1. Product And Company Identification

**Supplier**
Hercon Laboratories Corporation
101 Sinking Springs Lane
Emigsville, PA 17318

Telephone Number: 717-764-1191
FAX Number: 717-764-5395

**Manufacturer**
Hercon Laboratories Corporation
101 Sinking Springs Lane
Emigsville, PA 17318

Telephone Number: 717-764-1191
FAX Number: 717-764-5395

**Supplier Emergency Contacts & Phone Number**
Safety Coordinator: 717-764-1191

**Manufacturer Emergency Contacts & Phone Number**
Safety Coordinator: 717-764-1191

**Issue Date:** 08/16/2005

**Product Name:** NITROGLYCERIN TRANSDERMAL SYSTEM

**MSDS Number:** 815

**FDA ANDA #:** 89-884, 89-885, 89-886

2. Composition/Information On Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>CAS Number</th>
<th>Percent Of Total Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>acrylic solids</td>
<td></td>
<td>43.8</td>
</tr>
<tr>
<td>NITROGLYCERIN</td>
<td>55-63-0</td>
<td>56.2</td>
</tr>
</tbody>
</table>

3. Hazards Identification

**Primary Routes(s) Of Entry**

- **Skin**
  - **Eye Hazards**
    - No effects expected. The physical form of the product prevents significant eye contact.
  - **Skin Hazards**
    - No effects are expected in most individuals from normal use or accidental contact. This product does not deliver drug at a sufficiently rapid rate to cause or prevent an acute anginal episode. Allergic reactions, such as contact dermatitis and mild skin irritation, are extremely rare but may occur from repeated use. Consult the package insert for further information.
  - **Ingestion Hazards**
    - No effects expected. This product is not likely to be ingested due to its physical form.
  - **Inhalation Hazards**
    - No effects expected due to the physical form of the product and low volatility of nitroglycerin.
  - **Chronic/Carcinogenicity Effects**
    - Nitroglycerin is not classified as potentially carcinogenic by IARC, NTP, OSHA or ACGIH.
  - **Conditions Aggravated By Exposure**
    - The vasodilatory effects of nitroglycerin may be amplified by the use of certain drugs, such as sildenafil. Consult the package insert for further information.

4. First Aid Measures

**Eye**

- In case of contact, immediately flush eyes with plenty of water.

**Skin**

- In case of accidental contact, wash affected areas with soap and water. Consult a physician if irritation or dermatitis develops.
### 4. First Aid Measures - Continued

<table>
<thead>
<tr>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion is unlikely. Seek immediate medical attention if this product is ingested.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation is considered unlikely. Contact a physician if symptoms develop.</td>
</tr>
</tbody>
</table>

### 5. Fire Fighting Measures

**Fire And Explosion Hazards**

This product is not considered to be flammable. However, the backing materials and adhesives may burn if ignited. Burning may give off a yellowish nitrous smoke and irritating fumes from thermal decomposition.

**Extinguishing Media**

Use the appropriate extinguishing media for the surrounding fire.

**Fire Fighting Instructions**

Avoid breathing vapors, gases and fumes. Firefighters should wear self-contained breathing apparatus and full protective gear. Water can be used to cool and protect exposed material.

### 6. Accidental Release Measures

Pick up spilled packages of product and recover, or dispose in a proper disposal container.

### 7. Handling And Storage

**Handling And Storage Precautions**

Store at temperatures between 59 to 86 deg F (15-30 deg C). Do not refrigerate. Keep out of reach of children.

**Work/Hygienic Practices**

Use good personal hygiene. If handling large quantities of product, wash thoroughly after handling.

### 8. Exposure Controls/Personal Protection

**Engineering Controls**

None normally required.

**Eye/Face Protection**

None normally required.

**Skin Protection**

None normally required.

**Respiratory Protection**

None normally required. General room ventilation is normally adequate.

**Ingredient(s) - Exposure Limits**

<table>
<thead>
<tr>
<th>NITROGLYCERIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV-TWA: 0.05 ppm (Skin)</td>
</tr>
<tr>
<td>OSHA PEL-CEILING: 0.2 ppm (Skin)</td>
</tr>
</tbody>
</table>

### 9. Physical And Chemical Properties

**Appearance**

The Nitroglycerin Transdermal System is comprised of 3 layers: (1) a transparent outer backing layer composed of a plastic film, printed with the name and strength of the drug; (2) nitroglycerin in an acrylic-based polymer adhesive; and (3) a protective white, translucent peelable liner which covers the second layer, and must be removed prior to use.

**Odor**

None

**Chemical Type:** Mixture
9. Physical And Chemical Properties - Continued

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor - Continued</td>
<td></td>
</tr>
<tr>
<td>Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Melting Point</td>
<td>13° C</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>0.0002 mm Hg @ 20° C *</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>7.8*</td>
</tr>
<tr>
<td>Solubility</td>
<td>soluble in water*</td>
</tr>
</tbody>
</table>

* The above physical properties are indicated for pure nitroglycerin.

10. Stability And Reactivity

<table>
<thead>
<tr>
<th>Stability</th>
<th>Stable in the concentration provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</td>
</tr>
</tbody>
</table>

**Conditions To Avoid (Stability)**
- Burning or heating the product at high temperatures. Diluted nitroglycerin, as contained in this product, is NOT EXPLOSIVE.

**Incompatible Materials**
- Avoid exposure to high temperatures, ozone, strong oxidizing agents and acids.

**Hazardous Decomposition Products**
- Thermal decomposition of nitroglycerin may produce irritating nitrous vapors. Burning the plastic backing and films may produce a dense, irritating black smoke.

11. Toxicological Information

**Teratogenicity (Birth Defects)**
- Animal teratology studies have not been conducted on transdermal systems. No toxic effects have been observed either to the mother or fetuses, however, on topically applied nitroglycerin to laboratory animals.

**Mutagenicity (Genetic Effects)**
- Nitroglycerin is weakly mutagenic in Ames tests performed at 2 laboratories. Nevertheless, there was no evidence of mutagenicity in in-vivo studies in rats and dogs.

**Miscellaneous Toxicological Information**
- Daily headaches sometimes accompany treatment with nitroglycerin. Adverse reactions to nitroglycerin are generally dose-related, and almost all of these reactions are the result of nitroglycerin's activity as a vasodilator. Headache, which may be severe, is the most commonly reported side effect. Transient episodes of lightheadedness, occasionally related to blood pressure changes, may also occur. These effects may be more frequent with persons who have consumed alcohol.
- Industrial workers who had long-term exposure to unknown (and presumably high) doses of organic nitrates developed tolerances. Cardiovascular effects, such as chest pain, acute myocardial infarction and even sudden death have been known to occur from the temporary withdrawal of nitrates from these workers.

12. Ecological Information

**Other Environmental Information**
- No information available for this product.

13. Disposal Considerations

Dispose in accordance with applicable federal, state and local government regulations.

14. Transport Information

**Proper Shipping Name**
- Not a regulated Hazardous Material
15. Regulatory Information

**U.S. Regulatory Information**
All ingredients of this product are listed or are excluded from listing under the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

**SARA Title III - Section 313 Supplier Notification**
This product contains the following toxic chemicals that are subject to the reporting requirements of section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986 and of 40 CFR 372.

NITROGLYCERIN (55-63-0)  56.2 %

This information must be included on all MSDSs that are copied and distributed for this material.

**Ingredient(s) - U.S. Regulatory Information**
- NITROGLYCERIN
  - SARA Title III - Section 313 Form "R"/TRI Reportable Chemical

**Ingredient(s) - State Regulations**
- NITROGLYCERIN
  - New Jersey - Workplace Hazard
  - New Jersey - Environmental Hazard
  - New Jersey - Special Hazard
  - Pennsylvania - Workplace Hazard
  - Pennsylvania - Environmental Hazard
  - Massachusetts - Hazardous Substance
  - New York City - Hazardous Substance

16. Other Information

**NFPA Rating**
- Health: 0
- Fire: 1
- Reactivity: 0

**HMIS Rating**
- Health: 0
- Fire: 1
- Reactivity: 0

**Disclaimer**
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Hercon Laboratories Corporation