

MATERIAL SAFETY DATA SHEET

PRODUCT NAME: PSB-60

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product Identifier

Product name PSB-60

Chemical Name sorbitan monostearate, ethoxylated

Capmul Glycosperse S-20 Tween 60, Polysorbate 60 Polysorbate 80 Polysorbate 85 Polysorbate 61 Liposorb S-20,

Synonyms polyethylene glycol sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, sorbitan, monooctadecanoate, poly(oxy-1,2-ethanediyl) derivs., sorbitan, monostearate polyoxyethylene deriv.

Other means of identification : Not Available

CAS number : 9005-67-8

Relevant identified uses of the substance or mixture and uses

Relevant identified uses : Nonionic surfactant.

Additive for food, pharmaceuticals and cosmetics.

Details of the supplier:

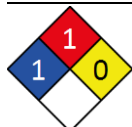
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SECTION 2: HAZARDS IDENTIFICATION



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue =Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification Not Classified

Label elements

Hazard pictogram(s) Not Applicable

SIGNAL WORD Not Applicable

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CAS No	%[weight]	Name
9005-67-8	>98	Polysorbate 60

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Mixtures

See section above for composition of Substance

SECTION 4: FIRST AID MEASURES

Description of first aid measures

Eye Contact : 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. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Skin Contact : If skin or hair contact occurs :Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Inhalation : If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.

Ingestion : 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.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

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

Special hazards arising from the substrate or mixture

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

Advice for firefighters

- Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control

Fire Fighting fire and cool adjacent area.

- **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. Equipment should be thoroughly decontaminated after use.

Fire/Explosion Hazard

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

- Mists containing combustible materials may be explosive. Combustion products include: ,carbon monoxide (CO) ,carbon dioxide (CO2),other pyrolysis products typical of burning organic material May emit poisonous fumes. May emit corrosive fumes.

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SECTION 6: ACCIDENTAL SPILLING MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills: Slippery when spilt. Clean up all spills immediately. Avoid contact with skin and eyes. Wear impervious gloves and safety goggles. Trowel up/scrape up. Place spilled material in clean, dry, sealed container. Flush spill area with water.

- Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for

Major Spills: recycling. Neutralise/decontaminate residue (see Section 13 for specific agent). Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. After clean-up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. If contamination of drains or waterways occurs, advise emergency services. Slippery when spilt.

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

SECTION 7- HANDLING AND STORAGE

Precautions for safe handling

Safe handling

- Overheating of ethoxylates/ alkoxyates 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 minimise the potential for ethoxylate oxidation. Prolonged storage in the presence of air or oxygen may cause product degradation. Oxidation is not expected when stored under a nitrogen atmosphere. Inert gas blanket and breathing system needed to maintain color stability. Use dry inert gas having at least -40 C dew point. 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. DO NOT allow material to contact humans, exposed food or food utensils.** 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. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. Ethoxylates/ alkoxyates react slowly with air or oxygen. Storage under heated conditions in the presence of air or oxygen increases reaction rate. For example, after storing at 95 F/ 35 C for 30 days in the presence of air, there is measurable oxidation of the ethoxylate. Lower temperatures will allow for longer storage time and higher temperatures will shorten the

Other information

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- Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

Suitable container: Glass container is suitable for laboratory quantities Metal can or drum Packaging as recommended by manufacturer. Check all containers are clearly labelled and free from leaks.

Storage incompatibility: Avoid reaction with oxidising agents

SECTION 8- EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
sorbitan monostearate, ethoxylated	Sorbitan monostearate polyoxyethylene; (Ethoxylated sorbitan monostearate)	7.3 mg/m ³	81 mg/m ³	480 mg/m ³

Ingredient	Original IDLH	Revised IDLH
sorbitan monostearate, ethoxylated	Not Available	Not Available

MATERIAL DATA

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.

Exposure controls

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Appropriate engineering controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure. General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, wear 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:

solvent, vapours, degreasing etc., evaporating from tank (in still air).
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)
direct spray, spray painting in shallow booths, drum filling,
conveyer loading, crusher dusts, gas discharge
(active generation into zone of rapid air motion)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts
(released at high initial velocity into zone of very high rapid air motion).

Air Speed:

0.25-0.5 m/s (50- 100 f/min)
0.5-1 m/s (100-200 f/min.)

1-2.5 m/s (200-500 f/min.)

2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range

- 1: Room air currents minimal or favourable to capture
- 2: Contaminants of low toxicity or of nuisance value only.
- 3: Intermittent, low production.
- 4: Large hood or large air mass in motion

Upper end of the range

- 1: Disturbing room air currents
- 2: Contaminants of high toxicity
- 3: High production, heavy use
- 4: Small hood-local control only

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

Personal protection



Eye and face protection: Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel

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should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

Skin protection See Hand protection below

Hands/feet protection Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber

Body protection See Other protection below

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

Thermal hazards Not Available

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A P1 Air-line*	- -	A PAPR-P1 -
up to 50 x ES	Air-line**	A P2	A PAPR-P2
up to 100 x ES	-	A P3 Air-line**	- -
100+ x ES	-	Air-line**	A PAPR-P3

* - Negative pressure demand ** - Continuous flow A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC) Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content. The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance Gelatinous mass, clear liquid

Physical state	Liquid	Relative density (Water = 1)	1.06
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Applicable	Decomposition temperature	Not available
Melting point / freezing point (°C).	Not available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	>200	Molecular weight (g/mol)	1311.90
Flash point (°C)	>150	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not available.	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not available.	Volatile Component (%vol)	3 max.(water)
Vapour pressure (kPa)	<0.1 @ 20 C.	Gas group	Not Available

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Solubility in water (g/L)	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10- STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11- TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled: The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic 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

Ingestion: Accidental ingestion of the material may be damaging to the health of the individual. Nonionic surfactants may produce localised irritation of the oral or gastrointestinal mucosa and induce vomiting and mild diarrhoea.

Skin Contact: The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives 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. One of the mechanisms of skin irritation caused by surfactants is considered to be denaturation of the proteins of skin. It has also been established that there is a connection between the potential of surfactants to denature protein in vitro and their effect on the skin. Nonionic surfactants do not carry any net charge and, therefore, they can only form hydrophobic bonds with proteins. For this reason, proteins are not deactivated by nonionic surfactants, and proteins with poor solubility are not solubilized by nonionic surfactants. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Eye: Limited evidence exists, or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals and/or is expected to produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur. Some nonionic surfactants may produce a localised anaesthetic effect on the cornea; this may effectively eliminate the warning discomfort produced by other substances and lead to corneal injury. Irritant effects range from minimal to severe dependent on the nature of the surfactant, its concentration and the duration of contact. Pain and corneal damage represent the most severe manifestation of irritation.

Chronic: Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. Prolonged or repeated skin contact may cause degreasing with drying, cracking and dermatitis following.

Sorbitan monostearate, ethoxylated

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TOXICITY	IRRITATION
Oral (rat) LD50: >63600 mg/kg[2]	Nil reported [Manufacturer]*

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

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

Sensitisation: Sorbitan fatty acid esters were generally minimal to mild skin irritants and were nonsensitising, but sorbitan sesquioleate did produce an allergic reaction in fewer than 1% of patients with suspected contact dermatitis and addition of sorbitan sesquioleate to the components of a fragrance mix used in patch testing increased both irritant and allergic reactions to the fragrance mix.

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 tetra ester (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.

Carcinogenicity: Overall these esters and their corresponding fatty acids were not mutagenic, but sorbitan oleate was reported to reduce DNA repair following ultraviolet radiation exposure in human lymphocytes in culture. sorbitan laurate and sorbitan trioleate were cocarcinogens in one mouse study, but sorbitan trioleate and sorbitan oleate were not tumour promoters in another study. Reproductive effector in rats. Equivocal tumorigen by RTECS criteria

Acute Toxicity

Skin Irritation/Corrosion

Serious Eye Damage/Irritation

Respiratory or Skin sensitisation

Mutagenicity

Carcinogenicity

Reproductivity

STOT - Single Exposure

STOT - Repeated Exposure

Aspiration Hazard

Legend:– Data available but does not fill the criteria for classification

– Data required to make classification available

– Data Not Available to make classification

SECTION 12- ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
Sorbitan monostearate, ethoxylated	LC50	96	Fish	121.984542847mg/L	2
	EC50	48	Crustacea	114.601844788mg/L	2
	EC50	72	Algae or other aquatic plants	52.605606079mg/L	2
	NOEC	72	Algae or other aquatic plants	55.535552979mg/L	2

For Group D aliphatic esters:(sorbitan fatty esters)

Environmental fate: The chain-length of the fatty acid in the sorbitan monoesters influences water solubility, boiling point and lipophilicity. The degree of esterification (monooleate versus trioleate) will also influence these properties. Hence, the water solubility of sorbitan monolaurate (C12 acid) (CAS 1338-39-2) is predicted to be much greater than that of sorbitan monostearate or sorbitan monooleate (C18 acids). The monooleate was predicted to have greater solubility in water than the corresponding sesquioleate or trioleate ester of sorbitan.

Biodegradation: The biodegradation of sorbitan monolaurate, sorbitan monooleate and sorbitan, fatty acid C6-10 tetra ester (CAS 228573-47-5), has been reported. These three sorbitan esters were biodegraded to the extent of 60-70% in 28-days, which indicate these materials undergo metabolism and degradation extensively in the aerobic environment. The sorbitan esters tested covered the range of carbon numbers (C18-C38) and included relatively water soluble (i.e., sorbitan monolaurate) as well as water-insoluble [i.e., sorbitan fatty acid C6-10 tetra ester (CAS 228573-47-5)] members of the group. The high degree of biodegradation (70% in 28 days) for sorbitan tetra ester (CAS 228573-47-5), in spite of its poor water solubility, indicates that enzymatic cleavage of the multiple ester linkage must be taking place in order to achieve the observed level of biodegradation. This would be consistent with the fact that fatty acids (e.g., oleic, stearic acid) arising from enzymatic ester bond cleavage of the sorbitan esters would be expected to be rapidly biodegraded. In addition, enzymatic ester cleavage of sorbitan

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trioleate and sesquioleate would lead to sorbitan monooleate, for which biodegradation data exist. Thus, there is sufficient information to "read-across" for the other sorbitan esters, based on the available data and the similarities in chemistry and metabolism.

Persistence and degradability
Ingredient
Persistence: Water/Soil

No Data available for all ingredients

Persistence: Air

No Data available for all ingredients

Bioaccumulative potential
Ingredient
Bioaccumulation

No Data available for all ingredients

Mobility in soil
Ingredient
Mobility

No Data available for all ingredients

SECTION 13: DISPOSAL CONSIDERATION
Waste treatment methods

Product / Packaging disposal: Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Authority for disposal. Bury or incinerate residue at an approved site. Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14- TRANSPORT INFORMATION
Labels Required
Marine Pollutant NO

Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

SECTION 15- REGULATORY INFORMATION
Safety, health and environmental regulations / legislation specific for the substance or mixture
SORBITAN MONOSTEARATE, ETHOXYLATED(9005-67-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory
Status

Australia - AICS

Y

Canada - DSL

Y

Canada - NDSL

N (sorbitan monostearate, ethoxylated)

China - IECSC

Y

Europe - EINEC / ELINCS / NLP

Y

Japan - ENCS

Y

Korea - KECI

Y

New Zealand - NZIoC

Y

Corporate Office:

Monachem House, C-42, Krishna Industrial Estate, Opp. Gorwa BIDC, Vadodara – 390 016

Philippines - PICCS

Y

USA - TSCA

Y

Legend:

Y = All ingredients are on the inventory

N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16: OTHER INFORMATION

CONTACT POINT

Disclaimer : While Monachem Specialities LLP endeavor to ensure that all advice given relating to the use and / or application of our products (whether in this leaflet or otherwise) is both correct and useful, the information is base partly on data made available to us from other sources and is not intended in a way to able to us from other sources and is not intended in a way to exhaustive or as a substitute for the customers own product testing, evaluation and safety procedures. If you have any queries over this suitability or safety precautions required for you particular application, please contact us and we will endeavor to assist you further.

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. A list of reference resources used to assist the committee may be found at: www.chemwatch.net The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average

PC – STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL: No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index