



SAFETY DATA SHEET

Product Name: Nitroglycerin in 5% Dextrose Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Nitroglycerin in Dextrose Injection
Synonyms	1,2,3-propanetriol trinitrate

2. HAZARD(S) IDENTIFICATION

Emergency Overview	Nitroglycerin in Dextrose 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; 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.
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U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Not Classified	Not Classified

Health Hazards	Hazard Class	Hazard Category
	Not Classified	Not Classified

Label Element(s)	
Pictogram	NA
Signal Word	NA
Hazard Statement(s)	NA

Precautionary Statement(s)

Prevention Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response Get medical attention if you feel unwell.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Nitroglycerin
Chemical Formula C₃H₅N₃O₉

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Nitroglycerin	≤ 0.04	55-63-0	QX2100000

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.

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. Although dry nitroglycerin is explosive, nitroglycerin in 5% dextrose is not.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

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 control 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

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Nitroglycerin	8-hr TWA: 0.2 ppm (2 mg/m3), ceiling	8-hr TWA: 0.05 ppm; skin	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8-hour Time Weighted Average.

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

Appearance/Physical State	A clear and practically colorless sterile, nonpyrogenic solution in water
Odor	NA
Odor Threshold	NA
pH	4.0 (3.0 to 6.5)
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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 active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Nitroglycerin	100	LD50	Oral	105	mg/kg	Rat
				115	mg/kg	Mouse
				1607	mg/kg	Rabbit
				1450	mg/kg	Guinea Pig
Nitroglycerin	100	LD50	Intravenous	23.2	mg/kg	Rat
				30, 10.6	mg/kg	Mouse
				45	mg/kg	Rabbit
				19	mg/kg	Dog
Nitroglycerin	100	LD50	Dermal	>29.2	mg/kg	Rat
				>35.2	mg/kg	Mouse
				>280	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. 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.

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. However, inadvertent contact of this product with eyes may produce irritation.

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

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects	None anticipated from normal handling of this product. 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 F ₀ generation with treatment continuing through successive F ₁ and F ₂ 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 F ₀ 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.
Mutagenicity	Nitroglycerin was weakly mutagenic in Ames tests performed in two different laboratories. Nevertheless, there was no evidence of mutagenicity in an <i>in vivo</i> dominant lethal assay with male rats treated with dosages up to about 363 mg/kg/day, p.o., or in <i>in vitro</i> 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.
Carcinogen Lists	IARC: Not listed NTP: Not listed OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	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.

Notes:

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

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt. However, nitroglycerin is listed on the TSCA inventory
US CERCLA Status	RQ for nitroglycerin is 10 lb (4.54 kg)
US SARA 302 Status	Not listed
US SARA 313 Status	Form R reporting required for 1.0% de minimis concentration
US RCRA Status	Nitroglycerin is a P-listed reactive waste (P081)
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA
Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling			
Response	Get medical attention if you feel unwell. 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.			

EU Classification* *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the 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
LD ₅₀	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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