

# Ilium Opticin Eye Ointment

## Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: 3

Chemwatch: 5398-92  
 Version No: 4.1.1.1  
 Safety Data Sheet according to WHS and ADG requirements

Issue Date: 11/08/2020  
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 S.GHS.AUS.EN

### SECTION 1 Identification of the substance / mixture and of the company / undertaking

#### Product Identifier

Product name	Ilium Opticin Eye Ointment
Synonyms	APVMA number: 38629
Other means of identification	Not Available

#### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Topical treatment of conjunctivitis in dogs and cats. To be used as directed on product label.
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#### Details of the supplier of the safety data sheet

Registered company name	Troy Laboratories Pty Ltd
Address	37 Glendenning Road Glendenning NSW 2761 Australia
Telephone	02 8808 3600
Fax	02 9677 9300
Website	<a href="http://www.Troylab.com.au">www.Troylab.com.au</a>
Email	admin@troylab.com.au

#### Emergency telephone number

Association / Organisation	Troy Laboratories Pty Ltd
Emergency telephone numbers	02 8808 3600 (Office hours (8am – 4pm, Monday to Friday))
Other emergency telephone numbers	Not Available

### SECTION 2 Hazards identification

#### Classification of the substance or mixture

Poisons Schedule	S3
Classification [1]	Skin Sensitizer Category 1, Respiratory Sensitizer Category 1, Germ cell mutagenicity Category 1B, Carcinogenicity Category 1B, Chronic Aquatic Hazard Category 3
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	
Signal word	Danger

#### Hazard statement(s)

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H340	May cause genetic defects.
H350	May cause cancer.
H412	Harmful to aquatic life with long lasting effects.

#### Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.

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P285	In case of inadequate ventilation wear respiratory protection.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.

### Precautionary statement(s) Response

P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see advice on this label).
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P363	Wash contaminated clothing before reuse.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

### Precautionary statement(s) Storage

P405	Store locked up.
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### Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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## SECTION 3 Composition / information on ingredients

### Substances

See section below for composition of Mixtures

### Mixtures

CAS No	%[weight]	Name
8002-74-2	>60	<u>paraffin wax</u>
8012-95-1.	10-30	<u>paraffin oils</u>
56-75-7	1-10	<u>chloramphenicol</u>
Not Available	balance	Ingredients determined not to be hazardous

## SECTION 4 First aid measures

### Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>Wash out immediately with fresh running water.</li> <li>Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</li> <li>Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>Immediately remove all contaminated clothing, including footwear.</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>If fumes or combustion products are inhaled remove from contaminated area.</li> <li>Lay patient down. Keep warm and rested.</li> <li>Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> <li>Transport to hospital, or doctor.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>For advice, contact a Poisons Information Centre or a doctor at once.</li> <li>Urgent hospital treatment is likely to be needed.</li> <li><b>If swallowed do NOT induce vomiting.</b></li> <li>If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>Observe the patient carefully.</li> <li>Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>Transport to hospital or doctor without delay.</li> </ul>

### Indication of any immediate medical attention and special treatment needed

- Heavy and persistent skin contamination over many years may lead to dysplastic changes. Pre-existing skin disorders may be aggravated by exposure to this product.
- In general, emesis induction is unnecessary with high viscosity, low volatility products, i.e. most oils and greases.
- High pressure accidental injection through the skin should be assessed for possible incision, irrigation and/or debridement.

**NOTE:** Injuries may not seem serious at first, but within a few hours tissue may become swollen, discoloured and extremely painful with extensive subcutaneous necrosis. Product may be forced through considerable distances along tissue planes.

## SECTION 5 Firefighting measures

### Extinguishing media

- Foam.
- Dry chemical powder.

- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.
- ▶ Water spray or fog - Large fires only.

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use water delivered as a fine spray to control fire and cool adjacent area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Combustible.</li> <li>▶ Slight fire hazard when exposed to heat or flame.</li> <li>▶ Heating may cause expansion or decomposition leading to violent rupture of containers.</li> <li>▶ On combustion, may emit toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acrid smoke.</li> <li>▶ Mists containing combustible materials may be explosive.</li> </ul> <p>Combustion products include: carbon dioxide (CO<sub>2</sub>) other pyrolysis products typical of burning organic material.</p> <p><b>NOTE:</b> Burns with intense heat. Produces melting, flowing, burning liquid and dense acrid black smoke. May emit poisonous fumes. May emit corrosive fumes.</p> <p><b>CARE:</b> Water in contact with hot liquid may cause foaming and a steam explosion with wide scattering of hot oil and possible severe burns. Foaming may cause overflow of containers and may result in possible fire.</p>
<b>HAZCHEM</b>	Not Applicable

## SECTION 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Wear impervious gloves and safety goggles.</li> <li>▶ Trowel up/scrape up.</li> <li>▶ Place spilled material in clean, dry, sealed container.</li> <li>▶ Flush spill area with water.</li> </ul>
<b>Major Spills</b>	<ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear full body protective clothing with breathing apparatus.</li> <li>▶ Prevent, by all means available, spillage from entering drains or water courses.</li> <li>▶ Consider evacuation (or protect in place).</li> <li>▶ No smoking, naked lights or ignition sources.</li> <li>▶ Increase ventilation.</li> <li>▶ Stop leak if safe to do so.</li> <li>▶ Water spray or fog may be used to disperse / absorb vapour.</li> <li>▶ Contain or absorb spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Collect solid residues and seal in labelled drums for disposal.</li> <li>▶ Wash area and prevent runoff into drains.</li> <li>▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.</li> <li>▶ If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

Personal Protective Equipment advice is contained in Section 8 of the SDS.

## SECTION 7 Handling and storage

### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> </ul>
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	<ul style="list-style-type: none"> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ No smoking, naked lights or ignition sources.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

**Conditions for safe storage, including any incompatibilities**

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Metal can or drum</li> <li>▶ Packaging as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid reaction with oxidising agents</li> </ul>

**SECTION 8 Exposure controls / personal protection****Control parameters****Occupational Exposure Limits (OEL)****INGREDIENT DATA**

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	paraffin wax	Paraffin wax (fume)	2 mg/m <sup>3</sup>	Not Available	Not Available	Not Available
Australia Exposure Standards	paraffin oils	Oil mist, refined mineral	5 mg/m <sup>3</sup>	Not Available	Not Available	Not Available

**Emergency Limits**

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
paraffin oils	Mineral oil, heavy or light; (paraffin oil; Deobase, deodorized; heavy paraffinic; heavy naphthenic); distillates; includes 64741-53-3, 64741-88-4, 8042-47-5, 8012-95-1; 64742-54-7	140 mg/m <sup>3</sup>	1,500 mg/m <sup>3</sup>	8,900 mg/m <sup>3</sup>
chloramphenicol	Chloramphenicol	1.5 mg/m <sup>3</sup>	10 mg/m <sup>3</sup>	500 mg/m <sup>3</sup>

Ingredient	Original IDLH	Revised IDLH
paraffin wax	Not Available	Not Available
paraffin oils	2,500 mg/m <sup>3</sup>	Not Available
chloramphenicol	Not Available	Not Available

**Occupational Exposure Banding**

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
chloramphenicol	E	≤ 0.01 mg/m <sup>3</sup>

**Notes:**

*Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.*

**Exposure controls**

<b>Appropriate engineering controls</b>	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <ul style="list-style-type: none"> <li>▶ Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.</li> <li>▶ Work should be undertaken in an isolated system such as a "glove-box". Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.</li> <li>▶ Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.</li> <li>▶ Open-vessel systems are prohibited.</li> <li>▶ Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.</li> <li>▶ Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.</li> <li>▶ For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.</li> <li>▶ Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).</li> <li>▶ Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.</li> <li>▶ Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 0.76 m/sec with a minimum of 0.64 m/sec. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.</li> </ul>
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## Ilium Opticin Eye Ointment

<b>Personal protection</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C apron.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> <li>▶ Eye wash unit.</li> </ul>

**Respiratory protection**

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

For molten materials:

**SECTION 9 Physical and chemical properties****Information on basic physical and chemical properties**

<b>Appearance</b>	Light yellow ointment; does not mix with water.		
<b>Physical state</b>	Non Slump Paste	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Applicable	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Available	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Immiscible	<b>pH as a solution (1%)</b>	Not Applicable
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available

**SECTION 10 Stability and reactivity**

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<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

**SECTION 11 Toxicological information**

**Information on toxicological effects**

<b>Inhaled</b>	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo.</p> <p>Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p>There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.</p> <p>Inhalation hazard is increased at higher temperatures.</p>
<b>Ingestion</b>	<p>The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.</p>
<b>Skin Contact</b>	<p>There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.</p> <p>Molten material is capable of causing burns.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
<b>Eye</b>	<p>Limited evidence or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised by a temporary redness of the conjunctiva (similar to windburn).</p>
<b>Chronic</b>	<p>Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>There is ample evidence that this material can be regarded as being able to cause cancer in humans based on experiments and other information.</p> <p>Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.</p> <p>Ample evidence from experiments exists that there is a suspicion this material directly reduces fertility.</p> <p>Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.</p> <p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.</p> <p>Oil may contact the skin or be inhaled. Extended exposure can lead to eczema, inflammation of hair follicles, pigmentation of the face and warts on the soles of the feet.</p>

	<b>TOXICITY</b>	<b>IRRITATION</b>
<b>Ilium Opticin Eye Ointment</b>	Not Available	Not Available
<b>paraffin wax</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (rabbit): 100 mg/24 hr-mild
	Oral (rat) LD50: >3750 mg/kg <sup>[2]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>
		Skin (rabbit): 500 mg/24 hr-mild
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>
<b>paraffin oils</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Inhalation (rat) LC50: 2059.647258 mg/l/4H <sup>[2]</sup>	Eye (rabbit): 500 mg moderate
	Oral (rat) LD50: >24000 mg/kg <sup>[2]</sup>	Skin (rabbit): 100 mg/24h mild
<b>chloramphenicol</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (rat) LD50: 2500 mg/kg <sup>[2]</sup>	Not Available

**Legend:** 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.\* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

<b>PARAFFIN WAX</b>	<p>"Hydrocarbon wax" describes a group of solid C20 to C36 paraffinic hydrocarbons which are not absorbed in the gastro-intestinal tract and in small quantity will pass through undigested.</p> <p>Refined waxes are used widely in cosmetic surgery over many years and this demonstrates their low toxicity; many guidelines exist for their safe use. However, occasionally there are reports of adverse effects with these products. Deposits under the skin, referred to as "paraffinoma" have been described, but these are not normally associated with other progressive changes.</p> <p>Long-term toxicity studies indicated that petroleum-derived paraffin and microcrystalline waxes are non-toxic and do not cause cancer.</p> <p>Animal studies indicate that normal, branched and cyclic paraffins are absorbed from the gastrointestinal tract and that the absorption of n-paraffins is inversely proportional to the carbon chain length, with little absorption above C30. With respect to the carbon chain lengths likely to be present in mineral oil, n-paraffins may be absorbed to a greater extent than iso- or cyclo-paraffins.</p>
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	<p>The major classes of hydrocarbons are well absorbed into the gastrointestinal tract in various species. In many cases, the hydrophobic hydrocarbons are ingested in association with fats in the diet. Some hydrocarbons may appear unchanged as in the lipoprotein particles in the gut lymph, but most hydrocarbons partly separate from fats and undergo metabolism in the gut cell. The gut cell may play a major role in determining the proportion of hydrocarbon that becomes available to be deposited unchanged in peripheral tissues such as in the body fat stores or the liver.</p> <p>Tumorigenic in rats</p>
<b>PARAFFIN OILS</b>	<p>Equivocal tumorigen by RTECS criteria</p>
<b>CHLORAMPHENICOL</b>	<p>Reproductive effector in rats</p> <p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p> <p>Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.</p> <p>Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.</p> <p>Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.</p> <p>Chloramphenicol causes dose-related, reversible depression of bone marrow function in humans, usually seen as a mild anaemia. More seriously, a non-dose-related aplastic anaemia can rarely occur, with very high (&gt;50%) mortality. Other toxic effects have included circulatory collapse (grey baby syndrome) in newborns. Contact sensitivity occurs rarely. Chloramphenicol requires extreme caution in nursing mothers, and, in patients with pre-existing blood disorders or liver failure and newborns, should be avoided unless there are no other effective antibiotics available.</p> <p><b>WARNING:</b> This substance has been classified by the IARC as Group 2A: Probably Carcinogenic to Humans. Tenth Annual Report on Carcinogens: Substance anticipated to be Carcinogen [National Toxicology Program: U.S. Dep. of Health &amp; Human Services 2002]</p>
<b>PARAFFIN WAX &amp; PARAFFIN OILS</b>	<p>The materials included in the Lubricating Base Oils category are related from both process and physical-chemical perspectives; The potential toxicity of a specific distillate base oil is inversely related to the severity or extent of processing the oil has undergone, since:</p> <ul style="list-style-type: none"> <li>The adverse effects of these materials are associated with undesirable components, and</li> <li>The levels of the undesirable components are inversely related to the degree of processing;</li> <li>Distillate base oils receiving the same degree or extent of processing will have similar toxicities;</li> <li>The potential toxicity of residual base oils is independent of the degree of processing the oil receives.</li> <li>The reproductive and developmental toxicity of the distillate base oils is inversely related to the degree of processing.</li> </ul> <p>Unrefined &amp; mildly refined distillate base oils contain the highest levels of undesirable components, have the largest variation of hydrocarbon molecules and have shown the highest potential cancer-causing and mutation-causing activities. Highly and severely refined distillate base oils are produced from unrefined and mildly refined oils by removing or transforming undesirable components. In comparison to unrefined and mildly refined base oils, the highly and severely refined distillate base oils have a smaller range of hydrocarbon molecules and have demonstrated very low mammalian toxicity. Testing of residual oils for mutation-causing and cancer-causing potential has shown negative results, supporting the belief that these materials lack biologically active components or the components are largely non-bioavailable due to their molecular size.</p> <p>Toxicity testing has consistently shown that lubricating base oils have low acute toxicities. Numerous tests have shown that a lubricating base oil's mutagenic and carcinogenic potential correlates with its 3-7 ring polycyclic aromatic compound (PAC) content, and the level of DMSO extractables (e.g. IP346 assay), both characteristics that are directly related to the degree/conditions of processing.</p> <p>For highly and severely refined distillate base oils:</p> <p>In animal studies, the acute, oral, semilethal dose is &gt;5g/kg body weight and the semilethal dose by skin contact is &gt;2g/kg body weight. The semilethal concentration for inhalation is 2.18 to &gt;4 mg/L. The materials have varied from "non-irritating" to "moderately irritating" when tested for skin and eye irritation. Testing for sensitisation has been negative. The effects of repeated exposure vary by species; in animals, effects to the testes and lung have been observed, as well as the formation of granulomas. In animals, these substances have not been found to cause reproductive toxicity or significant increases in birth defects. They are also not considered to cause cancer, mutations or chromosome aberrations.</p>

<b>Acute Toxicity</b>	✗	<b>Carcinogenicity</b>	✓
<b>Skin Irritation/Corrosion</b>	✗	<b>Reproductivity</b>	✗
<b>Serious Eye Damage/Irritation</b>	✗	<b>STOT - Single Exposure</b>	✗
<b>Respiratory or Skin sensitisation</b>	✓	<b>STOT - Repeated Exposure</b>	✗
<b>Mutagenicity</b>	✓	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## SECTION 12 Ecological information

### Toxicity

Ilium Opticin Eye Ointment	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
paraffin wax	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	>1-mg/L	2
	EC50	48	Crustacea	>10-mg/L	2
EC50	72	Algae or other aquatic plants	>1-mg/L	2	

Ilium Opticin Eye Ointment

paraffin oils	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	>100mg/L	4

  

chloramphenicol	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	0.969mg/L	3
	EC50	48	Crustacea	>50mg/L	4
	EC50	96	Algae or other aquatic plants	0.105mg/L	3
	NOEC	24	Crustacea	2mg/L	4

**Legend:** *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
**DO NOT discharge into sewer or waterways.**

**Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
chloramphenicol	HIGH	HIGH

**Bioaccumulative potential**

Ingredient	Bioaccumulation
chloramphenicol	LOW (LogKOW = 1.14)

**Mobility in soil**

Ingredient	Mobility
chloramphenicol	LOW (KOC = 10)

**SECTION 13 Disposal considerations**

**Waste treatment methods**

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Authority for disposal.</li> <li>▶ Bury or incinerate residue at an approved site.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> </ul>
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**SECTION 14 Transport information**

**Labels Required**

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

**Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**

**Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**SECTION 15 Regulatory information**

**Safety, health and environmental regulations / legislation specific for the substance or mixture**

**paraffin wax is found on the following regulatory lists**

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australian Inventory of Industrial Chemicals (AIIC)

**paraffin oils is found on the following regulatory lists**

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

Australian Inventory of Industrial Chemicals (AIIC)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1 : Carcinogenic to humans

Chemical Footprint Project - Chemicals of High Concern List

**chloramphenicol is found on the following regulatory lists**

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 3

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2A: Probably carcinogenic to humans

#### National Inventory Status

National Inventory	Status
Australia - AIIC	No (chloramphenicol)
Australia - AIIC / Australia Non-Industrial Use	No (paraffin wax; paraffin oils)
Canada - DSL	Yes
Canada - NDSL	No (paraffin wax; paraffin oils; chloramphenicol)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (paraffin oils)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - ARIPS	Yes
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

#### SECTION 16 Other information

<b>Revision Date</b>	11/08/2020
<b>Initial Date</b>	11/05/2020

#### SDS Version Summary

Version	Issue Date	Sections Updated
3.1.1.1	12/05/2020	First Aid (skin), Ingredients
4.1.1.1	11/08/2020	Classification

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

#### Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average  
 PC—STEL: Permissible Concentration-Short Term Exposure Limit  
 IARC: International Agency for Research on Cancer  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 STEL: Short Term Exposure Limit  
 TEEL: Temporary Emergency Exposure Limit.  
 IDLH: Immediately Dangerous to Life or Health Concentrations  
 OSF: Odour Safety Factor  
 NOAEL :No Observed Adverse Effect Level  
 LOAEL: Lowest Observed Adverse Effect Level  
 TLV: Threshold Limit Value  
 LOD: Limit Of Detection  
 OTV: Odour Threshold Value  
 BCF: BioConcentration Factors  
 BEI: Biological Exposure Index

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