SAFETY DATA SHEET

1. Identification

Product identifier **NICORETTE LOZENGE 2MG & 4MG (MINT)**

Other means of identification

Synonyms NICOTINE POLACRILEX 2MG TABLET * NICOTINE POLACRILEX 4MG TABLET * FM NICOTINE 4MG SF LOZ PEPPERMINT * FM NICOTINE 2MG SF LOZ PEPPERMINT * PRODUCT NUMBER 873AG (4MG) * PRODUCT NUMBER 344AH (2MG) * 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

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

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

Supplemental information 10.11% of the mixture consists of component(s) of unknown acute dermal toxicity. 10.11% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 10.11% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
NICOTINE POLACRILEX	NPA NICOTINE POLACRILEX, USP FORMULA NO: 10449-005-0001	96055-45-7	1 - < 3
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	5.36
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT BISODIUM CARBONATE DISODIUM CARBONATE SODA ASH	497-19-8	2.12
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	1.78
ASPARTAME	L-PHENYLALANINE, N-L-ALPHA-ASPARTYL-1-METHYL ESTER N-L-ALPHA-ASPARTYL-1-METHYL ESTER L-PHENYLALANINE SUCCINAMIC ACID, 3-AMINO-N-(ALPHA-CARBOXYPHENETHYL)-, ASPARTYLPHENYLALANINE METHYL ESTER METHYL ASPARTYLPHENYLALANATE NUTRASWEET	22839-47-0	0.78
PEPPERMINT OIL	OILS, PEPPERMINT OIL OF PEPPERMINT ESSENTIAL OILS, MENTHA PIPERITA ESSENTIAL PEPPERMINT OIL PEPPERMINT LEAF OIL PEPPERMINT TERPENES PEPPERMINT OIL (MENTHA PIPERITA) PEPPERMINT OIL (PEPPERMINT AMERICAN, MENTHA PIPERITA)	8006-90-4	0.47
POTASSIUM BICARBONATE	POTASSIUM ACID CARBONATE POTASSIUM CARBONATE, HYDROGEN CARBONIC ACID, MONOPOTASSIUM SALT POTASSIUM HYDROGEN CARBONATE HYDROGEN POTASSIUM CARBONATE MONOPOTASSIUM CARBONATE	298-14-6	0.34
Other components below reportable levels			86 - < 89

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).

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: increased heart rate, salivation, depression. Headache. Dizziness. Abdominal pain.

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. The need for pre-placement and periodic health surveillance must be determined by risk assessment.

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. 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. Following product recovery, flush area with water. 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 No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product. Avoid prolonged exposure.

Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in 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
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
POTASSIUM BICARBONATE (CAS 298-14-6)	8 HR TWA	5000 mcg/m3	

GSK Components	Type	Value	Note
	OHC	1	
SODIUM CARBONATE (CAS 497-19-8)	OHC	1	>1000 - </=5000 mcg/m3
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

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

Exposure guidelines

US - California OELs: Skin designation

NICOTINE POLACRILEX (CAS 96055-45-7) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

NICOTINE POLACRILEX (CAS 96055-45-7) Skin designation applies.

US - Tennessee OELs: Skin designation

NICOTINE POLACRILEX (CAS 96055-45-7) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

NICOTINE POLACRILEX (CAS 96055-45-7) Can be absorbed through the skin.

US NIOSH Pocket Guide to Chemical Hazards: Skin designation

NICOTINE POLACRILEX (CAS 96055-45-7) Can be absorbed through the skin.

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

NICOTINE POLACRILEX (CAS 96055-45-7) Can be absorbed through the skin.

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.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed.

Skin protection

Hand protection Not normally needed.

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/pastille.

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 available.
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	No hazardous decomposition products are 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. May be harmful if swallowed. Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: increased heart rate, salivation, depression. Headache. Dizziness. Abdominal pain.

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**
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
NICOTINE POLACRILEX (CAS 96055-45-7)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	< 2000 mg/kg
PEPPERMINT OIL (CAS 8006-90-4)		
Acute		
Oral		
LD50	Rat	2426 mg/kg
SODIUM CARBONATE (CAS 497-19-8)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
Aerosol		
LC50	Rat	2300 mg/m3, 2 Hours
LC50	Rat	2.3 mg/l, 2 Hours
Oral		
LD50	Rat	2800 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/kg

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

PEPPERMINT OIL	Literature search Result: Positive

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

MAGNESIUM STEARATE	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
PEPPERMINT OIL	Literature search Result: Mild/moderate Irritant

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization No studies have been conducted.

Skin sensitization None known. This product is not expected to cause skin sensitization.

Sensitization

PEPPERMINT OIL	Literature search Result: Positive

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

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Contains no ingredient listed as toxic to reproduction.

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 Prolonged inhalation may be harmful.

Further information Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
POTASSIUM BICARBONATE (CAS 298-14-6)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	630 mg/l, 48 hours US EPA 600/4-90/027
Fish	LC50	Rainbow trout (Adult Oncorhyncus mykiss)	1300 mg/l, 96 hours FIFRA 72-1
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
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

Hydrolysis

Half-life (Hydrolysis-basic)

ASPARTAME	< 1 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE	77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
MAGNESIUM STEARATE	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated
MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

ASPARTAME	1.78 Estimated
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general Not available.

Volatility

Henry's law

ASPARTAME	< 0 atm m^3/mol Estimated

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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 POLACRILEX (CAS 96055-45-7)	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).

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.

Read safety instructions, SDS and emergency procedures before handling.

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 This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

NICOTINE POLACRILEX (CAS 96055-45-7) Listed.

SARA 304 Emergency release notification

PYRIDINE, 3-(1-METHYL-2-PYRROLIDINYL)-,(S)-(CAS 96055-45-7) 100 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No (Exempt)

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
NICOTINE POLACRILEX	96055-45-7	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

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. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

NICOTINE POLACRILEX (CAS 96055-45-7) Listed: April 1, 1990

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

NICOTINE POLACRILEX (CAS 96055-45-7)

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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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 03-03-2021

Version # 01

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.