

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	MEDIDERM™ (Cream Base)
PRODUCT CODE	0738
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)	May cause an allergic reaction.		
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

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
CHLOROCRESOL	59-50-7	200-431-6	*Proprietary
MINERAL OIL (highly-refined)	8042-47-5	232-455-8	*Proprietary
PARAFFIN WAX (Petroleum)	8002-74-2	232-315-6	*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 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 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, 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.

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: CHLOROCRESOL CAS #: 59-50-7

	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	N/L	N/L	N/L	N/L	N/L	N/A	N/A
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	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Poland	N/L	5(1)	N/L	N/L	N/L	N/L	N/A	(1) Inhalable fraction

GESTIS	Sweden	N/L	3	N/L	6(1)	N/L	N/L	N/A	(1) 15 minutes average value
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Chemical Name: MINERAL OIL (highly-refined) CAS #: 8042-47-5

	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	N/L	N/L	N/L	N/L	N/L	N/A	N/A
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	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Germany (AGS)	N/L	5(1)	N/L	20(1)(2)	N/L	N/L	N/A	(1) Respirable fraction (2) 15 minutes average value
GESTIS	Germany (DFG)	N/L	5(1)	N/L	20(1)(2)	N/L	N/L	N/A	(1) Respirable fraction (2) 15 minutes average value
GESTIS	Romania	N/L	5	N/L	10(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Switzerland	N/L	5(1)	N/L	N/L	N/L	N/L	N/A	(1) Inhalable fraction

Chemical Name: PARAFFIN WAX (Petroleum) CAS #: 8002-74-2

	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	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	2	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	2	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	2	N/L	6	N/L	N/L	N/A	N/A
GESTIS	Canada-Ontario	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Canada-Quebec	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Denmark	N/L	2	N/L	4	N/L	N/L	N/A	N/A
GESTIS	Finland	N/L	1	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	France	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Ireland	N/L	2	N/L	6(1)	N/L	N/L	N/A	(1) 15 minutes reference period
GESTIS	New Zealand	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Norway	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	China	N/L	2	N/L	4(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Poland	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Romania	N/L	2	N/L	6(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	Singapore	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Africa	N/L	4	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	South Africa Mining	N/L	2	N/L	6(1)	N/L	N/L	N/A	(1) 15 minutes average value
GESTIS	South Korea	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Spain	N/L	2	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Switzerland	N/L	2	N/L	N/L	N/L	N/L	N/A	Respirable aerosol
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

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	White, homogenous oil-in-water emulsion with faint odor.				
SOLUBILITY	Partially soluble in water.				
ODOR	Faint odor				
FLAMMABILITY	May be combustibile 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	Not available
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	5.25 - 6.50
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.89 - 0.99	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

 Based on available data, the classification criteria are not met.
 Contains skin irritants: Ceteth-20, Paraffin wax, Potassium Sorbate and Disodium EDTA.

SERIOUS EYE DAMAGE/EYE IRRITATION

 Based on available data, the classification criteria are not met.
 Contains eye irritants: Ceteth-20, Paraffin wax, Mineral Oil, Disodium EDTA and Sodium Benzoate.
 Contains Chlorocresol, corrosive to eyes.

RESPIRATORY SENSITIZATION

 Based on available data, the classification criteria are not met.
 Contains Sodium Benzoate: benzoates can cause hypersensitivity reactions.

SKIN SENSITIZATION

 Based on available data, the classification criteria are not met.
 Contains Chlorocresol: Skin: Guinea pig: Sensitizing. May cause an allergic skin reaction.
 Contains Sodium Benzoate: benzoates can cause hypersensitivity reactions.

GERM CELL MUTAGENICITY

Due to lack of data the classification is not possible.

CARCINOGENICITY
OSHA No component of this product, present at $\geq 0.1\%$, is listed.

NTP No component of this product, present at $\geq 0.1\%$, is listed.

IARC MINERAL OIL (highly-refined) is listed in group 3 (not classifiable as to its carcinogenicity to humans).
 No other component of this product, present at $\geq 0.1\%$ has been evaluated.

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.

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

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

SIGNS AND SYMPTOMS OF EXPOSURE

 ROUTES OF EXPOSURE:
 Oral, Dermal, Inhalation, Eye contact
 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.

POTENTIAL HEALTH EFFECTS
Inhalation Not expected to present a significant hazard under anticipated conditions of normal use.
 May cause irritation.

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 skin reaction.

Eyes Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY 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 Partially soluble in water.

OTHER ADVERSE EFFECTS Not available
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.

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	
MINERAL OIL (highly-refined) 8042-47-5	N/L	N/L	N/L	N/L	X	X	X	N/L
CHLOROCRESOL 59-50-7	X	N/L	N/L	N/L	X	X	X	N/L
PARAFFIN WAX (Petroleum) 8002-74-2	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
MINERAL OIL (highly-refined) 8042-47-5	N/L	N/L*	N/L	N/L*	N/L	N/L
CHLOROCRESOL 59-50-7	N/L	Listed as Schedule 5	N/L	Listed	N/L	N/L
PARAFFIN WAX (Petroleum) 8002-74-2	N/L	Listed as Schedule 5	N/L	Listed	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
MINERAL OIL (highly-refined) 8042-47-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L
CHLOROCRESOL 59-50-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L
PARAFFIN WAX (Petroleum) 8002-74-2	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

NOTES

*Pharmaceutical grade mineral oils are exempt.

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

06/2023

SUPERSEDES

03/2019

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.