Polysorbate 80

sc-255444

Material Safety Data Sheet



The Power to Oscotion

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Polysorbate 80

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc. 2145 Delaware Avenue Santa Cruz, California 95060 800.457.3801 or 831.457.3800

EMERGENCY ChemWatch

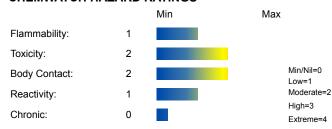
Within the US & Canada: 877–715–9305 Outside the US & Canada: +800 2436 2255 (1–800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C32H60O10, "poly(oxy-1, 2-ethandiyl), sorbitan, mono-9-octadecenoate", "polyoxyethylene sorbitan monooleate derivative", "polyethylene glycol sorbitan oleate", "ethyoxylated sorbitan monooleate", "polyethylene glycol sorbitan monooleate", "glycols, polyethylene, ether with sorbitan monoleate", "sorbitan, mono 9-octadecenoate, poly(oxy-1, 2-ethanediyl), derivs., (Z)-", "Armotan PMO-20", "Atlox 1087", "Capmul POE-O", "Crill 10, 11, S 10 Crillet 4", "Drewmulse POE-SMO", "Durfax 80", "Emsorb 6900", "Glycosperse O-20, O-20 Veg, O-20X", "Hodag SVO 9", "Liposorb O-20", "MO 55F", Monitan, "Montanox 80", "Nikkol TO TO10", Olothorb, "Peganate O 20", "Polysorban 80", "Polysorbate 80 B.P.C., U.S.P", Polysobate, "Protasorb O-20", "Romulgin O", "Sorbimacrogol Oleate, 300, ", "Sorbitol O 20", "Sorbon T 80", "Sorethytan (20) monoleate", Sorlate, "SVO 9", "TO 10", "Tween 81", "Tween 80 A", "Sigma P4780"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS



CANADIAN WHMIS SYMBOLS

None

EMERGENCY OVERVIEW RISK

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.

FYF

- Limited evidence or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals.
- Prolonged eye contact may cause inflammation characterized by a temporary redness of the conjunctiva (similar to windburn).
- 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

- The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
- Repeated exposure may cause skin cracking, flaking or drying following normal handling and use.
- 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.

■ Not normally a hazard due to non-volatile nature of product.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course.

Prolonged or repeated skin contact may cause degreasing with drying, cracking and dermatitis following.

Continu 2	COMPOSITION	/ INFORMATION O	N INCREDIENTS
Section 3 -	COMPOSITION	INFORMATION	N INGREDIENTS

NAME	CAS RN	%
sorbitan monooleate, ethoxylated	9005-65-6	100

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.

FYF

■ 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.

SKIN

■ If skin or hair contact occurs: · 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. · Other measures are usually unnecessary.

NOTES TO PHYSICIAN

■ Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES				
Vapour Pressure (mmHG):	Negligible			
Upper Explosive Limit (%):	Not available			
Specific Gravity (water=1):	1.080			
Lower Explosive Limit (%):	Not available			

EXTINGUISHING MEDIA

- · Alcohol stable foam.
- · Dry chemical powder.

FIRE FIGHTING

- · Alert Emergency Responders and tell them location and nature of hazard.
- · Wear full body protective clothing with breathing apparatus.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- · Combustible.
- · Slight fire hazard when exposed to heat or flame.

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:

Safety Glasses.

Chemical goggles.

Gloves:

Respirator:

Type A-P Filter of sufficient capacity

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Slippery when spilt.
- · Remove all ignition sources.
- · Clean up all spills immediately.

MAJOR SPILLS

■ Slippery when spilt.

Moderate hazard.

- · Clear area of personnel and move upwind.
- · Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- · 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.
- · Avoid all personal contact, including inhalation.
- · Wear protective clothing when risk of exposure occurs.

RECOMMENDED STORAGE METHODS

- Glass container
- · Metal can or drum
- $\cdot \ {\hbox{Packing as recommended by manufacturer}}.$

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.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• sorbitan monooleate, ethoxylated: CAS:9005-65-6

PERSONAL PROTECTION









RESPIRATOR

· type a-p filter of sufficient capacity.

FYF

- · Safety glasses with side shields.
- · Chemical goggles.

HANDS/FEET

- 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.

Wear chemical protective gloves, eg. PVC.

OTHER

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

ENGINEERING CONTROLS

■ General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

State	Liquid	Molecular Weight	604.81
Melting Range (°F)	Not available	Viscosity	Not Available
Boiling Range (°F)	>212	Solubility in water (g/L)	Miscible
Flash Point (°F)	298	pH (1% solution)	Not available
Decomposition Temp (°F)	Not available	pH (as supplied)	Not available
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	1.080
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not available
Volatile Component (%vol)	Not available	Evaporation Rate	Not available

APPEARANCE

Yellow oily liquid; mixes with water. Insoluble in mineral and vegetable oils. Viscosity @ 25 deg. C: 425 cps.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- · Presence of incompatible materials.
- · Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

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

Section 11 - TOXICOLOGICAL INFORMATION

sorbitan monooleate, ethoxylated

TOXICITY AND IRRITATION

SORBITAN MONOOLEATE, ETHOXYLATED:

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

TOXICITY IRRITATION

Oral (mouse) LD50: 25000 mg/kg Eye (rabbit): 150 mg - Mild

Skin (rabbit): - slight

■ 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 sesquioleate 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 monoleate, 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 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.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient Persistence: Water/Soil Persistence: Air Bioaccumulation Mobility

sorbitan monooleate, No Data Available No Data Available

GESAMP/EHS COMPOSITE LIST - GESAMP Hazard Profiles

Legend: EHS=EHS Number (EHS=GESAMP Working Group on the Evaluation of the Hazards of Harmful Substances Carried by Ships) NRT=Net Register Tonnage, A1a=Bioaccumulation log Pow, A1b=Bioaccumulation BCF, A1=Bioaccumulation, A2=Biodegradation, B1=Acuteaquatic toxicity LC/ECIC50 (mg/l), B2=Chronic aquatic toxicity NOEC (mg/l), C1=Acute mammalian oral toxicity LD50 (mg/kg), C2=Acutemammalian dermal toxicity LD50 (mg/kg), C3=Acute mammalian inhalation toxicity LC50 (mg/kg), D1=Skin irritation & corrosion, D2=Eye irritation & corrosion, D3=Long-term health effects, E1=Tainting, E2=Physical effects on wildlife & benthic habitats, E3=Interference with coastal amenities, For column A2: R=Readily biodegradable, NR=Not readily biodegradable. For column D3: C=Carcinogen, M=Mutagenic, R=Reprotoxic, S=Sensitising, A=Aspiration hazard, T=Target organ systemic toxicity, L=Lunginjury, N=Neurotoxic, I=Immunotoxic. For column E1: NT=Not tainting (tested), T=Tainting test positive. For column E2: Fp=Persistent floater, F=Floater, S=Sinking substances. The numerical scales start from 0 (no hazard), while higher numbers reflect increasing hazard. (GESAMP/EHS Composite List of Hazard Profiles - Hazard evaluation of substances transported by ships)

Section 13 - DISPOSAL CONSIDERATIONS

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.

Section 14 - TRANSPORTATION INFORMATION

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

Section 15 - REGULATORY INFORMATION

sorbitan monooleate, ethoxylated (CAS: 9005-65-6) is found on the following regulatory lists;

"GESAMP/EHS Composite List - GESAMP Hazard Profiles", "International Fragrance Association (IFRA) Survey: Transparency List", "US DOE Temporary Emergency Exposure Limits (TEELs)", "US FDA Indirect Food Additives: Adhesives and Components of Coatings - Substances for Use Only as Components of Adhesives - Adhesives", "US Food Additive Database", "US NFPA 30B Manufacture and Storage of Aerosol Products - Chemical Heat of Combustion", "US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

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- 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.

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