

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	GUM BASE (Gelatin)
PRODUCT CODE	2779
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	A

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME Not applicable

BOTANICAL NAME Not applicable

SYNONYM Not applicable

CHEMICAL FORMULA Not applicable

CHEMICAL FAMILY Not applicable

CAS NUMBER Not applicable

ALTERNATE CAS NUMBER Not applicable

MOLECULAR WEIGHT Not applicable

COMPOSITION

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

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.

NOTES

*Proprietary: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as trade secret.

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

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

Not expected to be a hazard under anticipated conditions of normal use. 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 combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, 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

Shut off all sources of ignition. Evacuate the area. 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.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours.

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 fraction (2) Respirable fraction
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 Africa Mining	10	N/L	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

Not needed for normal use. Operate according to good working practices.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Light yellow solid gel like pieces, consisting of a pre-mixed blend of gelatin, water and glycerin.

SOLUBILITY

Not available

ODOR

Not available

FLAMMABILITY	May be combustible at high temperature				
AUTO-IGNITION TEMPERATURE	Not available	BOILING POINT	Not available	DECOMPOSITION TEMPERATURE	Not available
EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available	FLASH POINT	Not available
log P (OCTANOL-WATER)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(42 - 47)°C, (107.6-116.6)°F
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	Not available	VISCOSITY	Not available

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
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): Not available Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Due to lack of data the classification is not possible.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible.
SKIN SENSITIZATION	Due to lack of data the classification is not possible.

GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.
CARCINOGENICITY	<p>OSHA No component of this product, present at $\geq 0.1\%$, is listed.</p> <p>NTP No component of this product, present at $\geq 0.1\%$, is listed.</p> <p>IARC No component of this product, present at $\geq 0.1\%$ has been evaluated.</p> <p>California Proposition No component of this product, present at $\geq 0.1\%$ is known to the State of California to cause cancer, birth defects, or any other reproductive harm.</p>
ADDITIONAL CARCINOGENICITY INFORMATION	Due to lack of data the classification is not possible.
REPRODUCTIVE TOXICITY	Due to lack of data the classification is not possible.
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	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Not available</p> <p>Not expected to present a significant hazard under anticipated conditions of normal use.</p>
POTENTIAL HEALTH EFFECTS	<p>Inhalation Not expected to present a significant hazard.</p> <p>Ingestion Not expected to present a significant hazard.</p> <p>Skin Not expected to present a significant hazard.</p> <p>Eyes May cause eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available</p> <p>LC50: 96 Hr: Fish: (mg/L): Not available</p> <p>EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Not available
OTHER ADVERSE EFFECTS	<p>Not available</p> <p>This product is not intended to be released into the environment</p>

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

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE Not Listed

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		Pennsylvania	Right-to-know			California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts		
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	Listed

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

Available upon request

ABBREVIATIONS AND ACRONYMS

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

03/2024

SUPERSEDES

03/2023

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.