SAFETY DATA SHEET

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NGHS / English

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1. IDENTIFICATION

Product identifier

Product Name Nicotine 4mg Uncoated USP Gum

Other means of identification

Product Code(s) 1551069

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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New York
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Emergency telephone number

Company Emergency Phone Number 516-986-1700

2. HAZARDS IDENTIFICATION

Classification

Acute toxicity - Oral	Category 2
Acute toxicity - Dermal	Category 1
Acute toxicity - Inhalation (Dusts/Mists)	Category 2

Appearance No information available **Physical state** Solid **Odor** Sweet

GHS Label elements, including precautionary statements

Danger

Hazard statements
Fatal if swallowed
Fatal in contact with skin
Fatal 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
Do not get in eyes, on skin, or on clothing
Wear protective gloves/protective clothing
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wear respiratory protection
Precautionary Statements - Response
Specific treatment is urgent (see supplemental first aid instructions on this label)
Skin
IF ON SKIN: Wash with plenty of water and soap
Immediately call a POISON CENTER or doctor
Take off immediately all contaminated clothing and wash it before reuse
Inhalation
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
Ingestion
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage
Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Other information
Unknown acute toxicity 95.63 % of the mixture consists of ingredient(s) of unknown toxicity
82.07 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
95.63 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
95.63 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
95.63 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
95.63 % 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)
Potassium acesulfame	55589-62-3	12.12	-	-
Nicotine polacrilex	96055-45-7	2.38	-	-
Sodium carbonate	497-19-8	1.44	-	-

4. FIRST AID MEASURES

Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

Inhalation If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.

Skin contact Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

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

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. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. 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.

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. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak.

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. Take off contaminated clothing and wash before reuse. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

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. Impervious gloves.

Skin and body protection Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid
Appearance	No information available
Odor	Sweet
Color	No information available
Odor Threshold	Not applicable

Property	**Values**	**Remarks Method**
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		None known
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	Slightly soluble	
Solubility(ies)	No data available	None known
Partition coefficient: n-octanol/water	0	
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 Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components).

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

Skin contact Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components).

Ingestion Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing.

Numerical measures of toxicity

Acute Toxicity

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

ATEmix (oral)	35.90 mg/kg
ATEmix (dermal)	9.18 mg/kg
ATEmix (inhalation-gas)	183.63 ppm

ATEmix (inhalation-dust/mist) 0.09 mg/L
ATEmix (inhalation-vapor) 0.92 mg/L

Unknown acute toxicity 95.63 % of the mixture consists of ingredient(s) of unknown toxicity
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Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium carbonate	= 4090 mg/kg (Rat)	-	-

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 No information available.

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	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Potassium acesulfame	-	96h LC50: 1800 - 2500 mg/L (Danio rerio)	-	-
Sodium carbonate	120h EC50: = 242 mg/L (Nitzschia)	96h LC50: 310 - 1220 mg/L (Pimephales promelas) 96h LC50: = 300 mg/L (Lepomis macrochirus)	-	48h EC50: = 265 mg/L

Persistence and Degradability No information available.

Bioaccumulation There is no data for this product.

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

14. TRANSPORT INFORMATION

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

TDG Not regulated

MEX Not regulated

ICAO Not regulated

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

IMDG/IMO Not regulated
Hazard Class N/A

RID Not regulated

ADR Not regulated

ADN Not regulated

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	2.38	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 does not contain any Proposition 65 chemicals.

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	

16. OTHER INFORMATION

NFPA	**Health hazards** 4	**Flammability** 0	**Instability** 0	**Physical and Chemical Properties** -
HMIS	**Health hazards** 4	**Flammability** 0	**Physical hazards** 0	**Personal Protection** X

Prepared By

Product Stewardship
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Latham, NY 12110
1-800-572-6501

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Revision Note No information available

Disclaimer

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End of Safety Data Sheet