



# SAFETY DATA SHEET

Revision date: 12-Apr-2015

Version: 3.2

Page 1 of 11

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Nitroglycerin Tablets (0.4, and 0.6 mg)

**Trade Name:** NITROSTAT; VERNIES

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product for the treatment of angina pectoris

### Details of the Supplier of the Safety Data Sheet

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
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Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Acute Oral Toxicity: Category 4  
Acute Toxicity - Dusts and Mists: Category 4  
Specific target organ systemic toxicity (repeated exposure): Category 2

#### EU Classification:

EU Indication of danger: Toxic

EU Risk Phrases:

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.  
R33 - Danger of cumulative effects.

### Label Elements

**Signal Word:** Warning

**Hazard Statements:**  
H304 - May be fatal if swallowed and enters airways  
H332 - Harmful if inhaled  
H373 - May cause damage to organs through prolonged or repeated exposure: cardiovascular

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 2 of 11  
Version: 3.2

### Precautionary Statements:

P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P271 - Use only outdoors or in a well-ventilated area  
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing  
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell  
P330 - Rinse mouth  
P314 - Get medical attention/advice if you feel unwell  
P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards  
Australian Hazard Classification  
(NOHSC):

No data available  
Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Nitroglycerin	55-63-0	200-240-8	T+; R26/27/28 E; R3 R33 N; R51-53	Acute Tox. 2 (H300) Acute Tox. 2 (H310) STOT RE 2 (H373) Aquatic Chronic 2 (H411) Acute Tox. 2 (H330) Unst. Expl. (H200)	1.14 - 1.5
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 3 of 11  
Version: 3.2

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Not applicable

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 4 of 11  
Version: 3.2

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Nitroglycerin

ACGIH Threshold Limit Value (TWA)	0.05 ppm
ACGIH - Skin Absorption Designation	Skin - potential significant contribution to overall exposure by the cutaneous route
Australia TWA	0.05 ppm
	0.46 mg/m <sup>3</sup>
Austria OEL - MAKs	0.05 ppm
	0.5 mg/m <sup>3</sup>
Belgium OEL - TWA	0.05 ppm
	0.47 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.5 mg/m <sup>3</sup>
Estonia OEL - TWA	0.03 ppm
	0.3 mg/m <sup>3</sup>
Finland OEL - TWA	0.03 ppm
	0.3 mg/m <sup>3</sup>
France OEL - TWA	0.1 ppm
	1 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.01 ppm
	0.094 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.01 ppm
	0.094 mg/m <sup>3</sup>
Germany - Biological Exposure Limit:	0.5 µg/L
Greece OEL - TWA	0.2 ppm
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	0.5 mg/m <sup>3</sup>
Ireland OEL - TWAs	0.05 ppm
	0.5 mg/m <sup>3</sup>
Japan - OELs - Ceilings	0.05 ppm
	0.46 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.03 ppm
	0.3 mg/m <sup>3</sup>
OSHA - Final PELs - Skin Notations:	prevent or reduce skin absorption

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 5 of 11  
Version: 3.2

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Portugal OEL - TWA	0.05 ppm
Romania OEL - TWA	0.006 ppm
	0.05 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.05 ppm
	0.47 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.05 ppm
	0.47 mg/m <sup>3</sup>
Spain OEL - TWA	0.05 ppm
	0.5 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.03 ppm
	0.3 mg/m <sup>3</sup>
Switzerland OEL -TWAs	0.01 ppm
	0.094 mg/m <sup>3</sup>
UK - Biological Exposure Limit:	15 µmol/mol creatinine
Vietnam OEL - TWAs	0.5 mg/m <sup>3</sup>
<b>Glyceryl monostearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Silicon dioxide, colloidal NF</b>	
Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Switzerland OEL -TWAs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
<b>Calcium stearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Starch, pregelatinized</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 6 of 11  
Version: 3.2

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	White
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Calcium stearate			
No data available			
Glyceryl monostearate			
No data available			
Lactose NF, monohydrate			
No data available			
Nitroglycerin			
No data available			
Silicon dioxide, colloidal NF			
No data available			
Starch, pregelatinized			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 7 of 11  
Version: 3.2

Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

The active ingredient in this formulation is highly explosive. However, based on the amount of active ingredient contained in this product it is not expected to pose an explosion risk.

Polymerization: Will not occur

## 10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	None known

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

General Information:	The information included in this section describes the potential hazards of the individual ingredients.
Short Term:	May be absorbed through the skin and cause systemic effects. Chest pain, acute myocardial infarction, and sudden death have occurred during temporary withdrawal of organic nitrates from industrial workers exposed for long periods of time.
Known Clinical Effects:	Headache, which may be severe and persistent, may occur immediately after use. Vertigo, dizziness, weakness, palpitation, and other manifestations of postural hypotension may develop occasionally. Flushing, drug rash, and exfoliative dermatitis have been reported in patients receiving nitrate therapy.

### Acute Toxicity: (Species, Route, End Point, Dose)

#### Glyceryl monostearate

Mouse IP LD50 200 mg/kg

#### Nitroglycerin

Rat Oral LD50 105 mg/kg

Mouse Oral LD50 115mg/kg

Rabbit Dermal LD50 > 280mg/kg

Rat Dermal LD50 > 29mg/kg

Rat IV LD50 23.2mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 8 of 11  
Version: 3.2

### 11. TOXICOLOGICAL INFORMATION

#### Nitroglycerin

Fertility and Embryonic Development Rat Oral 434 mg/kg/day NOEL Negative  
Embryo / Fetal Development Rabbit Oral 240 mg/kg/day NOEL Not Teratogenic

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Nitroglycerin

Bacterial Mutagenicity (Ames) *Salmonella* Positive  
*In Vivo* Dominant Lethal Assay Rat Negative  
*In Vitro* Cytogenetics Rat Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Nitroglycerin

2 Year(s) Rat Oral 434 mg/kg/day LOEL Liver, Male reproductive system  
2 Year(s) Mouse Oral 1058 mg/kg/day NOEL Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

#### Silicon dioxide, colloidal NF

##### IARC:

Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

#### Toxicity:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Nitroglycerin

*Lepomis macrochirus* (Bluegill Sunfish) LC50 96 Hours 1.91 mg/L  
Midge LC50 48 Hours 20 mg/L

#### Persistence and Degradability:

No data available

#### Bio-accumulative Potential:

No data available

#### Mobility in Soil:

No data available



## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 9 of 11  
Version: 3.2

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Nitroglycerin  
RCRA - P Series Wastes  
Listed

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



#### Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb
California Proposition 65	4.54 kg
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 3
	Schedule 4
	200-240-8

#### Glyceryl monostearate

CERCLA/SARA 313 Emission reporting	Not Listed
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## SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)  
Revision date: 12-Apr-2015

Page 10 of 11  
Version: 3.2

### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	250-705-4
<b>Lactose NF, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed
<b>Silicon dioxide, colloidal NF</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4
<b>Calcium stearate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-472-8
<b>Starch, pregelatinized</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Explosives-Unstable explosives; H200 - Unstable explosive  
Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed  
Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin  
Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled  
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure  
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

E - Explosive  
T+ - Very toxic  
N - Dangerous for the environment

## SAFETY DATA SHEET

**Material Name:** Nitroglycerin Tablets (0.4, and 0.6 mg)  
**Revision date:** 12-Apr-2015

**Page 11 of 11**  
**Version: 3.2**

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R 3 - Extreme risk of explosion by shock, friction, fire or other sources of ignition.

R33 - Danger of cumulative effects.

R26/27/28 - Very toxic by inhalation, in contact with skin and if swallowed.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage.

**Revision date:** 12-Apr-2015

Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**