

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

### 1.1. Product identifier

**Trade name or designation of the mixture** ZOFRAN ODT ORALLY DISINTEGRATING TABLETS

**Registration number** -

**Synonyms** ZOFRAN ORALLY DISINTEGRATING TABLETS 4 MG \* ZOFRAN ORALLY DISINTEGRATING TABLETS 8 MG \* ZOFRAN MELT 4 MG \* ZOFRAN ZYDIS \* ZOFRAN ZYDIS WAFER \* IZOFRAN ZYDIS TABLETS \* ZOPHREN ZYDIS TABLETS \* ONDANSETRON BASE TABLETS \* ONDANSETRON BASE, FORMULATED PRODUCT

**Issue date** 11-August-2014

**Version number** 09

**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** None.

### 2.3. Other hazards

Caution - Potent 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
MANNITOL	20 - < 30	69-65-8 200-711-8	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
ONDANSETRON BASE	20 - < 30	99614-02-5	-	-	
<b>Classification:</b>	<b>DSD:</b> T;R25, Xi;R41, N;R50-53				
	<b>CLP:</b> Acute Tox. 3;H301, Eye Dam. 1;H318, Aquatic Acute 1;H400, Aquatic Chronic 1;H410				
ASPARTAME	3 - < 5	22839-47-0 245-261-3	-	-	
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
SODIUM METHYL PARABEN	< 1	5026-62-0 225-714-1	-	-	
<b>Classification:</b>	<b>DSD:</b> Xn;R22				
	<b>CLP:</b> Acute Tox. 4;H302				

Other components below reportable levels 40 - < 50

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

<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
<b>4.1. Description of first aid measures</b>	
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Get medical attention if symptoms occur. Take off contaminated clothing and wash before reuse.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.
<b>4.2. Most important symptoms and effects, both acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: headache; flushing; constipation; abnormal nervous system sensations; burning; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).
<b>4.3. Indication of any immediate medical attention and special treatment needed</b>	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

<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>5.1. Extinguishing media</b>	
<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>5.2. Special hazards arising from the substance or mixture</b>	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.

#### 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 personal protective equipment. 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 release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. 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. Collect spillage. Prevent product from entering drains. 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 prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

### 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).

### 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

ASPARTAME (CAS 22839-47-0)

8 HR TWA

5000 mcg/m3

OHC

1

MANNITOL (CAS 69-65-8)

OHC

1

ONDANSETRON BASE (CAS 99614-02-5)

8 HR TWA

30 mcg/m3

OHC

3

SODIUM METHYL PARABEN (CAS 5026-62-0)

8 HR TWA

5000 mcg/m3

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

<b>General information</b>	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.
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
<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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- <b>Other</b>	Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)
<b>Respiratory protection</b>	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). When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<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. 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.
<b>Environmental exposure controls</b>	
<b>Hazard guidance and control recommendations</b>	Contain spills and prevent releases and observe national regulations on emissions. 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.
<b>Upper/lower flammability or explosive limits</b>	
<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.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</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.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	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.

### Information on likely routes of exposure

**Ingestion** Harmful if swallowed.  
**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.  
**Eye contact** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Symptoms** The following adverse effects have been noted with therapeutic use of this material: headache; constipation; abnormal nervous system sensations; burning; flushing; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

### 11.1. Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

Components	Species	Test results
MANNITOL (CAS 69-65-8)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	13.5 g/kg
ONDANSETRON BASE (CAS 99614-02-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	100 - 150 mg/kg Results from ondansetron HCl.
<b>Chronic</b>		
<i>Oral</i>		
LD	Rat	> 36 mg/kg/day Results from ondansetron HCl.
LOEL	Dog	1 mg/kg/day, 52 weeks Results from ondansetron HCl.
NOAEL	Rat	1 mg/kg/day, 18 months Results from ondansetron HCl.
SODIUM METHYL PARABEN (CAS 5026-62-0)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	2 g/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

ONDANSETRON BASE 50 %, Results from ondansetron HCl. Formulated in soft paraffin.  
Result: Non-irritant  
Species: Guinea pig

**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

<b>Eye</b>	ONDANSETRON BASE	OECD 405, Results from ondansetron HCl. Result: Severe Irritant Species: Rabbit
<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Skin sensitisation</b>	This product is not expected to cause skin sensitisation.	
<b>Maximisation assay (Magnusson and Kligman)</b>	ZOFTRAN ODT ORALLY DISINTEGRATING TABLETS	Result:
<b>Sensitisation</b>	ONDANSETRON BASE	Split adjuvant assay, Results from ondansetron HCl. Result: negative Species: Guinea pig
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Mutagenicity</b>	ONDANSETRON BASE	Ames, Results from ondansetron HCl. Result: negative Chromosomal Aberration Assay In Vitro, Results from ondansetron HCl. Result: positive HPRT gene mutation in human lymphocytes, Results from ondansetron HCl. Result: negative Micronucleus test, Results from ondansetron HCl. Result: negative Species: Mouse V79 Cell Mutagenicity Assay, Results from ondansetron HCl. Result: negative
<b>Carcinogenicity</b>	ONDANSETRON BASE	Not classifiable as to carcinogenicity to humans. ICH S1B, Results from ondansetron HCl. Result: negative Species: Mouse ICH S1B, Results from ondansetron HCl. Result: negative Species: Rat
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction	
<b>Reproductivity</b>	ONDANSETRON BASE	Embryofetal Development, Results from ondansetron HCl. Result: No effect Species: Rabbit Embryofetal Development, Results from ondansetron HCl. Result: No effect Species: Rat Fertility, Results from ondansetron HCl. Result: No effect Species: Rat Pre- and Post-natal development, Results from ondansetron HCl. Result: negative Species: Rat
<b>Specific target organ toxicity - single exposure</b>	Central nervous system.	
<b>Specific target organ toxicity - repeated exposure</b>	None known.	
<b>Aspiration hazard</b>	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** Contains a substance which causes risk of hazardous effects to the environment. Very toxic to aquatic life with long lasting effects.

Components	Species	Test results
ONDANSETRON BASE (CAS 99614-02-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Activated Sludge Respiration	IC50 Residential sludge	> 802 mg/l, 3 hours OECD 209
Algae	EC50 Green algae (Selenastrum capricornutum)	0.7 mg/l, 72 hours Static ., OECD 201
	NOEC Green algae (Selenastrum capricornutum)	0.25 mg/l, 72 hours Measured
Crustacea	EC50 Water flea (Daphnia pulex)	22 mg/l, 48 hours Static ., TAD 4.08
	NOEC Water flea (Daphnia pulex)	13 mg/l, 48 hours Measured
Fish	EC50 Rainbow trout (Adult Oncorhyncus mykiss)	5.2 mg/l, 96 hours Static ., OECD 203
	NOEC Rainbow trout (Adult Oncorhyncus mykiss)	2.1 mg/l, 96 hours Measured
<i>Chronic</i>		
Crustacea	EC50 Water flea (Ceriodaphnia dubia)	1 mg/l, 8 days Static renewal ., EPA 1002
	LOEC Water flea (Ceriodaphnia dubia)	0.8 mg/l, 8 days
	NOEC Water flea (Ceriodaphnia dubia)	0.3 mg/l, 8 days

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

**12.2. Persistence and degradability** No data is available on the degradability of this product.

**Photolysis**

**UV/visible spectrum wavelength**

ONDANSETRON BASE 310 nm Measured, pH 5-9

**Hydrolysis**

**Half-life (Hydrolysis-basic)**

ASPARTAME < 1 Days Measured

**Half-life (Hydrolysis-neutral)**

ONDANSETRON BASE > 1 years

**Biodegradability**

**Percent degradation (Aerobic biodegradation-ready)**

ASPARTAME 60 - 90 %, 5 days  
ONDANSETRON BASE 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge

**Percent degradation (Aerobic biodegradation-soil)**

ONDANSETRON BASE 20.3 - 99.9 %, 64 days, Soil

**12.3. Bioaccumulative potential** No data available.

**Partition coefficient n-octanol/water (log Kow)**

MANNITOL -3.1

ONDANSETRON BASE 0.8

**Bioconcentration factor (BCF)**

ASPARTAME 1 Estimated

MANNITOL 1 Estimated

**12.4. Mobility in soil** No data available.

**Adsorption**

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

ONDANSETRON BASE 3.95 - 4.23 Calculated

**Soil/sediment sorption - log Koc**

ASPARTAME 1.78 Estimated

MANNITOL 0.7 Estimated

ONDANSETRON BASE 4.22 - 4.51 Measured

**Mobility in general**

**Volatility**

**Henry's law**

ASPARTAME < 0 atm m<sup>3</sup>/mol Estimated

MANNITOL 0 atm m<sup>3</sup>/mol

## Distribution

### Octanol/water distribution coefficient log DOW

ONDANSETRON BASE

0.23, pH 5

0.99, pH 7

1.26, pH 9

**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).

**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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Special precautions** Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

**General** 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.

### ADR

**14.1. UN number** UN3077

**14.2. UN proper shipping name** Environmentally hazardous substances, solid, n.o.s. (ONDANSETRON BASE TABLETS)

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

**Class** 9

**Subsidiary risk** -

**Label(s)** 9

**Hazard No. (ADR)** Not available.

**Tunnel code** Not available.

**14.4. Packing group** III

**14.5. Environmental hazards** Yes

**14.6. Special precautions for user** Not available.

### IATA

**14.1. UN number** UN3077

**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (ONDANSETRON BASE TABLETS)

**14.3. Transport hazard class(es)** 9

**Subsidiary class(es)** -

**14.4. Packing group** III

**Labels required** 9

**14.5. Environmental hazards** No.

**ERG Code** 9L

**14.6. Special precautions for user** Not available.

**Other information**

**Cargo aircraft only** Allowed.

**Additional Information:**

**Passenger & cargo** Allowed.



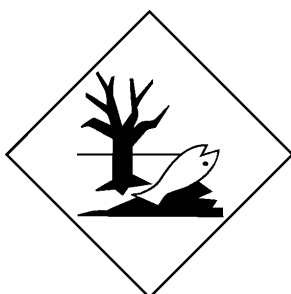
## IMDG

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ONDANSETRON BASE 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



General information

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.

## 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**

R22 Harmful if swallowed.  
R25 Toxic if swallowed.  
R41 Risk of serious damage to eyes.  
R50 Very toxic to aquatic organisms.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R53 May cause long term adverse effects in the aquatic environment.  
H301 Toxic if swallowed.  
H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

**Revision information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties:  
Ecological Information: Mobility  
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.