

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

1.1. Product identifier

Trade name or designation of the mixture ZYBAN SR TABLETS

Registration number -

Synonyms ZYBAN SUSTAINED -RELEASE TABLETS 150MG * ZYBAN TABLETS 150MG 60'S REFILL * ZYBAN TABLETS 150MG STARTER KIT * ZYBAN COMPRESSE * ZYBAN COMPRIMES * ZYBAN COMPRIMIDOS * ZYBAN COMPRIMIDOS DE LIBERTACAO PROLONGADA * ZYBAN DEPOTTABLETTER * ZYBAN ILGSTOSAS DARBIBAS TABLETES * ZYBAN POTAHOVANE TABLETY * ZYBAN RETARDTABLETTE * ZYBAN SR TABLETTE * ZYBAN TABLETAS * ZYBAN TABLETID * ZYBAN TABLETKI POWLEKANE * ZYBAN TABLETTE * ZYBAN TABLETY * NDC NO 0173-0556-01 * NDC NO 0173-0556-02 * BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT

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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

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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MICROCRYSTALLINE CELLULOSE	40 - < 50	9004-34-6 232-674-9	-	-	
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Classification: **DSD:** -
 CLP: -

BUPROPION HYDROCHLORIDE	33.8	31677-93-7 250-759-9	-	-	
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Classification: **DSD:** Xn;R22, Xi;R36, N;R50-53
 CLP: Acute Tox. 4;H302, Eye Irrit. 2;H319, Aquatic Acute 1;H400, Aquatic Chronic 1;H410

HYDROXYPROPYL METHYL CELLULOSE	5 - < 10	9004-65-3 -	-	-	
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Classification: **DSD:** -
 CLP: -

MAGNESIUM STEARATE	< 1	557-04-0 209-150-3	-	-	
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Classification: **DSD:** Xi;R36/37/38
 CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335

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. 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 if symptoms occur.
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	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	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.

4.2. Most important symptoms and effects, both acute and delayed Irritation of eyes and mucous membranes. The following adverse effects have been noted with therapeutic use of this material: insomnia; agitation; anxiety; headache; tremor; visual disturbances; dry mouth; nausea; vomiting; rash; depression; constipation; convulsions.

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.

5.1. Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
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 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

Do not taste or swallow. Avoid contact with eyes. 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. 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 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

BUPROPION
HYDROCHLORIDE (CAS
31677-93-7)

8 HR TWA

1000 mcg/m3

HYDROXYPROPYL
METHYL CELLULOSE
(CAS 9004-65-3)

OHC

2

OHC

1

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/m3

Inhalable dust.

TWA

4 mg/m3

Respirable dust.

10 mg/m3

Inhalable dust.

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	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. 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. Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Eye wash fountain is recommended.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended. (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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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. When using, do not eat, drink or smoke.
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	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.
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Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Inhalation	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.
Skin contact	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Symptoms	The following adverse effects have been noted with therapeutic use of this material: insomnia; agitation; anxiety; headache; tremor; visual disturbances; dry mouth; nausea; vomiting; rash; depression; constipation; convulsions.
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11.1. Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.
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Components	Species	Test results
BUPROPION HYDROCHLORIDE (CAS 31677-93-7)		
Acute		
<i>Oral</i>		
LD50	Mouse	544 - 636 mg/kg
	Rat	482 - 607 mg/kg
Chronic		
<i>Oral</i>		
LOEL	Dog	40 mg/kg/day, 52 weeks
	Rat	100 mg/kg/day, 104 weeks
		25 mg/kg/day, 55 weeks
NOAEL	Dog	40 mg/kg/day, 52 weeks
	Rat	100, 104 weeks
		100 mg/kg/day, 55 weeks
Subacute		
<i>Oral</i>		
NOAEL	Dog	150 mg/kg/day, 47 Day
Subchronic		
<i>Oral</i>		
NOAEL	Rat	450 mg/kg/day, 90 Day
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

Components	Species	Test results
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 2000 mg/kg
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
* Estimates for product may be based on additional component data not shown.		
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Corrosivity		
BUPROPION HYDROCHLORIDE	OECD 404	
	Result: Non-irritant	
	Species: Rabbit	
Irritation Corrosion - Skin: P.I.I. value		
MAGNESIUM STEARATE	0	
BUPROPION HYDROCHLORIDE	0.5	
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Eye		
BUPROPION HYDROCHLORIDE	Result: Irritant	
	Species: Rabbit	
Respiratory sensitisation	Not available.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Maximisation assay (Magnusson and Kligman)		
HYDROXYPROPYL METHYL CELLULOSE	Result: negative	
	Species: Guinea pig	
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		
BUPROPION HYDROCHLORIDE	Ames	
	Result: negative	
	L5178Y mouse lymphoma thymidine kinase locus assay	
	Result: negative	
	in vivo cytogenetics assay	
	Result: positive	
	Species: Rat	
Carcinogenicity	Health injuries are not known or expected under normal use.	
BUPROPION HYDROCHLORIDE	Result: negative	
	Species: Mouse	
	Result: negative	
	Species: Rat	
Reproductive toxicity	This product is not expected to cause reproductive or developmental effects.	
Reproductive toxicity		
Reproductivity		
BUPROPION HYDROCHLORIDE	Embryo-foetal development- Oral	
	Result: Maternal toxicity; adverse foetal effects	
	Species: Rabbit	
	Embryo-foetal development- Oral	
	Result: maternal toxicity	
	Species: Rat	
	Fertility	
	Result: No effect	
Specific target organ toxicity - single exposure	None known.	
Specific target organ toxicity - repeated exposure	None known.	
Aspiration hazard	Not available.	

Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity	No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.
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Components		Species	Test results
BUPROPION HYDROCHLORIDE (CAS 31677-93-7)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, Nominal
	NOEC	Residential sludge	100 mg/l, 3 hours, Nominal
Algae	EC50	Green algae (Scenedesmus subspicatus)	0.95 mg/l, 72 hours
	NOEC	Green algae (Scenedesmus subspicatus)	0.62 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	3.8 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	1 mg/l, 48 hours, Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	33 mg/l, 96 hours, Static renewal test, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	16 mg/l, 96 hours, Static renewal test
Microtox	MIC	Aspergillus flavus	1000 mg/l
		Azotobacter chroococcum	> 1000 mg/l
		Chaetomium globosum	1000 mg/l
		Nostoc sp.	1000 mg/l
		Pseudomonas fluorescens	> 1000 mg/l
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	> 0.4 mg/l, 7 days, 7 day static renewal, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	0.4 mg/l, 7 days
Fish	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.1 mg/l, 32 days, Static renewal test
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/l, 96 hours
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

* 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)

BUPROPION HYDROCHLORIDE 54 Hours

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

BUPROPION HYDROCHLORIDE 251 nm

Photolysis

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

BUPROPION HYDROCHLORIDE 16.7 Days

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

BUPROPION HYDROCHLORIDE 96 %, 14 days Modified Zahn-Wellens, Activated sludge

MAGNESIUM STEARATE 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

BUPROPION HYDROCHLORIDE 1.21 %, 14 days

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)

BUPROPION HYDROCHLORIDE 1.54

HYDROXYPROPYL METHYL CELLULOSE -5

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated

MAGNESIUM STEARATE > 9999 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

BUPROPION HYDROCHLORIDE 1.79 Measured, pH 7

Soil/sediment sorption - log Koc

BUPROPION HYDROCHLORIDE 2.93 Calculated

MAGNESIUM STEARATE 5.86 Estimated

Mobility in general

Volatility

Henry's law

BUPROPION HYDROCHLORIDE 0 atm m³/mol, 25 C Estimated

HYDROXYPROPYL METHYL CELLULOSE 0 atm m³/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

BUPROPION HYDROCHLORIDE -0.6, pH 1.2

-0.91, pH 6

1.54, pH 7.4

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. 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

ADR

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	Yes
Tunnel code	Not available.
Labels required	9
Additional information:	
Special Provisions	8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33

IATA

14.1. UN number	UN3077
14.2. UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	Not available.
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	956
Pkg Inst cargo only	956
Pkg Inst pasenger & cargo	Y956
LQ	
SP See 44	A97,A158,A179
Max net qty pkg	400 kg
Max net qty pkg cargo only	400 kg
Max net qty pkg LQ	30 kg G

IMDG

14.1. UN number	UN3077
14.2. UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT)
14.3. Transport hazard class(es)	9
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	
Marine pollutant	Yes
Labels required	Not available.
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





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

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

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

R22 Harmful if swallowed.

R36 Irritating to eyes.

R36/37/38 Irritating to eyes, respiratory system and skin.

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.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Revision information

Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:

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.