

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PLO GEL - MEDIFLO™ 30 PRE-MIXED
PRODUCT CODE	2501
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 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
USES	Vehicle for compounded preparations containing a lower concentration of active agents (<10%). Topical use.

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)	May cause an allergic reaction.			
AUSTRALIA-ONLY HAZARDS	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
CAS NUMBER	Not applicable
ALTERNATE CAS NUMBER	Not applicable

MOLECULAR WEIGHT	Not applicable		
COMPOSITION	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT
	THIMEROSAL	54-64-8	*Proprietary
	BENZALKONIUM CHLORIDE	8001-54-5	*Proprietary
NOTES	<p>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.</p> <p>*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.</p>		

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 normal use. Wash with soap and water if irritation occurs. Seek medical attention if irritation develops and persists.
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 normal use. Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
SYMPTOMS AND EFFECTS	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.
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	Shut off all sources of ignition. Evacuate the area. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. 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.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Avoid contact with eyes. 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 unlabelled 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. 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. Keep in well-closed containers at controlled room temperature. Keep away from heat.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION
Chemical Name: BENZALKONIUM CHLORIDE CAS #: 8001-54-5

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

Chemical Name: THIMEROSAL (listed as organo (alkyl) mercury) CAS #: 54-64-8

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	0.01 mg/m ³	0.04 mg/m ³	-	-	-	Table Z-2 (29 CFR 1910.1000)
ACGIH TLV	0.01 mg/m ³	N/L	0.03 mg/m ³	-	-	-
NIOSH	0.01 mg/m ³	N/L	0.03 mg/m ³	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	0.01 mg/m ³	N/L	0.03 mg/m ³	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

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

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Not needed for normal use. Operate according to good working practices. **Skin:** No special precaution must be adopted for normal use. Operate according to good working practices. **Clothing:** Not needed for normal use. Operate according to good working practices. **Respirators:** Not needed for normal use. Operate according to good working practices.

SPECIFIC ENGINEERING CONTROLS

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Creamy yellow to butterscotch colored gel. May darken after 30 days.

SOLUBILITY

Soluble in alcohol.

ODOR

Not available

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD	Not available	pH	6.0 - 7.0 (25°C)	MELTING POINT	Not available
BOILING POINT	Not available	FREEZING POINT	Not available	FLASH POINT	Not available
SPECIFIC GRAVITY	0.9350 - 1.0200 (25°C)	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	Not available
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

NOTES

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

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions.
MATERIALS TO AVOID	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	Based on available data, the classification criteria are not met. Contains POTASSIUM SORBATE that may cause irritation.
RESPIRATORY OR SKIN SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Contains soy based LECITHIN, THIMEROSAL and POTASSIUM SORBATE, may cause allergic reaction. Based on available data, the classification criteria are not met.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible.\
CARCINOGENICITY	OSHA No component of this product, present at ≥0.1%, is listed. NTP No component of this product, present at ≥0.1%, is listed.

IARC	No component of this product, present at $\geq 0.1\%$ has been evaluated.
California Proposition 65	This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: MERCURY COMPOUNDS (THIMEROSAL) No other 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.
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	Not expected to present a significant hazard under anticipated conditions of normal use.
POTENTIAL HEALTH EFFECTS	Inhalation Not expected to present a significant hazard under anticipated conditions of normal use. Ingestion May be harmful if swallowed. Skin Not expected to present a significant hazard under anticipated conditions of normal use. May cause skin irritation. May cause an allergic reaction. Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

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

SECTION 13: DISPOSAL CONSIDERATIONS

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

UNITED STATES & CANADA	
UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

YOUR TRUSTED PARTNER IN COMPOUNDING

AUSTRALIA

UN PROPER SHIPPING NAME Not dangerous good

UN NUMBER Not applicable

CLASS Not applicable

PACKING GROUP Not applicable

HAZCHEM Not Applicable

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
THIMEROSAL 54-64-8	X*	X*	N/L	N/L	X*	X*	N/L	X*
BENZALKONIUM CHLORIDE 8001-54-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
THIMEROSAL 54-64-8	N/L	N/L	N/L
BENZALKONIUM CHLORIDE 8001-54-5	N/L	Listed as Schedule 6	N/L

NOTES *Mercury compounds are listed.

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** – Mine Safety and Health Administration; **ACGIH** – American Conference of Governmental Industrial Hygienists; **IDHL** – Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** – Recommended Exposure Limit

LAST REVISION

03/2019

SUPERSEDES

12/2016

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.