# Ilium Opticin Eye Ointment

## Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: **3**

Chemwatch: **5398-92**
Version No: **6.1**
Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

Issue Date: **10/03/2023**
Print Date: **31/03/2025**
L.GHS.AUS.EN.E

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

### Product Identifier

| | |
|---|---|
| **Product name** | Ilium Opticin Eye Ointment |
| **Chemical Name** | Not Applicable |
| **Synonyms** | APVMA number: 38629 |
| **Chemical formula** | Not Applicable |
| **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. |

### Details of the manufacturer or 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** | www.Troylab.com.au |
| **Email** | admin@troylab.com.au |

### Emergency telephone number

| | |
|---|---|
| **Association / Organisation** | **Ixom Emergency Response Service** |
| **Emergency telephone number(s)** | 1800 033 111 (24 hours) |
| **Other emergency telephone number(s)** | Not Available |

## SECTION 2 Hazards identification

### Classification of the substance or mixture

| | |
|---|---|
| **Poisons Schedule** | S3 |
| **Classification [1]** | Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2B, Sensitisation (Respiratory) Category 1, Germ Cell Mutagenicity Category 1B, Carcinogenicity Category 1B, Hazardous to the Aquatic Environment Long-Term 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)** |  |

**Page 1 continued...**

| | |
|---|---|
| **Signal word** | **Danger** |

### Hazard statement(s)

| | |
|---|---|
| **H317** | May cause an allergic skin reaction. |
| **H320** | Causes eye irritation. |
| **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 and protective clothing. |
| **P284** | [In case of inadequate ventilation] wear respiratory protection. |
| **P273** | Avoid release to the environment. |
| **P264** | Wash all exposed external body areas thoroughly after handling. |
| **P272** | Contaminated work clothing should not be allowed out of the workplace. |

### Precautionary statement(s) Response

| | |
|---|---|
| **P304+P340** | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| **P308+P313** | IF exposed or concerned: Get medical advice/ attention. |
| **P342+P311** | If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider. |
| **P302+P352** | IF ON SKIN: Wash with plenty of water and soap. |
| **P305+P351+P338** | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| **P333+P313** | If skin irritation or rash occurs: Get medical advice/attention. |
| **P337+P313** | If eye irritation persists: Get medical advice/attention. |
| **P362+P364** | Take off contaminated clothing and wash it before reuse. |

### Precautionary statement(s) Storage

| | |
|---|---|
| **P405** | Store locked up. |

### Precautionary statement(s) Disposal

| | |
|---|---|
| **P501** | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |

## SECTION 3 Composition / information on ingredients

### Substances

See section below for composition of Mixtures

### Mixtures

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

| | |
|---|---|
| ***Legend:*** | ***1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available*** |

## SECTION 4 First aid measures

### Description of first aid measures

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|---|---|
| **Eye Contact** | If this product comes in contact with the eyes:<br>▸ Wash out immediately with fresh running water.<br>▸ 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. |

**Continued...**

| | |
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| | ▸ Seek medical attention without delay; if pain persists or recurs seek medical attention.<br>▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| **Skin Contact** | If skin contact occurs:<br>▸ Immediately remove all contaminated clothing, including footwear.<br>▸ Flush skin and hair with running water (and soap if available).<br>▸ Seek medical attention in event of irritation. |
| **Inhalation** | ▸ If fumes or combustion products are inhaled remove from contaminated area.<br>▸ Lay patient down. Keep warm and rested.<br>▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.<br>▸ 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.<br>▸ Transport to hospital, or doctor. |
| **Ingestion** | ▸ For advice, contact a Poisons Information Centre or a doctor at once.<br>▸ Urgent hospital treatment is likely to be needed.<br>▸ If swallowed do **NOT** induce vomiting.<br>▸ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.<br>▸ Observe the patient carefully.<br>▸ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.<br>▸ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.<br>▸ Transport to hospital or doctor without delay. |

### 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

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|---|---|
| **Fire Incompatibility** | ▸ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result |

### Advice for firefighters

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|---|---|
| **Fire Fighting** | ▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear breathing apparatus plus protective gloves.<br>▸ Prevent, by any means available, spillage from entering drains or water courses.<br>▸ Use water delivered as a fine spray to control fire and cool adjacent area.<br>▸ **DO NOT** approach containers suspected to be hot.<br>▸ Cool fire exposed containers with water spray from a protected location.<br>▸ If safe to do so, remove containers from path of fire.<br>▸ Equipment should be thoroughly decontaminated after use. |
| **Fire/Explosion Hazard** | ▸ Combustible.<br>▸ Slight fire hazard when exposed to heat or flame.<br>▸ Heating may cause expansion or decomposition leading to violent rupture of containers.<br>▸ On combustion, may emit toxic fumes of carbon monoxide (CO).<br>▸ May emit acrid smoke.<br>▸ Mists containing combustible materials may be explosive.<br>Combustion products include:<br>carbon dioxide ($CO_2$)<br>other pyrolysis products typical of burning organic material.<br><br>**NOTE:** Burns with intense heat. Produces melting, flowing, burning liquid and dense acrid black smoke.<br>May emit poisonous fumes.<br>May emit corrosive fumes.<br>**CARE**: 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. |
| **HAZCHEM** | Not Applicable |

**Continued...**

## 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

| | |
|---|---|
| **Minor Spills** | ▸ Clean up all spills immediately.<br>▸ Avoid contact with skin and eyes.<br>▸ Wear impervious gloves and safety goggles.<br>▸ Trowel up/scrape up.<br>▸ Place spilled material in clean, dry, sealed container.<br>▸ Flush spill area with water. |
| **Major Spills** | ▸ Clear area of personnel and move upwind.<br>▸ Alert Fire Brigade and tell them location and nature of hazard.<br>▸ Wear full body protective clothing with breathing apparatus.<br>▸ Prevent, by all means available, spillage from entering drains or water courses.<br>▸ Consider evacuation (or protect in place).<br>▸ No smoking, naked lights or ignition sources.<br>▸ Increase ventilation.<br>▸ Stop leak if safe to do so.<br>▸ Water spray or fog may be used to disperse / absorb vapour.<br>▸ Contain or absorb spill with sand, earth or vermiculite.<br>▸ Collect recoverable product into labelled containers for recycling.<br>▸ Collect solid residues and seal in labelled drums for disposal.<br>▸ Wash area and prevent runoff into drains.<br>▸ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.<br>▸ If contamination of drains or waterways occurs, advise emergency services. |

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

## SECTION 7 Handling and storage

### Precautions for safe handling

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|---|---|
| **Safe handling** | ▸ Avoid all personal contact, including inhalation.<br>▸ Wear protective clothing when risk of exposure occurs.<br>▸ Use in a well-ventilated area.<br>▸ Prevent concentration in hollows and sumps.<br>▸ **DO NOT** enter confined spaces until atmosphere has been checked.<br>▸ **DO NOT** allow material to contact humans, exposed food or food utensils.<br>▸ Avoid contact with incompatible materials.<br>▸ When handling, **DO NOT** eat, drink or smoke.<br>▸ Keep containers securely sealed when not in use.<br>▸ Avoid physical damage to containers.<br>▸ Always wash hands with soap and water after handling.<br>▸ Work clothes should be laundered separately. Launder contaminated clothing before re-use.<br>▸ Use good occupational work practice.<br>▸ Observe manufacturer's storage and handling recommendations contained within this SDS.<br>▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. |
| **Other information** | ▸ Store in original containers.<br>▸ Keep containers securely sealed.<br>▸ No smoking, naked lights or ignition sources.<br>▸ Store in a cool, dry, well-ventilated area.<br>▸ Store away from incompatible materials and foodstuff containers.<br>▸ Protect containers against physical damage and check regularly for leaks.<br>▸ Observe manufacturer's storage and handling recommendations contained within this SDS. |

### Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| **Suitable container** | ▸ Metal can or drum<br>▸ Packaging as recommended by manufacturer.<br>▸ Check all containers are clearly labelled and free from leaks. |
| **Storage incompatibility** | ▸ Avoid reaction with oxidising agents |

## SECTION 8 Exposure controls / personal protection

### Control parameters

**Continued...**

**Occupational Exposure Limits (OEL)**

**INGREDIENT DATA**

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---|---|---|---|---|---|---|
| Australia Exposure Standards | paraffin wax | Paraffin wax (fume) | 2 mg/m3 | Not Available | Not Available | Not Available |
| Australia Exposure Standards | paraffin oils | Oil mist, refined mineral | 5 mg/m3 | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|---|---|---|
| paraffin wax | Not Available | Not Available |
| paraffin oils | 2,500 mg/m3 | Not Available |
| chloramphenicol | Not Available | Not Available |

**MATERIAL DATA**

## Exposure controls

| | |
|---|---|
| **Appropriate engineering controls** | 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.<br>The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the risk.<br>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.<br>Employers may need to use multiple types of controls to prevent employee overexposure.<br><br>▸ Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.<br>▸ 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.<br>▸ 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.<br>▸ Open-vessel systems are prohibited.<br>▸ Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.<br>▸ 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.<br>▸ 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.<br>▸ Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).<br>▸ Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.<br>▸ 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. |
| **Individual protection measures, such as personal protective equipment** |  |
| **Eye and face protection** | ▸ Safety glasses with side shields.<br>▸ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]<br>▸ 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]. |
| **Skin protection** | See Hand protection below |
| **Hands/feet protection** | ▸ Wear chemical protective gloves, e.g. PVC.<br>▸ Wear safety footwear or safety gumboots, e.g. Rubber |
| **Body protection** | See Other protection below |
| **Other protection** | ▸ Overalls.<br>▸ P.V.C apron.<br>▸ Barrier cream.<br>▸ Skin cleansing cream. |

**Continued...**

| | |
|---|---|
| | ‣ Eye wash unit. |

### 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(SO2), G = Agricultural chemicals, K = Ammonia(NH3), 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:
76a-p()

## SECTION 9 Physical and chemical properties

### Information on basic physical and chemical properties

| | |
|---|---|
| **Appearance** | Light yellow ointment; does not mix with water. |

| | | | |
|---|---|---|---|
| **Physical state** | Non Slump Paste | **Relative density (Water = 1)** | Not Available |
| **Odour** | Not Available | **Partition coefficient n-octanol / water** | Not Available |
| **Odour threshold** | Not Available | **Auto-ignition temperature (°C)** | Not Available |
| **pH (as supplied)** | Not Applicable | **Decomposition temperature (°C)** | Not Available |
| **Melting point / freezing point (°C)** | Not Available | **Viscosity (cSt)** | Not Available |
| **Initial boiling point and boiling range (°C)** | Not Available | **Molecular weight (g/mol)** | Not Applicable |
| **Flash point (°C)** | Not Available | **Taste** | Not Available |
| **Evaporation rate** | Not Available | **Explosive properties** | Not Available |
| **Flammability** | Not Applicable | **Oxidising properties** | Not Available |
| **Upper Explosive Limit (%)** | Not Available | **Surface Tension (dyn/cm or mN/m)** | Not Available |
| **Lower Explosive Limit (%)** | Not Available | **Volatile Component (%vol)** | Not Available |
| **Vapour pressure (kPa)** | Not Available | **Gas group** | Not Available |
| **Solubility in water** | Immiscible | **pH as a solution (1%)** | Not Applicable |
| **Vapour density (Air = 1)** | Not Available | **VOC g/L** | Not Available |
| **Heat of Combustion (kJ/g)** | Not Available | **Ignition Distance (cm)** | Not Available |
| **Flame Height (cm)** | Not Available | **Flame Duration (s)** | Not Available |
| **Enclosed Space Ignition Time Equivalent (s/m3)** | Not Available | **Enclosed Space Ignition Deflagration Density (g/m3)** | Not Available |

## SECTION 10 Stability and reactivity

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|---|---|
| **Reactivity** | See section 7 |
| **Chemical stability** | ‣ Unstable in the presence of incompatible materials.<br>‣ Product is considered stable.<br>‣ Hazardous polymerisation will not occur. |

**Continued...**

| | |
|---|---|
| **Possibility of hazardous reactions** | See section 7 |
| **Conditions to avoid** | See section 7 |
| **Incompatible materials** | See section 7 |
| **Hazardous decomposition products** | See section 5 |

## SECTION 11 Toxicological information

### Information on toxicological effects

| | |
|---|---|
| **a) Acute Toxicity** | Based on available data, the classification criteria are not met. |
| **b) Skin Irritation/Corrosion** | Based on available data, the classification criteria are not met. |
| **c) Serious Eye Damage/Irritation** | There is sufficient evidence to classify this material as eye damaging or irritating |
| **d) Respiratory or Skin sensitisation** | There is sufficient evidence to classify this material as sensitising to skin or the respiratory system |
| **e) Mutagenicity** | There is sufficient evidence to classify this material as mutagenic |
| **f) Carcinogenicity** | There is sufficient evidence to classify this material as carcinogenic |
| **g) Reproductivity** | Based on available data, the classification criteria are not met. |
| **h) STOT - Single Exposure** | Based on available data, the classification criteria are not met. |
| **i) STOT - Repeated Exposure** | Based on available data, the classification criteria are not met. |
| **j) Aspiration Hazard** | Based on available data, the classification criteria are not met. |

| | |
|---|---|
| **Inhaled** | Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.<br>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.<br>Limited evidence or practical experience suggests that the material may produce irritation of the respiratory system, in a significant number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.<br>Inhalation hazard is increased at higher temperatures. |
| **Ingestion** | The material has **NOT** 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. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern. |
| **Skin Contact** | The material may produce mild skin irritation; limited evidence or practical experience suggests, that the material either:<br>▸ produces mild inflammation of the skin in a substantial number of individuals following direct contact, and/or<br>▸ produces significant, but mild, inflammation when applied to the healthy intact skin of animals (for up to four hours), such inflammation being present twenty-four hours or more after the end of the exposure period.<br><br>Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (non allergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.<br>Molten material is capable of causing burns.<br>Open cuts, abraded or irritated skin should not be exposed to this material<br>The material may accentuate any pre-existing dermatitis condition<br>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds 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. |
| **Eye** | Limited evidence or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur. |
| **Chronic** | Practical evidence shows that inhalation of the material is capable of inducing a sensitisation reaction in a substantial number of individuals at a greater frequency than would be expected from the response of a normal population.<br>Pulmonary sensitisation, resulting in hyperactive airway dysfunction and pulmonary allergy may be accompanied by fatigue, malaise and aching. Significant symptoms of exposure may persist for extended periods, even after exposure ceases. Symptoms can be activated by a variety of nonspecific environmental stimuli such as automobile exhaust, perfumes and passive smoking.<br>Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals. |

**Continued...**

Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.
Substances than can cuase occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers
Wherever it is reasonably practicable, exposure to substances that can cuase occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.
Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.
On the basis, primarily, of animal experiments, the material may be regarded as carcinogenic to humans. There is sufficient evidence to provide a strong presumption that human exposure to the material may result in cancer on the basis of:
- appropriate long-term animal studies
- other relevant information
There is sufficient evidence to provide a strong presumption that human exposure to the material may result in the development of heritable genetic damage, generally on the basis of
- appropriate animal studies,
- other relevant information
Exposure to the material may cause concerns for human fertility, generally on the basis that results in animal studies provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects.

Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, generally on the basis that results in appropriate animal studies provide strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.
Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
Principal route of exposure is by skin contact; lesser exposures include inhalation of fumes from hot oils, oil mists or droplets.
Prolonged contact with mineral oils carries with it the risk of skin conditions such as oil folliculitis, eczematous dermatitis, pigmentation of the face (melanosis) and warts on the sole of the foot (plantar warts). With highly refined mineral oils no appreciable systemic effects appear to result through skin absorption.
Exposure to oil mists frequently elicits respiratory conditions, such as asthma; the provoking agent is probably an additive. High oil mist concentrations may produce lipoid pneumonia although clinical evidence is equivocal. In animals exposed to concentrations of 100 mg/m3 oil mist, for periods of 12 to 26 months, the activity of lung and serum alkaline phosphatase enzyme was raised; 5 mg/m3 oil mist did not produce this response. These enzyme changes are sensitive early indicators of lung damage. Workers exposed to vapours of mineral oil and kerosene for 5 to 35 years showed an increased prevalence of slight basal lung fibrosis.

**Ilium Opticin Eye Ointment**

| TOXICITY | IRRITATION |
|---|---|
| Not Available | Not Available |

**paraffin wax**

| TOXICITY | IRRITATION |
|---|---|
| dermal (rat) LD50: >2000 mg/kg[1] | Eye (Rodent - rabbit): 100mg/24H - Mild |
| Oral (Rat) LD50: >5000 mg/kg[1] | Eye (Rodent - rabbit): 50% - Mild |
| | Eye: no adverse effect observed (not irritating)[1] |
| | Skin (Rodent - rabbit): 500mg/24H - Mild |
| | Skin: no adverse effect observed (not irritating)[1] |

**paraffin oils**

| TOXICITY | IRRITATION |
|---|---|
| Inhalation (Rat) LC50: 2062 ppm4h[2] | Eye (Rodent - rabbit): 100mg/1H - Mild |
| Oral (Mouse) LD50; 22000 mg/kg[2] | Eye (Rodent - rabbit): 500mg - Moderate |
| | Skin (Rodent - guinea pig): 100mg/24H - Mild |
| | Skin (Rodent - rabbit): 100mg/24H - Mild |

**chloramphenicol**

| TOXICITY | IRRITATION |
|---|---|
| Oral (Rat) LD50: 2500 mg/kg[2] | 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***

**Continued...**

| | |
|---|---|
| **PARAFFIN WAX** | Tumorigenic in rats<br>"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.<br>The widespread use in cosmetic and in cosmetic surgery over many years demonstrates the low toxicity of refined waxes and many guidelines exist for their safe use Notwithstanding this, there are occasional reports of adverse effects with these products. Subcutaneous deposits often referred to as paraffinoma, have been described frequently following injection of these materials under the skin but these are not normally associated with other progressive changes.<br>Paraffin wax and microcrystalline were each administered orally as a solution in arachis oil to groups of 5 male and 5 female rats at dose levels of 1000 and 5000 g/kg bw. produced no clinical signs of toxicity during the seven day observation period and growth rates were normal. There were no mortalities and no macroscopic changes were observed at autopsy.<br>Three samples of 50% paraffin in petrolatum were tested in repeated, open patch applications to 6 rabbits. Two samples produced erythema in four animals that lasted three days, and one produced erythema in one rabbit that lasted two days. A microcrystalline wax was slightly irritating, to rabbit skin, in a 24 hour occluded patch test.<br>Four 50% solutions of paraffin in petrolatum were each instilled into the eyes of six albino rabbits with no rinse. Eyes were observed for irritation for three days. Two of the samples caused mild irritation in one rabbit on day 1; the other samples were not irritating<br>In a long-term feeding study with Sprague-Dawley rats, no wax-related effects were observed. In a series of 180-day feeding studies in rats that were performed over a period of approximately 15 years (beginning in 1955) on chewing-gum bases containing hydrocarbon wax in proportions varying from 2% to 57% of the gum base, no compound-related effects were observed.<br>Long-term toxicity studies indicated that petroleum-derived paraffin and microcrystalline waxes are non-toxic and non-carcinogenic.<br>Eight slack waxes and eight aromatic hydrocarbon extracts derived from the slack waxes were tested for carcinogenicity after applying these to the skin of mice.The slack waxes showed only a low order of carcinogenicity at 250 days. However by 450 days every sample of slack wax had elicited papillomas and for 5 of them cancers as well. The aromatic extracts on the other hand exhibited a greater potency. At 250 days all but one sample had produced papillomas and 5 samples had produced cancers. At 450 days all but one sample had elicited cancers and all had elicited papillomas.The authors concluded that the carcinogenicity of slack wax can be attributed to the aromatic compounds found in the oils from which the waxes were pressed and which are retained on the waxes as impurities, and.is not due to paraffins.<br>Five petrolatum waxes were negative for local and systemic carcinogenicity or toxicity in skin-painting studies in mice and rabbits. However, wax disk implants, but not ground wax implants, were associated with the development of fibrosarcomas at the implantation site in rats.<br>A description of the accumulation of long-chain alkanes (C29, C31, and C33) in a patient who had died of heart disease led the author to conclude that these hydrocarbons were of dietary (plant) origin as judged by the tissue distribution of the alkanes.<br>The EU Scientific Committee for Food (SCF) reviewed the available information on mineral hydrocarbons, which included the petroleum waxes. Their opinion was published in 1995. The SCF reached the following conclusion:<br>There are sufficient data to allow a full Group ADI (Average daily Intake)of 0-20 mg/kg bw for waxes conforming to the following specification: -<br>· Highly refined waxes derived from petroleum based or synthetic hydrocarbon feedstocks, with viscosity not less than 11 m3/s (cSt) at 100 deg C<br>· Carbon number not less than 25 at the 5% boiling point<br>· Average molecular weight not less than 500<br>Studies indicate that normal, branched and cyclic paraffins are absorbed from the mammalian 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 that iso- or cyclo-paraffins.<br>The major classes of hydrocarbons have been shown to be well absorbed by the gastrointestinal tract in various species. In many cases, the hydrophobic hydrocarbons are ingested in association with dietary lipids. The dependence of hydrocarbon absorption on concomitant triglyceride digestion and absorption,is known as the "hydrocarbon continuum hypothesis", and asserts that a series of solubilising phases in the intestinal lumen, created by dietary triglycerides and their digestion products, afford hydrocarbons a route to the lipid phase of the intestinal absorptive cell (enterocyte) membrane. While some hydrocarbons may traverse the mucosal epithelium unmetabolised and appear as solutes in lipoprotein particles in intestinal lymph, there is evidence that most hydrocarbons partially separate from nutrient lipids and undergo metabolic transformation in the enterocyte. The enterocyte may play a major role in determining the proportion of an absorbed hydrocarbon that, by escaping initial biotransformation, becomes available for deposition in its unchanged form in peripheral tissues such as adipose tissue, or in the liver. |
| **PARAFFIN OILS** | Equivocal tumorigen by RTECS criteria<br>Paraffin oil (boiling in the kerosene boiling range) can pose certain health hazards, especially if it is inhaled or ingested and also due to repeated or prolonged skin exposure. Inhalation of paraffin oil can irritate the respiratory tract, and cause cough, shortness of breath, and occasionally, lead to hydrocarbon pneumonitis. On the other hand, prolonged skin exposure to this oil can cause skin irritation, which can lead to contact dermatitis, especially in individuals who already have skin disorders or diseases. Ingestion of paraffin oil can cause upset of the intestinal tract.<br>Paraffin oil, which has not been highly refined, is often considered as a carcinogen or cancer causing agent. Therefore, adequate precaution is required, while using paraffin oil. Ideally, liquid paraffin oil should be stored in a cool and well-ventilated place n a tightly closed container. As some paraffin oil is highly inflammable, be sure to keep it away from any source of heat or ignition and also out of direct sunlight. |
| **CHLORAMPHENICOL** | Reproductive effector in rats<br>The following information refers to contact allergens as a group and may not be specific to this product.<br>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. |

**Continued...**

| | |
|---|---|
| | Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens).<br>Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis.<br>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.<br>For chloramphenicol:<br>Chloramphenicol induces bone-marrow depression in humans. The more common dose-related bone-marrow depression is evident when the daily dose of chloramphenicol is >4 g in humans. Toxicity is reversible if the treatment is discontinued or the dosage is reduced. The condition is seen as a mild anaemia.<br>A more serious and unpredictable reaction is aplastic anaemia, which is not considered to be dose-related.This might also result in leukaemia in humans Although the incidence of aplastic anaemia has been shown to correlate with several risk factors, it is estimated to occur with a frequency of 1 in 24 000-40 000 courses of treatment with chloramphenicol. Mortality from aplastic anaemia occurs in >50% of cases. It is suggested that aplastic anaemia in humans is an idiosyncratic reaction to chloramphenicol, which has an immunological basis and which is related to the nitrobenzene structure. This hypothesis is supported by clinical evidence showing that 40-50% patients with aplastic anaemia have a partial or complete response to a variety of immunosuppressive agents.<br>The pathophysiology of aplastic anaemia in most cases can be characterized by a T-cell mediated destruction of bone-marrow haematopoietic cells.<br>Other indications of toxicity associated with treatment with chloramphenicol in humans have been recognised. Circulatory collapse ("grey baby syndrome") has occurred in human neonates treated with chloramphenicol. This adverse reaction may be explained by the poor hepatic biotransformation of the drug in neonates as a result of slow glucuronidation of chloramphenicol. Toxic concentrations of chloramphenicol in blood and tissues develop secondary to an inability to conjugate the drug or to excrete the conjugate efficiently. However, the precise reason for the occurrence of cardiovascular collapse in grey baby syndrome is poorly understood. It has been stated that nitro-reduction derivatives of chloramphenicol might play a role in causing hypotension, and the hypothesis was assessed by perfusion of chloramphenicol through the isolated lobules of human placenta. A decrease in blood pressure was found at the time coinciding with a peak in concentration of nitric oxide, which is a product of the nitroreduction of chloramphenicol.<br>Contact sensitivity to chloramphenicol is rare in humans. Two cases of skin ulcer, secondary to contact dermatitis, were reported in a woman aged 48 years and a man aged 46 years. Both patients had applied chloramphenicol in the form of chloromycetin cream to their wounds for about 1 month and developed skin ulcer at the application sites. Hypersensitivity to chloramphenicol was confirmed by patch tests in both patients. The ulcer healed after use of the drug was discontinued<br>In patients with pre-existing haematologic abnormalities or hepatic failure, or in neonates, chloramphenicol is only used when no other effective antibiotics are available.<br>Chloramphenicol has not been determined to be safe for use during pregnancy. The drug may decrease protein synthesis in the fetus, particularly in the bone marrow. Chloramphenicol is found in human milk at 50% of serum concentrations in humans and therefore the drug should be given with extreme caution to nursing mothers.<br>Chloramphenicol is reasonably anticipated to be a human carcinogen, based on limited evidence of carcinogenicity from human cancer studies. Numerous case reports have shown leukemia to occur following chloramphenicol-induced aplastic anemia (IARC 1990). Three case reports have documented the occurrence of leukemia following chloramphenicol therapy in the absence of intervening aplastic anemia (IARC 1990). A case-control study in China reported, elevated risks of childhood leukemia which increased significantly with the number of days chloramphenicol was taken. Chloramphenicol use was reported to be associated with an increased risk of soft-tissue sarcoma. . Two case-control studies found no association of chloramphenicol use with risk of adult leukemia. Taken together, the many case reports implicating chloramphenicol as a cause of aplastic anemia, the evidence of a link between aplastic anemia and leukemia, and the increased risk of leukemia found in some case-control studies support the conclusion that an increased cancer risk is associated with chloramphenicol exposure. Children may be a particularly susceptible subgroup.<br>Chloramphenicol was reported in an abstract to increase the incidence of lymphoma in two strains of mice and liver tumors in one strain. However, because this study was incompletely reported, the findings are considered insufficient to establish a definitive link between chloramphenicol exposure and cancer in experimental animals.<br>Several studies show that the dehydrochloramphenicol metabolite produced by intestinal bacteria may be responsible for DNA damage and carcinogenicity. This metabolite can undergo nitroreduction in the bone marrow, where it causes DNA single-strand breaks. Mitochondrial abnormalities induced by chloramphenicol are similar to those observed in preleukemia, suggesting that mitochondrial DNA is involved in the pathogenesis of leukemia.<br>The available genotoxicity data show predominantly negative results in bacterial systems and mixed results in mammalian systems. The most consistently positive results were observed for cytogenetic effects in mammalian cells, including DNA single-strand breaks and increases in the frequencies of sister chromatid exchanges and chromosomal aberrations.<br><br>**WARNING:** This substance has been classified by the IARC as Group 2A: Probably Carcinogenic to Humans. |
| **PARAFFIN WAX & PARAFFIN OILS** | 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:<br>· The adverse effects of these materials are associated with undesirable components, and<br>· The levels of the undesirable components are inversely related to the degree of processing;<br>· Distillate base oils receiving the same degree or extent of processing will have similar toxicities;<br>· The potential toxicity of ***residual base oils*** is independent of the degree of processing the oil receives.<br>· The reproductive and developmental toxicity of the distillate base oils is inversely related to the degree of processing.<br>The degree of refining influences the carcinogenic potential of the oils. Whereas mild acid / earth refining processes are inadequate to substantially reduce the carcinogenic potential of lubricant base oils, hydrotreatment and / or solvent extraction methods can yield oils with no carcinogenic potential.<br>Unrefined and 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 carcinogenic and mutagenic activities. Highly and severely |

**Continued...**

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. Mutagenicity and carcinogenicity testing of residual oils has been negative, supporting the belief that these materials lack biologically active components or the components are largely non-bioavailable due to their molecular size.
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
Skin irritating is not significant (CONCAWE) based on 14 tests on 10 CASs from the OLBO class (Other Lubricant Base Oils). Each study lasted for 24 hours, a period of time 6 times longer than the duration recommended by the OECD method).
Eye irritation is not significant according to experimental data (CONCAWE studies) based on 9 “in vivo” tests on 7 CASs from the OLBO class(Other Lubricant Base Oils).
Sensitisation: The substance does not cause the sensitization of the respiratory tract or of the skin. (CONCAWE studies based on 14 tests on 11 CASs from the OLBO class(Other Lubricant Base Oils))
Germ cell mutagenicity: The tests performed within the ‘in vivo” studies regarding gene mutation at mice micronuclei indicated negative results (CONCAWE studies. AMES tests had negative results in 7 studies performed on 4 CASs from the OLBO class(Other Lubricant Base Oils)).
Reproduction toxicity: Reproduction / development toxicity monitoring according to OECD 421 or 422 methods. CONCAWE tests gave negative results in oral gavage studies. Pre-birth studies regarding toxicity in the unborn foetus development process showed a maternal LOAEL (Lowest Observed Adverse Effect Level) of 125 mg/kg body/day, based on dermal irritation and a NOAEL (No Observable Adverse Effect Level) of 2000 mg/kg body/day, which shows that the substance
is not toxic for reproduction.
STOT (toxicity on specific target organs) – repeated exposure: Studies with short term repeated doses (28-day test) on rabbit skin indicated the NOAEL value of 1000 mg/kg. NOAEL for inhalation, local effects > 280 mg/m3 and for systemic effects NOAEL > 980 mg/m3.
Sub-chronic toxicity
90-day study Dermal: NOAEL > 2000 mg/kg (CONCAWE studies).
Repeat dose toxicity:
Oral
NOAEL for heavy paraffinic distillate aromatic extract could not be identified and is less than 125 mg/kg/day when administered orally.
Inhalation
The NOAEL for lung changes associated with oil deposition in the lungs was 220 mg/m3. As no systemic toxicity was observed, the overall NOAEL for systemic effects was > 980 mg/m3.
Dermal
In a 90 day subchronic dermal study, the administration of Light paraffinic distillate solvent extract had an adverse effect on survivability, body weights, organ weights (particularly the liver and thymus), and variety of haematology and serum chemistry parameters in exposed animals. Histopathological changes which were treatment-related were most prominent in the adrenals, bone marrow, kidneys, liver, lymph nodes, skin, stomach, and thymus. Based on the results of this study, the NOAEL for the test material is less than 30 mg/kg/day.
Toxicity to reproduction:
Mineral oil (a white mineral oil) caused no reproductive or developmental toxicity with 1 mL/kg/day (i.e., 1000 mg/kg/day) in an OECD 421 guideline study, but did cause mild to moderate skin irritation. Therefore, the reproductive/developmental NOAEL for this study is =1000 mg/kg/day and no LOAEL was determined.
Developmental toxicity, teratogenicity:
Heavy paraffinic distillate furfural extract produced maternal, reproductive and foetal toxicity. Maternal toxicity was exhibited as vaginal discharge (dose-related), body weight decrease, reduction in thymus weight and increase in liver weight (125 mg/kg/day and higher) and aberrant haematology and serum chemistry (125 and/or 500 mg/kg/day). Evidence of potential reproductive effects was shown by an increased number of dams with resorptions and intrauterine death. Distillate aromatic extract (DAE) was developmentally toxic regardless of exposure duration as indicated by increased resorptions and decreased foetal body weights. Furthermore, when exposures were increased to 1000 mg/kg/day and given only during gestation days 10 through 12, cleft palate and ossification delays were observed. Cleft palate was considered to indicate a potential teratogenic effect of DAE.
The following Oil Industry Note (OIN) has been applied: OIN 8 - The classifications as a reproductive toxicant category 2; H361d (Suspected of damaging the unborn child) and specific target organ toxicant category 1; H372 (Causes damage to organs through prolonged or repeated exposure) need not apply if the substance is not classified as carcinogenic
Toxicokinetics of lubricant base oils has been examined in rodents. Absorption of other lubricant base oils across the small intestine is related to carbon chain length; hydrocarbons with smaller chain length are more readily absorbed than hydrocarbons with a longer chain length. The majority of an oral dose of mineral hydrocarbon is not absorbed and is excreted unchanged in the faeces. Distribution of mineral hydrocarbons following absorption has been observed in liver, fat, kidney, brain and spleen. Excretion of absorbed mineral hydrocarbons occurs via the faeces and urine. Based on the pharmacokinetic parameters and disposition profiles, the data indicate inherent strain differences in the total systemic exposure (~4 fold greater systemic dose in F344 vs SD rats), rate of metabolism, and hepatic and lymph node retention of C26H52, which may be associated with the different strain sensitivities to the formation of liver granulomas and MLN histiocytosis.
Highly and Severely Refined Distillate Base Oils
**Acute toxicity:** Multiple studies of the acute toxicity of highly & severely refined base oils have been reported. Irrespective of the crude source or the method or extent of processing, the oral LD50s have been observed to be >5 g/kg (bw) and the dermal LD50s have ranged from >2 to >5g/kg (bw). The LC50 for inhalation toxicity ranged from 2.18 mg/l to> 4 mg/l.
When tested for skin and eye irritation, the materials have been reported as “non-irritating” to “moderately irritating”
Testing in guinea pigs for sensitization has been negative
**Repeat dose toxicity: .** Several studies have been conducted with these oils**. T**he weight of evidence from all available data on highly & severely refined base oils support the presumption that a distillate base oil s toxicity is inversely related to the degree of processing it receives. Adverse effects have been reported with even the most severely refined white oils - these appear to depend on animal species and/ or the peculiarities of the study.

- The granulomatous lesions induced by the oral administration of white oils are essentially foreign body responses. The lesions occur only in rats, of which the Fischer 344 strain is particularly sensitive,

**Continued...**

- The testicular effects seen in rabbits after dermal administration of a highly to severely refined base oil were unique to a single study and may have been related to stress induced by skin irritation, and
- The accumulation of foamy macrophages in the alveolar spaces of rats exposed repeatedly via inhalation to high levels of highly to severely refined base oils is not unique to these oils, but would be seen after exposure to many water insoluble materials.

**Reproductive and developmental toxicity:** A highly refined base oil was used as the vehicle control in a one-generation reproduction study. The study was conducted according to the OECD Test Guideline 421. There was no effect on fertility and mating indices in either males or females. At necropsy, there were no consistent findings and organ weights and histopathology were considered normal by the study s authors.
A single generation study in which a white mineral oil (a food/ drug grade severely refined base oil) was used as a vehicle control is reported. Two separate groups of pregnant rats were administered 5 ml/kg (bw)/day of the base oil via gavage, on days 6 through 19 of gestation. In one of the two base oil dose groups, three malformed foetuses were found among three litters The study authors considered these malformations to be minor and within the normal ranges for the strain of rat.
**Genotoxicity**:
***In vitro*** (mutagenicity): Several studies have reported the results of testing different base oils for mutagenicity using a modified Ames assay Base oils with no or low concentrations of 3-7 ring PACs had low mutagenicity indices.
***In vivo*** (chromosomal aberrations): A total of seven base stocks were tested in male and female Sprague-Dawley rats using a bone marrow cytogenetics assay. The test materials were administered via gavage at dose levels ranging from 500 to 5000 mg/kg (bw). Dosing occurred for either a single day or for five consecutive days. None of the base oils produced a significant increase in aberrant cells.
**Carcinogenicity:** Highly & severely refined base oils are not carcinogens, when given either orally or dermally.

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

***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 |
|---|---|---|---|---|
| Not Available | Not Available | Not Available | Not Available | Not Available |

**paraffin oils**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 48h | Crustacea | 0.016-0.027mg/L | 4 |
| EC50(ECx) | 48h | Crustacea | 0.016-0.027mg/L | 4 |
| LC50 | 96h | Fish | >100mg/L | 4 |

**chloramphenicol**

| Endpoint | Test Duration (hr) | Species | Value | Source |
|---|---|---|---|---|
| EC50 | 48h | Crustacea | >50mg/L | 4 |
| EC50 | 72h | Algae or other aquatic plants | 0.006-0.24mg/l | 4 |
| EC50(ECx) | 72h | Algae or other aquatic plants | 0.006-0.24mg/l | 4 |

***Legend:*** ***Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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 |

**Continued...**

### Bioaccumulative potential

| Ingredient | Bioaccumulation |
|---|---|
| paraffin wax | LOW (LogKOW = 10.16) |
| paraffin oils | HIGH (LogKOW = 6.1) |
| chloramphenicol | LOW (LogKOW = 1.14) |

### Mobility in soil

| Ingredient | Mobility |
|---|---|
| chloramphenicol | LOW (Log KOC = 10) |

## SECTION 13 Disposal considerations

### Waste treatment methods

| | |
|---|---|
| **Product / Packaging disposal** | ▸ Recycle wherever possible or consult manufacturer for recycling options.<br>▸ Consult State Land Waste Authority for disposal.<br>▸ Bury or incinerate residue at an approved site.<br>▸ Recycle containers if possible, or dispose of in an authorised landfill.<br>▸ Containers may still present a chemical hazard/ danger when empty.<br>▸ Return to supplier for reuse/ recycling if possible.<br>Otherwise:<br>▸ 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.<br>▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product. |

## SECTION 14 Transport information

### Labels Required

| | |
|---|---|
| **Marine Pollutant** | NO |
| **HAZCHEM** | 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

### 14.7. Maritime transport in bulk according to IMO instruments

### 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

### 14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|---|---|
| paraffin wax | Not Available |
| paraffin oils | Not Available |
| chloramphenicol | Not Available |

### 14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|---|---|
| paraffin wax | Not Available |
| paraffin oils | Not Available |
| chloramphenicol | Not Available |

## 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**

Continued...

Australian Inventory of Industrial Chemicals (AIIC)
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

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

Australian Inventory of Industrial Chemicals (AIIC)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

**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

### Additional Regulatory Information

Not Applicable

### National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (paraffin wax; paraffin oils; chloramphenicol) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | All chemical substances in this product have been designated as TSCA Inventory 'Active' |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |
| ***Legend:*** | ***Yes = All CAS declared ingredients are on the inventory***<br>***No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.*** |

## SECTION 16 Other information

| | |
|---|---|
| **Revision Date** | 10/03/2023 |
| **Initial Date** | 11/05/2020 |

### SDS Version Summary

| Version | Date of Update | Sections Updated |
|---|---|---|
| 5.1 | 10/12/2021 | Classification change due to full database hazard calculation/update. |
| 6.1 | 10/03/2023 | Classification change due to full database hazard calculation/update. |

### 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

**Continued...**

- 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
- ES: Exposure Standard
- 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
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code

- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances