MATERIAL SAFETY DATA SHEET

Product Name: Glyceryl Trinitrate for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Hospira UK Limited
Queensway
Royal Leamington Spa
England

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Glyceryl Trinitrate for Injection

Synonyms 1,2,3-propanetriol trinitrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Nitroglycerin

Chemical Formula C₃H₅N₃O₉

Preparation Non-hazardous ingredients include Water for Injection.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>≤ 0.5</td>
<td>55-63-0</td>
<td>QX2100000</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>4.3</td>
<td>57-55-6</td>
<td>TY2000000</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>67</td>
<td>64-17-5</td>
<td>KQ6300000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview Glyceryl Trinitrate for Injection is a solution containing nitroglycerin, an organic nitrate vasodilator. Clinically, this material is indicated for treatment of peri-operative hypertension; for control of congestive heart failure in the setting of acute myocardial infarction, and for treatment of angina pectoris. The formulated product is a flammable liquid. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, a potential occupational reproductive hazard, and a potent drug. Based on clinical use, possible target organs include the cardiovascular system and blood.
Product Name: Glyceryl Trinitrate for Injection

Occupational Exposure Potential
Information on the absorption of this product via inhalation is not available. In clinical use, dermal patch formulations containing nitroglycerin are bioavailable and effective. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposures. In clinical use, adverse reactions to nitroglycerin are generally dose-related and may include headache which is severe and recurrent, transient episodes of lightheadedness, hypotension, syncope, crescendo angina, and rebound hypertension. At higher doses, vasodilation, venous pooling, reduced cardiac output, visual disturbances, nausea and vomiting, and hypotension may also occur. Allergic reactions are uncommon, and the majority of those reported are cases of contact dermatitis or fixed drug eruptions in patients receiving nitroglycerin in ointments or patches. There have been a few reports of genuine anaphylactoid reactions. Finally, extremely rarely, ordinary doses of organic nitrates have caused methemoglobinemia in normal-seeming patients.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to this material; pre-existing cardiovascular and blood disorders.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
Flashpoint: NA. Estimated flashpoint of formulated mixture is <80°F (27°C).

Fire & Explosion Hazard
Flammable liquid and vapor. Keep away from flames, sparks, and other sources of ignition. This product will burn in a fire. Vapors may form an explosive mixture with air. In the event of a large spill, the vapors are heavier than air, and may travel along the ground or be moved by ventilation and ignited by heat or other flames/ignition. Containers may explode in the heat of a fire.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Remove any sources of ignition from the spill area. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
Product Name: Glyceryl Trinitrate for Injection

### 7. HANDLING AND STORAGE

**Handling**  
No special handling required for hazard control under conditions of normal product use.

**Storage**  
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions**  
No special precautions required for hazard control.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>1000</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
<td>1000</td>
<td>1900</td>
<td></td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Australia NOHSC</td>
<td>N/A</td>
<td>1000</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>AIHA WEEL</td>
<td>10</td>
<td>N/A</td>
<td>N/A</td>
<td>8hr TWA</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>OSHA Ceiling</td>
<td>2</td>
<td>0.2</td>
<td>N/A</td>
<td>Ceiling</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>0.05</td>
<td>N/A</td>
<td>Skin</td>
</tr>
</tbody>
</table>

**Respiratory protection**  
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) and an organic vapor is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**  
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**  
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**  
Engineering controls are normally not needed during the normal use of this product.

### 9. PHYSICAL/CHEMICAL PROPERTIES

- **Appearance/Physical State**: Liquid
- **Color**: Clear, practically colorless
- **Odor**: NA
- **Odor Threshold**: NA
- **pH**: NA
- **Melting point/Freezing point**: NA
- **Initial Boiling Point/Boiling Point Range**: NA
- **Evaporation Rate**: NA
Product Name: Glyceryl Trinitrate for Injection

Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: LEL: 3.365 UEL: 19% based upon ethanol
Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: NA
Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined.

Conditions to avoid Not determined.

Incompatibilities Not determined. Nitroglycerin readily migrates into many plastics including PVC.

Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>105</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>115</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1607</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1450</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>23.2</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30, 10.6</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>&gt;29.2</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;35.2</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;280</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>3450 – 11,500</td>
<td>mg/kg</td>
<td>Guinea Pig, Rat, Mouse, Dog</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>1973</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LC50 (10h)</td>
<td>Inhalation</td>
<td>20,000</td>
<td>ppm</td>
<td>Rat</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>100</td>
<td>LD50 (4h)</td>
<td>Inhalation</td>
<td>39,000</td>
<td>mg/m3</td>
<td>Mouse</td>
</tr>
</tbody>
</table>
Product Name: Glyceryl Trinitrate for Injection

<table>
<thead>
<tr>
<th>Propylene Glycol</th>
<th>100</th>
<th>LD50</th>
<th>Oral</th>
<th>10,400 - 29,536</th>
<th>mg/kg</th>
<th>Rat, Mouse, Rabbit, Dog, Guinea Pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6423-6800</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6630-8000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product. However, inadvertent inhalation of the product aerosol may produce respiratory irritation.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce mild irritation with redness and discomfort. Ethanol may produce mild skin irritation with redness and dryness.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with stinging with redness, watering, and discomfort. Exposure to ethanol has produced severe eye irritation in studies in animals.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
In a three-generation reproduction study, rats received dietary nitroglycerin at dosages up to about 434 mg/kg/day for six months prior to mating of the F0 generation with treatment continuing through successive F1 and F2 generations. The high-dose was associated with decreased feed intake and body weight gain in both sexes at all matings. No specific effect on the fertility of the F0 generation was seen. Infertility noted in subsequent generations, however, was attributed to increased interstitial cell tissue and aspermatogenesis in the high dose males. In this three-generation study there was no clear evidence of teratogenicity. Animal teratology studies have not been conducted with nitroglycerin injection. Teratology studies in rats and rabbits were conducted with topically applied nitroglycerin ointment at dosages up to 80 mg/kg/day and 240 mg/kg/day, respectively, and no toxic effects on dams or fetuses were seen. Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Chronic prenatal exposure to ethanol has been associated with a distinct pattern of congenital malformations that have collectively been termed the "fetal alcohol syndrome".

Mutagenicity
Nitroglycerin was weakly mutagenic in Ames tests performed in two different laboratories. Nevertheless, there was no evidence of mutagenicity in an in vivo dominant lethal assay with male rats treated with doses up to about 363 mg/kg/day, p.o., or in in vitro cytogenetic tests in rat and dog tissues.

Carcinogenicity
Animal carcinogenesis studies with injectable nitroglycerin have not been performed. Rats receiving up to 434 mg/kg/day of dietary nitroglycerin for 2 years developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes. At high dose, the incidences of hepatocellular carcinomas in both sexes were 52% vs. 0% in controls, and incidences of testicular tumors were 52% vs. 8% in controls. Lifetime dietary administration of up to 1058 mg/kg/day of nitroglycerin was not tumorigenic in mice.

Target Organ Effects
Based on clinical use, possible target organs include the cardiovascular system and blood.
12. ECOLOGICAL INFORMATION

Aquatic Toxicity

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50(24 hr)</td>
<td>12,900 - 15,300 mg/L in rainbow trout for ethanol</td>
</tr>
<tr>
<td>LC50 (24 hr)</td>
<td>11,200 mg/L in fingerling trout for ethanol</td>
</tr>
<tr>
<td>LC50(48 hr)</td>
<td>9,268 - 14,221 mg/L in Daphnia magna for ethanol</td>
</tr>
<tr>
<td>EC50</td>
<td>9310 mg/L in Chlorella pyrenoidosa (green algae) for ethanol</td>
</tr>
<tr>
<td>LC50(96 hr)</td>
<td>51,600 mg/L in rainbow trout for propylene glycol</td>
</tr>
<tr>
<td>LC50(48 hr)</td>
<td>34,400 - 43,500 mg/L in Daphnia magna for propylene glycol</td>
</tr>
<tr>
<td>EC50(14 day)</td>
<td>19,000 mg/L in algae for propylene glycol</td>
</tr>
</tbody>
</table>

Persistence/Biodegradability

Not determined for product.

Ethanol was reported to be degraded between 45% and 74% in five days in two aqueous biodegradation assays.

Propylene glycol was reported to be 100% biodegradable after 24-hours in activated sludge.

Bioaccumulation

Not determined for product.

Because of its low octanol:water partition coefficient, ethanol is not anticipated to bioaccumulate.

Mobility in Soil

Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements. In the U.S., this product is classified as hazardous waste (D001) based on ignitability.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Regulated

Proper Shipping Name: Nitroglycerin Solution in Alcohol

Hazard Class: 3

UN number: UN1204

Packing group: II

Reportable Quantity: 10

IMDG STATUS: Regulated

Proper Shipping Name: Nitroglycerin Solution in Alcohol

Hazard Class: 3

UN number: UN1204

Packing group: II

Reportable Quantity: N/A

ICAO/IATA STATUS: Regulated
Product Name: Glyceryl Trinitrate for Injection

Proper Shipping Name: Nitroglycerin Solution in Alcohol
Hazard Class: 3
UN number: UN1204
Packing group: II
Reportable Quantity: N/A

Transport Comments: RQ listed for Road and Rail is in Pounds and is applicable for all modes of transport for shipments to/from the United States.

### 15. REGULATORY INFORMATION

#### USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
<tr>
<td>Nitroglycerin</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**: Nitroglycerin is a P-listed reactive waste (P081); product formulation classified as D001 based on ignitability

**U.S. OSHA Classification**
- Target Organ Toxin
- Possible Reproductive Toxin
- Flammable Liquid
- Possible Irritant

**GHS Classification**: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.*

- Hazard Class: Not Applicable
- Hazard Category: Not Applicable
- Signal Word: Not Applicable
- Symbol: Not Applicable
- Prevention: P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
- Hazard Statement: Not Applicable
- Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.
  - Get medical attention if you feel unwell.

**EU Classification**
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Nitroglycerin*

- Classification(s): Not Applicable
- Symbol: Not Applicable
Product Name: Glyceryl Trinitrate for Injection

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/28/2011
Obsolete Date: 04/07/2011

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