



SAFETY DATA SHEET

1. Identification

Product identifier	LAMICTAL XR
Other means of identification	
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
Recommended use	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.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M * GONIOSOL * ISOPRO ALKALINE * METHOCEL E,F,K * METHOCEL HG * METHYL CELLULOSE PROPYLENE GLYCOL ETHER * HYPROMELLOSE * CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER * METHYLHYDROXYPROPYLCELLULOSE * PHARMACOAT 603	9004-65-3	18 - < 40
LAMOTRIGINE	430C78 * G1267119X * 3,5-DIAMINO-6-(2,3-DICHLOROPHENYL) 1,2,4-TRIAZINE	84057-84-1	7 - < 50
METHACRYLIC ACID	ALPHA-METHYLACRYLIC ACID * 2-METHYLENE PROPENOIC ACID * 2-METHYLPROPENOIC ACID * UN 2531 * OHS14120 * RTECS OZ2975000	79-41-4	3 - < 5

Chemical name	Common name and synonyms	CAS number	%
TRIETHYL CITRATE	2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID, TRIETHYL ESTER * CITRIC ACID, TRIETHYL ESTER * ETHYL CITRATE * 1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRIETHYL ESTER * C12H20O7 * OHS84216 * RTECS GE8050000 * TRIETHYLCITRAT	77-93-0	0.3 - < 0.5
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.25 - < 0.5
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	< 0.5
GLYCERYL MONOSTEARATE	OCTADECANOIC ACID, MONOESTER WITH 1,2,3-PROPANETRIOL * GLYCEROL MONOSTEARATE * STEARIC ACID MONOGLYCERIDE * STEARIC MONOGLYCERIDE * CEFATIN	31566-31-1	0.05 - < 0.25
Other components below reportable levels			37.64

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, 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).
Indication of 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 center.
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.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	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.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. 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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials 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. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

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. Avoid release to the environment. Observe good industrial hygiene practices.

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).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value	Note
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
LAMOTRIGINE (CAS 84057-84-1)	8 HR TWA	200 mcg/m3	
TRIETHYL CITRATE (CAS 77-93-0)	OHC	2	
	OHC	2	PROVISIONAL

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components

Components	Type	Value
GLYCERYL MONOSTEARATE (CAS 31566-31-1)	TWA	10 mg/m3
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
METHACRYLIC ACID (CAS 79-41-4)	TWA	20 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Components	Type	Value
METHACRYLIC ACID (CAS 79-41-4)	TWA	70 mg/m3
		20 ppm
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3

Biological limit values

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

Exposure guidelines

US - California OELs: Skin designation

METHACRYLIC ACID (CAS 79-41-4)

Can be absorbed through the skin.

US - Tennessee OELs: Skin designation

METHACRYLIC ACID (CAS 79-41-4)

Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

METHACRYLIC ACID (CAS 79-41-4)

Can be absorbed through the skin.

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**Eye/face protection**

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection**Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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.

9. Physical and chemical properties**Appearance****Physical state**

Solid.

Form

Film-coated tablet.

Color

Not available.

Odor

Not available.

Odor 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.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)**Solubility (water)**

Not available.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics 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).

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
LAMOTRIGINE (CAS 84057-84-1)		
Acute		
<i>Oral</i>		
LD50	Mouse	269 mg/kg
	Rat	185 mg/kg
Chronic		
<i>Oral</i>		
LOEL	Monkey	5 mg/kg/day, 1 years
Subacute		
<i>Oral</i>		
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		
<i>Oral</i>		
LD	Monkey	20 mg/kg/day, 6 months Convulsive effects, Death.
	Rat	25 mg/kg/day, 6 months

Components	Species	Test Results
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		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
TRIETHYL CITRATE (CAS 77-93-0)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 5000 mg/kg
<i>Oral</i>		
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 or skin sensitization

Respiratory sensitization Not established.

Skin sensitization Not established.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE

Result: Negative

Species: Guinea pig

Sensitization

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

Mutagenicity
LAMOTRIGINE

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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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.

Chronic effects

None known.

Further information

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

12. Ecological information

Ecotoxicity

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

Components		Species	Test Results
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 Oncorhynchus mykiss)	85 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhynchus 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
<i>Chronic</i>			
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			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
METHACRYLIC ACID (CAS 79-41-4)			
Aquatic			
<i>Acute</i>			
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 Oncorhynchus mykiss)	85 mg/L, 96 hours Flow-through test
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	12 mg/L, 96 hours Flow-through test
<i>Chronic</i>			
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
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
<i>Acute</i>			
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

Components	Species	Test Results
Microtox	EC50	Microtox
		8700 mg/l, 15 minutes

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

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-soil)

MAGNESIUM STEARATE 50 %, 13 days

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

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 m³/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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

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

Waste from residues / unused products

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.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 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.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

METHACRYLIC ACID (CAS 79-41-4)

SILICON DIOXIDE (CAS 7631-86-9)

US. New Jersey Worker and Community Right-to-Know Act

METHACRYLIC ACID (CAS 79-41-4)

SILICON DIOXIDE (CAS 7631-86-9)

US. Pennsylvania Worker and Community Right-to-Know Law

METHACRYLIC ACID (CAS 79-41-4)

SILICON DIOXIDE (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	12-19-2014
Revision date	12-19-2014
Version #	08
Further information	HMIS® is a registered trade and service mark of the NPCA. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
References	GSK Hazard Determination
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.
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