

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name NICOTINE 4MG MINT COATED USP GUM (BK000546)

Other means of identification

Product Code(s) 1759465

Recommended use of the chemical and restrictions on use

Recommended Use Nicotine Replacement Therapy - Gum

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification PL Developments

Address 200 Hicks Street
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Emergency telephone number

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2. HAZARDS IDENTIFICATION

Classification

Acute toxicity - Oral	Category 3
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Acute toxicity - Dermal	Category 4
Acute toxicity - Inhalation (Vapors)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4

Appearance Yellow

Physical state Solid

Odor Mint-like

GHS Label elements, including precautionary statements

Danger

Hazard statements

Toxic if swallowed
Harmful in contact with skin
Harmful if inhaled



Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Wear protective gloves/protective clothing
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

Skin

IF ON SKIN: Wash with plenty of water and soap
Call a POISON CENTER or doctor if you feel unwell
Take off contaminated clothing and wash it before reuse

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing
Call a POISON CENTER or doctor if you feel unwell

Ingestion

IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Harmful to aquatic life with long lasting effects.

Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Nicotine polacrilex	96055-45-7	2.5	-	-
Sodium carbonate	497-19-8	1.13	-	-
Titanium dioxide	13463-67-7	0.59	-	-

4. FIRST AID MEASURES

Description of first aid measures

General advice
Inhalation

Show this safety data sheet to the doctor in attendance.
If breathing has stopped, give artificial respiration. Get medical attention immediately.
Remove to fresh air. If symptoms persist, call a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.
Consult a physician.

Skin contact

Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.

Ingestion

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person. Get medical attention.

Self-protection of the first aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid breathing dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms

Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.



5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Explosion Data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Avoid generation of dust. Do not breathe dust.
Other Information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid generation of dust. Do not eat, drink or smoke when using this product.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust (vacated) TWA: 10 mg/m ³ total dust	IDLH: 5000 mg/m ³	
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec
Titanium dioxide 13463-67-7	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid

Appearance Yellow

Odor Mint-like

Color No information available

Odor Threshold Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks</u> <u>Method</u>
pH	No data available	None known
Melting / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	No data available	None known
Evaporation Rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		



Upper flammability limit	No data available	
Lower flammability limit	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water Solubility	Soluble in water	
Solubility(ies)	No data available	None known
Partition coefficient: n-octanol/water¹		
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other Information

Explosive properties	No information available
Oxidizing properties	No information available
Softening Point	No information available
Molecular Weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk Density	No information available
Particle Size	No information available
Particle Size Distribution	No information available

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. Harmful by inhalation. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	May be absorbed through the skin in harmful amounts. Harmful in contact with skin. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Toxic if swallowed. (based on components).



Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	200.40 mg/kg
ATEmix (dermal)	2,000.00 mg/kg
ATEmix (inhalation-gas)	4,000.40 ppm
ATEmix (inhalation-dust/mist)	1.97 mg/L
ATEmix (inhalation-vapor)	20.00 mg/L

Unknown acute toxicity 0 % of the mixture consists of ingredient(s) of unknown toxicity

- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
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- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
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- 0 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Nicotine polacrilex	= 25 mg/kg (Rat)	= 350 mg/kg (Rabbit)	-
Sodium carbonate	= 4090 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	= 2300 mg/m ³ (Rat) 2 h
Titanium dioxide	> 10000 mg/kg (Rat)	-	= 5.09 mg/L (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity Classification based on data available for ingredients. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Titanium dioxide 13463-67-7	A3	Group 2B	-	X

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 2B - Possibly Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present



Reproductive toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium carbonate	No data available	96h LC50: 310 - 1220 mg/L (Pimephales promelas) 96h LC50: = 300 mg/L (Lepomis macrochirus)	No data available	48h EC50: = 265 mg/L (Daphnia magna)

Persistence and Degradability No information available.
Bioaccumulation No information available.
Mobility No information available.
Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging Do not reuse empty containers.
US EPA Waste Number P075

Chemical name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Nicotine polacrilex 96055-45-7		P075		

California Waste Codes 311

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	California Hazardous Waste
Nicotine polacrilex 96055-45-7	Toxic



Sodium carbonate 497-19-8	Corrosive
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14. TRANSPORT INFORMATION

DOT
 Proper Shipping Name NOT REGULATED
 Hazard Class NON-REGULATED
 N/A

TDG Not applicable

MEX Not applicable

ICAO Not applicable

IATA
 Proper Shipping Name Not applicable
 Hazard Class NON REGULATED
 N/A

IMDG/IMO
 Hazard Class Not applicable
 N/A

RID Not applicable

ADR Not applicable

ADN Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA Contact supplier for inventory compliance status.
DSL/NDSL Contact supplier for inventory compliance status.
EINECS/ELINCS Contact supplier for inventory compliance status.
ENCS Contact supplier for inventory compliance status.
KECL Contact supplier for inventory compliance status.
PICCS Contact supplier for inventory compliance status.
AICS Contact supplier for inventory compliance status.

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances



KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

Chemical name	CAS No	Weight-%	SARA 313 - Threshold Values %
Nicotine polacrilex - 96055-45-7	96055-45-7	2.5	1.0

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Nicotine polacrilex 96055-45-7	100 lb		RQ 100 lb final RQ RQ 45.4 kg final RQ

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals.

Chemical name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Nicotine polacrilex 96055-45-7	X			X	
Titanium dioxide 13463-67-7	X	X	X		

16. OTHER INFORMATION

<u>NFPA</u>	Health hazards 3	Flammability 0	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health hazards 2	Flammability 0	Physical hazards 0	Personal Protection X



Chronic Hazard Star Legend * = Chronic Health Hazard

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Revision Note No information available

Disclaimer

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End of Safety Data Sheet