SAFETY DATA SHEET

Nitroglycerin Trandermal Delivery System (TDS)

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

1. PRODUCT IDENTIFICATION

1.1 TRADE NAME (AS LABELED):	**Nitroglycerin Transdermal Delivery System**
SYNONYMS:	None known
CAS#:	Mixture
1.2 PRODUCT USE:	Pharmaceutical
1.3 MANUFACTURER'S NAME:	**Alvogen, Inc.**
ADDRESS:	10 Bloomfield Avenue, Bldg B, Pine Brook, NJ 07058
BUSINESS PHONE:	1-844-842-8672
FAX NUMBER:	1-973-807-1625
1.4 EMERGENCY PHONE NUMBER:	
EMERGENCY PHONE #:	1-844-842-8672
COMPANY WEB SITE INFORMATION:	www.alvogen.us.com
1.5 PREPARATION INFORMATION:	
DATE OF CURRENT REVISION:	June 2, 2015
DATE OF LAST REVISION:	New

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: This product is a transdermal patch (Solid) carrying nitroglycerin with no odor.

Health Hazards: Exposure to this product is not expected to cause irritation to eyes. Ingredients may be absorbed through skin and cause target organ effects. Acute nitroglycerin overexposure may cause hypotension, nausea, vomiting, abdominal cramps, headache, mental confusion, delirium, slowed breathing and heart rate, paralysis, convulsions, methemoglobinemia, cyanosis, circulatory collapse and death.

Flammability Hazards: This product is non-flammable.

Reactivity Hazards: None known

Environmental Hazards: The Environmental effects of this product have not been investigated. Release of this product is not expected to have significant adverse effects in the aquatic environment.

US DOT SYMBOLS

Non-Regulated Material

CANADA (WHMIS) SYMBOLS



EUROPEAN and (GHS) Hazard Symbols



Signal Word: **Warning!**

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:

Index Number:

Acrylic Copolymer is not listed in ESIS

CAS# 9002-88-4 is not listed in ESIS

EC# 200-240-8 Annex VI Index# 603-034-00-X

EC# 203-889-5 This substance is classified in the Annex VI of Directive 67/548/EEC. Index# 607-023-00-0

EC# 248-337-4 This substance is not classified in the Annex VI of Directive 67/548/EEC

Substances not listed either individually or in group entries must be self classified.

Component(s) Contributing to Classification(s)

Nitroglycerin

2.2 LABEL ELEMENTS:

GHS Hazard Classification(s):

STOT RE Category 2

Hazard Statement(s):
H373: Causes damage to organs through prolonged or repeated exposure

Precautionary Statement(s):
P264: Wash skin after handling.

2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of exposure for this product are by skin contact or skin absorption.

ACUTE:

INHALATION: No health effects are expected due to physical properties of the product.

CONTACT WITH SKIN: Contact with the skin during product use may result in mild irritation. May be absorbed through skin and cause target organ damage.

EYE CONTACT: Contact not expected due to physical properties of the product.

INGESTION: Physical blockage. Ingestion may cause gastrointestinal irritation which may include abdominal pain, nausea, diarrhea, and vomiting. May be absorbed following ingestion and cause target organ effects.

CHRONIC: Chronic overexposure may cause severe headaches, hallucinations and skin rash.

TARGET ORGANS: Acute: Skin **Chronic:** Various Target Organs

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS#	EINECS #	Hazard Classification	Hazard Statements
Acrylic Copolymer	60 – 75%	Not Assigned	Not Listed in ESIS	None	None
Nitoglycerin	25%	55-63-0	200-240-8	Toxic	H373 STOT RE Cat 2
Ethyl Oleate	2 – 10%	111-62-6	203-889-5	None	None
Glycerol	0.1 – 3%	27215-38-9	248-337-4	None	None
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).					

NOTE: This product has been classified in accordance with the hazard criteria of the CFR and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

4. FIRST-AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: Not a likely route of entry

SKIN CONTACT: If product contacts skin, wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Acute nitroglycerin overexposure may cause hypotension, nausea, vomiting, abdominal cramps, headache, mental confusion, delirium, slowed breathing and heart rate, paralysis, convulsions, methemoglobinemia, cyanosis, circulatory collapse and death.

4.3 RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS:

Use fire extinguishing methods below:

Water Spray: Yes
Carbon Dioxide: Yes
Foam: Yes
Dry Chemical: Yes
Halon: Yes
Other: Any "C" Class

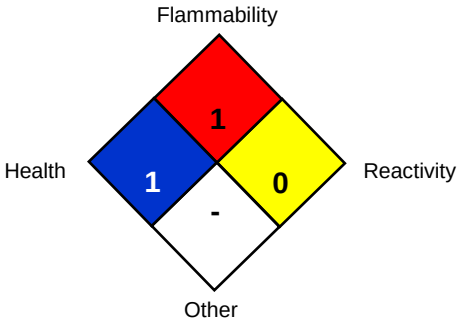
5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

Contains Nitroglycerin but has been determined to be Non-Explosive.
Explosion Sensitivity to Mechanical Impact: No
Explosion Sensitivity to Static Discharge: No

5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD (BLUE)	1
FLAMMABILITY HAZARD (RED)	1
PHYSICAL HAZARD (YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

See section 8.2 for Exposure Controls.

6.2 ENVIRONMENTAL PRECAUTIONS:

None known

6.3 SPILL AND LEAK RESPONSE:

Pickup and place in closed container approved for transportation. Seal tightly for proper disposal. Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces, those of Australia, Japan and EU Member States (see Section 13, Disposal Considerations).

7. HANDLING and STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Wash thoroughly after handling.

7.2 STORAGE AND HANDLING PRACTICES:

Keep in cool, dry, controlled room temperature between 59°-86°F. Protect containers from physical damage.

7.3 SPECIFIC USES:

Pharmaceutical

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Nitroglycerin	55-63-0	0.05 mg/m³ Skin	0.02 mg/m³ Skin

8.2 EXPOSURE CONTROLS:

VENTILATION AND ENGINEERING CONTROLS: Not Applicable

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.
EYE PROTECTION Not normally required with this product. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.
SKIN PROTECTION: Avoid skin contact. Select and use gloves and/or protective clothing to prevent skin contact based on results of an exposure assessment. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

9. PHYSICAL and CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

APPEARANCE (Physical State) and COLOR: This product is a film transdermal patch (Solid) with no odor.
ODOR: None
ODOR THRESHOLD: Not Applicable
pH: Not Applicable
MELTING/FREEZING POINT: Not Applicable
BOILING POINT: Not Applicable
FLASH POINT: Not Applicable
EVAPORATION RATE (n-BuAc=1): Not Applicable
FLAMMABILITY (SOLID, GAS): Not Applicable
UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS: Not Applicable
VAPOR PRESSURE (mm Hg @ 20°C (68°F): Not Applicable
VAPOR DENSITY: Not Applicable
RELATIVE DENSITY: Not Applicable
DENSITY: Not Applicable
SPECIFIC GRAVITY: . Not Applicable
SOLUBILITY IN WATER: Not Applicable
WEIGHT PER GALLON: Not Applicable
PARTITION COEFFICENT (n-octanol/water): Not Applicable
AUTO-IGNITION TEMPERATURE: Not Applicable
DECOMPOSITION TEMPERATURE: Not Applicable
VISCOSITY: Not Applicable
VOC g/l / Lb/gal: Not Applicable

9.2 OTHER INFORMATION:

No additional information available.

10. STABILITY and REACTIVITY

10.1 REACTIVITY:

This product is not reactive.

10.2 STABILITY:

Stable under conditions of normal storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

Will not occur

10.4 CONDITIONS TO AVOID:

None known

10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:

Strong Bases

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon dioxide, carbon monoxide and irritating vapors.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

TOXICITY DATA:
No LD 50 Data Available

SUSPECTED CANCER AGENT: None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are considered to be, or suspected to be, cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to skin.

SENSITIZATION TO THE PRODUCT: This product is not considered a respiratory system or skin sensitizer.

REPRODUCTIVE TOXICITY INFORMATION: One or more of the ingredients of this product may have adverse effects on the human reproductive system.

SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE: Skin

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE: Contains a chemical or chemicals which cause target organ damage

ASPIRATION HAZARD: None

12. ECOLOGICAL INFORMATION

12.1 TOXICITY:

No toxicity data available.

12.2 PERSISTENCE AND DEGRADABILITY:

No specific data available on this product.

12.3 BIOACCUMULATIVE POTENTIAL:

No specific data available on this product.

12.4 MOBILITY IN SOIL:

No specific data available on this product.

12.5 RESULTS OF PBT ANDvPvB ASSESSMENT:

No specific data available on this product.

12.6 OTHER ADVERSE EFFECTS:

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

12.7 WATER ENDANGERMENT CLASS:

Water endangering in accordance with EU Guideline 91/155-EWG. Not determined

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined

14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

14.1 PROPER SHIPPING NAME:	Non-Regulated Material
14.2 HAZARD CLASS NUMBER and DESCRIPTION:	None
14.3 UN IDENTIFICATION NUMBER:	None
14.4 PACKING GROUP:	None
14.5 DOT LABEL(S) REQUIRED:	None
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER:	None
RQ QUANTITY:	None

14.6 MARINE POLLUTANT: None of the components of this product are designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.7 SPECIAL PRECAUTIONS FOR USER:

Avoid exposure

14.8 INTERNATIONAL TRANSPORTION:

INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA): This product is not considered as dangerous goods.

INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO): This product is not considered as dangerous goods.

14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

15.1 UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: One of the components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
SARA 313 Reporting: Nitroglycerin CAS# 55-63-0 25%
U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.
U.S. CERCLA REPORTABLE QUANTITY (RQ): None
U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory or are exempted form listing. Commercial use of this material is regulated by the FDA.
OTHER U.S. FEDERAL REGULATIONS: None
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ingredients within this product are not on the Proposition 65 Lists.

15.2 CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.
OTHER CANADIAN REGULATIONS: Not applicable.
CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:
This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.
CANADIAN WHMIS CLASSIFICATION and SYMBOLS: This product is classified D2B, Materials causing other toxic effects, per WHMIS Controlled Product Regulations.



15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.
See Section 2 for full Details.

15.4 AUSTRALIAN INFORMATION FOR PRODUCT:

The components of this product are listed on the International Chemical Inventory list.

15.5 JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:
The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.
JAPANESE ENCS INVENTORY:
The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.
POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:
No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

16. OTHER INFORMATION

PREPARED BY: Paul Eigbrett – (**GHS MSDS Compliance PLUS)**
DATE OF PRINTING: June 2, 2015

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. Alvogen, Inc. assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are no adhered to as stipulated in the data sheet. Furthermore, Alvogen, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

END OF SDS SHEET