SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	LAMICTAL XR
Registration number	-
Synonyms	LAMICTAL XR TABLETS 25 MG * LAMICTAL XR TABLETS 50 MG * LAMICTAL XR TABLETS 100 MG * LAMICTAL XR TABLETS 200 MG * LAMICTAL XR TABLETS 250 MG * LAMICTAL XR TABLETS 300 MG * LAMOTRIGINE, FORMULATED PRODUCT
Issue date	19-December-2014
Version number	08
Revision date	19-December-2014

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
HYDROXYPROPYL METHYL CELLULOSE	18 - < 40	9004-65-3 -	-	-	
Classification: **DSD:** -					
CLP: -					
LAMOTRIGINE	7 - < 50	84057-84-1 281-901-8	-	-	
Classification: **DSD:** T;R25, R52					
CLP: Acute Tox. 3;H301					
methacrylic acid	3 - < 5	79-41-4 201-204-4	-	607-088-00-5	
Classification: **DSD:** C;R35, Xn;R21/22					D
CLP: Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Corr. 1A;H314, STOT SE 3;H335					
TRIETHYL CITRATE	0.3 - < 0.5	77-93-0 201-070-7	-	-	
Classification: **DSD:** -					
CLP: -					
MAGNESIUM STEARATE	0.25 - < 0.5	557-04-0 209-150-3	-	-	
Classification: **DSD:** -					
CLP: -					
Silicon dioxide	< 0.5	7631-86-9 231-545-4	-	-	
Classification: **DSD:** -					
CLP: -					
GLYCERYL MONOSTEARATE	0.05 - < 0.25	31566-31-1 250-705-4	-	-	
Classification: **DSD:** -					
CLP: -					
Other components below reportable levels	37.64				

List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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 Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
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. Do not induce vomiting without advice from poison control center.
4.2. Most important symptoms and effects, both acute and delayed	The following adverse effects have been noted with therapeutic use of this material: changes in behaviour; irritability; headache; somnolence; insomnia; dizziness; tremor; incoordination; blurred vision; nausea; vomiting; diarrhoea; back pain; fatigue; symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).
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. 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	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 upwind. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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 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. Prevent entry into waterways, sewer, basements or confined areas. 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 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid breaking or crushing tablets. Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
7.2. Conditions for safe storage, including any incompatibilities	Store locked up. 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	Note
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
LAMOTRIGINE (CAS 84057-84-1)	8 HR TWA	200 mcg/m3	

GSK

Components	Type	Value	Note
	OHC	2	
TRIETHYL CITRATE (CAS 77-93-0)	OHC	2	PROVISIONAL

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
methacrylic acid (CAS 79-41-4)	STEL	143 mg/m3	
		40 ppm	
	TWA	72 mg/m3	
		20 ppm	
Silicon dioxide (CAS 7631-86-9)	TWA	6 mg/m3	Inhalable dust.
		2.4 mg/m3	Respirable dust.

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no-effect level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate. 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.

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166).

Skin protection

- Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust).

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Film-coated 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)	
Solubility (water)	Not available.
Solubility (other)	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.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. However, ingestion is not likely to be a primary route of occupational exposure. May be harmful if swallowed.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: changes in behaviour; irritability; headache; somnolence; insomnia; dizziness; tremor; incoordination; blurred vision; nausea; vomiting; diarrhoea; back pain; fatigue; 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**
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

Components	Species	Test results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
LAMOTRIGINE (CAS 84057-84-1)		
Acute		
Oral		
LD50	Mouse	269 mg/kg
	Rat	185 mg/kg
Chronic		
Oral		
LOEL	Monkey	5 mg/kg/day, 1 years
Subacute		
Oral		
LD	Rat	50 mg/kg/day, 30 Day
LOEL	Monkey	10 mg/kg/day, 30 Day Behavioural effects.
	Rat	10 mg/kg/day, 30 Day Rat-specific kidney effects.
Subchronic		
Oral		
LD	Monkey	20 mg/kg/day, 6 months Convulsive effects, Death.
	Rat	25 mg/kg/day, 6 months
LOEL	Rat	1 mg/kg/day, 6 months Rat-specific kidney effects.
NOAEL	Monkey	5 mg/kg/day, 90 Day
NOEL	Monkey	10 mg/kg/day, 6 months
TD	Monkey	10 mg/kg/day, 90 Day Behavioural effects.
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
TRIETHYL CITRATE (CAS 77-93-0)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Oral		
LD50	Rat	5.9 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

LAMOTRIGINE	OECD 404 Result: Non-irritant Species: Rabbit

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

LAMOTRIGINE	0
MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

LAMOTRIGINE	OECD 405 Result: Mild irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

LAMOTRIGINE	3
MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory sensitisation Not established.

Skin sensitisation Not established.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: negative Species: Guinea pig

Sensitisation

LAMOTRIGINE	SAR / QSAR, DEREK, Lhasa, UK Result: negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

LAMOTRIGINE	<= 200 mg/kg/day Micronucleus Test Result: negative Species: Rat Ames Result: negative BlueScreen mammalian cell mutation assay Result: negative GreenScreen mammalian cell mutation assay Result: negative In vitro cytogenetic Assay Result: negative L5178Y mouse lymphoma thymidine kinase locus assay Result: negative

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

LAMOTRIGINE	10 - 15 mg/kg/day Result: negative Species: Rat 10 - 30 mg/kg/day Result: negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

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

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

LAMOTRIGINE	12.5 - 25 mg/kg/day Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat 20 mg/kg/day Fertility Result: Parental toxicity, no adverse effects on fertility. Species: Rat 5 - 20 mg/kg/day Pre- and Post-natal development Result: Maternal toxicity; adverse foetal effects Species: Rat 5 - 30 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rabbit 6.25 mg/kg/day Embryofetal Development Result: Maternal toxicity; Foetal NOAEL Species: Rat Breast feeding, Possible transient drug-induced effects in breast-fed infants. Species: Human

Specific target organ toxicity - single exposure Not assigned.

Specific target organ toxicity - repeated exposure Not assigned.

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance information No information available.

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

SECTION 12: Ecological information

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

Components		Species	Test results
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/l, 96 hours
LAMOTRIGINE (CAS 84057-84-1)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 hours
Algae	EC50	Green algae (Selenastrum capricornutum)	39.7 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	56 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	30 mg/l, 48 hours
Fish	LC50	Rainbow trout (Adult Oncorhyncus mykiss)	85 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	60 mg/l, 96 hours
Microtox	MIC	Aspergillus flavus	> 185 mg/l
		Azotobacter chroococcum	> 185 mg/l
		Nostoc sp.	> 185 mg/l
Other	MIC	Pseudomonas acidovorans	> 185 mg/l
Chronic			
Algae	NOEC	Green algae (Selenastrum capricornutum)	7.5 mg/l, 72 hours
Crustacea	LOEC	Ceriodaphnia dubia	> 10 mg/l, 7 days
	NOEC	Ceriodaphnia dubia	10 mg/l, 7 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
methacrylic acid (CAS 79-41-4)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	70000 mg/l, 30 minutes
Algae	EC50	Green algae (Selenastrum capricornutum)	0.59 mg/l, 96 hours
	NOEC	Green algae (Selenastrum capricornutum)	0.38 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 130 mg/l, 48 hours Flow-through test
	NOEC	Daphnia	130 mg/l
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	85 mg/l, 96 hours Flow-through test
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	12 mg/l, 96 hours Flow-through test
Chronic			
Crustacea	EC50	Water flea (Daphnia magna)	70 mg/l, 21 days
	LOEC	Water flea (Daphnia magna)	110 mg/l, 21 days
	NOEC	Water flea (Daphnia magna)	53 mg/l, 21 days

Components		Species	Test results
Silicon dioxide (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

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

12.2. Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated
methacrylic acid	6.12 Hours Estimated

UV/visible spectrum wavelength

LAMOTRIGINE	300 nm Measured, pH >6
MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

LAMOTRIGINE	> 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

LAMOTRIGINE	0 %, 14 days Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
methacrylic acid	> 95 %, 28 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

LAMOTRIGINE	0 %, 28 days Modified Sturm test.
MAGNESIUM STEARATE	95 %, 22 days Sturm test
methacrylic acid	86 %, 28 days Closed Bottle test, Activated sludge

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE	-5
LAMOTRIGINE	1.4 (Measured).
methacrylic acid	0.93

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
MAGNESIUM STEARATE	> 9999 Estimated
methacrylic acid	3 Estimated

12.4. Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

LAMOTRIGINE	1.15 Measured, pH 7

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
methacrylic acid	1.18 Estimated

Mobility in general

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated
LAMOTRIGINE	0 atm m^3/mol, 25 C Estimated
methacrylic acid	0.000001 atm m3/mol, 25 °C Estimated

Distribution

Octanol/water distribution coefficient log DOW

LAMOTRIGINE	1.4, pH 7 1.4, 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

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(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

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

methacrylic acid (CAS 79-41-4)

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

methacrylic acid (CAS 79-41-4)

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	R21/22 Harmful in contact with skin and if swallowed. R25 Toxic if swallowed. R35 Causes severe burns. R36/37/38 Irritating to eyes, respiratory system and skin. R52 Harmful to aquatic organisms. H301 Toxic if swallowed. H302 Harmful if swallowed. H312 Harmful in contact with skin. H314 Causes severe skin burns and eye damage. H335 May cause respiratory irritation.
Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Ecological Information: Ecotoxicity 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.