

SAFETY DATA SHEET

Not Dangerous Goods according to the ADG Code, nor IATA Regulations, nor IMDG Code
Not a Hazardous Chemical to the GHS Criteria in Australia and in New Zealand

1. IDENTIFICATION

Product identifier: **Liquid Paraffin Sterile (Tube) 5mg**
Synonyms: **5000023631**

Contact: Avaris Pharma
Address: 25-29 Delawney Street
Balcatta, Western Australia, 6021

Telephone number: +61 8 9441 7800
Australia Emergency telephone: **Poisons Information Centre: 13 11 26**
New Zealand Emergency telephone: **National Poisons Center: 0800764766**

Recommended use: Occlusive wound dressing and lubricant.
Restrictions on use: None known.
HSNO Number: Not applicable

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements

Not hazardous in accordance with the GHS.

Hazardous Substances Information:			
Not a Hazardous Substance to the Safe Work Australia Risk Phrase Criteria			
Poison Schedule	Not Applicable	Signal Word	Not Applicable
Dangerous Goods Information:			
NOT Dangerous Goods according to the ADG Code, nor IATA Regulations, nor IMDG Code.			

Acute Health Effects	
Swallowed	Not expected to be harmful if swallowed. These Process Mineral Oils are not likely to be aspirated into the lungs due to their high viscosity (≥ 20.5 centistokes). They may produce a laxative effect if swallowed.
Eye	Not expected to be harmful, may cause slight eye irritation. May cause a thermal burn from eye contact with splashed hot product.
Skin	Not normally expected to be harmful. High-pressure injection under the skin may cause serious damage. May cause a thermal burn from skin contact with hot product.
Inhaled	At room temperature there are no vapours and no inhalation hazard. Oil Mists may cause respiratory irritation, dizziness, nausea.

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If Overheated: May cause irritation of the nose, throat and lungs; and may cause headaches, and possible nausea.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Concentration	Classification
Refined White Mineral Oil (Petroleum)	8042-47-5	100%	Not Hazardous

4. FIRST AID MEASURES

Skin	<p>If this product comes into contact with skin, wash skin with soap and water. Remove contaminated clothing and footwear. Clothing and footwear contaminated with paraffin represents an increased flammability risk. Ensure contaminated clothing is thoroughly washed before using again. Discard contaminated clothing that cannot be cleaned.</p> <p>IF high-pressure product injection injuries occur, immediately seek professional medical attention. Do not wait for symptoms to develop. For minor thermal burns, cool the burn. Hold the burned area under cold running water for at least five minutes, or until the pain subsides. Body hypothermia must be avoided. Seek medical attention in all cases of serious burns.</p>
Inhaled	<p>If over-exposed to oil mist remove from further exposure. If respiratory irritation, dizziness, nausea or unconsciousness occurs, seek medical attention.</p> <p>If hot fumes are inhaled, remove to fresh air. Keep at rest until fully recovered. If unusual symptoms develop, seek medical attention.</p>
First-Aid Facilities	Eye wash and safety shower immediately available. Normal washroom facilities nearby.
Advice to Doctor	<p>Treat symptomatically. Material, IF aspirated into the lungs may cause chemical pneumonitis.</p> <p>INJECTION INJURY WARNING: If these products are injected into or under the skin, or into any part of the body, regardless of the appearance of the wound or its size, the individual should be evaluated immediately by a doctor as a surgical emergency. Even though initial symptoms from high pressure injection may be minimal or absent, early surgical treatment within the first few hours may significantly reduce the ultimate extent of injury.</p>

5. FIRE FIGHTING MEASURES

Fire or Explosion Hazard:	A Combustible Liquid Flash Point 170-240°C. See Section 9 for each product's values. They are not easily ignitable due to their high flash points, HOWEVER these materials can ignite and burn under fire conditions. Once ignited treat, as an Oil fire.
Extinguishing Media:	Carbon Dioxide, dry chemical, foam, water fog. Do not use direct water jets on the burning product.

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	Water jets or spray may cause splattering and frothing and spread the fire. Simultaneous use of foam and water on the same surface is to be avoided, as water destroys the foam.
Hazardous Combustion Products:	Incomplete combustion products, Aldehydes, unidentified organic compounds, Carbon Monoxide, Fumes and Smoke (if combustion is incomplete).
Special Protective Precautions and Procedures	Move containers from the fire area if it can be done without risk. Precautions & Burning liquid will float on water. Use water spray to cool fire exposed surfaces and Equipment containers. Water spray may be used to flush spills away from exposures. Prevent runoff from fire control or dilution from entering waterways, sewers or drinking water supply. Cut off "fuel"; depending on circumstances, either allow the fire to burn out under controlled conditions or extinguish the fire. Decomposition products are toxic. Fire-fighters may need to wear Self Contained Breathing Apparatus in enclosed spaces with overheated product or where combustion is incomplete.

6. ACCIDENTAL RELEASE MEASURES

Emergency Procedures, containment and Cleanup	<p>In event of a major spill, prevent spillage from entering drains or water courses. At room temperature, wear closed shoes, overalls and impervious gloves. Stop leak if contained & safe to do so, contain spill. For hot product spills remove all ignition sources.</p> <p>Return recoverable product into labelled containers for recycling or salvage.</p> <p>If necessary absorb onto an inert absorbent material, e.g. vermiculite, diatomaceous earth, etc, then shovel up and dispose of at an approved waste disposal facility. After spill cleanup, wash area, preventing run off from entering drains. If spills are likely to enter any drain, waterway or ground-water, contact your local Authorities.</p> <p>WATER SPILL: Floats on water. Confine the spill immediately with booms. Warn other ships in the vicinity. Notify port and other relevant authorities. Remove from the surface by skimming or with suitable absorbents. If permitted by regulatory authorities the use of suitable dispersants should be considered where recommended in local oil spill procedures.</p> <p>See Section 13 for Disposal Considerations</p>
Special Issues	Slippery on floors, especially when wet.
Environmental Precautions	Environmental Spillages or uncontrolled discharges into watercourses must be IMMEDIATELY precautions alerted to the Environmental Agency or other appropriate regulatory body.

7. Handling and Storage

Safe Handling	<p>Keep containers closed. Keep away from Oxidisers.</p> <p>Store and handle so as to prevent contamination from any source, especially when this material will be used in food or medical applications. No special precautions are necessary beyond normal good hygiene practices. Electrical equipment and fittings must comply with local regulations regarding fire prevention with these Flash Point 170-240°C Combustible Liquids. These materials accumulate static.</p>
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	AS1940 provides handling advice on these Combustible Liquids.
Safe Storage	<p>Store in cool, well ventilated, dry surroundings, away from sources of ignition.</p> <p>Do not store in open or unlabelled containers. Store away from strong oxidizing agents. See Section 15 for Regulatory information when storing this product.</p> <p>Storage, load and unload temperatures:- ambient to 40°C</p> <p>Store and handle in accordance with Work Health & Safety Regulations, Occupational Health & Safety Regulations, or Health & Safety Regulations at Work Regulations, in your jurisdiction</p>

8. Exposure Controls / Personal Protection

National Exposure Standards	Exposure Standards determined by the Safe Work Australia, and Worksafe New Zealand Workplace Exposure Standards. Standards Oil Mist 5 mg/m ³ TWA.
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Design and Engineering Control Measures	Ventilation at room temperature is not normally needed unless an Oil Mist is created. Where mist or heated fumes are generated use good ventilation to maintain the air concentration below the exposure standards. Storage and handling temperatures should be kept as low as feasible to minimize fume production.
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Personal Protective Equipment	<p>Avoid skin and eye contact. Avoid inhaling heated vapour or fumes. The following personal protective equipment should be used:</p> <p>Product at Room Temperature:</p> <p>Protective, oil resistant gloves are recommended to avoid unnecessary skin contact (e.g. Nitrile). If eye contact is likely, safety glasses with side shields are recommended.</p> <p>Heated Product:</p> <p>Safety glasses with side shields, or chemical goggles as appropriate. Wear heat protective gloves with long cuffs, or gauntlets. Closed shoes or safety boots as appropriate. Clean overalls or similar heat protective apparel, preferably with an apron. If a risk of vapour overexposure exists due to overheated product; use an organic vapour respirator meeting AS1715/1716.</p> <p>Product forming a Spray Mist:</p> <p>Safety glasses with side shields, or chemical goggles as appropriate. Wear Paraffin Mineral Oil resistant gloves (e.g. Nitrile) Closed shoes or safety boots as appropriate. Clean overalls or similar protective apparel, preferably with an apron. If a risk of oil mist overexposure exists due to the spray mist application of the product; use a P2 respirator designed for oil mists meeting AS1715/1716.</p> <p>Where applicable refer to the following Standards: AS/NZS 1337 Eye protectors for industrial applications.</p>
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	AS 2161	Industrial safety gloves and mittens.
	AS 2210	Safety footwear.
	AS 3765	Clothing for protection against hazardous chemicals.
	AS 1715	Selection, use and care of respiratory protection devices.
	AS 1716	Respiratory protection devices.
	Always wash hands before smoking, eating, drinking or using the toilet.	

9. Physical and Chemical Properties

Typical physical properties are given below. Consult the Product Data Sheet for specific details.	
Physical Form	Liquid
Appearance and Odour	Clear colourless to dark brown oily liquids with neutral mild odours.
Melting Point	MP < 0°C
Boiling Point	> 316°C
Decomposition Temperature	> 350°C
Vapour Pressure	Very low at 200°C (< 0.1 hPa calculated)
Density (typical values at 15°C)	0.856
Relative Vapour Density	>2 (air=1)
Solubility	Insoluble in water.
Percent volatile by volume	Nil at 20°C
pH	Not applicable
Odour Threshold	Not applicable
Viscosity (typical values)	(at 40°C): 70-80 mm ² /s (at 100°C): 8-9 mm ² /s
Pour Point (°C) (typical values)	-25°C

Flammable Properties	Combustible Liquid Flash Point 170-240°C. Will burn readily under fire conditions.
Flashpoint (COC)	(BP 350) 220-240°C (IP 36 / ASTM D-92)
Flammability Limits (FL) (%)	Estimated from similar oils Lower FL: 0.9% Upper FL: 7.0%
Auto-ignition Temp	Not Available

10. Stability and Reactivity

Chemical Stability:	Stable. Decomposes >350°C.
Incompatible Materials:	Contact with Strong Oxidizers (Peroxides, Chromates, etc.) may cause a fire hazard. A mixture with Nitrates or other Strong Oxidisers (e.g. Chlorates, Perchlorates, Liquid Oxygen) may create an explosive mass. Sensitivity to heat, friction or shock cannot be assessed in advance.
Unsuitable Container Materials:	Some synthetic materials may be unsuitable for containers or container linings depending on the material specification and intended use.
Hazardous Reactions:	Hazardous polymerisation will not occur.

11. Toxicological Information

(Based on testing of similar products and/or the components.)	
ORAL TOXICITY:	Practically non-toxic (LD50 (rat): >5000 mg/kg)
DERMAL TOXICITY:	Practically non-toxic (LD50 (rabbit): >2000 mg/kg)
INHALATION TOXICITY:	(LC50 (rat): >5 mg/L/4hrs or >5000 mg/m ³ /4hrs) Harmful concentrations of mists and/or vapours are unlikely to be encountered through any customary or reasonably foreseeable handling, use, or misuse of this product.
EYE IRRITATION:	Practically non-irritating. (Draize score: 0 or greater, but less than 6.) Chronic studies of white mineral oils and other highly refined mineral hydrocarbons have shown no indications of chronic toxicity or carcinogenicity.
SKIN IRRITATION:	Practically non-irritating. (Primary Irritation Index: 0.5 or less)
CHRONIC:	Chronic studies of white mineral oils and other highly refined mineral hydrocarbons have shown no indications of chronic toxicity or carcinogenicity.

<p>GHS CRITERIA: (CAS 8042-47-5)</p> <p>ACUTE ORAL TOXICITY</p> <p>ACUTE INHAL'N TOXICITY</p> <p>ACUTE SKIN TOXICITY SKIN</p> <p>CORROSION / IRRITATION</p> <p>SERIOUS EYE DAMAGE / IRRITATION</p> <p>SKIN SENSITISATION</p> <p>RESPIRATORY SENSITISATION</p> <p>GERM CELL MUTAGENICITY</p> <p>CARCINOGENICITY</p> <p>REPRODUCTIVE TOXICITY</p> <p>SPECIFIC TARGET ORGAN TOXICITY - Single Exposure:</p> <p>SPECIFIC TARGET ORGAN TOXICITY - Repeated Exposure:</p> <p>ASPIRATION HAZARD</p> <p>(ECHA Registered Substances Database)</p>	<p>: Not classified.</p>
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12. Ecological Information

General	No environmental issues expected. Not expected to be harmful to aquatic organisms. Slightly water polluting substance. Avoid contaminating waterways. Bioaccumulation is unlikely.
Ecotoxicity Data:	CAS 8042-47-5: Acute (short-term) fish toxicity (LC50): >1000 mg/l (96 h) Leuciscus Idus (Golden Orfe) Acute (short-term) toxicity to crustacea (LL50): >100 mg/l (48 h) Daphnia Magna Acute (short-term) toxicity to aquatic algae and cyanobacteria (NOEL): >100 mg/l (3d) Pseudokirchneriella Subcapitata

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	<p>Chronic (long-term) fish toxicity (NOEL): >1000 mg/l (28 d) QSAR (All the above are from the ECHA Dossier) Available ecotoxicity data on these oils indicates that adverse effects to aquatic organisms are not expected from this product range. Octanol/Water Partition Co-efficient - Log Pow: >3</p>
Persistence & Degradability	<p>These products are expected to be inherently biodegradable. Having the potential to bioaccumulate, however metabolism or physical properties may reduce the bioconcentration or limit bioavailability. Does not meet the PBT/vPvB criteria.</p>
Bio-accumulative potential	<p>White Mineral Oils all have the potential to bioaccumulate, however they are expected to be inherently biodegradable.</p>
Mobility:	<p>Insoluble in water. Floats and is expected to migrate from water to land. When released into the environment, adsorption to sediment and soil will be the predominant behavior.</p>
<p>GHS CRITERIA: (CAS 8042-47-5) HAZARDOUS TO THE AQUATIC ENVIRONMENT (acute/short-term): Not Classified HAZARDOUS TO THE AQUATIC ENVIRONMENT (long-term): Not Classified (ECHA Registered Substances Database)</p>	

13. Disposal Considerations

Disposal Methods & Containers	<p>Disposal to be in accordance with Local, State & Federal EPA waste regulations. Recover or recycle the product if possible. Product is suitable for burning in an enclosed, controlled burner for fuel value or disposal by supervised incineration. Such burning may be limited by your local Authority. In addition, the product is suitable for processing by an approved recycling facility or can be disposed of at any approved waste disposal site. Emptying Instructions: Turn upside down and tilt approx. 10° until non-dripping at < 1 drop / minute at 15°C. It may be necessary to scrape out high viscosity oils. Recycle containers wherever possible. Only re-use container for the same Oils as the compatibility of residues with other materials cannot be assessed.</p>
Special Precautions:	<p>Do NOT expose empty containers (that may have residue oil) to heat or ignition sources. Do not cut, weld, bore, burn or incinerate emptied containers, unless they have been cleaned and declared safe.</p>

14. Transport Information

ROAD & RAIL:	Not Dangerous Goods according to the ADG Code.
SEA:	Not Dangerous Goods according to the International Maritime Dangerous Goods Code (IMDG Code).
AIR:	Not Dangerous Goods according to the International Air Transport Association Dangerous Goods Regulations.

15. Regulatory Information

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Classification Basis:	<p>Not a Hazardous Chemical to the GHS Criteria in Australia and in New Zealand.</p> <p>Not a Scheduled Poison.</p> <p>Not Dangerous Goods.</p> <p>Not an Environmentally Hazardous Substance to the GHS Criteria.</p>
Packaging	Must be in suitable packaging for handling, transport and storage, that will withstand normal handling, under the expected weather conditions.

Chemical Control Schemes – Australia and New Zealand	
AICIS – AICI:	On the Australian Industrial Chemicals Inventory (AICI) Under the Australian Industrial Chemicals Introduction Scheme (AICIS) at https://www.industrialchemicals.gov.au/
Other Inventories	All components comply with the European EINECS/ELINCS, and the USA TSCA

16. Other Information

Acronyms Used	
ADG Code	Australian Dangerous Goods Code for the Transport of Dangerous Goods by Road & Rail
Safe Work Australia	Safe Work Australia (SWA) (since 2009) administers ASCC & NOHSC documents.
HCIS	Hazardous Chemicals Information System at: http://hcis.safeworkaustralia.gov.au/
NZ HSNO	New Zealand Hazardous Substances and New Organisms
NZ EPA HSNO CCID	Environmental Risk Management Authority New Zealand, HSNO Chemical Classification Information Database.
e-ChemPortal	Global Portal to Information on Chemical Substances https://www.echemportal.org/echemportal/substance-search
ECHA	European Chemicals Agency at http://echa.europa.eu/
ECHA RSD	ECHA Registered Substances Database (with SIEF results of chemical reviews) http://echa.europa.eu/information-on-chemicals/registered-substances
ECHA C&LI	ECHA Classification & Labelling Inventory http://echa.europa.eu/information-on-chemicals/cl-inventory-database
CAS No.	Chemical Abstracts Service Registry Number
UN No.	United Nations Dangerous Goods Number
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons

SDS Codes Used	<p>This SDS has been prepared according to the Australian SWA Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals July 2020 (122 page pdf)</p> <p>www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals</p>
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AND in accordance with the New Zealand Hazardous Substances (Safety Data Sheets) Notice 2017 (27 July 2017) (25 page pdf)

www.epa.govt.nz/industry-areas/hazardous-substances/rules-for-hazardous-substances/epa-notices-for-hazardous-substances/

SDS Dates and Revision.

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February 11, 2025