



Trade name: Nitrolingual Pumpspray

Date of issue: 2009/11/20

1. Identification of the substance/preparation and of the company/undertaking

Product details

Trade name

Nitrolingual Pumpspray

Identification of the manufacturer / supplier / distributor address

G. Pohl-Boskamp GmbH & Co. KG

Kieler Str. 11

D-25551 Hohenlockstedt

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

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

Sciele Pharma, Inc. (Headquarter)

Five Concourse Parkway

ATLANTA, GA 30328

UNITED STATES OF AMERICA

Product and Medical Information:

1-800-849-9707x 1454

Emergency telephone number

+49 (0) 4826 / 59-0

Use

Medicines for use to humans

2. Hazards identification

Classified as Hazardous according to EC and the criteria of NOHSC:1008(2004)

Hazard symbols

F Highly flammable

R phrases

11 Highly flammable

3. Composition / information on ingredients

Chemical characterization

Mixture (preparation)

Hazardous ingredients

ETHANOL

CAS No. 64-17-5

EC No. (ELINCS) 200-578-6

Concentration > 10 < 30 %-b.w.

Classification R11



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GLYCEROL TRINITRATE

CAS No.	55-63-0		
EC No. (ELINCS)	200-240-8		
Concentration	> 0,5	< 1	%-b.w.
Classification	R10		
	T+;R26/27/28		
	N; R51/53		
	R33		

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

CAS No.	91744-32-0		
EC No. (ELINCS)	294-594-0		
Concentration	> 1	< 5	%-b.w.
Classification	Xi; R38		

INGREDIENTS NOT CLASSIFIED AS HAZARDOUS

Concentration	> 60	< 90	%-b.w.
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Other Information

The pharmaceutical labelling complies with the pharmaceutical legislation.

4. 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.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air. In case of breathing difficulties give oxygen. Seek medical advice.

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

Seek medical advice immediately. Never give anything by mouth to an unconscious person.



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5. Fire-fighting measures

Suitable extinguishing media

Alcohol-resistant foam; Extinguishing powder; Water spray jet; Carbon dioxide

Extinguishing media that must not be used for safety reasons

Full water jet

Special protective equipment for firefighting

As in any fire, wear self-contained breathing apparatus pressure – demand and full protective gear.

Other information (chapter 5.)

Cool endangered containers with water spray jet. Suppress gases/vapours/mists with water spray jet.

6. Accidental release measures

Personal precautions

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Ensure adequate ventilation. Keep away sources of ignition.

Environmental precautions

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

Methods for cleaning up/taking up

Pick up with absorbent material (e.g. sand, sawdust, general-purpose binder, kieselguhr). Send in suitable containers for recovery or disposal.

7. Handling and storage

Handling

Advice on safe handling

Ensure adequate ventilation.

Advice on protection against fire and explosion

Vapours can form an explosive mixture with air. Take precautionary measures against static charges. Keep away from sources of ignition.

Storage

Requirements for storage rooms and vessels

Always keep in containers of same material as the original one.

Further information on storage conditions

Keep container tightly closed in a cool, well-ventilated place. Recommended storage temperature: room temperature.



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8. Exposure controls / personal protection

Additional hints on technical system design.

Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain solvent vapours concentration below the OEL, suitable respiratory protection must be worn.

National occupational exposure limits according to NOHSC

ETHANOL

TWA	1000 ppm	1880 mg/m ³
Ref	H	

NITROGLYCERIN (NG)

TWA	0,05 ppm	0,46 mg/m ³
Ref	H	Notices Sk

Personal protective equipment

Respiratory protection

If workers are exposed to concentrations above the exposure limit they must use appropriate, certified respirators. Use half-mask model with cartridge or air-fed, IOSH/MSHA approved.

Hand protection

Adhere to the professional organisation rule "Use of protective gloves". Appropriate chemicals resistant glove tested in compliance with AS 2161.

Before use, the protective glove should be tested in any case for its specific workstation suitability (i.e. mechanical resistance, product compatibility and antistatic properties).

Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.

Protective gloves shall be replaced immediately when physically damaged or worn.

Preventive hand protection (skin protection cream) recommended. Wash immediately contaminated skin. Design operations thus to avoid permanent use of protective gloves.

Eye protection

Use chemical splash goggles and face shield.

Skin protection

Chemistry-usual work clothes.

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. Do not inhale dust/fumes/aerosols. Wash hands before breaks and after work.



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9. Physical and chemical properties

General information

Form	liquid
Colour	light yellow, clear

Important health, safety and environmental information

Changes in physical state

Type	Boiling point
Value	78° C
Pressure	1013 mbar
Reference substance	Ethanol

Flash point

Value	14° C
Reference substance	Product

Self ignition

Value	425° C
Reference substance	Ethanol

Density

Value	0,92 g/cm ³
Reference temperature	20° C

Solubility in water

Remarks	insoluble
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10. Stability and reactivity

Conditions to avoid

Heat

Hazardous decomposition products

None known.

11. Toxicological Information

Acute toxicity

Acute oral toxicity	
LD50	105-884 mg/kg
Species	rat
Reference substance	Glycerol trinitrate
LD50	115-900 mg/kg
Species	mouse
Reference Substance	Glycerol trinitrate



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Acute dermal toxicity

LD50	> 180 mg/kg
Species	rabbit
Reference substance	Glycerol trinitrate

Experience in practice

Exposure of vapour concentration in excess of the stated OEL`s may result in adverse health effects such as mucous membrane and respiratory system irritation and adverse effects on kidney, liver and central nervous system. Symptoms and signs include headache, dizziness, fatigue muscular weakness, drowsiness and in extreme cases, loss of consciousness.

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. Substance effects hypotensive.

12. Ecological information

General information / ecology

There are no data available on the preparation itself. For components which are dangerous for the environment see section 2. Do not discharge product unmonitored into the environment.

13. Disposal considerations

Product

Ensure that collection, transport, treatment and disposal of waste product, containers and residue complies with all applicable laws and regulations. It is the responsibility of the product user or owner to determine at the time of disposal, whether the product is regulated as a hazardous waste.

Uncleaned packaging

Packaging should be disposed off in agreement with the regional waste disposal company.

14. Transport information

Land transport ADG

Class	3
Packaging group	II
Label	3
UN number	1204
Technical name	Nitroglycerin solution in alcohol



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Marine transport IMDG

Class	3
Packaging group	II
Label	3
UN number	1204
Proper shipping name	Nitroglycerin solution in alcohol
EmS	F-E, S-D

Air transport ICAO/IATA

Class	3
Packaging group	II
Label	3
UN number	1204
Proper shipping name	Nitroglycerin solution in alcohol

15. Regulatory information**Labelling in accordance with EC directives and NOHSC**

The pharmaceutical labelling complies with the pharmaceutical legislation.

Hazard symbols

F Highly flammable

R phrases

11 Highly flammable

S phrases

2 Keep out of the reach of children.
9 Keep container in a well-ventilated place.
51 Use only in well-ventilated areas.

NICNAS Status:

All ingredients used in this product are listed on the AICS

16. Other information

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.