

Date Printed 06/15/1999

Reviewed on 06/15/1999

*** 1 Substance Identification**

- **Product Name:** Nitrostat tablets (0.3, 0.4, and 0.6 mg)
- **Synonyms:** Nitroglycerin tablets, USP; MSDS #: P360F02
- **Step:** Formulated Pharmaceutical
- **Manufacturer/Supplier:**
Parke-Davis
A Division of the Warner-Lambert Company
201 Tabor Road
Morris Plains, NJ 07950
USA
- **Further information available from:**
Parke-Davis Medical Affairs
1-973-540-2000
- **Additional Information:**
This Material Safety Data Sheet conforms to 91/155/EEC and 93/112/EEC.

*** 2 Composition/Data on Ingredients**

- **Chemical Characterization:**

Dangerous Components:

55-63-0 glycerol trinitrate
T+, E; R 3-26/27/28-33

1.8 %

*** 3 Hazards Identification**

- **Hazard Description:**

T Toxic

- **W-L Occupational Hazard Labels:**

Toxic (USA/Canada)

Toxic (Europe)

Adverse Cardiovascular Effects

- **Information for Consumer Use:**

Use only as directed by product packaging.

Do not exceed maximum therapeutic dosage.

If the symptoms being treated persist, or other symptoms develop,
discontinued use and consult a physician.

In case of overdosage, seek professional medical assistance or contact
a Poison Control Center immediately.

Keep out of reach of children.

- **European Risk Phrases:**

R 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R 33 Danger of cumulative effects.

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Product Name: Nitrostat tablets (0.3, 0.4, and 0.6 mg)

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• Classification System:

The information in this data sheet is consistent with current EU regulations and been expanded by internal Warner-Lambert labeling.

• NFPA Ratings (scale 0-4):

Health = 3

Fire = 0

Reactivity = 0

• Additional Information:

If you do not understand the hazards or safety precautions described in this data sheet, contact the Warner-Lambert Company before handling this product.

4 First Aid Measures**• Eye Contact:**

In case of accidental contact, immediately flush eyes with water. Hold eyelids open to ensure adequate flushing. Get medical assistance.

• Skin Contact:

In case of accidental contact, immediately remove contaminated clothing and wash affected area with soap and water. Get medical assistance.

• Ingestion:

In case of accidental ingestion, administer 1-2 glasses of milk or water to dilute ingested material. Get immediate medical assistance.

• Inhalation:

Remove victim to fresh air. Get immediate medical assistance.

5 Fire Fighting Measures**• Suitable Extinguishing Agents:**

CO2, extinguishing powder or water spray.

• Fire Hazards: No Data Available**• Protective Equipment:**

Wear appropriate protective equipment, including self contained breathing apparatus (SCBA), during all fire fighting activities.

6 Accidental Release Measures**• Measures for Cleaning/Collecting:**

Place waste in an appropriate container for disposal.

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Product Name: Nitrostat tablets (0.3, 0.4, and 0.6 mg)**7 Handling and Storage****Handling:**

Manufacturing operations may require special handling procedures to limit exposure to this material or its ingredients.
Contact your supervisor or safety administrator for more information.

8 Exposure Controls and Personal Protection**Engineering Controls:**

Manufacturing operations may require the use of engineering controls to limit exposure to this material or its ingredients.
Contact your supervisor or safety administrator for more information.

Occupational Exposure Limits:

57-50-1 Sucrose

ACGIH TLV: STEL: 10, A4 mg/m³NIOSH REL: STEL: 10*; 5** mg/m³

*Total dust **Respirable

OSHA PEL: STEL: 15*; 5** mg/m³

*Total dust **Respirable

55-63-0 glycerol trinitrate

ACGIH TLV: STEL: 0.46 mg/m³, 0.05 ppm

Skin

NIOSH REL: 0.1 mg/m³

Skin

OSHA PEL: C 2 mg/m³, C 0.2 ppm

Skin

Personal Protective Equipment:

Manufacturing operations may require the use of personal protective equipment to limit exposure to this material or its ingredients.
Contact your supervisor or safety administrator for more information.

9 Physical and Chemical Properties**Form: Solid.****Flash Point:**

Value/Range	Unit	Method
Not Applicable		

Solubility:**Water:**

No Data Available

Organic Solvents:

No Data Available

10 Stability and Reactivity

Stability: This material is stable under normal conditions of use.

Dangerous Reactions: No dangerous reactions known

Hazardous Decomposition Products:

No dangerous decomposition products known

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Product Name: Nitrostat tablets (0.3, 0.4, and 0.6 mg)

* 11 Toxicological InformationAcute/Subacute Toxicity:

55-63-0 glycerol trinitrate

Oral: LD50: 115 mg/kg (mouse)

LD50: 105 mg/kg (rat)

Dermal: LD50: >280 mg/kg (rabbit)

LD50: >29 mg/kg (rat)

LD50 (IV): 23.2 mg/kg (rat)

- Irritation Effects: None
- Sensitization: No sensitizing effects known.

Human/Clinical Toxicity:

The following effects have been reported during therapeutic use:

Headache

Dizziness

Weakness

Changes in blood pressure

- Other Toxicological Effects:
Pregnancy Category: C - Risk cannot be ruled out.

Additional Information:

There are no other data available on the toxicological properties of this material.

* 12 Ecological Information

- General Notes:
Water hazard class 2 (Self-assessment): hazardous for water.

* 13 Disposal Considerations

- Disposal:
Dispose of waste in accordance with all applicable laws and regulations.

* 14 Transport Information

- DOT regulations:
- Hazard Class: 6.1
- Identification Number: UN2811
- Packing Group: III
- Proper Shipping Name: Toxic solid, organic, n.o.s. (contains nitroglycerin)
- Exceptions:
- Land transport ADR/RID (cross-border):
- ADR/RID Class: 6.1 Poisonous substances
- Item: 25c
- UN-Number: 2811
- Description of goods: 2811 Toxic solid, organic, n.o.s. (contains nitroglycerin)

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Product Name: Nitrostat tablets (0.3, 0.4, and 0.6 mg)

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- Maritime Transport IMDG:
- IMDG Class: 6.1
- UN Number: 2811
- Packaging Group: III
- Marine Pollutant: No
- Proper Shipping Name: Toxic solid, organic, n.o.s. (contains nitroglycerin)
- Air Transport ICAO-TI and IATA-DGR:
- UN/ID Number: 2811
- Packaging Group: III
- Proper Shipping Name: Toxic solid, organic, n.o.s. (contains nitroglycerin)

* 15 Regulatory Information

- European Regulations:
- Hazard Symbols:
 - T Toxic
- Hazard-determining components of labeling: glycerol trinitrate
- Risk phrases:
 - 23/24/25 Toxic by inhalation, in contact with skin and if swallowed.
 - 33 Danger of cumulative effects.
- Safety phrases:
 - 22 Do not breathe dust.
 - 23 Do not breathe gas/fumes/vapour/spray.
 - 36 Wear suitable protective clothing.
- European National Regulations:
- Water Hazard Class:
 - Water hazard class 2 (Self-assessment): hazardous for water.
- United States Regulations:
- OSHA Hazard Communication Labels:
 - Toxic (USA/Canada)
 - Adverse Cardiovascular Effects
- Canadian Regulations:
- WHMIS Classification: Class D, Division 1, Subdivision B

* 16 Other Information

- Department issuing MSDS: Corporate Safety and Industrial Hygiene
- Contact:
 - Tracy A. Kimmel, Ph.D.
 - +1-973-540-2000

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Disclaimer:

The information included in this data sheet is based on currently available scientific information and is accurate and reliable to the best of our knowledge. Warner-Lambert makes no other warranties, expressed or implied, and assumes no responsibility or liability for injury or damage caused by the material if reasonable safety procedures are not followed as specified in this data sheet.

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