MATERIAL SAFETY DATA SHEET

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

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Nitroglycerin Transdermal Patch

Trade Name: ADESITRIN, TRINIPATCH, NITRADISC
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of angina pectoris

2. HAZARDS IDENTIFICATION

Appearance: Patch
Signal Word: DANGER

Statement of Hazard:
Toxic if swallowed.
Toxic if inhaled.
Toxic in contact with skin.
Toxic to aquatic life with long lasting effects.

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
Dangerous for the Environment

EU Hazard Symbols:

EU Risk Phrases:
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.

2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

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	EU Classification	%
Nitroglycerin	55-63-0	200-240-8	E;R3 N;R51-53 R33 T+;R26/27/28	5, 10, or 15 mg

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Acrylic-vinyl acetate copolymer	Not assigned	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.

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. Avoid contact with eyes, skin and clothing. Avoid breathing dust. 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
Romania OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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:	Patch	**Color:**	No data available.
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

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
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)

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

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

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.

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided.
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: T N
EU Indication of danger: Toxic
Dangerous for the Environment

EU Risk Phrases:

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.

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).
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
DANGER
Toxic if swallowed.
Toxic if inhaled.
Toxic in contact with skin.
Toxic to aquatic life with long lasting effects.

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:	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

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.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet