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

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, Kent  
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+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

Material Name: Nitrostat tablets (0.3 mg)

**Trade Name:** Nitrostat  
**Synonyms:** Nitroglycerin tablets USP  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of angina pectoris

2. HAZARDS IDENTIFICATION

**Appearance:** Round, white tablet  
**Signal Word:** WARNING

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

**Additional Hazard Information:**  
**Short Term:** 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:** Harmful

**EU Hazard Symbols:** Xn

**EU Risk Phrases:** R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.
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>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>55-63-0</td>
<td>200-240-8</td>
<td>E;R3 N;R51-53 R33 T+;R26/27/28</td>
<td>&lt;1.0</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>
<td></td>
</tr>
<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</td>
<td>Not Listed</td>
<td></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>
<td></td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<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.
Fire / Explosion Hazards: Not applicable

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
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
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Glyceryl monostearate**
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

**Calcium stearate**
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Lithuania OEL - TWA: 5 mg/m³
- Sweden OEL - TWAs: 5 mg/m³

**Silicon dioxide, colloidal NF**
- Australia TWA: 2 mg/m³
- Austria OEL - MAKs: 4 mg/m³
- Czech Republic OEL - TWA: 0.1 mg/m³
- Estonia OEL - TWA: 2 mg/m³
- Finland OEL - TWA: 5 mg/m³
- Germany - TRGS 900 - TWAs: 4 mg/m³
- Germany (DFG) - MAK: 4 mg/m³
- Ireland OEL - TWAs: 6 mg/m³
- Latvia OEL - TWA: 1 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Listed
- Slovakia OEL - TWA: 4.0 mg/m³

**Starch, pregelatinized**
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:
- Engineering controls should be used as the primary means to control exposures. 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: Wear protective gloves when working with large quantities.
- Eyes: Wear safety glasses or goggles if eye contact is possible.
- Skin: Wear protective clothing when working with large quantities.
- 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

- Chemical 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

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
11. TOXICOLOGICAL INFORMATION

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 Oral 434 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rabbit Oral 240 mg/kg/day NOAEL Not Teratogenic
Teratogenicity Teratology studies conducted in rabbits with topically applied nitroglycerin at doses up to 240 mg/kg/day were negative.

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. See below

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.

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

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

| EU Symbol: | Xn |
| EU Indication of danger: | Harmful |
| EU Risk Phrases: | R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed. |

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:
WARNING
Harmful if swallowed.
Harmful if inhaled.
Harmful in contact with skin.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.
15. REGULATORY INFORMATION

Nitroglycerin
  CERCLA/SARA 313 Emission reporting  1.0 %
  CERCLA/SARA Hazardous Substances  10 lb
  and their Reportable Quantities:  4.54 kg
  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
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  250-705-4

Calcium stearate
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  216-472-8

Silicon dioxide, colloidal NF
  Inventory - United States TSCA - Sect. 8(b)  Present
  Australia (AICS):  Present
  EU EINECS/ELINCS List  231-545-4

Lactose NF, monohydrate
  Australia (AICS):  Present

Starch, pregelatinized
  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 mentioned in Section 3

R23 - Toxic by inhalation.
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.

Data Sources:  Publicly available toxicity information. Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Prepared by:  Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet