SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: NICOTINE MINI LOZENGE MINT (2mg and 4mg)
Synonyms: 734, E3P, 957, HY1

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – Stop Smoking Aid

2. HAZARD(S) IDENTIFICATION

Classification HCS 2024:

Physical	Health
Not hazardous	Not hazardous

Label Elements

Not hazardous in accordance with the GHS and OSHA HCS 2024.

Other Hazards: None known

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Nicotine Polacrilex 15%	96055-45-7	5.6% or 11.2%
Mannitol	69-65-8	Proprietary
Sodium Alginate	9005-38-3	Proprietary
Mint Flavor	Mixture	Proprietary
Sodium Carbonate	497-19-8	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Calcium Polycarbophil	25987-55-7	Proprietary
Xanthan Gum	11138-66-2	Proprietary
Potassium Bicarbonate	298-14-6	Proprietary
Sucralose	56038-13-2	Proprietary
Acesulfame Potassium	55589-62-3	Proprietary
Potassium carbonate	584-08-7	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: In the case of contact with crushed or broken lozenges, remove contaminated clothing. Wash skin with soap and water. If irritation or other symptoms develop, get immediate medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for overdosage.

Most important symptoms/effects, acute and delayed: May cause eye irritation. Swallowing amounts above the recommended dosage or widespread skin contact may cause nicotine overdose with symptoms of nervous system stimulation, nausea, vomiting, dizziness, diarrhea, weakness or rapid heartbeat

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for ingestion above the recommended dosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Lozenges are not a fire hazard but may burn under fire conditions.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If lozenges are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to lozenges (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Nicotine Polacrilex (as nicotine)	0.5 mg/m3 skin TWA OSHA PEL and ACGIH TLV 10 ug/m3 TWA, 20 ug/m3 STEL skin (Perrigo OEB3)
Mannitol	None Established
Sodium Alginate	None Established
Mint Flavor	None Established
Sodium Carbonate	None Established
Magnesium Stearate	10 mg/m3 TWA ACGIH TLV
Calcium Polycarbophil	10 ug/m3 TWA (Perrigo OEL)
Xanthan Gum (as PNOC)	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Potassium Bicarbonate	None Established
Sucralose	None Established
Acesulfame Potassium	None Established
Potassium Carbonate	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: Impervious gloves recommended for handling damaged or large amounts of lozenges.
Eye protection: Chemical safety goggles recommended for handling damaged lozenges.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid (lozenge)	**Color:** Off-white
Odor: Sweet, mint	**pH:** Not applicable
Melting point/freezing point: Not applicable	**Boiling Point:** Not applicable
Flash point: Not applicable	**Particle Characteristics:** Not applicable
Flammability: Not flammable	**VOC:** Not applicable
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not applicable	**Relative vapor density:** Not applicable
Relative density: Not available	**Solubility(ies):** Soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Kinematic Viscosity:** Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: No adverse effects.
Ingestion: Swallowing amounts above the recommended dosage may cause nicotine overdose with symptoms of nervous system stimulation, nausea, vomiting, dizziness, diarrhea, weakness or rapid heartbeat
Skin contact: Contact may cause slight irritation.
Eye contact: Contact may cause slight irritation with redness and tearing.
Chronic Effects: None known.
Sensitization: Components are not known to be sensitizers. \
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.
Reproductive Toxicity: Nicotine may cause adverse effects on development and fertility based on animal studies.
Carcinogenicity: None of the components is listed as a carcinogen by IARC, NTP, OSHA or ACGIH.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >4000 mg/kg. Acute Dermal Toxicity Estimate (ATE) calculated: >5,000 mg/kg.
Nicotine Polacrilex (15% nicotine): Oral rat LD50 >300 mg/kg; Dermal rabbit LD50 >1000 mg/kg.
Calcium Polycarbophil: Oral rat LD50 >2500 mg/kg; Dermal rabbit LD50 >3000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: If desorbed from the resin nicotine is toxic to aquatic organisms. Nicotine Polacrilex is classified as Aquatic Chronic Toxicity Category 2 based on 15% nicotine content. 2.5 - <25% Nicotine Polacrilex results in a classification of Chronic Aquatic Toxicity Category 3. Nicotine Toxicity: EC50 daphnia magna 0.242 mg/L/48 hr.; LC50 Oncorhynchus mykiss 4 mg/L/96 hr.
Persistence and degradability: Nicotine is slowly degradable**.**
Bioaccumulative potential: Nicotine has a low potential to bioaccumulate.
Mobility in soil: Although desorption from the resin would occur slowly, the estimated Koc of nicotine (100) indicates high soil mobility.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk according to IMO instruments: Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product has an RQ of 1786 lbs based on the RQ for nicotine and salts of 100 lbs. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
Nicotine and salts 5.6% - 11.2%

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1 Flammability = 1 Physical Hazard = 0

SDS Revision History: Update Perrigo OEL (Section 8), changes for HCS 2024.
Date of preparation: June 7, 2025

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).