1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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

Trade Name: NITROSTAT; VERNIES
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of angina pectoris

2. HAZARDS IDENTIFICATION

Appearance: Round, white tablet
Signal Word: DANGER

Statement of Hazard:
Toxic if swallowed.
Toxic if inhaled.
Toxic in contact with skin.

Additional Hazard Information:
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.

EU Indication of danger: Toxic

EU Hazard Symbols:

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

Australian Hazard Classification (NOHSC):
2. HAZARDS IDENTIFICATION

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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>55-63-0</td>
<td>200-240-8</td>
<td>E; R3</td>
<td>1.14 - 1.5</td>
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</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>31566-31-1</td>
<td>250-705-4</td>
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<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</td>
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<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
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<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
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<td>*</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

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

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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

General 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 hands and any exposed skin after removal of PPE. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Nitroglycerin

ACGIH Threshold Limit Value (TWA) 0.05 ppm TWA
ACGIH - Skin Absorption Designation Listed
Australia TWA 0.05 ppm
0.46 mg/m³

Austria OEL - MAKs Listed
Belgium OEL - TWA Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Finland OEL - TWA Listed
France OEL - TWA Listed
Germany - Biological Exposure Limit: Listed
Greece OEL - TWA Listed
Hungary OEL - TWA Listed
Ireland OEL - TWAs Listed
Japan - OELs - Ceilings 0.05 ppm
0.46 mg/m³

Lithuania OEL - TWA Listed
OSHA - Final PELs - Skin Notations: Listed
Poland OEL - TWA Listed
Portugal OEL - TWA Listed
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Glyceryl monostearate

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>ACGIH TWA</td>
<td>10 mg/m³ TWA</td>
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<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
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<td>Lithuania OEL - TWA</td>
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<tr>
<td>Portugal OEL - TWA</td>
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<tr>
<td>Spain OEL - TWA</td>
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<td>Sweden OEL - TWAs</td>
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### Calcium stearate

<table>
<thead>
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<th>Value</th>
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</thead>
<tbody>
<tr>
<td>ACGIH TWA</td>
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<td>Australia TWA</td>
<td>10 mg/m³</td>
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<td>Ireland OEL - TWAs</td>
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<tr>
<td>Lithuania OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
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<td>Spain OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
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### Starch, pregelatinized

<table>
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<tbody>
<tr>
<td>ACGIH TWA</td>
<td>10 mg/m³ TWA</td>
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<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
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<tr>
<td>Bulgaria OEL - TWA</td>
<td>Listed</td>
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<tr>
<td>Czech Republic OEL - TWA</td>
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<tr>
<td>Greece OEL - TWA</td>
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<td>Ireland OEL - TWAs</td>
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<td>OSHA - Final PELS - TWAs:</td>
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<td>Portugal OEL - TWA</td>
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### Silicon dioxide, colloidal NF

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
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</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>Listed</td>
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<tr>
<td>Estonia OEL - TWA</td>
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</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
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<tr>
<td>Germany (DFG) - MAK</td>
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<td>Ireland OEL - TWAs</td>
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<tr>
<td>Latvia OEL - TWA</td>
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<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>- (80)(% SiO2) mg/m³ TWA TWA-20 mppcf</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>Listed</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Molecular Formula: Mixture

Color: White

Molecular Weight: Mixture

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

Stability: Stable under normal conditions of use.

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

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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.
11. TOXICOLOGICAL INFORMATION

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

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

Silicon dioxide, colloidal NF
IARC:  Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview:  Based on the concentration of the active ingredient in the formulation, no harmful effects to aquatic organisms are expected.

Bioaccumulation and Toxicity:  See aquatic toxicity data, below.

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.
MATERIAL SAFETY DATA SHEET

Material Name: Nitroglycerin Tablets (0.4, and 0.6 mg)
Revision date: 16-Dec-2009

14. TRANSPORT INFORMATION

15. REGULATORY INFORMATION

EU Symbol: T
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).

OSHA Label:
DANGER
Toxic if swallowed.
Toxic if inhaled.
Toxic in contact with skin.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Nitroglycerin
- CERCLA/SARA 313 Emission reporting: 1.0% de minimis concentration
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - Inventory - United States TSCA - Sect. 8(b): Listed
  - Australia (AICS): Listed
  - Standard for the Uniform Scheduling for Drugs and Poisons:
    - Schedule 2
    - Schedule 3
    - Schedule 4
  - EU EINECS/ELINCS List: 200-240-8

Glyceryl monostearate
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium stearate</td>
<td>250-705-4</td>
</tr>
<tr>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>216-472-8</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>232-679-6</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>231-545-4</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet