MATERIAL SAFETY DATA SHEET

Product Name: Nitroglycerin in Dextrose Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

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  
Nitroglycerin in Dextrose 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 and dextrose. Hazardous ingredients present at less than 1% may include propylene glycol. Nitric acid is added to adjust the pH.

<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>≤ 0.04</td>
<td>55-63-0</td>
<td>QX2100000</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>Nitroglycerin</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview  
Nitroglycerin in Dextrose Injection is a solution containing nitroglycerin, a 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; for treatment of angina pectoris. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potent drug. Based on clinical use, possible target organs include the cardiovascular system and blood.

Occupational Exposure Potential  
Information on the absorption of this product via inhalation is not available. In clinical use, dermal patch formulations containing nitroglycerin are available 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, vasodilatation, 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
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

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 firefighting 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. 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.

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>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) 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Practically colorless</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>4.0 (3.0 to 6.5)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Nitroglycerin in Dextrose Injection

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>
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<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>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. Nitroglycerin was mildly irritating in a skin irritation study in animals.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation.

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 dosage 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...
Product Name: Nitroglycerin in Dextrose Injection

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.

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
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

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.

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

14. TRANSPORTATION INFORMATION

DOT STATUS
Not regulated

IMDG STATUS:
Not regulated

ICAO/IATA STATUS:
Not regulated
Product Name: Nitroglycerin in Dextrose Injection

15. REGULATORY INFORMATION

<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>
</tr>
</thead>
<tbody>
<tr>
<td>Nitroglycerin</td>
<td>Listed</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
Nitroglycerin is a P-listed reactive waste (P081)

**U.S. OSHA Classification**
Target Organ Toxin

**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

**Indication of Danger:**
Not Applicable

**Risk Phrases:**
Not Applicable

**Safety Phrases:**
S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with 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: 10/21/2008

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