



OSD/LT

Drew Marine

Chemwatch: 24-0207

Version No: 3.1.1.1

Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

Chemwatch Hazard Alert Code: 2

Issue Date: 01/01/2013

Print Date: 12/10/2014

Initial Date: Not Available

S.GHS.USA.EN

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

| | |
|-------------------------------|----------------|
| Product name | OSD/LT |
| Chemical Name | Not Applicable |
| Proper shipping name | Not Applicable |
| Chemical formula | Not Applicable |
| Other means of identification | Not Available |
| CAS number | Not Applicable |

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

| | |
|--------------------------|---|
| Relevant identified uses | Use according to manufacturer's directions. |
|--------------------------|---|

Details of the manufacturer/importer

| | |
|-------------------------|--|
| Registered company name | Drew Marine |
| Address | 100 South Jefferson Road Whippany 07981 NJ United States |
| Telephone | 973 526-5700. |
| Fax | Not Available |
| Website | Not Available |
| Email | Not Available |

Emergency telephone number

| | |
|-----------------------------------|--|
| Association / Organisation | Not Available |
| Emergency telephone numbers | The numbers below are for EMERGENCY USE ONLY. Use the corporate number above for all other calls. |
| Other emergency telephone numbers | CHEMWATCH: From within the US and CANADA: 1 877-715-9305 OR call + 613 9573 3112. From outside the US and Canada: + 800 2436 2255 (+800 CHEMCALL) or +613 9573 3112 |

CHEMWATCH EMERGENCY RESPONSE

| Primary Number | Alternative Number 1 | Alternative Number 2 |
|----------------|----------------------|----------------------|
| 877 715 9305 | +612 9186 1132 | Not Available |

Once connected and if the message is not in your preferred language then please dial 01

Una vez conectado y si el mensaje no está en su idioma preferido, por favor marque 02

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

| | |
|--------------------|---|
| GHS Classification | Flammable Liquid Category 4, Skin Corrosion/Irritation Category 2, Germ Cell Mutagen Category 2, Carcinogen Category 2, STOT - SE (Narcosis) Category 3, Aspiration Hazard Category 1 |
|--------------------|---|

Label elements

| | |
|--------------------|--|
| GHS label elements | |
|--------------------|--|

SIGNAL WORD DANGER

Hazard statement(s)

| | |
|------|--------------------------------------|
| H227 | Combustible liquid |
| H315 | Causes skin irritation |
| H341 | Suspected of causing genetic defects |

Continued...

OSD/LT

| | |
|------|--|
| H351 | Suspected of causing cancer |
| H336 | May cause drowsiness or dizziness |
| H304 | May be fatal if swallowed and enters airways |

Supplementary statement(s)

Not Applicable

Precautionary statement(s): Prevention

| | |
|------|--|
| P201 | Obtain special instructions before use. |
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P271 | Use only outdoors or in a well-ventilated area. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray. |

Precautionary statement(s): Response

| | |
|-----------|---|
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider |
| P308+P313 | IF exposed or concerned: Get medical advice/attention. |
| P331 | Do NOT induce vomiting. |
| P370+P378 | In case of fire: Use... to extinguish. |
| P312 | Call a POISON CENTER/doctor/physician/first aider/if you feel unwell. |
| P302+P352 | IF ON SKIN: Wash with plenty of water and soap |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |

Precautionary statement(s): Storage

| | |
|-----------|--|
| P403+P235 | Store in a well-ventilated place. Keep cool. |
| P405 | Store locked up. |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed. |

Precautionary statement(s): Disposal

| | |
|------|--|
| P501 | Dispose of contents/container to authorised chemical landfill or if organic to high temperature incineration |
|------|--|

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

See section below for composition of Mixtures

Mixtures

| CAS No | %[weight] | Name |
|------------|-----------|---|
| 64742-47-8 | 80-85 | distillates, petroleum, light, hydrotreated |
| 9005-65-6 | 5-15 | sorbitan monooleate, ethoxylated |
| 9004-96-0 | 1-4 | polyethylene glycol monooleate |
| | | Note: Manufacturer has supplied full ingredient |
| | | information to allow CHEMWATCH assessment. |

*Note: Manufacturer has supplied full ingredient information to allow CHEMWATCH assessment.***SECTION 4 FIRST AID MEASURES****Description of first aid measures**

| | |
|---------------------|---|
| Eye Contact | <p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> Wash out immediately with fresh running water. 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. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin Contact | <p>If skin contact occurs:</p> <ul style="list-style-type: none"> Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation. |
| Inhalation | <ul style="list-style-type: none"> If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. 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. Transport to hospital, or doctor. |
| Ingestion | <ul style="list-style-type: none"> If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. |

Continued...

OSD/LT

- ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- ▶ Seek medical advice.
- ▶ Avoid giving milk or oils.
- ▶ Avoid giving alcohol.
- ▶ If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus.

Indication of any immediate medical attention and special treatment needed

Any material aspirated during vomiting may produce lung injury. Therefore emesis should not be induced mechanically or pharmacologically. Mechanical means should be used if it is considered necessary to evacuate the stomach contents; these include gastric lavage after endotracheal intubation. If spontaneous vomiting has occurred after ingestion, the patient should be monitored for difficult breathing, as adverse effects of aspiration into the lungs may be delayed up to 48 hours.

For acute or short term repeated exposures to petroleum distillates or related hydrocarbons:

- ▶ Primary threat to life, from pure petroleum distillate ingestion and/or inhalation, is respiratory failure.
- ▶ Patients should be quickly evaluated for signs of respiratory distress (e.g. cyanosis, tachypnoea, intercostal retraction, obtundation) and given oxygen. Patients with inadequate tidal volumes or poor arterial blood gases (pO₂ 50 mm Hg) should be intubated.
- ▶ Arrhythmias complicate some hydrocarbon ingestion and/or inhalation and electrocardiographic evidence of myocardial injury has been reported; intravenous lines and cardiac monitors should be established in obviously symptomatic patients. The lungs excrete inhaled solvents, so that hyperventilation improves clearance.
- ▶ A chest x-ray should be taken immediately after stabilisation of breathing and circulation to document aspiration and detect the presence of pneumothorax.
- ▶ Epinephrine (adrenalin) is not recommended for treatment of bronchospasm because of potential myocardial sensitisation to catecholamines. Inhaled cardioselective bronchodilators (e.g. Alupent, Salbutamol) are the preferred agents, with aminophylline a second choice.
- ▶ Lavage is indicated in patients who require decontamination; ensure use of cuffed endotracheal tube in adult patients. [Ellenhorn and Barceloux: Medical Toxicology]

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

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

Advice for firefighters**Fire Fighting**

- ▶ Alert Fire Brigade and tell them location and nature of hazard.
- ▶ Wear full body protective clothing with breathing apparatus.
- ▶ Prevent, by any means available, spillage from entering drains or water course.
- ▶ Use water delivered as a fine spray to control fire and cool adjacent area.
- ▶ Avoid spraying water onto liquid pools.
- ▶ **DO NOT** approach containers suspected to be hot.
- ▶ Cool fire exposed containers with water spray from a protected location.
- ▶ If safe to do so, remove containers from path of fire.

Fire/Explosion Hazard

- ▶ Combustible.
- ▶ Slight fire hazard when exposed to heat or flame.
- ▶ Heating may cause expansion or decomposition leading to violent rupture of containers.
- ▶ On combustion, may emit toxic fumes of carbon monoxide (CO).
- ▶ May emit acrid smoke.
- ▶ Mists containing combustible materials may be explosive.

Combustion products include: carbon dioxide (CO₂), other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

SECTION 6 ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures****Minor Spills**

- ▶ Remove all ignition sources.
- ▶ Clean up all spills immediately.
- ▶ Avoid breathing vapours and contact with skin and eyes.
- ▶ Control personal contact with the substance, by using protective equipment.
- ▶ Contain and absorb spill with sand, earth, inert material or vermiculite.
- ▶ Wipe up.
- ▶ Place in a suitable, labelled container for waste disposal.

Major Spills

Moderate hazard.

- ▶ Clear area of personnel and move upwind.
- ▶ Alert Fire Brigade and tell them location and nature of hazard.
- ▶ Wear breathing apparatus plus protective gloves.
- ▶ Prevent, by any means available, spillage from entering drains or water course.
- ▶ No smoking, naked lights or ignition sources.
- ▶ Increase ventilation.
- ▶ Stop leak if safe to do so.
- ▶ Contain spill with sand, earth or vermiculite.
- ▶ Collect recoverable product into labelled containers for recycling.
- ▶ Absorb remaining product with sand, earth or vermiculite.
- ▶ Collect solid residues and seal in labelled drums for disposal.
- ▶ Wash area and prevent runoff into drains.
- ▶ If contamination of drains or waterways occurs, advise emergency services.

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

SECTION 7 HANDLING AND STORAGE

OSD/LT

Precautions for safe handling

| | |
|-------------------|---|
| Safe handling | <ul style="list-style-type: none"> Containers, even those that have been emptied, may contain explosive vapours. Do NOT cut, drill, grind, weld or perform similar operations on or near containers. DO NOT allow clothing wet with material to stay in contact with skin Electrostatic discharge may be generated during pumping - this may result in fire. Ensure electrical continuity by bonding and grounding (earthing) all equipment. Restrict line velocity during pumping in order to avoid generation of electrostatic discharge (≤ 1 m/sec until fill pipe submerged to twice its diameter, then ≤ 7 m/sec). Avoid splash filling. Do NOT use compressed air for filling discharging or handling operations. Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid smoking, naked lights or ignition sources. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this MSDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions. |
| Other information | <ul style="list-style-type: none"> Store in original containers. Keep containers securely sealed. No smoking, naked lights or ignition sources. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this MSDS. |

Conditions for safe storage, including any incompatibilities

| | |
|-------------------------|---|
| Suitable container | <ul style="list-style-type: none"> Glass container is suitable for laboratory quantities Metal can or drum Packaging as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. |
| Storage incompatibility | <ul style="list-style-type: none"> Avoid reaction with oxidising agents |

PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---|---|---|---------|---------------|---------------|---------------------|
| US OSHA Permissible Exposure Levels (PELs) - Table Z1 | distillates, petroleum, light, hydrotreated | Oil mist, mineral | 5 mg/m3 | Not Available | Not Available | Not Available |
| US ACGIH Threshold Limit Values (TLV) | distillates, petroleum, light, hydrotreated | Mineral oil, excluding metal working fluids - Pure, highly and severely refined / Mineral oil, excluding metal working fluids - Poorly and mildly refined | 5 mg/m3 | Not Available | Not Available | TLV® Basis: URT irr |
| US NIOSH Recommended Exposure Limits (RELs) | distillates, petroleum, light, hydrotreated | Heavy mineral oil mist, Paraffin oil mist, White mineral oil mist | 5 mg/m3 | 10 mg/m3 | Not Available | Not Available |

EMERGENCY LIMITS

| Ingredient | TEEL-0 | TEEL-1 | TEEL-2 | TEEL-3 |
|------------|---------------|---------------|---------------|---------------|
| OSD/LT | Not Available | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|---|---------------|---------------|
| distillates, petroleum, light, hydrotreated | Not Available | Not Available |
| sorbitan monooleate, ethoxylated | Not Available | Not Available |
| polyethylene glycol monooleate | Not Available | Not Available |

Exposure controls

| | |
|----------------------------------|---|
| Appropriate engineering controls | <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.</p> <p>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> |
|----------------------------------|---|

Continued...

OSD/LT

Employers may need to use multiple types of controls to prevent employee overexposure.

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection.

Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.

An approved self contained breathing apparatus (SCBA) may be required in some situations.

Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

| Type of Contaminant: | Air Speed: |
|---|------------------------------|
| solvent, vapours, degreasing etc., evaporating from tank (in still air). | 0.25-0.5 m/s (50-100 f/min.) |
| aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.) |
| direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min.) |
| grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). | 2.5-10 m/s (500-2000 f/min.) |

Within each range the appropriate value depends on:

| Lower end of the range | Upper end of the range |
|--|----------------------------------|
| 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents |
| 2: Contaminants of low toxicity or of nuisance value only. | 2: Contaminants of high toxicity |
| 3: Intermittent, low production. | 3: High production, heavy use |
| 4: Large hood or large air mass in motion | 4: Small hood-local control only |

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Personal protection



Eye and face protection

- ▶ Safety glasses with side shields.
- ▶ Chemical goggles.
- ▶ 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]

Skin protection

See Hand protection below

Hands/feet protection

- ▶ Wear chemical protective gloves, e.g. PVC.
 - ▶ Wear safety footwear or safety gumboots, e.g. Rubber
- The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:
- ▶ frequency and duration of contact,
 - ▶ chemical resistance of glove material,
 - ▶ glove thickness and
 - ▶ dexterity
- Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
- ▶ When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
 - ▶ When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
 - ▶ Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
 - ▶ Contaminated gloves should be replaced.
- Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Body protection

See Other protection below

Other protection

- ▶ Overalls.
- ▶ P.V.C. apron.
- ▶ Barrier cream.
- ▶ Skin cleansing cream.
- ▶ Eye wash unit.

Thermal hazards

Not Available

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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

Continued...

OSD/LT

OSD/LT Not Available

varies with Type of filter.

| Material | CPI |
|----------|-----|
|----------|-----|

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

| 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)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| Appearance | Light yellow colour liquid with hydrocarbon-like odour. | | |
|--|---|---|----------------|
| Physical state | Liquid | Relative density (Water = 1) | 0.81 |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | 4-7 | Decomposition temperature | Not Available |
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | 100 | Molecular weight (g/mol) | Not Applicable |
| Flash point (°C) | 84.99 | Taste | Not Available |
| Evaporation rate | >1 Ether = 1 | Explosive properties | Not Available |
| Flammability | Combustible. | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | 7.0 | Surface Tension (dyn/cm or mN/m) | Not Available |
| Lower Explosive Limit (%) | 0.6 | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | 0 | Gas group | Not Available |
| Solubility in water (g/L) | Not Available | pH as a solution(1%) | Not Available |
| Vapour density (Air = 1) | >1 | VOC g/L | Not Available |

SECTION 10 STABILITY AND REACTIVITY

| | |
|------------------------------------|--|
| Reactivity | See section 7 |
| Chemical stability | <ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur. |
| 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

| | |
|-----------|--|
| Inhaled | <p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination 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>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.</p> <p>Inhalation hazard is increased at higher temperatures.</p> <p>Acute effects from inhalation of high concentrations of vapour are pulmonary irritation, including coughing, with nausea; central nervous system depression - characterised by headache and dizziness, increased reaction time, fatigue and loss of co-ordination</p> |
| Ingestion | Accidental ingestion of the material may be damaging to the health of the individual. |

Continued...

OSD/LT

| | |
|---------------------|--|
| Skin Contact | <p>Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant 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. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). 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.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>Repeated exposure may cause skin cracking, flaking or drying following normal handling and use.</p> <p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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.</p> |
| Eye | <p>Limited evidence exists, or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals and/or is expected to produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. 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.</p> |
| Chronic | <p>On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.</p> <p>Prolonged or repeated skin contact may cause drying with cracking, irritation and possible dermatitis following.</p> <p>Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.</p> <p>Repeated or prolonged exposure to mixed hydrocarbons may produce narcosis with dizziness, weakness, irritability, concentration and/or memory loss, tremor in the fingers and tongue, vertigo, olfactory disorders, constriction of visual field, paraesthesias of the extremities, weight loss and anaemia and degenerative changes in the liver and kidney. Chronic exposure by petroleum workers, to the lighter hydrocarbons, has been associated with visual disturbances, damage to the central nervous system, peripheral neuropathies (including numbness and paraesthesias), psychological and neurophysiological deficits, bone marrow toxicities (including hypoplasia possibly due to benzene) and hepatic and renal involvement. Chronic dermal exposure to petroleum hydrocarbons may result in defatting which produces localised dermatoses. Surface cracking and erosion may also increase susceptibility to infection by microorganisms. One epidemiological study of petroleum refinery workers has reported elevations in standard mortality ratios for skin cancer along with a dose-response relationship indicating an association between routine workplace exposure to petroleum or one of its constituents and skin cancer, particularly melanoma. Other studies have been unable to confirm this finding.</p> <p>Prolonged or repeated skin contact may cause degreasing with drying, cracking and dermatitis following.</p> <p>Repeated application of mildly hydrotreated oils (principally paraffinic), to mouse skin, induced skin tumours; no tumours were induced with severely hydrotreated oils.</p> |

| OSD/LT | TOXICITY | IRRITATION |
|---|--|-----------------------------------|
| | Not Available | Not Available |
| distillates, petroleum, light, hydrotreated | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| sorbitan monooleate, ethoxylated | TOXICITY | IRRITATION |
| | Intraperitoneal (Mouse) LD50: 7600 mg/kg | Eye (rabbit): 150 mg - mild |
| | Intraperitoneal (Rat) LD50: 6804 mg/kg | Skin (rabbit): - slight |
| | Intravenous (Mouse) LD50: 1790 mg/kg | |
| | Intravenous (Rat) LD50: 1790 mg/kg | |
| | Oral (mouse) LD50: 25000 mg/kg | |
| | Not Available | Not Available |
| polyethylene glycol monooleate | TOXICITY | IRRITATION |
| | Oral (rat) LD50: 3000 mg/kg* | [Harcros]* |
| | | Eye (rabbit): 500 mg/24h - mild |
| | | Eye (rabbit): moderate to SEVERE* |
| | | Skin (rabbit): 500 mg/24h -mild |
| | | Skin (rabbit): mild* |
| | Not Available | Not Available |

Not available. Refer to individual constituents.

| | |
|--|---|
| DISTILLATES, PETROLEUM, LIGHT, HYDROTREATED | <p>For "kerosenes"</p> <p>Acute toxicity: Oral LD50s for three kerosenes (Jet A, CAS No. 8008-20-6 and CAS No. 64742-81-0) ranged from > 2 to >20 g/kg. The dermal LD50s of the same three kerosenes were all >2.0 g/kg. Inhalation LC50 values in Sprague-Dawley rats for straight run kerosene (CAS No. 8008-20-6) and hydrodesulfurized kerosene (CAS No. 64742-81-0) were reported to be > 5 and > 5.2 mg/l, respectively. No mortalities in rats were reported in rats when exposed for eight hours to saturated vapor of deodorised kerosene (probably a desulfurised kerosene). Six hour exposures of cats to the same material produced an LC50 of >6.4 mg/l</p> <p>When tested in rabbits for skin irritation, straight run kerosene (CAS No. 8008-20-6) produced "moderate" to "severe" irritation. Six additional skin irritation studies on a range of kerosenes produced "mild" to "severe" irritation.</p> <p>An eye irritation in rabbits of straight run kerosene (CAS No. 8008-20-6) produced Draize scores of 0.7 and 2.0 (unwashed and washed eyes) at 1 hour. By 24 hours, the Draize scores had returned to zero. Eye irritation studies have also been reported for hydrodesulfurized kerosene and jet fuel. These materials produced more irritation in the unwashed eyes at 1 hour than had the straight run kerosene. The eye irritation persisted longer than that seen with straight run kerosene, but by day 7 had resolved.</p> <p>Straight run kerosene (CAS No. 8008-20-6), Jet A, and hydrodesulfurized kerosene (CAS No. 64742-81-0) have not produced sensitisation when tested in</p> |
|--|---|

Continued...

OSD/LT

guinea pigs

Repeat-Dose toxicity: Multiple repeat-dose toxicity studies have been reported on a variety of kerosenes or jet fuels. When applied dermally, kerosenes and jet fuels have been shown to produce dermal and systemic effects

Dose levels of 200, 1000 and 2000 mg/kg of a straight run kerosene (CAS No. 8008-20-6) were applied undiluted to the skin of male and female New Zealand white rabbits. The test material was applied 3x/week for 28 days. One male and one female in the 2000 mg/kg dose group found dead on days 10 and 24 respectively were thought to be treatment-related. Clinical signs that were considered to be treatment-related included: thinness, nasal discharge, lethargy, soiled anal area, anal discharge, wheezing. The high dose group appeared to have a treatment related mean body weight loss when compared to controls. Dose-related skin irritation was observed, ranging from "slight" to "moderate" in the low and high dose groups, respectively. Other treatment-related dermal findings included cracked, flaky and/or leathery skin, crusts and/or hair loss. Reductions in RBC, haemoglobin and haematocrit were seen in the male dose groups. There were no treatment related effects on a variety of clinical chemistry values. Absolute and relative weights for a number of organs were normal, with the following exceptions that were judged to be treatment-related:

- increased relative heart weights for the mid- and high- dose males and females,
- increased absolute and relative spleen weights in treated females, and
- differences in absolute and relative adrenal weights in both male and female treated animals (considered to be stress-related and therefore, indirectly related to treatment).

Gross necropsy findings were confined largely to the skin. Enlarged spleens were seen in the female groups. Microscopic examination of tissues taken at necropsy found proliferative inflammatory changes in the treated skin of all male and female animals in the high dose group. These changes were, in the majority of animals, accompanied by an increase in granulopoiesis of the bone marrow. Four of six high dose males had testicular changes (multifocal or diffuse tubular hypoplasia) that were considered by the study authors to be secondary to the skin and/or weight changes.

In a different study, hydrodesulfurised kerosene was tested in a thirteen-week dermal study using Sprague-Dawley rats. Test material was applied 5x/week to the skin of male and female rats at dose levels of 165, 330 and 495 mg/kg. Aside from skin irritation at the site of application, there were no treatment-related clinical signs during the study. Screening of all animals using a functional observation battery (FOB) did not find any substance-related effects.

Ophthalmological examination of all animals also found no treatment-related effects. There were no treatment-related effects on growth rates, hematological or clinical chemical values, or absolute or relative organ weights. Microscopic examination of tissues from animals surviving to termination found no treatment-related changes, with the exception of a minimal degree of a proliferative and inflammatory changes in the skin.

A hydrodesulfurised middle distillate (CAS no. 64742-80-9) has also been tested in a four week inhalation study. In the study, Sprague-Dawley rats were exposed to a nominal concentration of 25mg/m³ kerosene. Exposures were for approximately 6 hr/day, five days each week for four consecutive weeks.

There were no treatment-related effects on clinical condition, growth rate, absolute or relative organ weights, or any of the hematological or clinical chemistry determinations. Microscopic examination found no treatment-related changes observed in any tissues.

Carcinogenicity: In addition to the repeat-dose studies discussed above, a number of dermal carcinogenicity studies have been performed on kerosenes or jet fuels. Following the discovery that hydrodesulfurised (HDS) kerosene caused skin tumors in lifetime mouse skin painting studies, the role of dermal irritation in tumor formation was extensively studied. HDS kerosene proved to be a mouse skin tumor promoter rather than initiator, and this promotion required prolonged dermal irritation. If the equivalent dose of kerosene was applied to the skin in manner that did not cause significant skin irritation (eg, dilution with a mineral oil) no skin tumors occurred. Dermal bioavailability studies in mice confirmed that the reduced irritation seen with samples in mineral oil was not due to decreased skin penetration. The effect of chronic acanthosis on the dermal tumorigenicity of a hydrodesulfurised kerosene was studied and the author concluded that hyperplasia was essential for tumor promotion. However, the author also concluded that subacute inflammation did not appear to be a significant factor.

A sample of a hydrodesulfurised kerosene has been tested in an initiation-promotion assay in male CD-1 mice. Animal survivals were not effected by exposure to the kerosene. The study's authors concluded that the kerosene was not an initiator but it did show tumor promoting activity.

In-Vitro (Genotoxicity): The potential *in vitro* genotoxicities of kerosene and jet fuel have been evaluated in a variety of studies. Standard Ames assays on two kerosene samples and a sample of Jet A produced negative results with/without activation. Modified Ames assays on four kerosenes also produced negative results (with/without activation) except for one positive assay that occurred with activation. The testing of five kerosene and jet fuel samples in mouse lymphoma assays produced a mixture of negative and positive results. Hydrodesulfurized kerosene tested in a sister chromatid exchange assay produced negative results (with/without activation).

In-Vivo Genotoxicity: Multiple *in vivo* genotoxicity studies have been done on a variety of kerosene-based materials. Four samples of kerosene were negative and a sample of Jet A was positive in *in vivo* bone marrow cytogenetic tests in Sprague-Dawley rats. One of the kerosene samples produced a positive response in male mice and negative results in females when tested in a sister chromatid exchange assay. Both deodorised kerosene and Jet A samples produced negative results in dominant lethal assays. The kerosene was administered to both mice and rats intraperitoneally, while the jet fuel was administered only to mice via inhalation.

Reproductive/Developmental Toxicity Either 0, 20, 40 or 60% (v/v) kerosene in mineral oil was applied to the skin of the rats. The dose per body weight equivalents were 0, 165, 330 and 494 mg/kg. Test material was applied daily, 7 days/week from 14 days pre-mating through 20 days of gestation. There were no treatment-related effects on mortality and no clinical signs of toxicity were observed. There were no compound-related effects on any of the reproductive/developmental parameters. The authors concluded that the no observable effect level (NOEL) for reproductive/developmental toxicity of HDS kerosene under the treatment conditions of the study was 494 mg/kg/day.

Developmental toxicity screening studies on a kerosene and a sample of Jet A have been reported. There were no compound-related deaths in either study. While kerosene produced no clinical signs, the jet fuel produced a dose-related eye irritation (or infection). The signs of irritation lasted from 2 to 8 days with most animals showing signs for 3 days. Neither of the test materials had an effect on body weights or food consumption. Examination of offspring at delivery did not reveal any treatment-related abnormalities, soft tissue changes or skeletal abnormalities. The sex ratio of the fetuses was also unaffected by treatment with either of the compounds.

No significant acute toxicological data identified in literature search.

SORBITAN MONOOLEATE, ETHOXYLATED

Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

No significant acute toxicological data identified in literature search.

For Group D aliphatic esters:(sorbitan fatty esters)

According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel, Group D substances are esters of monoacids, mainly common fatty acids, and sorbitan (which is derived from sorbitol - a natural carbohydrate sweetener). The fatty acids include lauric, stearic, oleic acids and coca fatty acids (mainly lauric and myristic acids). The hydroxy group in the sorbitan represents the alcohol portion of the ester linkage. The Group D esters are carbohydrate-derived esters since the ester linkage is connected to the hydroxy group(s) of sorbitan. They may have single ester linkages (i.e., sorbitan monoester) or may have multiple ester linkages, as in the case of sorbitan sesquileate and sorbitan trioleate. Multiple ester linkages with long-chain fatty acids increase lipophilicity and also tend to diminish water solubility. The sorbitan esters are non-ionic surfactant-active agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products.

Acute toxicity: Sorbitan esters do not represent a toxicological concern since they are derived from naturally occurring materials and the parent esters are ultimately metabolised back to these same natural constituents: namely, sorbitan and common fatty acids, both of which have low orders of toxicity. The oral LD50 in rats ranged from >2.9 g/kg to > 39.8 g/kg. Numerous sorbitan esters have been studied by acute oral and dermal administration. Results from these studies support the general conclusion that sorbitan fatty acid esters have low orders of acute toxicity.

Repeated Dose Toxicity. A large number of subchronic oral and dermal studies and chronic oral feeding studies have been carried out for sorbitan monolaurate, sorbitan monostearate and sorbitan monooleate. For sorbitan monostearate, no adverse effects were reported in rats fed 5% concentrations of the test substance in the diet for 6 weeks. The NOAEL was estimated to be 5% or approximately 2500 mg/kg/day. In 2-year feeding studies at 5, 10 and 20% in the diet rats tolerated sorbitan monostearate with no adverse effects. However, at 20%, there was a small but significant decrease on growth rate

OSD/LT

in male rates. Hence, the NOAEL was 10% in the diet or approximately 5000 mg/kg/day in rats, based on these findings. In a 80-week dietary study in mice, no adverse effects were observed for sorbitan monostearate at 2% concentration in the diet and the NOAEL was 2% or approximately 2600 mg/kg/day. Subchronic studies have also been carried out with sorbitan, fatty acids C6-10, tetraester (CAS 228573-47-5).. Oral gavage studies for 28 days at dose levels up to 1000 mg/kg/day resulted in no systemic toxicity. Therefore, the NOAEL was 1000 mg/kg/day for this tetraester. Since the sesquioleate and trioleate of sorbitan are merely multiple ester homologs of sorbitan monooleate, they would be expected to show similar effects, given their structural similarities and potential to be metabolised to the monooleate.

Reproductive and developmental toxicity: Limited reproductive toxicity data have been reported for the sorbitan esters. In a 2-year feeding studies in rats with sorbitan monostearate, there were no effects on gestation and fertility at any dose level (0, 5, 10 and 20% in the diet) but survival of the newborn animals and maternal lactation were slightly diminished at the 20% level. Sorbitol was also studied indirectly as part of a mixture of hydrogenated starch hydrolysates (HSH) which contained about 7% sorbitol as part of the polyhydric alcohol mixture. The HSH mixture was investigated as part of a two-year ingestion study, a multigeneration reproduction study and a teratology study. At concentrations of 18% in drinking water (3000-7000 mg/kg/day), HSH did not produce reproductive or developmental effects. These results indicate that sorbitol does not cause reproductive/ developmental toxicity in animals. Given these findings and the low order of toxicity of natural fatty acids, it seems unlikely that sorbitan esters would present reproductive and developmental toxicity concerns.

Genotoxicity: Sorbitan monostearate (CAS 1338-41-6) was found to be negative in the Ames assay. In addition, the non-HPV substance, sorbitan fatty acid C6-10 tetraester (CAS 228573-47-5), did not cause any mutagenic effects in the Salmonella in vitro test. These substances bridge the low and high carbon range of most of the sorbitan esters and the chemistry of the sorbitan esters (i.e., sorbitan/ sorbitol, natural fatty acids) does not suggest the likelihood that the sorbitan esters are electrophilic or reactive in nature. Thus, it is not likely that the substances in Group D cause mutagenic effects. Sorbitan monostearate did not transform primary Syrian golden hamster embryo cells. As discussed above for point mutation, the chemistry of the sorbitan esters does not suggest the likelihood that these substances, or their constituent substructures (i.e., sorbitol, fatty acids) are reactive or electrophilic in nature.

The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

Polyoxyethylene sorbitan monooleate (TW80) is widely used as an emulsifier or solubilizer in a variety of foods, cosmetics and other commercial Products. In addition, TW80 in water has been used as a vehicle for the delivery of other chemical agents to pregnant laboratory animals by the oral route of administration (eg. by gavage or in the drinking water). Based upon the large population of pregnant women potentially exposed to TW80, and because of its use as a vehicle in laboratory animal studies, TW80 was evaluated for potential developmental toxicity. Timed-mated Sprague-Dawley-derived (CD®) rats (25 per group) were exposed to 0, 500 or 5000 mg/kg/day of TW80. Aqueous solutions were delivered by gavage in a volume of 5 mL/kg of body weight on gestational days (gd) 6 through 15. At termination (gd 20), the uterus was removed and examined to determine pregnancy status, and to evaluate the number of resorptions, and dead or live foetuses. Dead or live foetuses were weighed, and live foetuses were examined for external, visceral and skeletal defects. All treated females survived to scheduled necropsy and 19-23 pregnancies per group were confirmed. No dose-related signs of toxicity were observed for individual animals during the in-life phase of the study or at scheduled necropsy. Average maternal body weight (gd 0, 3, 6, 9, 12, 15, 18, or 20) did not differ among treatment groups, nor was there a treatment related change in maternal weight gain during treatment or gestation (absolute or corrected). There were no treatment-related effects upon the following maternal organ weights: gravid weight (absolute), kidney weight (absolute or relative), and heart weight (absolute or relative). Relative maternal liver weight (% body weight on gd 20 or % corrected body weight) was elevated in both TW80 groups and absolute liver weight was elevated at 500 mg/kg/day. Maternal food intake was comparable across groups during the pre- and post-treatment periods, but was decreased by 14% during the first 3 days of treatment at 5000 mg/kg/day relative to the vehicle control group. Maternal relative water intake was comparable among treatment groups throughout gestation. No differences among groups were noted for the number of corpora lutea per dam, the number of implantation sites per dam or the percent preimplantation loss per litter. No adverse effects were noted on the growth, viability or morphological development of the conceptuses. In conclusion, the maternal LOAEL was 500 mg/kg/day (based upon an increase in maternal relative liver weight). No definitive adverse effects of TW80 upon prenatal development were noted in this study. Thus, the developmental NOAEL was greater than 5000 mg/kg/day.

For glycol and diol aliphatic esters:(group C)

According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel, Group C substances are comprised of a monocarboxylic acid (generally natural fatty acids, e.g., oleic, stearic, C6-C10 fatty acids) and a dihydroxy alcohol (glycol or diol such as ethylene glycol, polyethylene glycol, propylene glycol, 2,2-dimethyl-1,3-propanediol). These esters are often referred to as "glycol or diol esters" or as "alkylidene or alkanediyl esters".

The rationale for grouping the glycol or diol esters is that they represent structurally similar ethylene/ propylene glycol esters in which the hydroxyl groups in the glycol are functionalised with fatty acids as ester derivatives. Esterification of the glycol with fatty acids such as stearic and oleic acid can provide glycol diesters in the 38 to 41 carbon number range, which typically make them relatively non-volatile and high boiling liquids with limited water solubility and with sufficient polar characteristics to make them useful as lubricants and solvents. In the case of the tri- and tetraethylene glycol diesters, the ether linkage in the polyalkylene portion of the glycol also imparts additional polar character to these glycol esters.

Metabolism of these glycol esters in animals would be expected to occur initially via enzymatic hydrolysis leading to the corresponding free fatty acids and free glycol alcohols (e.g., ethylene glycol, propylene glycol, 2,2-dimethyl-1,3-propanediol, polyethylene glycol). These free fatty acids and glycols can be further metabolised or conjugated (e.g., glucuronides, sulfates, etc.) to polar products that are excreted in the urine. The fatty acids, especially the natural occurring ones such as stearic and oleic acids, have low degrees of toxicity. The toxicity of the alkylidene or alkanediyl glycols has been extensively reviewed, especially in case of ethylene glycol and propylene glycol

Acute toxicity: Overall, the acute oral LD50 values for these substances is greater than the 2000 mg/kg, indicating a very low order of toxicity for the glycol esters. Acute dermal toxicity studies have also been carried out and reported for the various propylene glycol fatty acid esters and polyethylene glycol fatty acid esters, particularly those used in cosmetic applications. Overall, the glycol fatty acids exhibit very low degrees of acute oral and dermal toxicity.

Repeat dose toxicity: Studies have also been carried out for various propylene glycol fatty acid esters and polyethylene glycol esters. Data suggests that members of the glycol esters category would be expected to exhibit a low order of toxicity following repeated oral administration. Additional support data that glycol esters are likely to have low orders of repeated-dose toxicity are based on a number of feeding studies conducted in rats, dogs, mice, rabbits and monkeys for PEG-8 stearate. An expert panel has reviewed these studies and has reported that polyethylene glycol-8 stearate (PEG-8 stearate) produced no significant changes in growth mortality rates, histopathological observations or haematology values in long-term feeding studies in rats (i.e., 8-week feeding study at 2% in diet; 9-week feeding study at 4% in diet and 2-year 3-generation feeding studies at 4% in the diet) Repeated-dose toxicity studies carried out with PEG-40 stearate and PEG-100 stearate also have been reported to demonstrate low degrees of toxicity

Reproductive toxicity: Although no adequate reproductive toxicity studies were located on members of the glycol esters category, numerous regulatory bodies have determined that these substances do not pose a reproductive hazard. These hazard and/or risk assessments are based on the fact that glycol esters would be metabolised (hydrolysed) in vivo to the corresponding fatty acids and free glycol alcohols (e.g., ethylene glycol, propylene glycol) [WHO (2003)]. The free fatty acids and glycols can undergo further metabolism or conjugation to polar products that are either excreted or can be used as nutrients. In most cases, the parent fatty acids derived from the glycol esters are comprised of natural fatty acids that are typical of those (e.g., oleic, stearic acid) found in edible oils and fats.

Additional supporting data that glycol esters are unlikely to be reproductive toxicants are based on a multiple generation feeding of PEG-8 stearate. Animals receiving 4% PEG-8 stearate in their diet for three successive generations did not affect growth or fecundity. In another three-generation study in rats receiving diets containing 5%, 10%, or 20% PEG-8 stearate, reproduction and lactation responses were no different from controls at the 5% dose level. Newborn litter survival times were diminished most likely due to maternal neglect at the 10% and 20% dose levels. The overall level of reproductive performance (e.g., greater mortality rate of nurslings, impairment of lactation efficiency) was lower in animals fed the 20% PEG-8 stearate diet. Results from these studies showed a low order of reproductive/developmental toxicity. PEG stearates (including PEG-8 stearate) have been approved by the FDA for use in the bakery and pharmaceutical industries.

Although adequate reproductive and developmental studies have not been reported for ethylene glycol stearates or other ethylene glycol fatty acid esters, numerous studies have been conducted to evaluate reproductive and developmental effects of the parent glycol alcohol, namely, ethylene glycol (EG). EG itself is considered to have a relatively low order of toxicity; however, it is oxidized to more toxic metabolites such as glycolic acid, glycolaldehyde, glyoxalic acid, and oxalic acid. Accumulation of these C2 acid products leads to metabolic acidosis which is the underlying cause of EG systemic toxicity.

Developmental Toxicity/Teratogenicity: Although no adequate developmental toxicity studies are available on members of the glycol esters category,

POLYETHYLENE GLYCOL MONOOLEATE

OSD/LT

numerous regulatory bodies have determined that these substances do not pose a reproductive/developmental hazard. This is based on the previously discussed reproductive effects of related substances Propylene glycol (PG) was found not to be teratogenic in female mice given single oral doses of 10,000 ppm PG during gestation days 8-12. Fertility rates and all other parameters measured in mice given PG were not significantly different from controls. From these findings, it appears unlikely that glycol esters, as a category would pose developmental toxicity concerns

Genotoxicity: Tests on several glycol esters were shown to be negative for mutagenic activity, with and without metabolic activation. These findings indicate that the glycol esters are not expected to cause point mutations. Substances tested using in vitro cytogenetics assays for chromosomal aberration show negative results. This is consistent with the chemistry of the glycol esters, which does not suggest the likelihood that these substances, or their constituent glycols or fatty acids, are electrophilic or reactive in nature. Therefore, the likelihood that the glycol esters may cause chromosomal aberration is expected to be very low.

The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

| | | | |
|-----------------------------------|---|--------------------------|---|
| 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 required to make classification available
 ✗ – Data available but does not fill the criteria for classification
 ☐ – Data Not Available to make classification

CMR STATUS

Not Applicable

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

DO NOT discharge into sewer or waterways.

Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|---------------------------------------|---------------------------------------|
| | No Data available for all ingredients | No Data available for all ingredients |

Bioaccumulative potential

| Ingredient | Bioaccumulation |
|------------|---------------------------------------|
| | No Data available for all ingredients |

Mobility in soil

| Ingredient | Mobility |
|------------|---------------------------------------|
| | No Data available for all ingredients |

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

| | |
|------------------------------|--|
| Product / Packaging disposal | <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type.</p> <p>Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible or consult manufacturer for recycling options. ▶ Consult State Land Waste Authority for disposal. ▶ Bury or incinerate residue at an approved site. ▶ Recycle containers if possible, or dispose of in an authorised landfill. |
|------------------------------|--|

SECTION 14 TRANSPORT INFORMATION

Labels Required

| | |
|------------------|----|
| Marine Pollutant | NO |
|------------------|----|

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

Continued...

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 73 / 78 and the IBC code

| Source | Ingredient | Pollution Category |
|---|----------------------------------|--------------------|
| IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk | sorbitan monooleate, ethoxylated | Y |

SECTION 15 REGULATORY INFORMATION

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

| | |
|--|---|
| distillates, petroleum, light, hydrotreated(64742-47-8) is found on the following regulatory lists | "US ATSDR Minimal Risk Levels for Hazardous Substances (MRLs)", "US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants", "US - California Permissible Exposure Limits for Chemical Contaminants", "US - Idaho - Limits for Air Contaminants", "US - Hawaii Air Contaminant Limits", "US ACGIH Threshold Limit Values (TLV) - Carcinogens", "US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants", "US - Michigan Exposure Limits for Air Contaminants", "International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs", "US - Oregon Permissible Exposure Limits (Z-1)", "US NIOSH Recommended Exposure Limits (RELs)", "US - Alaska Limits for Air Contaminants", "US - Washington Permissible exposure limits of air contaminants", "US Priority List for the Development of Proposition 65 Safe Harbor Levels - No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity", "US - California Proposition 65 - Carcinogens", "US - Minnesota Permissible Exposure Limits (PELs)", "US ACGIH Threshold Limit Values (TLV)", "US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants", "US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory", "US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants", "US OSHA Permissible Exposure Levels (PELs) - Table Z1" |
| sorbitan monooleate, ethoxylated(9005-65-6) is found on the following regulatory lists | "US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants", "US - Idaho - Limits for Air Contaminants", "US - Hawaii Air Contaminant Limits", "US - California Permissible Exposure Limits for Chemical Contaminants", "US - California Proposition 65 - No Significant Risk Levels (NSRLs) for Carcinogens", "US ACGIH Threshold Limit Values (TLV) - Carcinogens", "US - Michigan Exposure Limits for Air Contaminants", "US EPA Carcinogens Listing", "US National Toxicology Program (NTP) 12th Report Part B. Reasonably Anticipated to be a Human Carcinogen", "US - New Jersey Right to Know - Special Health Hazard Substance List (SHHS): Mutagens", "US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants", "US - California - Proposition 65 - Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity", "International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs", "US - Oregon Permissible Exposure Limits (Z-1)", "US - Washington Toxic air pollutants and their ASIL, SQER and de minimis emission values", "US - California OEHHA/ARB - Acute Reference Exposure Levels and Target Organs (RELs)", "US NIOSH Recommended Exposure Limits (RELs)", "US - Alaska Limits for Air Contaminants", "US - Washington Permissible exposure limits of air contaminants", "US - California Proposition 65 - Carcinogens", "US National Toxicology Program (NTP) 12th Report Part A Known to be Human Carcinogens", "US Spacecraft Maximum Allowable Concentrations (SMACs) for Airborne Contaminants", "US - Minnesota Permissible Exposure Limits (PELs)", "US ACGIH Threshold Limit Values (TLV)", "US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants", "US - California OEHHA/ARB - Chronic Reference Exposure Levels and Target Organs (CRELs)", "US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory", "US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants", "US - New Jersey Right to Know - Special Health Hazard Substance List (SHHS): Carcinogens", "US OSHA Permissible Exposure Levels (PELs) - Table Z1" |
| polyethylene glycol monooleate(9004-96-0) is found on the following regulatory lists | "US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory" |

SECTION 16 OTHER INFORMATION

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.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references

The (M)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.