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

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

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
- P312 - Call a POISON CENTRE/doctor/physician if you feel unwell
- P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

Note: No data available

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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>55-63-0</td>
<td>200-240-8</td>
<td>Acute Tox. 2 (H300)</td>
<td>1.14 - 1.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2 (H310)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT RE 2 (H373)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 2 (H411)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2 (H330)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unst. Expl. (H200)</td>
<td></td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>31566-31-1</td>
<td>250-705-4</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>*</td>
</tr>
<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</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>*</td>
</tr>
</tbody>
</table>

**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.**

**Additional Information:**

* Proprietary

For the full text of the 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.
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.

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

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

### Nitroglycerin

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - MAK / TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
<th>Skin Absorption Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>0.05 ppm</td>
<td>0.1 ppm</td>
<td>prevent or reduce skin absorption</td>
</tr>
<tr>
<td>Austria</td>
<td>0.05 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>0.05 ppm</td>
<td>0.47 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic</td>
<td>0.03 ppm</td>
<td>0.3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Estonia</td>
<td>0.03 ppm</td>
<td>0.3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td>0.03 ppm</td>
<td>0.3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>0.1 ppm</td>
<td>1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>0.01 ppm</td>
<td>0.094 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Germany (DFG)</td>
<td>0.01 ppm</td>
<td>0.094 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Greece</td>
<td>0.2 ppm</td>
<td>2 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td>0.05 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>0.05 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>0.05 ppm</td>
<td>0.46 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania</td>
<td>0.03 ppm</td>
<td>0.3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA</td>
<td>0.01 ppm</td>
<td>0.094 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td>0.5 mg/m³</td>
<td>0.5 ppm</td>
<td></td>
</tr>
<tr>
<td>Portugal</td>
<td>0.05 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td>0.006 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td>0.05 ppm</td>
<td>0.47 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovenia</td>
<td>0.05 ppm</td>
<td>0.47 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>0.05 ppm</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>0.03 ppm</td>
<td>0.3 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>0.01 ppm</td>
<td>0.094 mg/m³</td>
<td></td>
</tr>
<tr>
<td>UK - Biological Exposure Limit</td>
<td>15 µmol/mol creatinine</td>
<td>0.5 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Glyceryl monostearate

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - MAK / TWA</th>
<th>ACGIH Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.01 ppm</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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:
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.

Silicon dioxide, colloidal NF

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

Calcium stearate

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

Starch, pregelatinized

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>3 mg/m³</td>
</tr>
</tbody>
</table>

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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) No data available

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
10. STABILITY AND REACTIVITY

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))

Nitroglycerin
Fertility and Embryonic Development  Rat   Oral434 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
11. TOXICOLOGICAL INFORMATION

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.

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

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

Glyceryl monostearate
- 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: 250-705-4

Silicon dioxide, colloidal NF
- 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

Calcium stearate
- 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

Starch, pregelatinized
- 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

Lactose NF, monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: Not Listed

16. OTHER INFORMATION

Text of CLP/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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Revision date: 28-Mar-2016
Prepared by: Product Stewardship Hazard Communication
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