SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Nitroglycerin Lingual Spray, 400 mcg
Synonym: 8A5

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 for treatment of angina pectoris.
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Flammable Liquid Category 3	Not Hazardous

Label Elements:
WARNING!



Hazard statement(s)

Flammable liquid and vapor

Precautionary statement(s)
Keep away from heat, sparks, open flames and hot surfaces. No smoking.
Keep container tightly closed.
Wear protective gloves and eye protection.

Precautionary statement(s)

IF on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
In case of fire: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam to extinguish.
Store in a well-ventilated place. Keep cool.
Dispose of container and contents in compliance with all national and local regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Nitroglycerin	55-63-0	<1%
Ethanol	64-17-5	<25%
Medium Chain Triglycerides	73398-61-5	Proprietary
Medium Chain Partial Glycerides	91744-32-0	Proprietary
Peppermint Oil	8006-90-4	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: Wash skin thoroughly with soap and water. If symptoms of exposure or irritation develops and persists, get medical attention. Remove and contaminated clothing and launder it before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for several minutes. Remove contact lenses, if present and easy to do after 5 minutes of flushing, then continue flushing. Get medical attention if irritation persists.
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.

Most important symptoms/effects, acute and delayed: May cause eye irritation. Skin absorption, ingestion or inhalation may cause headache (sometimes severe and persistent) and a drop in blood pressure. Symptoms include flushing, dizziness, and weakness. In some cases (nausea, vomiting, weakness, restlessness, pallor, perspiration and collapse have occurred.

Indication of immediate medical attention and special treatment, if necessary: For unintended exposure, seek medical advice if any symptoms develop.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water fog or spray, carbon dioxide, dry chemical or alcohol-resistant foam.

Specific hazards arising from the chemical: Flammable liquid and vapor. Vapors are heavier than air and can flow to remote ignition sources and flash back. Vapors may be explosive in confined areas. Vapors will collect in low areas. Vapors may be ignited by static sparks. Flames may be invisible in daylight.

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. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. Eliminate all ignition sources and ventilate the area with explosion-proof equipment.

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: Stop spill at the source if it is safe to do so. Absorb with an inert material. Use non-sparking tools and equipment. Collect into a suitable container for disposal. Clean spill area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid eye contact. Avoid breathing vapors and spray. Use only with adequate ventilation. Wash thoroughly after handling. Remove contaminated clothing and launder before re-use. Keep

product away from heat, sparks and all other sources of ignition. Do not smoke while using. Do not leave the container in direct sunlight.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging. Protect containers from physical damage. Store in a cool area. Keep away from excessive heat and open flames. Store out of direct sunlight. Store away from oxidizers.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Nitroglycerin	Perrigo OEB2 (100-1000 ug/m3) 0.05 ppm TWA skin ACGIH TLV 0.2 ppm Ceiling skin OSHA PEL
Ethanol	1000 ppm TWA OSHA PEL 1000 ppm STEL ACGIH TLV
Medium Chain Triglycerides	None Established
Medium Chain Partial Glycerides	None Established
Peppermint Oil	500 ug/m3 TWA Perrigo OEL

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels. Use explosion-proof equipment where required.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are exceeded or irritation is experienced, a NIOSH approved organic vapor or supplied air 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.
Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Colorless to yellow liquid
Odor: Menthol odor

Odor threshold: Not determined	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: 42.8°C (109°F)	**Evaporation rate:** Not determined
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: 3% (ethanol)	**UEL:** 19% (ethanol)
Vapor pressure: 59.3 mmHg @ 25°C (ethanol)	**Vapor density:** 1.59 (ethanol)
Relative density: Not determined	**Solubility(ies):** Soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not available
Decomposition temperature: Not available	**Viscosity:** Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: Reaction with strong oxidizers will generate heat and cause fire.

Conditions to avoid: Avoid heat, sparks, flames, and all other sources of ignition.
Incompatible materials: Avoid oxidizing agents, acids and bases.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of vapors or spray may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.
Ingestion: Nitrate overdosage may result in: severe hypotension, persistent throbbing headache, vertigo, palpitation, visual disturbance, flushing and perspiring skin (later becoming cold and cyanotic), nausea and vomiting (possibly with colic and even bloody diarrhea), syncope (especially in the upright posture), methemoglobinemia with cyanosis and anorexia, initial hyperpnea, dyspnea and slow breathing, slow pulse (dicrotic and intermittent), heart block, increased intracranial pressure with cerebral symptoms of confusion and moderate fever, paralysis and coma followed by clonic convulsions, and possibly death due to circulatory collapse.
Skin contact: Nitroglycerin is readily absorbed through the skin with symptoms as described under ingestion.
Eye contact: Contact may cause irritation with redness, pain and tearing.
Chronic Effects: Corticosteroids suppress the endocrine system. Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.
Sensitization: Components are not known to be sensitizers.
Germ Cell Mutagenicity: Nitroglycerin was weakly mutagenic in Ames tests performed in two different laboratories. Nevertheless, there was no evidence of mutagenicity in an *in vivo* dominant lethal assay with male rats treated with doses up to about 363 mg/kg/day, p.o., or in *in vitro* cytogenic tests in rat and dog tissues.
Reproductive Toxicity: In a three-generation reproduction study, rats received dietary nitroglycerin at doses up to about 434 mg/kg/day for six months prior to mating of the F0 generation with treatment continuing through successive F1 and F2 generations. The high dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F0 generation was seen. Infertility noted in subsequent generations, however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high-dose males. In this three-generation study there was no clear evidence of teratogenicity. Teratology studies in rats and rabbits, however, were conducted with topically applied nitroglycerin ointment at doses up to 80 mg/kg/day and 240 mg/kg/day, respectively. No toxic effects on dams or fetuses were seen at any dose tested.
Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. Rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At high dose, the incidences of hepatocellular carcinomas in both sexes were 52% vs. 0% in controls, and incidences of testicular tumors were 52% vs. 8% in controls. Lifetime dietary administration of up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice. Ingestion of alcoholic beverages is known to cause cancer in humans (IARC group 1).

Acute Toxicity Values: Acute Toxicity Estimate (ATE) calculated: Oral: >10,000 mg/kg; Dermal >10,000 mg/kg
Nitroglycerin: LD50 oral rat 105 mg/kg; LD50 dermal rabbit >280 mg/kg
Ethanol: LD50 oral rat 7060 mg/kg; LC50 inhalation rat 20000 ppm/10 hr.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available.
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
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	UN1170	Ethanol Solution	3	III	No
TDG	UN1170	Ethanol Solution	3	III	No
IMDG	UN1170	Ethanol Solution	3	III	No
IATA	UN1170	Ethanol Solution	3	III	No

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): 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 a RQ of 1000 lbs based on the RQ for nitroglycerin of 10 lbs. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Fire Hazard

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
Nitroglycerin below deminimus concentration

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.
Canadian WHMIS Classification: Drugs are exempt from WHMIS
This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 2 Instability = 0
HMIS Rating: Health = 1 Flammability = 2 Physical Hazard = 0

SDS Revision History: Convert to Hazcom 2012 format and content.
Date of preparation: August 21, 2015

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).