



SAFETY DATA SHEET

1. Identification

Product identifier

NICOTINE GUM

Other means of identification

Synonyms

NICORETTE GUM (SPEARMINT BURST) 2 MG * NICORETTE GUM (SPEARMINT BURST) 4 MG * NIQUITIN CQ GUM (EXTRA MINT) * NICORETTE FRUIT CHILL * NICORETTE CINNAMON SURGE * NICORETTE * NICORETTE DS * NICORETTE MINT * NICORETTE FRESH MINT * NICORETTE WHITE ICE MINT * NICORETTE ORIGINAL * COATED NICOTINE GUM 2MG AND 4MG * BULK NUMBER 1001820, 1001822 * 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

Telephone:

CHEMTREC EMERGENCY NUMBERS
+(1) 703 527 3887 (International)
24/7; multi-language response
CCN9484

Contract Number:

Telephone:

VERISK 3E GLOBAL INCIDENT RESPONSE
+(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	%
FLAVOURING		Unassigned	10 - < 20
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT CALCIUM MONOCARBONATE PRECIPITATED CALCIUM CARBONATE CHALK	471-34-1	0 - < 25

Chemical name	Common name and synonyms	CAS number	%
SODIUM CARBONATE	CARBONIC ACID, DISODIUM SALT BISODIUM CARBONATE DISODIUM CARBONATE SODA ASH	497-19-8	2 - < 5
OPTAMINT FLAVOUR		Unassigned	0 - 2
SPEARMINT FLAVOUR GIVAUDAN L-092281		Unassigned	0 - 2
MINT FLAVOUR		Unassigned	0 - < =1.1
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	0 - < =1
L-MENTHOL	CYCLOHEXANOL, 5-METHYL-2-(1-METHYLETHYL)-, (1R-(1ALPHA,2BETA,5ALPHA))- (1R-(1ALPHA,2BETA,5ALPHA))-5-METH YL-2-(1-METHYLETHYL)-CYCLOHEXAN OL LEVOMENTHOL L-MENTHOL (L)-MENTHOL	2216-51-5	0 - < =1
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 - < =1
SUCRALOSE	MICRONIZED SUCRALOSE POWDERED SUCRALOSE NEAT SUCRALOSE	56038-13-2	0 - < =1
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO ₂) PIGMENT WHITE 6	13463-67-7	0 - < =1
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-PYRROLIDINYLI)PYRI DIINI	54-11-5	0.15 - < 0.5
TUTTI FRUTTI	TUTTI FRUTTI 51880/A TUTTI FRUTTI FLAVOUR	Unassigned	< 0.3

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM OXIDE	GI197895X MAGNESIA MAGNESIUM MONOXIDE CALCINED MAGNESIA CALCINATED MAGNESIA CAUSTIC MAGNESITE MAGNESA PREPRATA MAGNESIUM (II) OXIDE SYNTHETIC PERICLASE BURNT MAGNESIA LIGHT MAGNESIA OXIDO DE MAGNESIO ÓXIDO DE MAGNESIO,	1309-48-4	< 0.1
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	0 - < 0.1
2,6-DI-TERT-BUTYL-P-CRESOL	BUTYLATED HYDROXYTOLUENE 4-METHYL-2,6-DI-TERT-BUTYLPHENOL BUTYLHYDROXYTOLUENE DIBUTYLATED HYDROXYTOLUENE 2,6-DI-TERT-BUTYL-1-HYDROXY - 4 - METHYLBENZENE 3,5-DI-TERT-BUTYL - 4 - HYDROXYTOLUENE 2,6-BIS(1,1-DIMETHYLETHYL)-4-METHY LPHENOL 2,6-TERT-BUTYL-4-METHYLPHENOL DI-TERT-BUTYLMETHYLPHENOL 2,6-DI-TERT-BUTYL-PARA-CRESOL BHT	128-37-0	0 - < = 0.05
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM	55589-62-3	0 - < = 0.05
TALC	TALCUM, NON-ASBESTOS FORM TALC HYDROUS MAGNESIUM SILICATE	14807-96-6	0 - < 0.01
Other components below reportable levels			>70.0

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

GSK

Components	Type	Value	Note
ACESULFAME K (CAS 55589-62-3)	OHC	1	
FLAVOURING	OHC	3	>10 - <= 100 mcg/m3 PROVISIONAL SKIN SENSITISER
L-MENTHOL (CAS 2216-51-5)	OHC	1	
NICOTINE (CAS 54-11-5)	15 MIN STEL 8 HR TWA OHC	200 mcg/m3 70 mcg/m3 3	REPRODUCTIVE HAZARD SKIN
SODIUM BICARBONATE (CAS 144-55-8)	8 HR TWA OHC	5000 mcg/m3 1	
SODIUM CARBONATE (CAS 497-19-8)	8 HR TWA OHC	5000 mcg/m3 1	
SUCRALOSE (CAS 56038-13-2)	OHC OHC	1 1	
TUTTI FRUTTI	8 HR TWA OHC	5000 mcg/m3 1	

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

Components	Type	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	PEL	5 mg/m3	Respirable fraction.
GLYCERIN (CAS 56-81-5)	PEL	15 mg/m3 5 mg/m3	Total dust. Respirable fraction.
MAGNESIUM OXIDE (CAS 1309-48-4)	PEL	15 mg/m3	Total dust.
NICOTINE (CAS 54-11-5)	PEL	15 mg/m3 0.5 mg/m3	Total particulate.

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

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

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

Components	Type	Value	Form
MAGNESIUM OXIDE (CAS 1309-48-4)	TWA	5 mg/m3	Respirable fraction.
TALC (CAS 14807-96-6)	TWA	15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.
		0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	20 mppcf	Respirable.
		2.4 mppcf	Respirable.
		5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
2,6-DI-TERT-BUTYL-P-CR ESOL (CAS 128-37-0)	TWA	2 mg/m3	Inhalable fraction and vapor.
MAGNESIUM OXIDE (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
2,6-DI-TERT-BUTYL-P-CR ESOL (CAS 128-37-0)	TWA	10 mg/m3	
CALCIUM CARBONATE (CAS 471-34-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
NICOTINE (CAS 54-11-5)	TWA	0.5 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

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. 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	Gum.
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

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Nitrogen oxides (NOx).

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
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)		
<u>Acute</u>		
Oral		
LD50	Rat	890 mg/kg
ACESULFAME K (CAS 55589-62-3)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
CALCIUM CARBONATE (CAS 471-34-1)		
<u>Acute</u>		
Oral		
LD50	Rat	6450 mg/kg
GLYCERIN (CAS 56-81-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
L-MENTHOL (CAS 2216-51-5)		
<u>Acute</u>		
Oral		
LD50	Rat	2400 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
NICOTINE (CAS 54-11-5)		
<u>Acute</u>		
Dermal		
LD50	Rat	140 mg/kg
Oral		
LD50	Rat	188 mg/kg
SODIUM BICARBONATE (CAS 144-55-8)		
<u>Acute</u>		
Oral		
LD50	Rat	>= 7300 mg/kg

Components	Species	Test Results
SODIUM CARBONATE (CAS 497-19-8)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Inhalation		
<i>Aerosol</i>		
LC50	Rat	2300 mg/m ³ , 2 Hours
Oral		
LD50	Rat	2800 mg/kg
SUCRALOSE (CAS 56038-13-2)		
<u>Acute</u>		
Oral		
LD50	Rat	10 g/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<u>Acute</u>		
Inhalation		
LC50	Rat	6820 mcg/m ³
Oral		
LD50	Rat	> 24 g/kg
<u>Chronic</u>		
Inhalation		
LOEC	Rat	8.6 mg/m ³ , 1 years TiO ₂ accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m ³ , 2 years Highest dose 5 mg/m ³ , 24 months
<u>Subacute</u>		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m ³ , 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m ³ , 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<u>Subchronic</u>		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m ³ , 8 min Accumulation of TiO ₂ in macrophages and evidence of pulmonary inflammation.

* 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

TITANIUM DIOXIDE

0, Literature data
Result: Non-irritant
Species: Guinea pig
0, Literature data
Result: Non-irritant
Species: Human

Irritation Corrosion - Skin

NICOTINE

Acute dermal irritation

Result: Positive

Species: Rabbit

TITANIUM DIOXIDE

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

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

TITANIUM DIOXIDE

OECD 405, Literature data

Result: Mild 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.

Sensitization

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum

Result: Negative

Species: Guinea pig

Test Duration: 48 hour exposure

NICOTINE

Local lymph node assay; OECD 429

Result: Negative

Species: Mouse

TITANIUM DIOXIDE

Patch test, Literature data

Result: Negative

Species: Human

Germ cell mutagenicity

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

Mutagenicity

NICOTINE

Ames

Result: Negative

TITANIUM DIOXIDE

Ames, Literature data

Result: Negative

NICOTINE

In vitro cytogenetics assay

Result: Negative

in vitro micronucleus assay

Result: Positive

Organ: gingivum

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

Micronucleus Assay in vitro, cultured human peripheral

lymphocytes, Literature data

Result: Positive

NICOTINE

Mouse micronucleus test

Result: Negative

sister chromatid exchange

Result: Positive

TITANIUM DIOXIDE

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Negative

WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell

lymphoblastoid, Literature data

Result: Positive

Carcinogenicity

Contains a material (Titanium Dioxide) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects. Health injuries are not known or expected under normal use.

TITANIUM DIOXIDE

0.5 mg/m³, Literature data
Result: Negative
Species: Rat
Test Duration: 24 months
0.72 - 14.8 mg/m³, Literature data
Result: Negative
Species: Mouse
10 - 250 mg/m³, Dietary study - Literature data.
Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.
Species: Rat
Test Duration: 24 months
25000 - 50000 ppm, Dietary study - Literature data.
Result: Negative
Species: Rat
25000 - 50000 ppm, Dietary study
Result: Negative
Species: Mouse
7.2 - 14.8 mg/m³, Literature data
Result: Lung tumour
Species: Rat
Test Duration: 24 months
Inhalation
Result: Negative
Species: Rat
oral
Result: Negative
Species: Rat
tumour promotor
Species: Mouse

NICOTINE

IARC Monographs. Overall Evaluation of Carcinogenicity

2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)
TALC (CAS 14807-96-6)

3 Not classifiable as to carcinogenicity to humans.
2B Possibly carcinogenic to humans.
3 Not classifiable as to carcinogenicity to humans.
2B Possibly carcinogenic to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects. 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.

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 product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

Components	Species		Test Results
2,6-DI-TERT-BUTYL-P-CRESOL (CAS 128-37-0)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Desmodesmus subspicatus)	> 0.4 mg/l, 72 hour EU Method C.3
Crustacea	EC50	Daphnia magna	0.61 mg/l, 48 hours OECD Guideline 202
Fish	LC0	Danio rerio	> 0.57 mg/l, 96 hour Directive 84/449/EEC, C.1
<i>Chronic</i>			
Crustacea	NOEC	Daphnia magna	0.316 mg/l, 21 day OECD Guide-line 202, part 2 "Daphnia sp., Reproduction Test"
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
<i>Acute</i>			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
<i>Chronic</i>			
Other	LC50	Bacteria	> 10000 mg/l
CALCIUM CARBONATE (CAS 471-34-1)			
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis)	> 56000 mg/l, 24 hours
L-MENTHOL (CAS 2216-51-5)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (Desmodesmus subspicatus)	21.4 mg/l, 72 hours OECD 201
Crustacea	EC50	Water flea (Daphnia magna)	37.7 mg/l, 24 hours OECD 202
Fish	LC50	Zebra danio (Danio rerio)	15.6 mg/l, 96 hours EU Method C.1
<i>Chronic</i>			
Algae	NOEC	Green algae (Desmodesmus subspicatus)	9.65 mg/l, 72 hours OECD 201
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
NICOTINE (CAS 54-11-5)			
Aquatic			
<i>Acute</i>			
Crustacea	EC50	Water flea (Daphnia pulex)	0.242 mg/l, 48 hours Static renewal test
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	4 mg/l, 96 hours
SODIUM BICARBONATE (CAS 144-55-8)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Algae (Nitscheria linearis)	650 mg/l, 5 days
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

Components	Species	Test Results
SODIUM CARBONATE (CAS 497-19-8)		
Aquatic		
<i>Acute</i>		
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)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours
Aquatic		
<i>Acute</i>		
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
TALC (CAS 14807-96-6)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Zebra fish (Adult Brachydanio rerio) > 100 g/l, 24 hours Static renewal test
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
Fish	LC50	Mummichog (Fundulus heteroclitus) > 1000 mg/l, 96 hours
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test

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

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

L-MENTHOL 16 Hours Estimated
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)

2,6-DI-TERT-BUTYL-P-CRESOL < 10 %, 20 Days Closed bottle test, Residential sludge
4.5 %, 28 days Modified MITI test, Activated sludge
L-MENTHOL 0 %, 28 days
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

Partition coefficient n-octanol / water (log Kow)

GLYCERIN -1.76
L-MENTHOL 3.3
NICOTINE 1.17

Bioconcentration factor (BCF)

2,6-DI-TERT-BUTYL-P-CRESOL	230 - 2500 Measured, Cyprinus carpio, carp
L-MENTHOL	1 - 15 Measured, Cyprinus carpio, carp
MAGNESIUM STEARATE	> 9999 Estimated
NICOTINE	5

Mobility in soil**Adsorption****Soil/sediment sorption - log Koc**

L-MENTHOL	3.18 Estimated
MAGNESIUM STEARATE	5.86 Estimated
NICOTINE	2 Estimated

Mobility in general**Volatility****Henry's law**

2,6-DI-TERT-BUTYL-P-CRESOL	0.000004, 25 Estimated
L-MENTHOL	0.000015 atm m ³ /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. 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
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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 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.
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SARA 304 Emergency release notification

NICOTINE (CAS 54-11-5)	100 LBS
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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)
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NICOTINE	54-11-5	100	100		
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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.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

US state regulations

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7) Listed: September 2, 2011

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))

MAGNESIUM OXIDE (CAS 1309-48-4)

NICOTINE (CAS 54-11-5)

TALC (CAS 14807-96-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

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
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 05-17-2018

Material name: NICOTINE GUM

128111 Version #: 08 Revision date: 05-17-2018 Issue date: 05-17-2018

SDS US

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Revision date 05-17-2018
Version # 08
Further information HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings Health: 1*
Flammability: 1
Physical hazard: 0
NFPA ratings Health: 1
Flammability: 1
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: Synonyms
Hazard(s) identification: Hazard(s) not otherwise classified (HNOC)
Composition / Information on Ingredients: Ingredients
Toxicological information: Carcinogenicity