



MATERIAL SAFETY DATA SHEET

Revision date: 16-Dec-2009

Version: 2.0

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

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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:

Known Clinical 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. 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:

Australian Hazard Classification (NOHSC):

R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.
Hazardous Substance. Non-Dangerous Goods.

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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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Nitroglycerin	55-63-0	200-240-8	E;R3 N;R51-53 R33 T+;R26/27/28	<1.0
Glyceryl monostearate	31566-31-1	250-705-4	Not Listed	*
Calcium stearate	1592-23-0	216-472-8	Not Listed	*
Starch, pregelatinized	9005-25-8	232-679-6	Not Listed	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*

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

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.

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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 TWA
ACGIH - Skin Absorption Designation	Listed
Australia TWA	0.05 ppm 0.46 mg/m ³
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/m ³
Lithuania OEL - TWA	Listed
OSHA - Final PELs - Skin Notations:	Listed
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed
UK - Biological Exposure Limit:	Listed

Glyceryl monostearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Calcium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Starch, pregelatinized

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
OSHA - Final PELs - TWAs:	15 mg/m ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Silicon dioxide, colloidal NF

Australia TWA	2 mg/m ³
Austria OEL - MAKs	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³ MAK
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - Table Z-3 Mineral D:	- (80)/(%) SiO ₂ mg/m ³ TWA TWA-20 mppcf
Slovenia OEL - TWA	Listed

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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	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: 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.
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

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.

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

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

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11. TOXICOLOGICAL INFORMATION

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

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.

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14. TRANSPORT INFORMATION

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.

Nitroglycerin

CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb final RQ 4.54 kg final RQ
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
EU EINECS/ELINCS List	250-705-4

Calcium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

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15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	216-472-8
Starch, pregelatinized	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
Silicon dioxide, colloidal NF	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4
Lactose NF, monohydrate	
Australia (AICS):	Listed

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.

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