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
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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
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):

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

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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.
### 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/m³
- **Austria OEL - MAKs:** 0.05 ppm 0.5 mg/m³
- **Belgium OEL - TWA:** 0.05 ppm 0.47 mg/m³
- **Czech Republic OEL - TWA:** 0.5 mg/m³
- **Estonia OEL - TWA:** 0.03 ppm 0.3 mg/m³
- **Finland OEL - TWA:** 0.03 ppm 0.3 mg/m³
- **France OEL - TWA:** 0.1 ppm 1 mg/m³
- **Germany - TRGS 900 - TWAs:** 0.01 ppm 0.094 mg/m³
- **Germany (DFG) - MAK:** 0.01 ppm 0.094 mg/m³
- **Germany - Biological Exposure Limit:** 0.5 µg/L
- **Greece OEL - TWA:** 0.2 ppm 2 mg/m³
- **Hungary OEL - TWA:** 0.5 mg/m³
- **Ireland OEL - TWAs:** 0.05 ppm 0.5 mg/m³
- **Japan - OELs - Ceilings:** 0.05 ppm 0.46 mg/m³
- **Lithuania OEL - TWA:** 0.03 ppm 0.3 mg/m³
- **OSHA - Final PELs - Skin Notations:** prevent or reduce skin absorption
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Control Value 1</th>
<th>Control Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>0.05 ppm</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>0.006 ppm</td>
<td>0.05 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>0.05 ppm</td>
<td>0.47 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>0.05 ppm</td>
<td>0.47 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>0.03 ppm</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>0.01 ppm</td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>UK - Biological Exposure Limit:</td>
<td>15 µmol/mol creatinine</td>
<td></td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Glyceryl monostearate

<table>
<thead>
<tr>
<th>Country</th>
<th>Control Value 1</th>
<th>Control Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Silicon dioxide, colloidal NF

<table>
<thead>
<tr>
<th>Country</th>
<th>Control Value 1</th>
<th>Control Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
<td>0.3 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
<td>2.4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
<td>Listed</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>4 mg/m³</td>
<td>0.3 mg/m³</td>
</tr>
</tbody>
</table>

Calcium stearate

<table>
<thead>
<tr>
<th>Country</th>
<th>Control Value 1</th>
<th>Control Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Starch, pregelatinized

<table>
<thead>
<tr>
<th>Country</th>
<th>Control Value 1</th>
<th>Control Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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:

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
Odor: No data available.
Molecular Formula: Mixture
Color: White
Odor Threshold: No data available.
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
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 115 mg/kg
- Rabbit Dermal LD50 > 280 mg/kg
- Rat Dermal LD50 > 29 mg/kg
- Rat IV LD50 23.2 mg/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))
11. TOXICOLOGICAL INFORMATION

Nitroglycerin
Fertility and Embryonic Development  Rat  Oral 434 mg/kg/day  NOAEL  Negative
Embryo / Fetal Development  Rabbit  Oral  240 mg/kg/day  NOAEL  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  LOAEL  Liver, Male reproductive system
2 Year(s)  Mouse  Oral  1058 mg/kg/day  NOAEL  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
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.

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
RCRA - P Series Wastes
Listed

Glyceryl monostearate
CERCLA/SARA 313 Emission reporting
Not Listed

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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, monohydrate</td>
<td></td>
<td>Not Listed</td>
<td>Present</td>
<td>250-705-4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td></td>
<td>Not Listed</td>
<td>Present</td>
<td>231-545-4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium stearate</td>
<td></td>
<td>Not Listed</td>
<td>Present</td>
<td>216-472-8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td></td>
<td>Not Listed</td>
<td>Present</td>
<td>232-679-6</td>
</tr>
</tbody>
</table>

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

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
Prepared by:  
Product Stewardship Hazard Communication

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