Polyoxyethylene (25) propylene glycol stearate

sc-281133

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

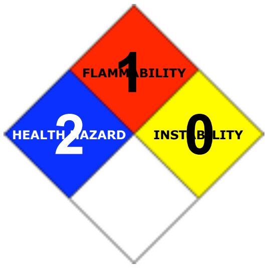
PRODUCT NAME

Polyoxyethylene (25) propylene glycol stearate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Company: Santa Cruz Biotechnology, Inc.
Address:
2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE

Used as emulsifier and stabiliser.

SYNONYMS

"oxirane, methyl-, polymer with oxirane, monooctadecanoate, ", "oxirane, methyl-, polymer with oxirane, octadecanoate", "poly(propylene oxide, ethylene oxide), ester with stearic acid", "polyoxyethylene propylene glycol stearate", G2162

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

Irritating to skin.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

• Accidental ingestion of the material may be damaging to the health of the individual.
• Nonionic surfactants may produce localized irritation of the oral or gastrointestinal lining and induce vomiting and mild diarrhea.

EYE

• There is some evidence to suggest that this material can causeeye 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

• This material can cause inflammation of the skin oncontact in some persons.
• The material may accentuate any pre-existing dermatitis condition.
• Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions.
• 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

• The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

CHRONIC HEALTH EFFECTS

• There is some evidence that inhaling this product 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

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

NAME	CAS RN	%
polyethylene/ polypropylene glycol stearate	37231-60-0	>98
may contain residuals as		
ethylene oxide	75-21-8	

Section 4 - FIRST AID MEASURES

SWALLOWED

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- 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

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- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

• Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	<0.13 (20 C)
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	1.04
Lower Explosive Limit (%):	Not available.

EXTINGUISHING MEDIA

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

FIRE FIGHTING

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- 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

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- 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.

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:
Respirator:
Type AX-P Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

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- 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

• Chemical Class: alcohols and glycols

For release onto land: recommended sorbents listed in order of priority.

SORBENT TYPE	RANK	APPLICATION	COLLECTION	LIMITATIONS
LAND SPILL - SMALL				
cross-linked polymer - particulate	1	shovel	shovel	R, W, SS
cross-linked polymer - pillow	1	throw	pitchfork	R, DGC, RT
sorbent clay - particulate	2	shovel	shovel	R,I, P
wood fiber - pillow	3	throw	pitchfork	R, P, DGC, RT
treated wood fiber - pillow	3	throw	pitchfork	DGC, RT
foamed glass - pillow	4	throw	pichfork	R, P, DGC, RT
LAND SPILL - MEDIUM				
cross-linked polymer - particulate	1	blower	skiploader	R,W, SS
polypropylene - particulate	2	blower	skiploader	W, SS, DGC
sorbent clay - particulate	2	blower	skiploader	R, I, W, P, DGC
polypropylene - mat	3	throw	skiploader	DGC, RT
expanded mineral - particulate	3	blower	skiploader	R, I, W, P, DGC
polyurethane - mat	4	throw	skiploader	DGC, RT

Legend
DGC: Not effective where ground cover is dense
R; Not reusable
I: Not incinerable
P: Effectiveness reduced when rainy
RT:Not effective where terrain is rugged
SS: Not for use within environmentally sensitive sites
W: Effectiveness reduced when windy
Reference: Sorbents for Liquid Hazardous Substance Cleanup and Control;
R.W Melvold et al: Pollution Technology Review No. 150: Noyes Data Corporation 1988.

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.

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

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- DO NOT allow clothing wet with material to stay in contact with skin
- Overheating of ethoxylates in air should be avoided. When some ethoxylates are heated vigorously in the presence of air or oxygen, at temperatures exceeding 160 C, they may undergo exothermic oxidative degeneration resulting in self-heating and autoignition.
- Nitrogen blanketing will minimize the potential for ethoxylate oxidation.
- Trace quantities of ethylene oxide may be present in the material. Although these may accumulate in the headspace of storage and transport vessels, concentrations are not expected to exceed levels which might produce a flammability or worker exposure hazard.

- 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.

RECOMMENDED STORAGE METHODS

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

STORAGE REQUIREMENTS

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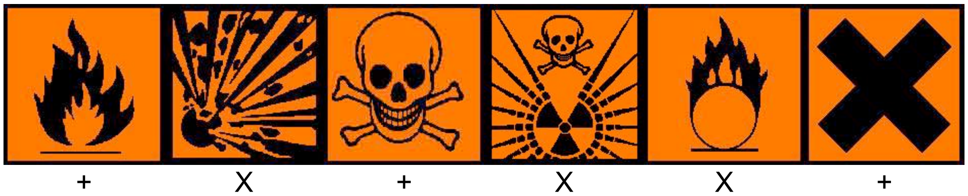
- Store in original containers.
- Keep containers securely sealed.
- No smoking, naked lights or ignition sources.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- 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 - Alberta Occupational Exposure Limits	ethylene oxide (Ethylene oxide)	1	1.8						
Canada - British Columbia Occupational Exposure Limits	ethylene oxide (Ethylene oxide)	0.1		1					A2, 1; R
US OSHA Permissible Exposure Levels (PELs) - Table Z1	ethylene oxide (Ethylene oxide; see 1910.1047)	1		5					(STEL (Excursion limit)(as averaged over a sampling period of 15 minutes))
US ACGIH Threshold Limit Values (TLV)	ethylene oxide (Ethylene oxide)	1							TLV Basis: cancer; central nervous system impairment
US NIOSH Recommended Exposure Limits (RELs)	ethylene oxide (Ethylene oxide)	<0.1	0.18			5	9		See Appendix A; Ca; (Ceiling ([10-min/day]))
US ATSDR Minimal Risk Levels for Hazardous Substances (MRLs)	ethylene oxide (ETHYLENE OXIDE)	0.09							

US - California Permissible Exposure Limits for Chemical Contaminants	ethylene oxide (Ethylene oxide; see Section 5220)	1	2	5				
US - Hawaii Air Contaminant Limits	ethylene oxide (Ethylene oxide)	1						See º12-202-35
Canada - Yukon Permissible Concentrations for Airborne Contaminant Substances	ethylene oxide (Ethylene oxide)	50	90	75	135			
US - Washington Permissible exposure limits of air contaminants	ethylene oxide (Ethylene oxide (see chapter 296-855 WAC))	1		5				
Canada - Saskatchewan Occupational Health and Safety Regulations - Contamination Limits	ethylene oxide (Ethylene oxide)	1		2				T20
US - Michigan Exposure Limits for Air Contaminants	ethylene oxide (Ethylene oxide; see R 325.51151 et seq.F)	1	1.8	5	9.0			
Canada - Prince Edward Island Occupational Exposure Limits	ethylene oxide (Ethylene oxide)	1						TLV Basis: cancer; central nervous system impairment
US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants	ethylene oxide (Ethylene oxide; see 1910.1047)	1						
Canada - Quebec Permissible Exposure Values for Airborne Contaminants (English)	ethylene oxide (Ethylene oxide)	1	1.8					
US - Oregon Permissible Exposure Limits (Z-1)	ethylene oxide (Ethylene oxide)	1						TWA (See 1910.1047)
Canada - Northwest Territories Occupational Exposure Limits (English)	ethylene oxide (Ethylene oxide)	10	20	50	100			
Canada - Nova Scotia Occupational Exposure Limits	ethylene oxide (Ethylene oxide)	1						TLV Basis: cancer; central nervous system impairment

The following materials had no OELs on our records

- polyethylene/ polypropylene glycol stearate: CAS:37231-60-0

EMERGENCY EXPOSURE LIMITS

Material	Revised IDLH Value (mg/m3)	Revised IDLH Value (ppm)
ethylene oxide		800 [Unch]

MATERIAL DATA

ETHYLENE OXIDE:
POLYETHYLENE/ POLYPROPYLENE GLYCOL STEARATE:

- for ethylene oxide:

Odour Threshold Value: 257-690 ppm (detection), 493 ppm (recognition)
NOTE: Detector tubes for ethylene oxide, measuring in excess of 1 ppm, are available commercially.
Exposure at or below the TLV-TWA is thought reduce the potential oncogenic risk and the risk from potential, non-neoplastic adverse effects non lungs, liver, kidneys, endocrine system, blood forming elements and the central nervous system. OSHA recognised that ethylene oxide exposures at 1 ppm still might produce significant health risks. A quantitative risk assessment shows an excess cancer mortality risk of 12 to 23 deaths per 10,000 workers at this level. It must be stated that risk assessment models are fraught with much uncertainty.
Odour Safety Factor(OSF)
OSF=0.0023 (ETHYLENE OXIDE).
POLYETHYLENE/ POLYPROPYLENE GLYCOL STEARATE:

- No exposure limits set by NOHSC or ACGIH.

PERSONAL PROTECTION




Consult your EHS staff for recommendations

EYE

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- 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.

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

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- 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	AX-1 P	-
1000	50	-	AX-1 P
5000	50	Airline*	-
5000	100	-	AX-2 P
10000	100	-	AX-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 specific circumstances. If risk of overexposure exists, wear an approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed 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.
Mixes with water.

State	Liquid	Molecular Weight	Not applicable
Melting Range (°F)	Not available	Viscosity	Not available
Boiling Range (°F)	>212	Solubility in water (g/L)	Miscible
Flash Point (°F)	>300.02 (COC)	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available.	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available.	Vapour Pressure (mmHG)	<0.13 (20 C)
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	1.04
Lower Explosive Limit (%)	Not available.	Relative Vapor Density (air=1)	Not available.
Volatile Component (%vol)	Not available	Evaporation Rate	Not available

APPEARANCE

• Family of products which vary in their physical properties as a result of variations in production. Data presented here is for typical family member. Cream-coloured semi-solid; mixes with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

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- 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

polyethylene/ polypropylene glycol stearate

TOXICITY AND IRRITATION

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

TOXICITY	IRRITATION
Oral (rat) LD50: >25100 mg/kg *	Eye (rabbit): non-irritating *
	Skin (human): non-irritating *

• 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, 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.

* ICI Americas Inc

CARCINOGEN

Ethylene oxide (NB: Overall evaluation upgraded from 2A to 1 based on mechanistic and other relevant data)	International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs	Group	1
Ethylene oxide	ND	Carcinogen Category	A2
ETHYLENE OXIDE	US Environmental Defense Scorecard Recognized Carcinogens	Reference(s)	P65
ETHYLENE OXIDE	US Environmental Defense Scorecard Suspected Carcinogens	Reference(s)	P65
Ethylene oxide	US Air Toxics Hot Spots TSD for Describing Available Cancer Potency Factors	IARC Class	1
Ethyleneoxide	ND	Carcinogen	Ca

REPROTOXIN

ethylene oxide	ILO Chemicals in the electronics industry that have toxic effects on reproduction	Reduced fertility or sterility	A

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:
ETHYLENE OXIDE:
POLYETHYLENE/ POLYPROPYLENE GLYCOL STEARATE:
- DO NOT discharge into sewer or waterways.

POLYETHYLENE/ POLYPROPYLENE GLYCOL STEARATE:
- For glycol and diol aliphatic esters:

Environmental fate:
Solubility: In general, the glycol monoesters with shorter carbon-number fatty acids (C6-C7) were predicted to be more water-soluble and less lipophilic than the corresponding glycol monoesters containing long-chain fatty acids such as stearic and oleic acids. The glycol diesters were predicted to be more lipophilic and less water-soluble than the corresponding glycol monoesters [e.g., ethylene glycol distearate (CAS 627-83-8) versus its monostearate (CAS 111-60-4); 2,2-dimethyl-1,3-propanediol dioleate (CAS 42222-50-4) versus its monooleate (CAS 67989-24-6)]. In addition, the glycol diesters have higher boiling points than the corresponding monoesters.
Polyethylene glycol (or polyoxyethylene) esters, that contain more than one repeating ethylene glycol unit, generally showed greater water solubility than the corresponding monoethylene glycol esters, owing to the increased polarity of multiple ether linkages; this was consistent with what would be expected . The greater degree of ether linkage was also consistent with the lower lipophilicity (log P) values predicted by EPIWIN.
The distribution between the environmental compartments for glycol esters appears to be influenced by lipophilicity or water solubility. For lipophilic glycol esters with calculated log Kow >7, the EQC (Level III) model predicted a greater chemical distribution in the sediment and soil compartment . Conversely, for glycol esters with greater water solubility characteristics [e.g., heptanoic acid, ester with 2,2,4-trimethyl-1,3-pentanediol (CAS 71839-38-8); triethylene glycol, diheptanoate (CAS 7434-40-4); heptanoic acid, oxybis(2,1-ethanediyloxy-2,1-ethanediyl) ester (CAS 70729-68-9)], the EQC Level III model predicted greater distribution in the water compartment, in comparison to other very water-insoluble glycol esters
Biodegradability: It is expected that the glycol esters would be rapidly and extensively biodegraded in the environment. The extent of biodegradation has been reported to range from 65% to 98% in 28 days for four glycol esters. These results indicate that the glycol esters are rapidly and extensively biodegraded. The tested substances covered the C15-C23 carbon range for the glycol esters. Glycol esters above C30 appear to be mainly comprised of the glycol diesters such as the dioleates and distearates, and several are simply to be diester homologs of the corresponding monooleate or monostearate esters. These diesters are expected to be microbially metabolized in the environment to the corresponding monoesters, some of which have been reported to be extensively biodegraded. For example, the glycol monooleate ester, 9-octadecenoic acid (Z)-, ester with 2,2-dimethyl-1,3-propanediol (CAS 67989-24-6) has been demonstrated to be readily biodegradable in the OECD 301B modified Sturm test. Since 9-octadecenoic acid (Z)-, 2,2-dimethyl-1,3-propanediyl (di)ester (CAS 4222-50-4) is the corresponding diester derivative of the above glycol monooleate (i.e., CAS 67989-24-6), it is not unexpected that the dioleate would be extensively biodegraded as well. This is based on the premise that the dioleate would be expected to be microbially metabolized (hydrolyzed) to the monooleate, which has already been found to be readily biodegradable.
Biodegradation or enzymatic (microbial) breakdown of the glycol esters would be expected to ultimately lead to the free glycol such as propylene glycol, ethylene glycol, polyethylene glycol and to the corresponding free fatty acids, including stearic acid and oleic acid. There are adequate biodegradability data in the scientific literature to support the premise that these constituent components, namely, the free glycols and the free fatty acids, would be expected to be rapidly and extensively biodegraded in aerobic systems (e.g., sewage, activated sludge, wastewater) in the environment
Ecotoxicity:
The available data for the tested glycol esters indicate that acute aquatic toxicity would not be expected at the water solubility limit or water saturation levels (WSL) of the tested glycol ester materials. While the higher molecular weight glycol esters (>C38, MW ~600) have not been evaluated, they are probably expected to have low degrees of aquatic toxicity due to their very low water solubility.
It is of interest to note that ethylene glycol and propylene glycol are not acutely toxic to aquatic organisms In addition, free fatty acids (e.g., stearic and oleic acids) that may be generated from enzymatic metabolism of the glycol esters are expected to have low degrees of aquatic toxicity.
- 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.

ETHYLENE OXIDE:

• Hazardous Air Pollutant:	Yes
• Fish LC50 (96hr.) (mg/l):	90 (24hr)
• log Kow (Sangster 1997):	- 0.3
• BOD5:	0.06
• COD:	1.74
• Half- life Soil - High (hours):	285
• Half- life Soil - Low (hours):	251

• Half- life Air - High (hours):	9167
• Half- life Air - Low (hours):	917
• Half- life Surface water - High (hours):	285
• Half- life Surface water - Low (hours):	251
• Half- life Ground water - High (hours):	285
• Half- life Ground water - Low (hours):	251
• Aqueous biodegradation - Aerobic - High (hours):	4320
• Aqueous biodegradation - Aerobic - Low (hours):	672
• Aqueous biodegradation - Anaerobic - High (hours):	17280
• Aqueous biodegradation - Anaerobic - Low (hours):	2688
• Photooxidation half- life air - High (hours):	9167
• Photooxidation half- life air - Low (hours):	917
• First order hydrolysis half- life (hours):	285
• Base rate constant [MOH)- HR]- 1:	1.0E- 04 M-

• for ethylene oxide:
log Kow : -0.3
Koc : 16
Half-life (hr) air : 2880
Half-life (hr) H2O surface water : 216-336
Henry's atm m3 /mol: 1.20E-04
BOD 5: 0.06
COD : 1.74

Ethylene oxide is not expected to bioaccumulate in the environment. Fish are the most susceptible aquatic organisms. An LC50 of 90 mg/litre was observed for goldfish exposed for 24 h. 2-Chloroethanol, a degradation product in saline water, is equally toxic but, 1,2-ethanediol, a major degradation product, is much less toxic.

In the atmosphere, ethylene oxide degrades slowly by reacting with hydroxy-radicals; the estimated half-life is 100-200 days. In water it is removed by volatilisation, hydrolysis and to a lesser extent, biodegradation.

Volatilisation half-lives for a model river and lake are estimated to be 5.9 hours and 38 days respectively.

Ethylene oxide is not strongly adsorbed to soil and is not expected to bioconcentrate in the food chain

Environmental fate:

The main pathway of entry of ethylene oxide into the environment is through its escape into the atmosphere due to evaporation and with vented gases during production, handling, storage, transport, and use. Most of the ethylene oxide applied as a sterilant or fumigant will enter the atmosphere

At ambient levels, ethylene oxide will be removed from the atmosphere via oxidation by hydroxyl radicals. On the basis of a theoretical rate constant for this reaction, the atmospheric residence time of ethylene oxide was estimated to be 5.8 days. However, experimental data have shown the residence time to be 100 - 215 days, depending on the hydroxyl radical concentration and the ambient temperature (US EPA, 1985). Because of its high water solubility, ethylene oxide levels in air will also be reduced through washout by rain. The photochemical reactivity of ethylene oxide, in terms of its ozone-forming ability, is low. Evaporation from water is a significant removal process. Under specific conditions, a half-life of 1 h for the evaporation of ethylene oxide from water has been calculated. In the environment, chemical degradation in water through ionic reactions appears to be comparatively slow. In neutral, fresh water at 25 C, ethylene oxide is broken down to form 1,2-ethanediol with a half-life of 14 days. At 0 C, the half-life is 309 days. The reaction is acid- and base-catalysed. In the presence of halide ions, 2-haloethanol will also be formed. In neutral water of 3% salinity, at 25 C, 77% of ethylene oxide was found to react to form 1,2-ethanediol and 23%, to form 2- chloroethanol with a half-life of 9 days.

Ethylene oxide and its possible metabolites can be biodegraded slowly by aerobic microorganisms. Biological oxygen demands of 3 - 5% and 52% of the theoretical oxygen demand were determined for ethylene oxide after 5 and 20 days, respectively, using a domestic sewage seed.

Ecotoxicity:

LC50s of ethylene oxide for aquatic species have been reported to range from 90 mg/litre (goldfish, 24-h exposure) to 745 mg/litre (brine shrimp, 48-h exposure). Microorganisms in activated sludge showed 50% inhibition at concentrations between 10 and 100 mg/litre. Hydrolysis to 1,2-ethanediol results in detoxification. The toxicity of 2-chloroethanol for aquatic organisms resembles that of ethylene oxide, though 2-chloroethanol seems to be more toxic for Daphnia magna. Nevertheless, under environmental conditions, the conversion of ethylene oxide to 2-chloroethanol or 1,2-ethanediol will be slow.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
ethylene oxide	LOW	HIGH	LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

US EPA Waste Number & Descriptions

B. Component Waste Numbers

When ethylene oxide is present as a solid waste as a discarded commercial chemical product, off-specification species, as a container residue, or a spill residue, use EPA waste number U115 (waste code I,T).

Disposal Instructions

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

• 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

polyethylene/ polypropylene glycol stearate (CAS: 37231-60-0) is found on the following regulatory lists;

"Canada Domestic Substances List (DSL)","US Toxic Substances Control Act (TSCA) - Inventory"

Regulations for ingredients

ethylene oxide (CAS: 75-21-8) is found on the following regulatory lists;

"Canada - Alberta Ambient Air Quality Objectives","Canada - Alberta Occupational Exposure Limits","Canada - British Columbia Occupational Exposure Limits","Canada - Northwest Territories Occupational Exposure Limits (English)","Canada - Nova Scotia Occupational Exposure Limits","Canada - Prince Edward Island Occupational Exposure Limits","Canada - Prince Edward Island Occupational Exposure Limits - Carcinogens","Canada - Quebec Permissible Exposure Values for Airborne Contaminants (English)","Canada - Saskatchewan Occupational Health and Safety Regulations - Contamination Limits","Canada - Saskatchewan Occupational Health and Safety Regulations - Designated Chemical Substances","Canada - Yukon Permissible Concentrations for Airborne Contaminant Substances","Canada ARET (Accelerated Reduction / Elimination of Toxics) Substance List","Canada Environmental Protection Act (CEPA) 1999 - Schedule 1 Toxic Substances List","Canada Environmental Protection Act (CEPA) 1999 - Schedule 3 Export Control List - Part 2 Substances Subject to Notification or Consent","Canada Ingredient Disclosure List (SOR/88-64)","Canada National Pollutant Release Inventory (NPRI)","Canada Priority Substances List (PSL1, PSL 2)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (English)","Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS (French)","GESAMP/EHS Composite List - GESAMP Hazard Profiles","International Agency for Research on Cancer (IARC) - Agents Reviewed by the IARC Monographs","International Chemical Secretariat (ChemSec) REACH SIN* List (*Substitute It Now!) 1.0","International Council of Chemical Associations (ICCA) - High Production Volume List","OECD Representative List of High Production Volume (HPV) Chemicals","United Nations List of Prior Informed Consent Chemicals (English)","US - Alaska Limits for Air Contaminants","US - California Air Toxics ""Hot Spots"" List (Assembly Bill 2588) Substances for which emissions must be quantified","US - California Occupational Safety and Health Regulations (CAL/OSHA) - Hazardous Substances List","US - California OEHHA/ARB - Chronic Reference Exposure Levels and Target Organs (CRELs)","US - California Permissible Exposure Limits for Chemical Contaminants","US - Califomia Proposition 65 - Carcinogens","US - California Proposition 65 - Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity","US - California Proposition 65 - No Significant Risk Levels (NSRLs) for Carcinogens","US - California Proposition 65 - Reproductive Toxicity","US - California Toxic Air Contaminant List Category II","US - Connecticut Hazardous Air Pollutants","US - Hawaii Air Contaminant Limits","US - Idaho - Limits for Air Contaminants","US - Maine Chemicals of High Concern List","US - Massachusetts Oil & Hazardous Material List","US - Michigan Exposure Limits for Air Contaminants","US - Minnesota Hazardous Substance List","US - Minnesota Permissible Exposure Limits (PELs)","US - New Jersey Right to Know Hazardous Substances","US - Oregon Hazardous Materials","US - Oregon Permissible Exposure Limits (Z-1)","US - Pennsylvania - Hazardous Substance List","US - Rhode Island Hazardous Substance List","US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants","US - Vermont Hazardous Constituents","US - Vermont Hazardous wastes which are Discarded Commercial Chemical Products or Off-Specification Batches of Commercial Chemical Products or Spill Residues of Either","US - Vermont Permissible Exposure Limits Table Z-1-A Final Rule Limits for Air Contaminants","US - Vermont Permissible Exposure Limits Table Z-1-A Transitional Limits for Air Contaminants","US - Washington Class A toxic air pollutants: Known and Probable Carcinogens","US - Washington Dangerous waste constituents list","US - Washington Discarded Chemical Products List - ""U"" Chemical Products","US - Washington Permissible exposure limits of air contaminants","US - Wyoming List of Highly Hazardous Chemicals, Toxics and Reactives","US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants","US ACGIH Threshold Limit Values (TLV)","US ACGIH Threshold Limit Values (TLV) - Carcinogens","US ATSDR Minimal Risk Levels for Hazardous Substances (MRLs)","US CAA (Clean Air Act) - HON Rule - Organic HAPs (Hazardous Air Pollutants)","US Clean Air Act - Hazardous Air Pollutants","US Department of Homeland Security Chemical Facility Anti-Terrorism Standards - Chemicals of Interest","US Department of Transportation (DOT) List of Hazardous Substances and Reportable Quantities - Hazardous Substances Other Than Radionuclides","US DOE Temporary Emergency Exposure Limits (TEELs)","US EPA Acute Exposure Guideline Levels (AEGLs) - Interim","US EPA High Production Volume Program Chemical List","US EPCRA Section 313 Chemical List","US Food Additive Database","US List of Lists - Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-to-Know Act (EPCRA) and Section 112(r) of the Clean Air Act","US National Toxicology Program (NTP) 11th Report Part A Known to be Human Carcinogens","US NFPA 45 Fire Protection for Laboratories Using Chemicals - Flammability Characteristics of Common Compressed and Liquefied Gases","US NIOSH Recommended Exposure Limits (RELs)","US OSHA Carcinogens Listing","US OSHA List of Highly Hazardous Chemicals, Toxics and Reactives","US OSHA Permissible Exposure Levels (PELs) - Table Z1","US RCRA (Resource Conservation & Recovery Act) - Hazardous Constituents - Appendix VIII to 40 CFR 261","US RCRA (Resource Conservation & Recovery Act) - List of Hazardous Wastes","US RCRA (Resource Conservation & Recovery Act) - Phase 4 LDR Rule - Universal Treatment Standards","US SARA Section 302 Extremely Hazardous Substances","US Toxic Substances Control Act (TSCA) -

Inventory","US TSCA Section 8 (d) - Health and Safety Data Reporting","USA: Chemical Facility Anti-Terrorism Standards - List Appendix A - 6CFR 27"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Ingestion may produce health damage*.
- May produce discomfort of the eyes*.
- Possible respiratory sensitizer*.
- Repeated exposure potentially causes skin dryness and cracking*.

* (limited evidence).

REPRODUCTIVE HEALTH GUIDELINES

- Established occupational exposure limits frequently do not take into consideration reproductive end points that are clearly below the thresholds for other toxic effects. Occupational reproductive guidelines (ORGs) have been suggested as an additional standard. These have been established after a literature search for reproductive no-observed-adverse effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL). In addition the US EPA's procedures for risk assessment for hazard identification and dose-response assessment as applied by NIOSH were used in the creation of such limits. Uncertainty factors (UFs) have also been incorporated.

Ingredient	ORG	UF	Endpoint	CR	Adeq TLV
ethylene oxide	1.8 mg/m3	NA	D	600	Yes

- These exposure guidelines have been derived from a screening level of risk assessment and should not be construed as unequivocally safe limits. ORGS represent an 8-hour time-weighted average unless specified otherwise. CR = Cancer Risk/10000; UF = Uncertainty factor: TLV believed to be adequate to protect reproductive health: LOD: Limit of detection Toxic endpoints have also been identified as: D = Developmental; R = Reproductive; TC = Transplacental carcinogen Jankovic J., Drake F.: A Screening Method for Occupational Reproductive Health Risk: American Industrial Hygiene Association Journal 57: 641-649 (1996).

- 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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