

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	GLYCERIN, USP
PRODUCT CODE	0613
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Based on available data, the classification criteria are not met.			
PICTOGRAM	Not Applicable			
SIGNAL WORD	Not applicable			
HAZARD STATEMENT(S)	Not applicable			
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not applicable			
PRECAUTIONARY STATEMENT(S)	Prevention	Not applicable		
	Response	Not applicable		
	Storage	Not applicable		
	Disposal	Not applicable		
HMS CLASSIFICATION	Health Hazard	0	Flammability	0
	Reactivity	0	Personal Protection	C

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	1, 2, 3 Propanetriol
BOTANICAL NAME	Not applicable
SYNONYM	Glycerolum; Glycerol
CHEMICAL FORMULA	C ₃ H ₈ O ₃
CHEMICAL FAMILY	Linear aliphatic derivative; alcohol.
CAS NUMBER	56-81-5
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	92.11
COMPOSITION	

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
GLYCERIN	56-81-5	200-289-5	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustibile at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: GLYCERIN CAS #: 56-81-5

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	15(1) 5(2)	N/L	N/L	N/L	N/L	N/A	(1) Inhalable dust (2) Respirable dust
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	10 (1)	N/L	N/L	N/L	N/L	N/A	(1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
HSE	UK	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Belgium	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Ontario	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada - Quebec	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Finland	N/L	20	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	France	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A

GESTIS	Germany (AGS)	N/L	200 (1)	N/L	400 (1)(2)	N/L	N/L	N/A	(1) Inhalable fraction (2) 15 minutes average value
GESTIS	Germany (DFG)	N/L	200 (1)	N/L	400 (1)(2)	N/L	N/L	N/A	(1) Inhalable fraction (2) 15 minutes average value
GESTIS	Ireland	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	New Zealand	N/L	10 (1)	N/L	N/L	N/L	N/L	N/A	(1) The value for inhalable dust containing no asbestos and less than 1% free silica
GESTIS	Poland	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Singapore	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Korea	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	10	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Switzerland	N/L	50 (1)	N/L	100 (1)	N/L	N/L	N/A	(1) Inhalable aerosol

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

Inhalation risk: Evaporation at 20°C is negligible; a nuisance-causing concentration of airborne particles can, however, be reached quickly on spraying.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Liquid

DESCRIPTION

Clear, colorless, syrupy liquid. Has not more than a slight characteristic odor, which is neither harsh nor disagreeable. Is hygroscopic.

SOLUBILITY

Miscible with water and with alcohol. Insoluble in chloroform, in ether, and in fixed and volatile oils.

ODOR

Odorless or slight characteristic odor.

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

393°C, 739.4°F

BOILING POINT

290°C, 554°F
(101.325 kPa)

DECOMPOSITION TEMPERATURE

290°C, 554°F

EVAPORATION RATE	Negligible at 20°C	EXPLOSIVE LIMIT	Not available	FLASH POINT	177°C, 350.6°F (open cup)
log P (OCTANOL-WATER)	- 1.76	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	0.9 %	MELTING/FREEZING POINT	(17-18)°C, (62.6-64.4)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5 - 7.5 (1%)
RELATIVE DENSITY (WATER = 1)	1.261	SPECIFIC GRAVITY	>= 1.249 (25°C)	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	3.17	VAPOR PRESSURE	< 0.1 (20 °C)	VISCOSITY	1300 mPa.s (20 °C)

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	The violent or explosive reactions exhibited by glycerol in contact with many solid oxidants are due to its unique properties of having three centres of reactivity, of being a liquid which ensures good contact, and of high boiling point and viscosity which prevents dissipation of oxidative heat.
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants agents such as Nitric Acid or other strong acids, Chromium Trioxide, Potassium Chlorate, or Potassium Permanganate may cause an explosion.
HAZARDOUS DECOMPOSITION PRODUCTS	Pure glycerol is not prone to oxidation by the atmosphere under ordinary conditions, but it decomposes on heating with the evolution of toxic acrolein.
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 12 600 Dermal: Rabbit LD50: (mg/kg): 10 000 Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. 500 mg Eye irritancy (Draize); Result: Mild irritation; Species: Rabbit; Test Duration: 24 hours 500 mg Skin irritancy (Draize); Result: Mild irritation; Species: Rabbit; Test Duration: 24 hours Skin irritancy (50% solution); Result: Non-irritating; Species: Human
SERIOUS EYE DAMAGE/EYE IRRITATION	Based on available data, the classification criteria are not met. Eye irritancy; Result: Non-irritating; Species: Human
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.

SKIN SENSITIZATION

Based on available data, the classification criteria are not met.

Human patch test; Result: Non-sensitizing; Patch test (0.1 ml of a 0.1% solution); Result: Non-sensitizing;

Species: Guinea pig

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY

OSHA GLYCERIN is not listed.

NTP GLYCERIN is not listed.

IARC GLYCERIN is not evaluated.

California Proposition This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Based on available data, the classification criteria are not met.

ADDITIONAL CARCINOGENICITY INFORMATION
REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Due to lack of data the classification is not possible.

ASPIRATION HAZARDS

Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE

ROUTES OF EXPOSURE:

Oral

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics
Headache. Nausea. Vomiting. Diarrhea. Dizziness. Dry mouth. Thirst. Confusion.

Medical conditions aggravated by exposure

Heart disease. Impaired liver function. Impaired kidney function. Diabetes mellitus.

POTENTIAL HEALTH EFFECTS

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion Small amounts swallowed incidental to normal handling operations are not likely to cause injury. Swallowing larger amounts may cause injury. Glycerin used as a multiple purpose GRAS food substance in food for human consumption is generally recognized as safe when used in accordance with good manufacturing practice.

Skin Not expected to cause skin irritation.

Eyes May cause slight temporary eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: *Oncorhynchus mykiss*: (mg/L): 51000 - 57000

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Readily biodegradable (OECD 301)

BIOACCUMULATIVE POTENTIAL

Low: LogPow: - 1.76

MOBILITY IN SOIL	Miscible with water. Low potential for sorption to soil. Glycerol will partition primarily to water. Water Solubility: 1.00E+06 mg/L (25°C) Henry's Law Constant: 1.73E-08 atm-m ³ /mole (25°C)
OTHER ADVERSE EFFECTS	The product contains volatile organic compounds which have a photochemical ozone creation potential This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA HAZCHEM	Not applicable
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EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not Listed
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ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
GLYCERIN 56-81-5	N/L	N/L	N/L	N/L	X	X	X	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
GLYCERIN 56-81-5	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
GLYCERIN 56-81-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES
ABBREVIATIONS AND ACRONYMS

Available upon request

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

01/2023

SUPERSEDES

10/2020

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.