

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME MINERAL OIL, USP (Light)

PRODUCT CODE 0037

SUPPLIER MEDISCA Inc.

Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 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

National Chemical Emergency Centre 44(0)1235239670

RECOMMENDED USES Manufacturing and Compounding

RESTRICTIONS ON USE Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION Aspiration Hazard (Category 1)
Eye Irritation (Category 2B)

PICTOGRAM

SIGNAL WORD Dang

HAZARD STATEMENT(S) May be fatal if swallowed and enters airways.

Causes eye irritation.

DVERSE PHYSIOCHEMICAL, HUMAN Not Applicable.

ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL

EFFECTS

PRECAUTIONARY STATEMENT(S) PreventionWash 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

CHEMICAL FAMILY

CAS NUMBER

ALTERNATE CAS NUMBER

Not available

8042-47-5

8012-95-1

MOLECULAR WEIGHT Not applicable

 COMPOSITION
 CHEMICAL NAME
 CAS NUMBER
 EC NUMBER
 % BY WEIGHT

 MINERAL OIL (Light)
 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.

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 ail 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

NOTES

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.

Last Revision: 03/2023 MINERAL OIL, USP (Light) Page 2 of 8



SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

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.

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

CLEANUP PROCEDURE

On land, sweep or shovel into suitable containers.

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 SECTIONSSee 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

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 (Light) CAS #: 8042-47-5

	Country	Country Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes	
		ppm	mg/m³	ppm	mg/m³					
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

PHYSICAL STATE

DESCRIPTION

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.

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

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

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

Liquid

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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 (325-355)°C, **BOILING POINT** (218-643)°C, DECOMPOSITION Not available **TEMPERATURE** TEMPERATURE (617-671)°F (424.4-1189.4)°F Not available >112°C, **EVAPORATION RATE** Not available EXPLOSIVE LIMIT **FLASH POINT** >233.6°F (Closed (quD Not available Not available LOWER FLAMMABLE/ **MELTING/FREEZING** > 6 (OCTANOL-WATER) **POINT** EXPLOSIVE LIMIT(S) OXIDIZING PROPERTY Not available Not available **PARTICLE** Not available pΗ **CHARACTERISTICS** 0.845 - 0.905 **RELATIVE DENSITY** Not available SPECIFIC GRAVITY UPPER FLAMMABLE/ Not available (WATER = 1)**EXPLOSIVE LIMIT(S)** VAPOR DENSITY Not available VAPOR PRESSURE < 0.008 VISCOSITY 34.5 - 150.0 (AIR = 1)hPa(20°C) mm2·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

HAZARDOUS POLYMERIZATION

POSSIBLITY OF HAZARDOUS

REACTION

CONDITIONS TO AVOID

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

Will not occur

Not established

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 Causes eye irritation.

IRRITATION Irritancy test: Rabbit: Eye: Irritating.

RESPIRATORY SENSITIZATIONRespiratory 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).

California This product does not contain any chemicals known to the State of California to cause

Proposition 65 cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY

INFORMATION

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

Carcinogenicity study: 2 years: Mouse: 75 $\mu\text{L/kg}$: No carcinogenetic effect.

Lifetime carcinogenicity study: Mouse: 75 µL/kg: No carcinogenetic effects observed.

REPRODUCTIVE TOXICITY 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.

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 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).

SIGNS AND SYMPTOMS OF

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

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Not available

Symptoms related to the physical, chemical, and toxicological characteristics:

Nausea. Vomiting. Diarrhea. Laxative effects.

Medical conditions aggravated by exposure:

Appendicitis. Intestinal problems. Ulcerative colitis. Rectal bleeding.

POTENTIAL HEALTH EFFECTS Inhalation May be harmful if inhaled. May cause respiratory tract irritation. May be fatal if swallowed

> and enters airways. Ingestion May be harmful if swallowed. May be fatal if swallowed and enters airways.

Skin May be harmful if absorbed through skin. May cause skin irritation

Causes eye irritation. Eyes

SECTION 12: ECOLOGICAL INFORMATION

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

Not available

LC50: 96 Hr: Fish: (mg/L): > 10000

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

PERSISTENCE AND DEGRADABILITY

BIOACCUMULATIVE POTENTIAL High: LogPow: > 6. MOBILITY IN SOIL Insoluble 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

Last Revision: 03/2023 MINERAL OIL, USP (Light) Page 6 of 8



AUSTRALIA

HAZCHEM Not applicable

EU

TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE

IBC CODE

Not Listed

IBC CODE

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 Part 372.65	EPA 40 CFR Part 355		Pennsylvania	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 Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials	
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

Not applicable

AGREEMENT

NOTES

*Pharmaceutical grade mineral oils are exempt.

SECTION 16: OTHER INFORMATION

REFERENCES Available upon request

Last Revision: 03/2023 MINERAL OIL, USP (Light) Page 7 of 8



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 - Instituto 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 SUPERSEDES 03/2023

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.