

Product Name:  
**NITROLINGUAL PUMPSPRAY / NITROLINGUAL N SPRAY**

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## MATERIAL SAFETY DATA SHEET

### 1. PRODUCT AND COMPANY IDENTIFICATION

NITROLINGUAL PUMPSPRAY / NITROLINGUAL-SPRAY N

Horizon  
Pharmaceutical Corporation  
660 Hembree Parkway,  
Suite 106  
Roswell, GA 30076  
United States of America

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Component</u>	<u>Cas-No.</u>	<u>Exposure limits</u>	<u>% by Wt</u>
Nitroglycerin	55-63-0	0,05 ppm ACGIH 0,2 ppm OSHA (skin notation)	0,8

Plus inactive ingredients:

Medium chained partial glycerides, medium chained triglycerides (Cas-No. 73398-61-5 and 91744-56-8), dehydrated ethanol (Cas-No. 64-17-5) peppermint oil (Cas-No. 8006-90-4).

### 3. HAZARDS IDENTIFICATION

#### Emergency Overview

Nitroglycerin Spray in transparent glas bottle. If several containers rupture, nitroglycerin may migrate and may burn if sufficient heat is present. Concentrated nitroglycerin, even in small amounts, is a dangerous explosive hazard.

In the event of a fire, evacuate personnel not involved in fire fighting. Keep all persons away until the fire and smoldering material are extinguished.

#### Potential Health Hazards

##### Nitroglycerin:

Eye: Irritant

Skin: Nitroglycerin is absorbed through the skin and mucous membranes effects similar to inhalation.

Ingestion: Product usage involves spray to underside of tongue, but not swallowing.

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Overdosage may result in a severe drop in blood pressure, persistent throbbing headache, dizziness, heart palpitation, disturbed vision, flushing and perspiring skin, nausea and vomiting, and more serious effects including death due to circulatory collapse.

Because of the rapid metabolism of nitroglycerin in the liver (first pass effect), there is only a bioavailability of 1 % after oral application and ingestion.

Inhalation: Same effects as by absorption through skin and mucous membranes (ingestion).

Chronic effects: Tolerance occurs in industrial workers continuously exposed to nitroglycerin. Abrupt withdrawal from exposure has caused chest pain, heart attack, and even sudden death.

#### 4. FIRST AID MEASURES

Eyes: Flush with water for 15 minutes. Obtain medical attention for irritation.

Skin: Immediately wash with soap and water. Obtain medical attention for any adverse effects.

Ingestion: Obtain medical attention for any adverse effects.

Inhalation: Obtain medical attention for any adverse effects. Administer oxygen and artificial ventilation necessary.

#### 5. FIRE FIGHTING MEASURES

Flammable Properties:

Flash Point: 14°C

Flammable Limits:

Lower flammable limit: no data

Upper flammable limit: no data

Autoignition Temperature: 425 °C (Ethanol)

Hazardous Combustion Products: see Emergency Overview

Extinguishing Media: Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

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Firefighting Instrucions: See Emergency Overview. Firefighting in confined spaces requires full protective gear and supplied air respiratory protection. Caution: Containers may burst with fire exposure.

## 6. ACCIDENTIAL RELEASE MEASURES

Small Spill: Ventilate area. Wear impervious gloves. Absorb on suitable medium and place in closed container for disposal. Wash area.

Large Spill: See Emergency Overview. Evacuate area. Wear supplied air respiratory protection, impervious gloves and other skin protection to prevent contact. Ventilate area. Absorb on a suitable medium and place in close container for disposal. Wash area.

## 7. HANDLING AND STORAGE

Handling: Avoid contact with this material. If contact is likely, wear nitroglycerin impervious protective gloves and clothing and supply respiratory equipment.

Storage: Store at room temperature.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Manufacturing and packaging operations should be designed to offer no significant exposure to this material.

Respiratory Protection: Once packaged in metered dose vial, non required except for accidental release.

Skin Protection: Once packaged in metered dose vial, none required except for accidental release. Must be nitroglycerin impervious material.

Eye Protection: If contact is likely, wear safety goggles or faceshield.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	78 °C (1013hPa) for ethanol
Melting Point:	no data
Vapor Pressure:	59 hPa (20°C9) for ethanol
Vapor Density:	no data
Solubility in Water:	insoluble
Specific Gravity:	0,92 g/ml
pH:	no data
Odor:	no data
Appearance:	clear, slightly yellow liquid in glass bottle (Pumpspray)

## 10. STABILITY AND REACTIVITY

Chemical Stability:	Product has a shelf life
Incompatibility:	Heat, strong oxidizers
Hazardous Decomposition Products:	no data
Hazardous Polymerization:	will not occur

## 11. TOXICOLOGICAL INFORMATION

For nitroglycerin, oral dose lethal to 50 % of test mice was 115 mg/kg of body weight.

## 12. ECOLOGICAL INFORMATION

No data

## 13. DISPOSAL CONSIDERATIONS

No data

## 14. TRANSPORT INFORMATION

Proper Shipping Name / Description:

**Nitroglycerin solution in alcohol**

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**14.1 Land transport (ADR)**

Class: 3  
Number / Letter: 7b  
UN No.: 1204

**14.2 Marine Shipping, GGV Sea**

IMO-Class: 3.2  
EMS: 3/06  
Un No. 1204  
Packing Group II  
MFAAG Table No. 235  
Label: Flamm. Liquid

**14.3 Air Transport**


Class: 3  
Hazard Label: Flamm. Liquid  
Packing Group II  
Packing instructions: 306  
UN No.: 1204

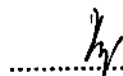
**15. REGULATORY INFORMATION**

No additional data

**16. OTHER INFORMATION**

Report to the manufacturer any allegations of adverse effects related to handling or accidental contact with this material.

  
16.12.99  
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Dr. Schmidt

  
16.12.99  
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Dr. BlöB