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	NICORETTE & NICOBATE MINI LOZENGES, 2MG & 4MG SWEETMINT
Registration number	-
Synonyms	MFC51283A, 2 MG SWEETMINT * MFC51283B, 4 MG SWEETMINT * NICOTINE POLACRILEX, FORMULATED PRODUCT
Issue date	14-June-2018
Version number	01

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

Company name	GlaxoSmithKline UK
Address:	980 Great West Road Brentford, Middlesex TW8 9GS UK
Telephone:	+44-20-8047-5000 (General Inquiries)
Email:	msds@gsk.com
Website:	www.gsk.com

EMERGENCY CONTACTS

	CHEMTREC EMERGENCY NUMBERS
Telephone:	+(44)-870-8200418 (In country) +(1) 703 527 3887 (International) 24/7; multi-language response
Contract Number:	CCN9484
	VERISK 3E GLOBAL INCIDENT RESPONSE
Telephone:	+(44) 20 35147487 or 0 800 680 0425 (In country) +(1) 760 476 3961 (International) 24/7; multi-language response
Contract Number:	334878

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
N&A FL SWEET MINT TYPE	5.2	Unassigned -	-	-	
Classification: Skin Irrit. 2;H315, Skin Sens. 1;H317, Eye Irrit. 2;H319					
HYDROXYPROPYL METHYL CELLULOSE	3.7	9004-65-3 -	-	-	
Classification: -					
Sodium carbonate	3.07	497-19-8 207-838-8	-	011-005-00-2	
Classification: Eye Irrit. 2;H319					
XANTHAN GUM	2.22	11138-66-2 234-394-2	-	-	
Classification: -					
NICOTINE	1 - < 3	54-11-5 200-193-3	-	614-001-00-4	#
Classification: Acute Tox. 3;H301, Acute Tox. 1;H310, Skin Irrit. 2;H315, Eye Irrit. 2;H319, Repr. 2;H361, Aquatic Acute 1;H400, Aquatic Chronic 2;H411					
MAGNESIUM STEARATE	1.74	557-04-0 209-150-3	-	-	
Classification: -					
ACESULFAME K	1	55589-62-3 259-715-3	-	-	
Classification: -					
SUCRALOSE	1	56038-13-2 259-952-2	-	-	
Classification: -					
Other components below reportable levels	80 - < 90				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).
M: M-factor
PBT: persistent, bioaccumulative and toxic substance.
vPvB: very persistent and very bioaccumulative substance.
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments The full text for all H-statements 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.

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

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

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.

Never return spills to original containers for re-use.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities 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
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	Reproductive hazard
		3	Skin
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	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
NICOTINE (CAS 54-11-5)	STEL	1.5 mg/m3

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
	TWA	0.5 mg/m3

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

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).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines

UK EH40 WEL: Skin designation

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

8.2. Exposure controls

Appropriate engineering controls General ventilation normally adequate.

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 Lozenge.

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.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
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	Caution - Pharmaceutical agent. 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. May be irritating to eyes.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Symptoms	The possible symptoms of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; headache; depression; respiratory depression; dizziness.

11.1. 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

Components	Species	Test results
NICOTINE (CAS 54-11-5)		
Acute		
Dermal		
LD50	Rat	140 mg/kg
Oral		
LD50	Rat	188 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
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.

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.

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

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

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE	Result: negative Species: Guinea pig

Sensitisation

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

Mutagenicity

NICOTINE

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

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 Due to partial or complete lack of data the classification is not possible.

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 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

Components		Species	Test results
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 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.

12.2. 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

12.3. Bioaccumulative potential No data available for this product.

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

12.4. 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

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

12.7. Additional information None known.

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 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.

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

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not 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

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

Not available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

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 and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

NICOTINE (CAS 54-11-5)

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

NICOTINE (CAS 54-11-5)

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 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, as amended

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, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

NICOTINE (CAS 54-11-5)

Other regulations	Pregnant women should not work with the product, if there is the least risk of exposure. The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended. Additional information is given in the Safety Data Sheet.
National regulations	Follow national regulation for work with chemical agents. Young people under 18 years old are not allowed to work with this product according to EU Directive 94/33/EC on the protection of young people at work, as amended.
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 H-statements not written out in full under Sections 2 to 15	H301 Toxic if swallowed. H310 Fatal in contact with skin. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H361 Suspected of damaging fertility or the unborn child. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.
Revision information	None.
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.