SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name

Nitrolingual® Pumpspray, buffered

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses of the substance or mixture

Medicinal product for use on humans

1.3 Details of the supplier of the safety data sheet

Address

G. Pohl-Boskamp GmbH & Co. KG
Kieler Str. 11
25551 Hohenlockstedt
GERMANY

Telephone no. +49 (0) 4826 59-0
Fax no. +49 (0) 4826 59-109

Information provided by / telephone
+49 (0) 4826 / 59-0

Advice on Safety Data Sheet
info@pohl-boskamp.de

1.4 Emergency telephone

+49 (0) 4826 / 59-0

SECTION 2: Hazards identification

2.1 Immediate hazards

General

WARNING

Flammable liquid and vapor.

May cause skin irritation

2.2 Potential Health Effects

Cancer

None of the components present in this material at concentrations equal or greater than 0.1% is listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

SECTION 3: Composition / information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

Mixture

Hazardous ingredients

ETHANOL

CAS no. 64-17-5
Concentration > 10,00 < 30,00 %-b.w.

GLYCERIDES, C8-10 mono-, di- and tri

CAS no. 91744-32-0
Concentration > 1,00 < 5,00 %-b.w.

GLYCEROL TRINITRATE

CAS no. 55-63-0
Concentration > 0,50 < 1,00 %-b.w.
3.3 Other information
The information given in this material safety data sheet refers to and is based on the chemical safety legislation. The pharmaceutical labelling complies with the pharmaceutical legislation.

SECTION 4: First aid measures

4.1 Description of first aid measures
General information
In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing. If the patient is likely to become unconscious, place and transport in stable sideways position.

After inhalation
Remove affected person from the immediate area. Ensure supply of fresh air. Irregular breathing/no breathing: artificial respiration. Summon a doctor immediately.

After skin contact
Wash off immediately with soap and water.

After eye contact
Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion
Do not induce vomiting. Summon a doctor immediately. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
No data available.

4.3 Indication of any immediate medical attention and special treatment needed
No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media
Alcohol-resistant foam; Extinguishing powder; Carbon dioxide

Unsuitable extinguishing media
Full water jet

5.2 Special hazards arising from the substance or mixture
In the event of fire, the following can be released: Carbon dioxide (CO2); Carbon monoxide (CO)

5.3 Advice for firefighters
Cool endangered containers with water spray jet. Suppress gases/vapours/mists with water spray jet. As in any fire, wear self-contained breathing apparatus pressure - demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
For non-emergency personnel
Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Do not inhale vapours. Keep away sources of ignition.

For emergency responders
No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions
Do not discharge into the drains/surface waters/groundwater. Do not discharge into the subsoil/soil.

6.3 Methods and material for containment and cleaning up
Take up with absorbent material (e.g., sand, diatomaceous earth, universal binder). Send in suitable containers for recovery or disposal.
6.4 Reference to other sections
No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling
Ensure adequate ventilation. If workplace exposure limits are exceeded, respiratory protection approved for this particular job must be worn.

General protective and hygiene measures
Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Do not inhale vapours. Wash hands before breaks and after work.

Advice on protection against fire and explosion
Vapours can form an explosive mixture with air. Keep away from sources of heat and ignition.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions
Keep container tightly closed and dry in a cool, well-ventilated place. Protect from heat and direct sunlight.

Requirements for storage rooms and vessels
Always keep in containers of same material as the original one.

Hints on storage assembly
None known

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Occupational exposure limit values

<table>
<thead>
<tr>
<th>No</th>
<th>Substance name</th>
<th>CAS no.</th>
<th>EC no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ETHANOL</td>
<td>64-17-5</td>
<td>200-578-6</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethanol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>1000</td>
<td>ml/m³</td>
</tr>
<tr>
<td></td>
<td>LIMITS FOR AIR CONTAMINANTS (OSHA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethyl alcohol</td>
<td>1900</td>
<td>mg/m³</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>1000</td>
<td>ml/m³</td>
</tr>
<tr>
<td>2</td>
<td>GLYCEROL TRINITRATE</td>
<td>55-63-0</td>
<td>200-240-8</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nitroglycerin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.05</td>
<td>ml/m³</td>
</tr>
<tr>
<td></td>
<td>LIMITS FOR AIR CONTAMINANTS (OSHA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nitroglycerin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ceiling Limit</td>
<td>2</td>
<td>mg/m³</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Appropriate engineering controls
No data available.

Personal protective equipment

Respiratory protection
Respiratory protection is required under exceptional conditions such as unintentional release of chemicals, exceeding of threshold values for air.

Eye / face protection
Use chemical splash goggles and face shield (ANSI Z87.1 or approved equivalent).
**Material Safety Data Sheet**

**Trade name:** Nitrolingual® Pumpspray, buffered

**Current version:** 1.0.0, issued: 26.04.2012

**Region:** USA

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form/Color</strong></td>
<td>liquid</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Not data available</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not data available</td>
</tr>
<tr>
<td><strong>pH value</strong></td>
<td>Not data available</td>
</tr>
<tr>
<td><strong>Boiling point / boiling range</strong></td>
<td>172.4 °F, 1013 hPa</td>
</tr>
<tr>
<td><strong>Melting point / melting range</strong></td>
<td>Not data available</td>
</tr>
<tr>
<td><strong>Decomposition point / decomposition range</strong></td>
<td>Not data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>57.2 °F</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>797 °F</td>
</tr>
</tbody>
</table>
### Oxidising properties
No data available.

### Explosive properties
No data available.

### Flammability (solid, gas)
No data available.

### Lower flammability or explosive limits
No data available.

### Upper flammability or explosive limits
No data available.

### Vapor pressure
No data available.

### Vapour density
No data available.

### Evaporation rate
No data available.

### Relative density
No data available.

### Density
<table>
<thead>
<tr>
<th>Value</th>
<th>Reference temperature</th>
<th>7.67 lbs/gallon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>68 °F</td>
</tr>
</tbody>
</table>

### Solubility in water
Remarks: insoluble.

### Solubility(ies)
No data available.

### Partition coefficient: n-octanol/water
No data available.

### Viscosity
No data available.

#### 9.2 Other information

### Other information
No data available.

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
No data available.

#### 10.2 Chemical stability
No data available.

#### 10.3 Possibility of hazardous reactions
No data available.

#### 10.4 Conditions to avoid
Heat.

#### 10.5 Incompatible materials
None known.

#### 10.6 Hazardous decomposition products
No hazardous decomposition products known.
### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>105 - 884</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Species</td>
<td>rat</td>
<td></td>
</tr>
<tr>
<td>Reference substance</td>
<td>glycerol trinitrate</td>
<td></td>
</tr>
<tr>
<td>Source</td>
<td>Literature value</td>
<td></td>
</tr>
</tbody>
</table>

| **Acute dermal toxicity** |          |          |
| LD50                     | 1607     | mg/l     |
| Species                  | rabbit   |          |
| Reference substance      | glycerol trinitrate | |
| Source                   | Literature value | |

| **Acute inhalational toxicity** |          |          |
| No data available | | |

| **Skin corrosion/irritation** |          |          |
| No data available | | |

| **Serious eye damage/irritation** |          |          |
| No data available | | |

| **Respiratory or skin sensitisation** |          |          |
| No data available | | |

| **Germ cell mutagenicity** |          |          |
| No data available | | |

| **Reproduction toxicity** |          |          |
| No data available | | |

| **Carcinogenicity** |          |          |
| No data available | | |

| **STOT-single exposure** |          |          |
| No data available | | |

| **STOT-repeated exposure** |          |          |
| No data available | | |

| **Aspiration hazard** |          |          |
| No data available | | |

| **Delayed and immediate effects as well as chronic effects from short and long-term exposure** |          |          |
| Inhalation of vapours may lead to headache, drowsiness and dizziness. Inhalations of vapours in higher concentration may lead to irritation of eyes, nose and respiratory tract. Repeated and prolonged skin contact may lead to defatting and irritation of the skin. Eye contact with the product may lead to irritation. Substance effects hypotensive. | | |
SECTION 12: Ecological information

12.1 Toxicity

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish toxicity</td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Daphnia toxicity</td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Algae toxicity</td>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Bacteria toxicity</td>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability
No data available.

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
No data available.

12.6 Other adverse effects
No data available.

12.7 Other information

<table>
<thead>
<tr>
<th>Other information</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Do not discharge product unmonitored into the environment.</td>
</tr>
</tbody>
</table>

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product
Dispose in accordance with federal, state and local regulations.

SECTION 14: Transport information

14.1 US DOT

<table>
<thead>
<tr>
<th>DOT Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
<td>3</td>
</tr>
<tr>
<td>Packaging group</td>
<td>II</td>
</tr>
<tr>
<td>Label</td>
<td>3</td>
</tr>
<tr>
<td>UN/NA number</td>
<td>UN1204</td>
</tr>
<tr>
<td>Technical name</td>
<td>Nitroglycerin solution in alcohol</td>
</tr>
</tbody>
</table>

14.2 Transport IMDG

<table>
<thead>
<tr>
<th>IMDG Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
<td>3</td>
</tr>
<tr>
<td>Packaging group</td>
<td>II</td>
</tr>
<tr>
<td>UN number</td>
<td>UN1204</td>
</tr>
<tr>
<td>Proper shipping name</td>
<td>NITROGLYCERIN SOLUTION IN ALCOHOL</td>
</tr>
<tr>
<td>EmS</td>
<td>F-E+S-D</td>
</tr>
<tr>
<td>Label</td>
<td>3</td>
</tr>
</tbody>
</table>

14.3 Transport ICAO-TI / IATA

<table>
<thead>
<tr>
<th>IATA Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class</td>
<td>3</td>
</tr>
<tr>
<td>Packaging group</td>
<td>II</td>
</tr>
<tr>
<td>UN number</td>
<td>UN1204</td>
</tr>
<tr>
<td>Proper shipping name</td>
<td>Nitroglycerin solution in alcohol</td>
</tr>
<tr>
<td>Label</td>
<td>3</td>
</tr>
</tbody>
</table>
14.4 Other information
No data available.

SECTION 15: Regulatory information

US FEDERAL REGULATIONS

Toxic Substances Control Act (TSCA)
All of the components of this product are either listed on the TSCA Inventory or are not subject to the notification requirements (exempt).

Clean Water Act (CWA)
None of the ingredients is listed.

OSHA
CAS no. 64-17-5; 91744-32-0; 55-63-0

SARA Section 302 (RQ):
Following ingredients are listed:
CAS no. 55-63-0

SARA 311/312
Hazard category Fire, Health Hazards.

SARA Section 313
Following ingredients are listed:
CAS no. 55-63-0

HAPS Hazardous Air Pollutants
None of the ingredients is listed.

Volatile organic compounds (VOC)
Value 7.63 pound / gallon

HMIS Classification
Health 1
Flammability 3
Physical Hazard 1
Personal Protection B

NFPA Rating
Health 1
Flammability 3
Physical Hazard 1

CARCINOGENICITY

IARC
None of the ingredients is listed in group 1, 2A or 2B.

US STATE REGULATIONS

New Jersey Worker and Community Right to Know Act.
Following ingredients are listed:
CAS no. 64-17-5; 55-63-0

California Proposition 65.
None of the ingredients is listed.

Pennsylvania HAZARDOUS SUBSTANCE LIST
Following ingredients are listed:
CAS no. 64-17-5; 55-63-0
SECTION 16: Other information

Other information
Abbreviations:
ACGIH American Conference of Governmental Hygienics
CAS Chemical Abstracts Service
HAPS Hazardous Air Pollutants
HMIS Hazardous Material Identification System
IARC International Agency for Research on Cancer
IDLH Immediate Dangerous to Life and Health
LEL Lower Explosion Limit
NTP National Toxicology Program
OEL Occupational Exposure Limit
OSHA Occupational Safety and Health Administration
PEL Permissible Exposure Limit
PPE Personal Protection Equipment
SARA Superfund Amendments and Reauthorization Act
STEL Short-Term Exposure Level (15 minutes)
TWA Time-Weighted Average (8 hours)
UEL Upper Explosion Limit
VOC Volatile Organic Compounds
WEEL Workplace Environmental Exposure Level
Canadian Abbreviations:
DSL Domestic Substance List
NDSSL Non-Domestic Substance List
NPRI National Pollutant Release Inventory
TDG Transport Dangerous Goods Directorate
WHMIS Workplace Hazardous Materials Information System

Department issuing safety data sheet
UMCO Umwelt Consult GmbH
Georg-Wilhelm-Str. 183, D-21107 Hamburg
Tel.: +49 40 / 79 02 36 300   Fax: +49 40 / 79 02 36 357   e-mail: umco@umco.de

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.