

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

1.1. Product identifier

Trade name or designation of the mixture	ADARTREL TABLETS
Registration number	-
Synonyms	ADARTREL 0.25 MG TABLETS * ADARTREL 0.5 MG TABLETS * ADARTREL 2 MG TABLETS * REPREVE TABLETS * ROPINIROLE HYDROCHLORIDE, FORMULATED PRODUCT
Issue date	28-October-2013
Version number	04
Revision date	28-October-2013

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.

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
---------------	---	------------------	------------------------	-----------	-------

MAGNESIUM STEARATE	<10.0	557-04-0 209-150-3	-	-	
--------------------	-------	-----------------------	---	---	--

Classification: **DSD:** Xi;R36/37/38
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335

ROPINIROLE HYDROCHLORIDE	<10.0	91374-20-8	-	-	
--------------------------	-------	------------	---	---	--

Classification: **DSD:** Xn;R22, R64, R52-53
CLP: Acute Tox. 4;H302, Lact.;H362, Aquatic Chronic 3;H412

Titanium dioxide	<2.0	13463-67-7 236-675-5	-	-	
------------------	------	-------------------------	---	---	--

Classification: **DSD:** -
CLP: -

Other components below reportable levels >88.0

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 IF exposed or concerned: Get medical advice/attention. 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.

4.1. Description of first aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

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

Ingestion Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed The following adverse effects have been noted with therapeutic use of this material: somnolence; dizziness; fainting; incoordination; nausea; abdominal pain; vomiting; constipation; swelling; vertigo; fatigue; hallucinations.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

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 (CO2).

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 In the event of fire, cool tanks with water spray.

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 MSDS.

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 Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

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
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1	
ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)	8 HR TWA	20 mcg/m3	
	OHC	3	Reproductive hazard
UK. EH40 Workplace Exposure Limits (WELs) Components	Type	Value	Form
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	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. 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	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. An eye wash station should be available.
Eye/face protection	Wear safety glasses with side shields (or goggles). (eg. EN 166)
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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. 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).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	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	Tablet.
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)	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 Not 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 Caution - Pharmaceutical agent. 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 Direct contact with eyes may cause temporary irritation.

Symptoms The following adverse effects have been noted with therapeutic use of this material: somnolence; dizziness; fainting; incoordination; nausea; abdominal pain; vomiting; constipation; swelling; anxiety; vertigo; fatigue; hallucinations.

11.1. Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)		
Acute		
<i>Oral</i>		
LD50	Mouse	600 mg/kg
	Rat	983 mg/kg
Chronic		
<i>Oral</i>		
LOEL	Human	0.08 mg/kg/day, Inhibition of prolactin secretion.
	Monkey	>= 5 mg/kg/day, 1 years, Inhibition of prolactin secretion.
NOEL	Rat	5 mg/kg/day, 1 years, Inhibition of prolactin secretion.
Titanium dioxide (CAS 13463-67-7)		
Acute		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
Chronic		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years, TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years, Highest dose 5 mg/m3, 24 months
Subacute		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks, Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks, No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day, Dietary study, highest dose tested.

Components	Species	Test results
Subchronic <i>Inhalation</i> LOEC	Rat	3.2 - 20 mg/m ³ , 8 min, Accumulation of TiO ₂ in macrophages and evidence of pulmonary inflammation.
* 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		
TITANIUM DIOXIDE		Acute dermal irritation; OECD 404, Literature data Result: Non-irritant Species: Rabbit
ROPINIROLE HYDROCHLORIDE		Acute dermal irritation; OECD 404, P.I.I. = 0.3 Result: Slightly irritating Species: Rabbit
TITANIUM DIOXIDE		Literature data Result: Non-irritant Species: Guinea pig Literature data Result: Non-irritant Species: Human
Irritation Corrosion - Skin: P.I.I. value		
MAGNESIUM STEARATE		0
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Eye		
ROPINIROLE HYDROCHLORIDE		OECD 405, Kay and Calandra grade 5; Group mean score 5 (unwashed) Result: Irritant Species: Rabbit
TITANIUM DIOXIDE		OECD 405, Literature data Result: Mild irritant Species: Rabbit
ROPINIROLE HYDROCHLORIDE		Single rabbit (Washed): Group mean score; 11. Result: Irritant Species: Rabbit
Respiratory sensitisation	Due to partial or complete lack of data the classification is not possible.	
Skin sensitisation	This product is not expected to cause skin sensitisation.	
Sensitisation		
TITANIUM DIOXIDE		5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: negative Species: Guinea pig Test Duration: 48 hour exposure
ROPINIROLE HYDROCHLORIDE		OECD 406, 0 % Response rate. Result: negative Species: Rabbit
TITANIUM DIOXIDE		Patch test, Literature data Result: negative Species: Human
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Germ cell mutagenicity		
Mutagenicity		
ROPINIROLE HYDROCHLORIDE		Ames, GLP Result: negative
TITANIUM DIOXIDE		Ames, Literature data Result: negative
ROPINIROLE HYDROCHLORIDE		Chromosomal Aberration Assay In Vitro, GLP Result: negative GreenScreen Result: negative L5178Y mouse lymphoma thymidine kinase locus assay, GLP Result: negative
TITANIUM DIOXIDE		Micronucleus Assay in vitro, CHO cells, Literature data Result: negative

Mutagenicity

TITANIUM DIOXIDE

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: positive

ROPINIROLE HYDROCHLORIDE

Micronucleus Assay, GLP

Result: negative

Species: Mouse

TITANIUM DIOXIDE

Syrian Hamster Embryo (SHE) cell transformation assay

Result: negative

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell

lymphoblastoid, Literature data

Result: positive

Carcinogenicity

Contains a material (titanium dioxide) classified as a carcinogen by external agencies. Carcinogenic activity was seen in inhalation studies using laboratory animals. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE

0.5 mg/m³, Literature data

Result: negative

Species: Rat

Test Duration: 24 months

0.72 - 14.8 mg/m³, Literature data

Result: negative

Species: Mouse

ROPINIROLE HYDROCHLORIDE

1.5 mg/kg/day

Result: NOAEL

Species: Rat

Test Duration: 2 years

TITANIUM DIOXIDE

10 - 250 mg/m³, Dietary study - Literature data.

Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.

Species: Rat

Test Duration: 24 months

ROPINIROLE HYDROCHLORIDE

15 - 50 mg/kg/day, Species-specific

Result: positive

Species: Rat

Organ: testes - leydig cell

Test Duration: 2 years

TITANIUM DIOXIDE

25000 - 50000 ppm, Dietary study

Result: negative

Species: Mouse

25000 - 50000 ppm, Dietary study - Literature data.

Result: negative

Species: Rat

ROPINIROLE HYDROCHLORIDE

5 - 50 mg/kg/day

Species: Mouse

Test Duration: 18 months

TITANIUM DIOXIDE

7.2 - 14.8 mg/m³, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

Titanium dioxide (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity**Reproductivity**

ROPINIROLE HYDROCHLORIDE

120 mg/kg/day Embryo-foetal development

Result: foetal digit malformations.

Species: Rat

<= 20 mg/kg/day Embryo-foetal development

Result: Foetal NOAEL

Species: Rabbit

>= 60 mg/kg/day Embryo-foetal development,

Species-specific

Result: foetal toxicity- decreased foetal weight and increased post-implantation loss.

Species: Rat

Fertility

Result: negative

Species: Rat

Reproductivity
ROPINIROLE HYDROCHLORIDE

Pre- and Post-natal development
Result: negative
Species: Rat

Specific target organ toxicity - single exposure	Central nervous system.
Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
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.

Components			Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)				
Aquatic				
Acute				
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours	
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes	
ROPINIROLE HYDROCHLORIDE (CAS 91374-20-8)				
Aquatic				
Acute				
Activated Sludge Respiration	IC50	Residential sludge	500 mg/l, 3 hours, OECD 209	
Algae	EC50	Green algae (Selenastrum capricornutum)	29.3 mg/l, 72 hours, OECD 201	
	NOEC	Green algae (Selenastrum capricornutum)	8.8 mg/l, 72 hours	
Crustacea	EC50	Water flea (Daphnia magna)	41.1 mg/l, 48 hours, Static test, OECD 202	
	NOEC	Water flea (Daphnia magna)	4.4 mg/l, 48 hours, Static test	
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	11 mg/l, 96 hours, Static test, OECD 203	
	NOEC	Bluegill sunfish (Adult Lepomis macrochirus)	3.7 mg/l, 96 hours, Static test	
Microtox	EC50	Microtox	362 mg/l, 15 minutes	
Chronic				
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	7.7 mg/l, 8 days, 7 day static renewal, EPA 1002	
	LOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 8 days	
	NOEC	Water flea (Ceriodaphnia dubia)	3.2 mg/l, 8 days	
Titanium dioxide (CAS 13463-67-7)				
Aquatic				
Acute				
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test	

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

12.2. Persistence and degradability

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

ROPINIROLE HYDROCHLORIDE

433 - 13700 Days Measured

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ROPINIROLE HYDROCHLORIDE 163 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

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)

ROPINIROLE HYDROCHLORIDE 2.84 (Measured).

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ROPINIROLE HYDROCHLORIDE 1.92, pH 7

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

ROPINIROLE HYDROCHLORIDE 0.74 Calculated, pH 7

Mobility in general

Distribution

Octanol/water distribution coefficient log DOW

ROPINIROLE HYDROCHLORIDE 2.33, pH 8.4

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. 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

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

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.

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.

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.
R36/37/38 Irritating to eyes, respiratory system and skin.
R52 Harmful to aquatic organisms.
R53 May cause long term adverse effects in the aquatic environment.
R64 May cause harm to breastfed babies.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H362 May cause harm to breast-fed children.
H412 Harmful to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients

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.