

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name NICOTINE 2MG MINT COATED USP GUM

Other means of identification

Product Code(s) 1753184

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

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2. HAZARDS IDENTIFICATION

Classification

Acute toxicity - Oral

Category 4



Acute toxicity - Inhalation (Gases)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Respiratory sensitization	Category 1
Skin sensitization	Category 1

Appearance White**Physical state** Solid**Odor** Mint-like**GHS Label elements, including precautionary statements****Danger****Hazard statements**

Harmful if swallowed

Harmful if inhaled

May cause allergy or asthma symptoms or breathing difficulties if inhaled

May cause an allergic skin reaction

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

In case of inadequate ventilation wear respiratory protection

Contaminated work clothing must not be allowed out of the workplace

Wear protective gloves

Precautionary Statements - Response

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

Skin

IF ON SKIN: Wash with plenty of water and soap

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing

If experiencing respiratory symptoms: Call a POISON CENTER or doctor

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information**Unknown acute toxicity** 2.8 % of the mixture consists of ingredient(s) of unknown toxicity

2.8 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

2.8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

2.8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 2.8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 2.8 % 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)
Guar gum	9000-30-0	50.58	-	-
Magnesium Oxide	1309-48-4	1.72	-	-
Sodium carbonate	497-19-8	1.47	-	-
Nicotine polacrilex	96055-45-7	1.25	-	-
Cellulose	9004-34-6	1.09	-	-
Titanium dioxide	13463-67-7	0.51	-	-

4. FIRST AID MEASURES

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention.

Eye contact

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

Skin contact

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see 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. May produce an allergic reaction. Get immediate medical advice/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 contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information. Avoid breathing dust/fume/gas/mist/vapors/spray.

Most important symptoms and effects, both acute and delayed

Symptoms

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed



Note to physicians May cause sensitization in susceptible persons. 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	Product is or contains a sensitizer. May cause sensitization by inhalation and skin contact.
Hazardous Combustion Products	Carbon oxides.
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. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. 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. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid generation of dust.
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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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters****Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Magnesium Oxide 1309-48-4	TWA: 10 mg/m ³ inhalable particulate matter	TWA: 15 mg/m ³ fume, total particulate (vacated) TWA: 10 mg/m ³ fume and total particulate	IDLH: 750 mg/m ³ fume	
Cellulose 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust	
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
Magnesium Oxide 1309-48-4	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³ STEL: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³
Cellulose 9004-34-6	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
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.

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 Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Avoid breathing dust/fume/gas/mist/vapors/spray. Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid
Appearance	White
Odor	Mint-like
Color	No information available
Odor Threshold	Not applicable

<u>Property</u>	<u>Values</u>	<u>Remarks 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	Partially soluble	
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.
Hazardous Polymerization	Hazardous polymerization does not occur.

Conditions to avoid Excessive heat.

Incompatible materials None known based on information supplied.

Hazardous Decomposition Products Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation Harmful by inhalation. May cause sensitization in susceptible persons (based on components). Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact May be harmful in contact with skin. May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons (based on components). Specific test data for the substance or mixture is not available.

Ingestion Harmful if swallowed. May cause additional affects as listed under "Inhalation" (based on components). Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching. Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

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

ATEmix (oral) 388.50 mg/kg
ATEmix (dermal) 4,000.00 mg/kg
ATEmix (inhalation-gas) 8,000.80 ppm
ATEmix (inhalation-dust/mist) 3.81 mg/L
ATEmix (inhalation-vapor) 40.10 mg/L

Unknown acute toxicity 2.8 % of the mixture consists of ingredient(s) of unknown toxicity
 2.8 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
 2.8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
 2.8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
 2.8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
 2.8 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information			
Component Information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Guar gum	= 6770 mg/kg (Rat)	-	-
Magnesium Oxide	= 3870 mg/kg (Rat) = 3990 mg/kg (Rat)	-	-



Sodium carbonate	= 4090 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	= 2300 mg/m ³ (Rat) 2 h
Nicotine polacrilex	-	= 50 mg/kg (Rabbit) = 140 mg/kg (Rat)	-
Cellulose	> 5 g/kg (Rat)	> 2000 mg/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 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** May cause sensitization by inhalation. May cause sensitization by skin contact.
- 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 The environmental impact of this product has not been fully investigated.

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
Sodium carbonate 497-19-8	Corrosive
Nicotine polacrilex 96055-45-7	Toxic

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	1.25	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 does not contain any substances regulated as 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
Magnesium Oxide 1309-48-4	X	X	X		
Nicotine polacrilex 96055-45-7	X			X	
Cellulose 9004-34-6	X	X	X	-	X
Titanium dioxide 13463-67-7	X	X	X		

16. OTHER INFORMATION

NFPA	Health hazards 2	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 2 *	Flammability 0	Physical hazards 0	Personal Protection X
<i>Chronic Hazard Star Legend</i>	* = Chronic Health Hazard			

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Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet

