polyvinylpyrrolidone 0 %, 28 days Modified MITI test, 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** Not available.  
**n-octanol/water (log Kow)**

### Bioconcentration factor (BCF)

ALBENDAZOLE 1.16 Measured, *Lepomis macrochirus*, bluegill sunfish

MAGNESIUM STEARATE > 9999 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Soil/sediment sorption - log Koc

ALBENDAZOLE 3.89 - 4.44 Measured

MAGNESIUM STEARATE 5.86 Estimated

### Mobility in general

#### Distribution

##### Octanol/water distribution coefficient log DOW

ALBENDAZOLE 3.47

##### Octanol/water distribution coefficient pH

ALBENDAZOLE 7

**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.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

<b>General</b>	Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.
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### ADR

<b>14.1. UN number</b>	UN3077
<b>14.2. UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (ALBENDAZOLE TABLETS)
<b>14.3. Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	9
<b>Hazard No. (ADR)</b>	Not available.
<b>Tunnel code</b>	Not available.
<b>14.4. Packing group</b>	III
<b>14.5. Environmental hazards</b>	Yes
<b>14.6. Special precautions for user</b>	Not available.
<b>Additional information:</b>	
<b>Special Provisions</b>	8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33

### IATA

<b>14.1. UN number</b>	UN3077
<b>14.2. UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. (ALBENDAZOLE TABLETS)
<b>14.3. Transport hazard class(es)</b>	9
<b>Subsidiary class(es)</b>	-
<b>14.4. Packing group</b>	III
<b>14.5. Environmental hazards</b>	No.
<b>Labels required</b>	9
<b>ERG Code</b>	9L
<b>14.6. Special precautions for user</b>	Not available.
<b>Other information</b>	
<b>Cargo aircraft only</b>	Allowed.
<b>Additional Information:</b>	
<b>Passenger &amp; cargo</b>	Allowed.
<b>Packaging Instruction</b>	956
<b>Pkg Inst cargo only</b>	956
<b>Pkg Inst pasenger &amp; cargo</b>	Y956
<b>LQ</b>	
<b>SP See 44</b>	A97,A158,A179
<b>Max net qty pkg</b>	400 kg
<b>Max net qty pkg cargo only</b>	400 kg
<b>Max net qty pkg LQ</b>	30 kg G

### IMDG

<b>14.1. UN number</b>	UN3077
<b>14.2. UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ALBENDAZOLE TABLETS)



#### 14.3. Transport hazard class(es)

Class 9  
Subsidiary risk -  
Label(s) 9

14.4. Packing group III

#### 14.5. Environmental hazards

Marine pollutant Yes

EmS F-A, S-F

14.6. Special precautions for user Not available.

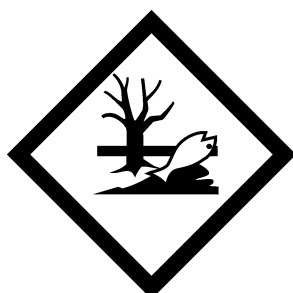
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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.

ADR; IATA; IMDG



Marine pollutant



## 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. Pregnant women should not work with the product, if there is the least risk of exposure.

#### **National regulations**

Follow national regulation for work with chemical agents. 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.

#### **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**

R22 Harmful if swallowed.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R61 May cause harm to the unborn child.  
H302 Harmful if swallowed.  
H360 May damage the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.  
H412 Harmful to aquatic life with long lasting effects.

#### **Revision information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
Toxicological Information: Irritation Corrosion  
Transport Information: Material Transportation Information  
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.