


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	MINERAL OIL, USP (Heavy)
PRODUCT CODE	0949
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	Aspiration Hazard (Category 1) Eye Irritation (Category 2B)	
PICTOGRAM		
SIGNAL WORD	Danger	
HAZARD STATEMENT(S)	May be fatal if swallowed and enters airways. Causes eye irritation.	
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Not Applicable.	
PRECAUTIONARY STATEMENT(S)	Prevention	Wash hands thoroughly after handling. Do not touch eyes.
	Response	IF SWALLOWED: Immediately call a poison center or medical professional. Get emergency medical help immediately. Do NOT induce vomiting. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help.
	Storage	Store locked up.
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION	Health Hazard	1	Flammability	1
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Not applicable
BOTANICAL NAME	Not applicable
SYNONYM	Heavy White Mineral Oil; Heavy White Mineral Oil (Petroleum); Liquid Parrafin
CHEMICAL FORMULA	Not applicable
CHEMICAL FAMILY	Not available
CAS NUMBER	8042-47-5
ALTERNATE CAS NUMBER	8012-95-1
MOLECULAR WEIGHT	Not applicable

COMPOSITION	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
	MINERAL OIL (Heavy)	8042-47-5	232-455-8	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.

NOTES Light and Heavy Mineral Oils are purified mixtures of liquid hydrocarbons obtained from petroleum. Light Mineral Oil has similar characteristics to Heavy Mineral Oil but a lower kinematic viscosity.

Medicinal white oils are highly refined, colourless oils free of all unsaturated compounds, aromatic compounds and other constituents that influence colour, odour, taste and acceptability as a pharmaceutical and food-grade material.

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 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

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: MINERAL OIL (Heavy) 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	5	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	5	N/L	10	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	5	N/L	N/L	2500	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	5	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

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Liquid

DESCRIPTION

Colorless, transparent, oily liquid, free or practically free from fluorescence. Is odorless when cold, and develops not more than a faint odor of petroleum when heated.

SOLUBILITY

Insoluble in water and in alcohol; soluble in volatile oils. Miscible with most fixed oils but not with castor oil.

ODOR

Is odorless when cold, and develops not more than a faint odor of petroleum when heated.

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

(325- 355)°C,
(617-671)°F

BOILING POINT

(218-643)°C,
(424.4-1189.4)°F

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

>112°C,
>233.6°F
(Closed Cup)

log P (OCTANOL-WATER)

> 6

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

Not available

PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	Not available
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	0.845 - 0.905	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.008 hPa(20°C)	VISCOSITY	34.5 – 150.0 mm ² -s ⁻¹ (40°C)

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): > 5000 Dermal: Rabbit: LD50: (mg/kg): > 2000 Inhalation: Rat: LD50: (ppm/4hr): 2062
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Irritancy test: Guinea pig: Skin: Non-irritating. Irritancy test: Rabbit: Skin: Non-irritating.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation. Irritancy test: Rabbit: Eye: Irritating.
RESPIRATORY SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Based on available data, the classification criteria are not met. Guinea pig maximization test: Non-sensitizing.
SKIN SENSITIZATION	Not available
GERM CELL MUTAGENICITY	Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.
CARCINOGENICITY	OSHA MINERAL OIL (highly-refined) is not listed. NTP MINERAL OIL (highly-refined) is not listed. IARC MINERAL OIL (highly-refined) is listed in group 3 (not classifiable as to its carcinogenicity to humans).

ADDITIONAL CARCINOGENICITY INFORMATION	<p>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.</p> <p>Based on available data, the classification criteria are not met. Carcinogenicity study: 2 years: Mouse: 75 µL/kg: No carcinogenetic effect. Lifetime carcinogenicity study: Mouse: 75 µL/kg: No carcinogenetic effects observed.</p>
REPRODUCTIVE TOXICITY	<p>Based on available data, the classification criteria are not met. Hypothrombinemia and hemorrhagic disease of the newborn have occurred following chronic use of mineral oil during pregnancy.</p>
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	<p>Due to lack of data the classification is not possible.</p>
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	<p>Due to lack of data the classification is not possible.</p>
ASPIRATION HAZARDS	<p>May be fatal if swallowed and enters airways. This product is relatively non-toxic by ingestion unless aspiration occurs. Aspiration may lead to chemical pneumonitis, which is characterized by pulmonary edema and hemorrhage and may be fatal. Coughing, choking, and gagging are often noted at the time of aspiration. Gastrointestinal discomfort may develop, followed by vomiting with a further risk of aspiration. Product has laxative properties and may result in abdominal cramps and diarrhea. Exposure to a large single dose or repeated smaller doses of mineral oil by inhalation, aspiration or ingestion leading to aspiration can lead to lipid pneumonia or lipid granuloma. Shortness of breath and cough are the most common symptoms. Heavy Mineral Oil is a hydrocarbon with a kinematic viscosity that is greater than 20.5 mm²/s (40° C).</p>
SIGNS AND SYMPTOMS OF EXPOSURE	<p>ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics: Nausea. Vomiting. Diarrhea. Laxative effects.</p> <p>Medical conditions aggravated by exposure: Appendicitis. Intestinal problems. Ulcerative colitis. Rectal bleeding.</p>
POTENTIAL HEALTH EFFECTS	<p>Inhalation May be harmful if inhaled. May cause respiratory tract irritation. May be fatal if swallowed and enters airways.</p> <p>Ingestion May be harmful if swallowed. May be fatal if swallowed and enters airways.</p> <p>Skin May be harmful if absorbed through skin. May cause skin irritation</p> <p>Eyes Causes eye irritation.</p>

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	<p>EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): > 10000 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p>
PERSISTENCE AND DEGRADABILITY	<p>Not available</p>
BIOACCUMULATIVE POTENTIAL	<p>High: LogPow: > 6.</p>
MOBILITY IN SOIL	<p>Insoluble in water.</p>
OTHER ADVERSE EFFECTS	<p>Not available</p>

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 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
MINERAL OIL (highly-refined) 8042-47-5	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
MINERAL OIL (highly-refined) 8042-47-5	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
MINERAL OIL (highly-refined) 8042-47-5	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

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

03/2023

SUPERSEDES

05/2020

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.