SAFETY DATA SHEET

1. Identification

Product identifier **NICORETTE & NICOBATE MINI LOZENGES, 2MG & 4MG SWEETMINT**

Other means of identification

Synonyms MFC51283A, 2 MG SWEETMINT * MFC51283B, 4 MG SWEETMINT * NICOTINE POLACRILEX, 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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)
24/7; multi-language response

Contract Number: CCN9484

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

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	%
N&A FL SWEET MINT TYPE		Unassigned	5.2

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	3.7
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT BISODIUM CARBONATE DISODIUM CARBONATE SODA ASH	497-19-8	3.07
XANTHAN GUM	ACTIGUM CX 9 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 GALAXY XB KELFLO KELTROL (GUM) KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 XANFLOOD XANTHOMONAS GUM	11138-66-2	2.22
NICOTINE	1-METHYL-2-(3-PYRIDYL) PYRROLIDONE NICOCIDE NICO-FUME L-3-(1-METHYL 1-2-PYRROLIDYL) PYRIDINE BLACK LEAF BETA-PYRIDYL-ALPHA-N-METHYLPYRROLIDINE NICOTINE ALKALOID O-3825 RCRA P075 OHS16430 RTECS QS5250000 3-(N-METHYL-2-PYRROLIDINYL) PYRIDINE 3-(N-METYYLI-2-PYRROLIDINYYLI)PYRIDIINI	54-11-5	1 - < 3
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	1.74
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM ACESULFAME POTASSIUM	55589-62-3	1
SUCRALOSE	MICRONIZED SUCRALOSE POWDERED SUCRALOSE NEAT SUCRALOSE	56038-13-2	1

Chemical name	Common name and synonyms	CAS number	%
SODIUM BICARBONATE	BAKING SODA BICARBONATE OF SODA CARBONIC ACID MONOSODIUM SALT CARBONIC ACID SODIUM SALT (1:1) MONOSODIUM CARBONATE MONOSODIUM HYDROGEN CARBONATE RTECS VZ0950000 SODIUM ACID CARBONATE SODIUM HYDROGEN CARBONATE	144-55-8	0.38
Other components below reportable levels			80 - < 90

*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 possible consequences of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; headache; depression; respiratory depression.

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.

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. 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.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities 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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Note
ACESULFAME K (CAS 55589-62-3)	OHC	1	
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)	OHC	1	
NICOTINE (CAS 54-11-5)	15 MIN STEL	200 mcg/m3	
	8 HR TWA	70 mcg/m3	
	OHC	3	SKIN
		3	REPRODUCTIVE HAZARD
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SODIUM CARBONATE (CAS 497-19-8)	8 HR TWA	5000 mcg/m3	
	OHC	1	
SUCRALOSE (CAS 56038-13-2)	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
NICOTINE (CAS 54-11-5)	PEL	0.5 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3

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

Exposure guidelines

US - California OELs: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

NICOTINE (CAS 54-11-5) Skin designation applies.

US - Tennessee OELs: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

NICOTINE (CAS 54-11-5) Can be absorbed through the skin.

Appropriate engineering controls General ventilation normally adequate.

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	Lozenge.
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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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. May be irritating to eyes.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	The possible symptoms of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; headache; depression; respiratory depression; dizziness.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use. May be harmful if swallowed.

Components	Species	Test Results
ACESULFAME K (CAS 55589-62-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
NICOTINE (CAS 54-11-5)		
Acute		
Dermal		
LD50	Rat	140 mg/kg
Oral		
LD50	Rat	188 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
Acute		
Oral		
LD50	Rat	>= 7300 mg/kg
SODIUM CARBONATE (CAS 497-19-8)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
Aerosol		
LC50	Rat	2300 mg/m3, 2 Hours
Oral		
LD50	Rat	2800 mg/kg
SUCRALOSE (CAS 56038-13-2)		
Acute		
Oral		
LD50	Rat	10 g/kg

Components	Species	Test Results
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 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. Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

NICOTINE	Acute dermal irritation Result: Positive Species: Rabbit

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

MAGNESIUM STEARATE	0
SUCRALOSE	0

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

Eye

SODIUM CARBONATE	Acute ocular irritation; OECD 405 Result: Moderate Irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

SUCRALOSE	4
MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitization Health injuries are not known or expected under normal use.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: Negative Species: Guinea pig

Sensitization

NICOTINE	Local lymph node assay; OECD 429 Result: Negative Species: Mouse

Germ cell mutagenicity Health injuries are not known or expected under normal use. Contains components that produced genotoxicity in laboratory tests. Not expected to be genotoxic under occupational exposure conditions.

Mutagenicity

NICOTINE	Ames Result: Negative In vitro cytogenetics assay Result: Negative in vitro micronucleus assay Result: Positive Organ: gingivum Mouse micronucleus test Result: Negative sister chromatid exchange Result: Positive

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

NICOTINE	Inhalation Result: Negative Species: Rat oral Result: Negative Species: Rat tumour promotor Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Health injuries are not known or expected under normal use. 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

NICOTINE

Result: Developmental effects including cleft palate.
Species: Mouse
Result: Developmental toxicity.
Species: Rabbit
Result: Developmental toxicity.
Species: Rat

Specific target organ toxicity - single exposure nervous system

Specific target organ toxicity - repeated exposure Causes damage to organs (Circulatory System) through prolonged or repeated exposure.

Aspiration hazard Not available.

Chronic effects Causes damage to organs through prolonged or repeated exposure.

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

12. Ecological information

Ecotoxicity No information is available about the potential of this material to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 10000 mg/l
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
NICOTINE (CAS 54-11-5)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia pulex)	0.242 mg/l, 48 hours Static renewal test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4 mg/l, 96 hours
SODIUM BICARBONATE (CAS 144-55-8)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days

Components		Species	Test Results
Crustacea	EC50	Water flea (Daphnia magna)	2350 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	8250 - 9000 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	7550 mg/l, 96 hours Static test
SODIUM CARBONATE (CAS 497-19-8)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 800 mg/l
Crustacea	EC50	Water flea (Daphnia magna)	265 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	300 mg/l, 96 hours Static test
		Fathead minnow (Juvenile Pimephales promelas)	< 850 mg/l, 96 hours Static test
		Mosquito fish (Adult Gambusia affinis)	740 mg/l, 96 hours Static test
SUCRALOSE (CAS 56038-13-2)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	100 mg/l, 48 hours Static test
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

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

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE	210 nm

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACESULFAME K	0 - 8 %, 25 days Batch activated sludge (BAS), Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD
SUCRALOSE	1 %, 28 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE	95 %, 22 days Sturm test
NICOTINE	83.43 % , 28 days, OECD 301 CO2 evol

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE	-5
NICOTINE	1.17

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE	3.2 Estimated
MAGNESIUM STEARATE	> 9999 Estimated
NICOTINE	5

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE	5.86 Estimated
NICOTINE	2 Estimated

Mobility in general Not available.

Volatility

Henry's law

HYDROXYPROPYL METHYL CELLULOSE	0 atm m3/mol Estimated
NICOTINE	0 atm m^3/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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 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.

US RCRA Hazardous Waste P List: Reference

NICOTINE (CAS 54-11-5)	P075

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

14. Transport information

DOT

Not regulated as a dangerous good.

Not available.

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 Not applicable.

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)

NICOTINE (CAS 54-11-5)	Listed.

SARA 304 Emergency release notification

NICOTINE (CAS 54-11-5)	100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
NICOTINE	54-11-5	100	100		

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
NICOTINE	54-11-5	1 - < 3

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 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

NICOTINE (CAS 54-11-5) Listed: April 1, 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

NICOTINE (CAS 54-11-5)

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 06-14-2018

Version # 01

Further information HMIS® is a registered trade and service mark of the ACA.

HMIS® ratings Health: 1*
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 1
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.