

Freund's Complete Adjuvant

sc-3727

Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key: **EXTREME** **HIGH** **MODERATE** **LOW**

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Freund's Complete Adjuvant

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Company: Santa Cruz Biotechnology, Inc.
2145 Delaware Ave
Santa Cruz, CA 95060
800.457.3801 or 831.457.3800

CHEMWATCH

From within the US and Canada: 877-715-9305

From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE

■ Used according to manufacturer's directions.

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability:	1	
Toxicity:	2	
Body Contact:	2	
Reactivity:	1	
Chronic:	2	

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

Harmful by inhalation.

May cause SENSITIZATION by inhalation and skin contact.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

- Accidental ingestion of the material may be damaging to the health of the individual.

EYE

- There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
- Non-ionic surfactants can cause numbing of the cornea, which masks discomfort normally caused by other agents and leads to corneal injury. Irritation varies depending on the duration of contact, the nature and concentration of the surfactant.

SKIN

- Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
- There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.
- Open cuts, abraded or irritated skin should not be exposed to this material.
- Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

- Inhalation of vapors or aerosols (mists, fumes), generated by the material during the course of normal handling, may be harmful.
- There is some evidence to suggest that the material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.

CHRONIC HEALTH EFFECTS

- Inhaling this product is more likely to cause a sensitization reaction in some persons compared to the general population. Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population. Prolonged or repeated skin contact may cause degreasing with drying, cracking and dermatitis following.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
mannide monooleate	9049-98-3	15
hydrocarbon oils	8020-83-5	0.85
mycobacterium (autoclaved) lyophilized cell powder		0.1

Section 4 - FIRST AID MEASURES

SWALLOWED

-
- 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.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

EYE

- If this product comes in contact with the eyes:
 - 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.
 - If pain persists or recurs seek medical attention.
 - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

- If skin contact occurs:
 - 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.

INHALED

-
- 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.

NOTES TO PHYSICIAN

- Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Not Available
Upper Explosive Limit (%):	Not Available
Specific Gravity (water=1):	Not Available
Lower Explosive Limit (%):	Not Available

EXTINGUISHING MEDIA

-
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

FIRE FIGHTING

-
- Alert Emergency Responders 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.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

-
- 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.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

PVC chemical resistant type.

Respirator:

Type A-P Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

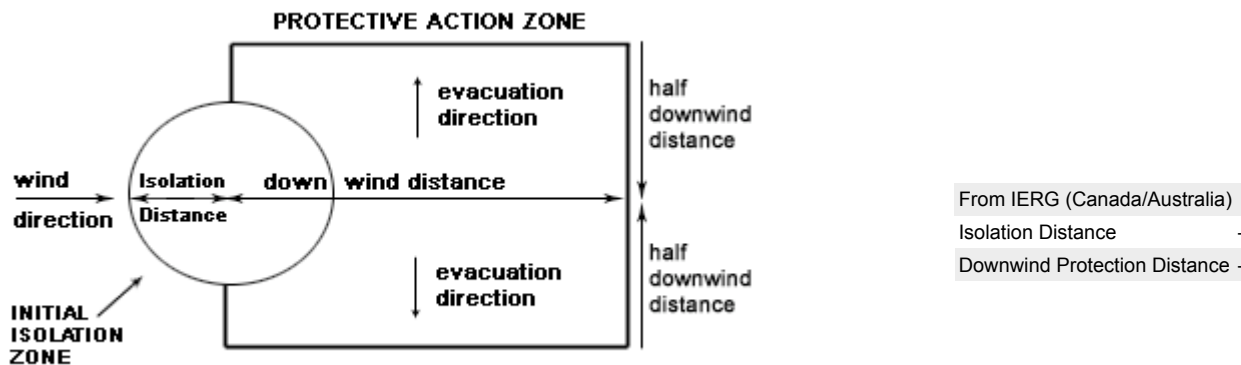
-
- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid breathing vapors and contact with skin and eyes.
- Control personal contact by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.
- Wipe up.
- Place in a suitable labeled container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

MAJOR SPILLS

- Moderate hazard.
- Clear area of personnel and move upwind.
- Alert Emergency Responders 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 labeled containers for recycling.
- Absorb remaining product with sand, earth or vermiculite.
- Collect solid residues and seal in labeled drums for disposal.
- Wash area and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL



From US Emergency Response Guide 2000 Guide No guide found.

FOOTNOTES

1 PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapour plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.

2 PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapour concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.

3 INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localised wind reversal may expose nearly all persons without appropriate protection to life-threatening concentrations of the material.

4 SMALL SPILLS involve a leaking package of 200 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres and compressed gas leaking from a small cylinder are also considered "small spills". LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one-tonne" compressed gas cylinder.

5 Guide No guide found. is taken from the US DOT emergency response guide book.

6 IERG information is derived from CANUTEC - Transport Canada.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

AEGL 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

AEGL 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

AEGL 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- 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 storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions.
- DO NOT allow clothing wet with material to stay in contact with skin

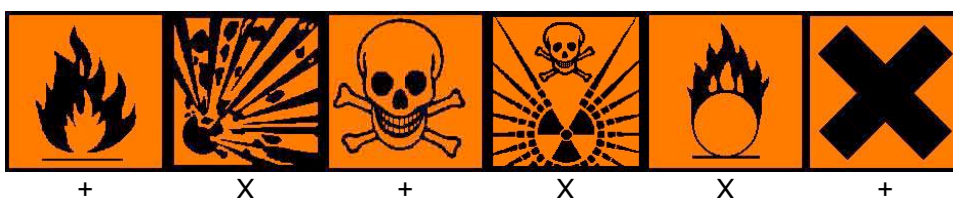
RECOMMENDED STORAGE METHODS

-
- Metal can or drum
- Packing as recommended by manufacturer.
- Check all containers are clearly labeled and free from leaks.

STORAGE REQUIREMENTS

-
- 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 storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



X: Must not be stored together
 O: May be stored together with specific preventions
 +: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC	Notes
Canada - Ontario Occupational Exposure Limits	hydrocarbon oils (Turpentine and selected monoterpenes)	20							
Canada - British Columbia Occupational Exposure Limits	hydrocarbon oils (Turpentine and selected monoterpenes Revised 2003)	20							S
Canada - Saskatchewan Occupational Health and Safety Regulations - Contamination Limits	hydrocarbon oils (Diesel fuel as total hydrocarbons, (vapour))		100		150				Skin
Canada - Ontario Occupational Exposure Limits	hydrocarbon oils (Diesel fuel, as total hydrocarbons, vapour and aerosol)		100						Skin
Canada - Alberta Occupational Exposure Limits	hydrocarbon oils (Kerosene/Jet fuels, as total hydrocarbon vapour)		200						
Canada - Alberta Occupational Exposure Limits	hydrocarbon oils (Diesel fuel, as total hydrocarbons)		100						

US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants	hydrocarbon oils (Oil mist, mineral)	5			
US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants	hydrocarbon oils (Oil mist, mineral)	5			
US - Idaho - Limits for Air Contaminants	hydrocarbon oils (Oil mist, mineral)	5			
US - Alaska Limits for Air Contaminants	hydrocarbon oils (Oil mist, mineral)	5			
US - Washington Permissible exposure limits of air contaminants	hydrocarbon oils (Oil mist mineral (particulate))	5		10	
Canada - Yukon Permissible Concentrations for Airborne Contaminant Substances	hydrocarbon oils (Oil mist, mineral)	-	5	-	10
Canada - Nova Scotia Occupational Exposure Limits	hydrocarbon oils (Oil mist - mineral)		5		10
					TLV Basis: lung. As sampled by method that does not collect vapor.
US - Minnesota Permissible Exposure Limits (PELs)	hydrocarbon oils (Oil mist, mineral)		5		
Canada - British Columbia Occupational Exposure Limits	hydrocarbon oils (Oil mist - mineral, severely refined)		1		
US OSHA Permissible Exposure Levels (PELs) - Table Z1	hydrocarbon oils (Oil mist, mineral)		5		
Canada - British Columbia Occupational Exposure Limits	hydrocarbon oils (Diesel fuel, as total hydrocarbons, Inhalable)		100 (V)		Skin

The following materials had no OELs on our records

- mannide monooleate: CAS:9049-98-3

MATERIAL DATA

MANNIDE MONOOLEATE:

Freund's Complete Adjuvant:

■ Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

HYDROCARBON OILS:

■ Toxicity and Irritation data for petroleum-based mineral oils are related to chemical components and vary as does the composition and source of the original crude.

A small but definite risk of occupational skin cancer occurs in workers exposed to persistent skin contamination by oils over a period of years. This risk has been attributed to the presence of certain polycyclic aromatic hydrocarbons (PAH) (typified by benz[a]pyrene).

Petroleum oils which are solvent refined/extracted or severely hydrotreated, contain very low concentrations of both.

Human exposure to oil mist alone has not been demonstrated to cause health effects except at levels above 5 mg/m³ (this applies to particulates sampled by a method that does not collect vapor). It is not advisable to apply this standard to oils containing unknown concentrations and types of additive.

PERSONAL PROTECTION



Consult your EHS staff for recommendations

EYE

-
- Safety glasses with side shields.
- Chemical goggles.
- Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them. DO NOT wear contact lenses.

HANDS/FEET

■ Wear chemical protective gloves, eg. PVC.

Wear safety footwear or safety gumboots, eg. Rubber.

NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- 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).

- 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) 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) is recommended.
- 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.

OTHER

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

RESPIRATOR

■ Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Breathing Zone Level ppm (volume)	Maximum Protection Factor	Half-face Respirator	Full-Face Respirator
1000	10	A-1 P	-
1000	50	-	A-1 P
5000	50	Airline*	-
5000	100	-	A-2 P
10000	100	-	A-3 P
	100+		Airline* *

* - Continuous Flow ** - Continuous-flow or positive pressure demand.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.

Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

ENGINEERING CONTROLS

■ General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of overexposure exists, wear an approved respirator. An approved respirator (supplied air type) may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed storage areas.

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, vapors, 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 favorable 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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Liquid.

State	Liquid	Molecular Weight	Not Applicable
Melting Range (°F)	Not Available	Viscosity	Not Available
Boiling Range (°F)	Not Available	Solubility in water (g/L)	Not Available
Flash Point (°F)	Not Available	pH (1% solution)	Not Available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not Available
Autoignition Temp (°F)	Not Available	Vapour Pressure (mmHG)	Not Available
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapor Density (air=1)	Not Available
Volatile Component (%vol)	Not Available	Evaporation Rate	Not Available

APPEARANCE

Liquid.

Group A substances are rather lipophilic (log Kow 10-15) in character due to the large number of carbon numbers in the ester molecule (e.g., 24,26, 31 carbons) and have relatively high boiling points. Owing to the non-volatile nature of these esters, their vapor pressures are very low and difficult to determine experimentally. Water solubility is also very low.

Material	Value

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

-
- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

Freund's Complete Adjuvant

TOXICITY AND IRRITATION

HYDROCARBON OILS:

MANNIDE MONOOLEATE:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

- Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterized by increased susceptibility to nasal inflammation, asthma and eczema.

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.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. 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 sensitization potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitizing substance which is widely distributed can be a more important allergen than one with stronger sensitizing 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.

MANNIDE MONOOLEATE:

- Group A aliphatic monoesters (fatty acid esters)

According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel, Group A substances are simple monoesters derived from a monofunctional alcohol, such as 2-ethylhexyl alcohol (C8-alcohol) or tridecyl alcohol (C13 alcohol) and fatty acids such as palmitic, stearic, oleic or linoleic acid. Metabolism of the parent esters is expected to yield the corresponding fatty acids and alcohols. The fatty acids are naturally occurring and have a low order of toxicity.

Group A substances are rather lipophilic (log Kow 10-15) in character due to the large number of carbon numbers in the ester molecule (e.g., 24,26, 31 carbons) and have relatively high boiling points. Owing to the non-volatile nature of these esters, their vapour pressures are very low and difficult to determine experimentally. Water solubility is also very low.

Mammalian Toxicity:

Acute Toxicity. Many higher fatty acid esters, such as the stearates, oleates and palmitates, have been cleared for use in the food industry ; thus, their general physiological response and toxicity are very low. Many of the higher fatty acid esters are considered safe for use in cosmetics.

Available acute toxicity data indicate that the fatty acid esters in Group A, in general, have a low order of toxicity [e.g., palmitic acid, 2-ethylhexyl ester (LD50 > 5 g/kg) and tall oil fatty acid 2-ethylhexyl ester (LD50 > 64 g/kg)]. Consistent with that, available data spanning the carbon range of C22 to C34 indicate that the alkyl fatty acid esters are not toxic by oral administration [rat LD50 (oral) > 5g/kg, with range from 5 g/kg to 64 kg/kg]. Butyl stearate is tolerated by rats without lethal effects at oral doses of 32 g/kg while octyl oleate has a reported LD50 of >40 ml/kg.

In addition, many alkyl fatty acid esters, such as the stearates, oleates and palmitates, have been demonstrated to be not toxic by dermal administration

Because of the low volatility of these substances, inhalation exposure at toxicological significant levels is not expected.

Repeated Dose Toxicity. 28-Day oral gavage studies in rats with decyl oleate (CAS 3687-46-5) at doses of 100,500 and 1000 mg/kg showed no toxicity as noted with respect to clinical symptoms, biochemistry, hematology, gross lesions or tissue/organ histopathology. The NOAEL was estimated to be 1000 mg/kg. Similarly, octyl or (2-ethylhexyl) stearate showed a NOAEL of 1000 mg/kg in 28-day oral gavage studies in rats.

In chronic two-year feeding studies with butyl stearate at concentrations of 1.25% or 6.25% in the diet, exposed rats showed no significant difference from control animals with respect to growth, survival, blood counts or other haematological parameters.

Besides the two substances above, various other long-chain fatty acid esters have also been studied for their repeated dose toxicity and the findings support a low order of toxicity.

Genotoxicity:

Genetic Toxicity (Salmonella). Fatty acid, C 16- 18 saturated and C 18 unsaturated, 2-ethylhexanoate (CAS 85049-37-2); octyl stearate (CAS 109-36-4); and decyl oleate (CAS 3687-46-5) were shown to be negative in the Ames assay. Since the monoesters are similar in chemical structure and carbon-number range, it is unlikely that esters in Group A will induce point mutation. In addition, the chemistry of the long-chain fatty acids does not suggest the likelihood that these substances or their constituent substructures (i.e., fatty acids, alcohols) are reactive or electrophilic in nature.

Genetic Toxicity (Chromosomal Aberrations). The chemistry of the long-chain fatty acid esters does not suggest the likelihood that these substances or their constituent substructures (i.e., fatty acids, alcohols) are reactive or electrophilic in nature. Therefore, the likelihood that the fatty acid monoesters may cause chromosomal mutation is very low.

Reproductive toxicity: Assessment of reproductive effects of alkyl fatty acid esters in Group A is based primarily on studies with butyl stearate. Fertility, litter size and survival of offspring were normal in rats fed diets containing 6.25% butyl stearate for 10 weeks. However, growth was reduced in offspring during the pre-weaning and post-weaning periods. No gross lesions were noted among the offspring killed at the end of the 21-day post-weaning periods. These results indicate that long-chain fatty acid esters do not cause reproductive toxicity in rats. Given the relative low order of toxicity for long-chain fatty acid esters and their relative non-electrophilic and non-reactive nature, it seems unlikely that the long-chain fatty acid esters would present serious reproductive concerns.

Developmental Toxicity/ Teratogenicity. Assessment of developmental effects for the long-chain fatty acid esters in this group was based primarily on data reported for fatty acid, C16-18, 2-ethylhexyl ester (CAS 91031-48-0). In oral gavage studies in rats administered doses of 100,300 and 1000 mg/kg during gestation, the maternal NOAEL was > 1000 mg/kg and the NOAEL for teratogenicity was >1000 mg/kg. Based on these findings and the fact Group A substances, are very chemically similar to the structure of the tested material, read-across assessment is thought to be appropriate.

Fatty acid esters have fairly low toxicity.

No significant acute toxicological data identified in literature search.

TOXICITY

HYDROCARBON OILS:

Oral (rat) LD50: 45000 mg/kg

IRRITATION

Skin (rabbit) 500 mg/24H Mild

Dermal (rabbit) LD50: 5000 mg/kg

Eye (rabbit) 100 mg/24H Mild

■ 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 on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

A small but definite risk of occupational skin cancer occurs in workers exposed to persistent skin contamination by oils over a period of years.

This risk has been attributed to the presence of polycyclic aromatic hydrocarbons (PAH) and, in particular, benz-alpha-pyrenes (BaP).

Petroleum oils which are solvent refined/extracted or severely hydrotreated, contain very low concentrations of both.

CARCINOGEN

Petroleum solvents	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	3
MINERAL OILS (UNTREATED AND MILDLY TREATED OILS)	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	IARC

SKIN

hydrocarbon oils	ND	Notes	Skin
hydrocarbon oils	ND	Notation	Skin
hydrocarbon oils	Canada - Alberta Occupational Exposure Limits - Skin	Substance Interaction	1

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:

MANNIDE MONOOLEATE:

HYDROCARBON OILS:

Freund's Complete Adjuvant

■ DO NOT discharge into sewer or waterways.

MANNIDE MONOOLEATE:

Freund's Complete Adjuvant

■ Octanol/ water partition coefficients cannot easily be determined for surfactants because one part of the molecule is hydrophilic and the other part is hydrophobic. Consequently they tend to accumulate at the interface and are not extracted into one or other of the liquid phases. As a result surfactants are expected to transfer slowly, for example, from water into the flesh of fish. During this process, readily biodegradable surfactants are expected to be metabolized rapidly during the process of bioaccumulation. This was emphasized by the OECD Expert Group stating that chemicals are not to be considered to show bioaccumulation potential if they are readily biodegradable. Several anionic and nonionic surfactants have been investigated to evaluate their potential to bioconcentrate in fish. BCF values (BCF - bioconcentration factor) ranging from 1 to 350 were found. These are absolute maximum values resulting from the radio labeling technique used. In all these studies, substantial oxidative metabolism was found resulting in the highest radioactivity in the gall bladder. This indicates liver transformation of the parent compound and biliary excretion of the metabolized compounds, so that "real" bioconcentration is overstated. After correction it can be expected that "real" parent BCF values are one order of magnitude less than those indicated above, i.e. "real" BCF is <100. Therefore the usual data used for classification by EU Directives to determine whether a substance is "Dangerous to the Environment" has little bearing on whether the use of the surfactant is environmentally acceptable.

Freund's Complete Adjuvant

MANNIDE MONOOLEATE:

■ For Group A aliphatic esters (fatty acid esters):

Environmental fate:

Group A substances are rather lipophilic (log Kow 10-15) in character due to the large number of carbon numbers in the ester molecule (e.g., 24,26, 31 carbons) and have relatively high boiling points. Owing to the non-volatile nature of these esters, their vapor pressures are very low and difficult to determine experimentally. Water solubility is also very low.

Hydrolysis half lives and atmospheric photodegradation rates were calculated by EPIWIN. The monoester hydrolysis rates were determined to be quite low and not a significant environmental fate route. Fugacity modeling indicates that the fatty acid esters have similar distribution patterns in the environmental compartments (e.g., air, water, soil, sediment).

Biodegradation of alkyl fatty acid esters are expected to occur extensively based on the reported 28 day test results (80-85% biodegradation, OECD 301D) for decyl oleate and for the 2-ethylhexyl ester of C16- 18 saturated and C18 unsaturated fatty acids (CAS 85049-37-2). Group A Substances are expected to be extensively biodegraded since the fatty acids in these esters are primarily comprised of palmitic, stearic or oleic acids, which are known to be rapidly biodegraded

Ecotoxicity:

Aquatic toxicity results have been reported for decyl oleate and fatty acid, C16- 18 saturated and C18 unsaturated, 2-ethylhexanoate They are not acutely toxic to fish (LC50 3200 mg/L). In daphnids, the acute LC50 was reported to be 17 mg/L and in algae, the LC50 was reported to be 40-42 mg/L based on biomass and growth rate endpoints. Because of their limited water solubility, the alkyl fatty acid esters and Group A esters are not likely to cause acute aquatic toxicity.

HYDROCARBON OILS:

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

! Puncture containers to prevent re-use and bury at an authorized landfill.

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.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

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. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult Waste Management Authority for disposal.
- Bury or incinerate residue at an approved site.
- Recycle containers if possible, or dispose of in an authorized landfill.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION



REGULATIONS

Regulations for ingredients

hydrocarbon oils (CAS: 8020-83-5) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)", "US - Pennsylvania - Hazardous Substance List", "US DOE Temporary Emergency Exposure Limits (TEELs)"

No data for Freund's Complete Adjuvant (CW: 18-0317)

No data for mannide monooleate (CAS: , 9049-98-3)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Skin contact and/or ingestion may produce health damage*.
 - May produce discomfort of the eyes, respiratory tract and skin*.
- * (limited evidence).

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the mixture 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.

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