



POLYSORBATE 80

CONSOLIDATED CHEMICAL CO

Chemwatch: 41581

Version No: 7.1

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Chemwatch Hazard Alert Code: 4

Issue Date: 07/09/2021

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SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	POLYSORBATE 80
Chemical Name	sorbitan monooleate, ethoxylated
Chemical formula	Not Available
Other means of identification	Not Available
CAS number	9005-65-6

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

Relevant identified uses	Personal care product. Nonionic surfactant. A polysorbate These ingredients mostly function as surfactants in cosmetics The ingredients (several of which are often referred to by the commercial trade name of Tween in the literature) are polyethoxylated sorbitan or sorbitol esters of fatty acids. Each ingredient has a common core structure of sorbitan or sorbitol, etherified with PEG chains, and esterified with fatty acids.
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Details of the manufacturer or supplier of the safety data sheet

Registered company name	SOAPMAID
Address	10-12 Hosken Street, Springvale South VIC 3172 Australia
Telephone	0411157311
Fax	n/a
Website	www.soapmaid.com
Email	soapmaid@gmail.com

Emergency telephone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+61 1800 951 288
Other emergency telephone numbers	+61 3 9573 3188

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


SECTION 2 Hazards identification

Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

Poisons Schedule	Not Applicable
Classification ^[1]	Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Germ Cell Mutagenicity Category 2, Carcinogenicity Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	
Signal word	Warning

Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H335	May cause respiratory irritation.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
P337+P313	eye irritation persists: Get medical advice/attention.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

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

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

CAS No	%[weight]	Name
9005-65-6	>98	<u>sorbitan monooleate, ethoxylated</u>
Not Available		may contain
50-00-0	0.002	<u>formaldehyde</u>
123-91-1	0.,001	<u>1,4-dioxane</u>
75-07-0	0.0003	<u>acetaldehyde</u>
75-21-8	0.0001	<u>ethylene oxide</u>

Legend: 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available

Mixtures

See section above for composition of Substances

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▶ Transport to hospital, or doctor, without delay.
Ingestion	<ul style="list-style-type: none"> ▶ IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. ▶ For advice, contact a Poisons Information Centre or a doctor. ▶ Urgent hospital treatment is likely to be needed. ▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. ▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. ▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. <p>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</p> <ul style="list-style-type: none"> ▶ INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ NOTE: Wear a protective glove when inducing vomiting by mechanical means.

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.

Special hazards arising from the substrate or mixture

Fire Incompatibility	<ul style="list-style-type: none"> ▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ 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). <p>Combustion products include: carbon dioxide (CO₂) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>
HAZCHEM	Not Applicable

SECTION 6 Accidental release 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	<ul style="list-style-type: none"> ▶ Slippery when spilt. ▶ Remove all ignition sources. ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. <p>Control personal contact with the substance, by using protective equipment.</p>
Major Spills	<ul style="list-style-type: none"> ▶ Slippery when spilt. ▶ Moderate hazard. ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. <p>Wear breathing apparatus plus protective gloves.</p>

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ 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. ▶ DO NOT allow clothing wet with material to stay in contact with skin ▶ 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.
Other information	<p>Ethoxylates/ alkoxyates react slowly with air or oxygen and may generate potentially sensitising intermediates (haptens).. 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 storage time if stored under an air or oxygen atmosphere.</p> <ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed.

Continued...

- ▶ No smoking, naked lights or ignition sources.
- ▶ Store in a cool, dry, well-ventilated area.

Conditions for safe storage, including any incompatibilities

Suitable container	<p>For ethoxylates suitable containers include carbon steel coated with baked phenolic. Any moisture may cause rusting of carbon steel. If product is moisture free, uncoated carbon steel tanks may be used.</p> <ul style="list-style-type: none"> ▶ Glass container is suitable for laboratory quantities ▶ Metal can or drum ▶ Packaging as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ 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. ▶ Avoid reaction with oxidising agents



X— Must not be stored together

O— May be stored together with specific preventions

+— May be stored together

Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	formaldehyde	Formaldehyde	1 ppm / 1.2 mg/m ³	2.5 mg/m ³ / 2 ppm	Not Available	Not Available
Australia Exposure Standards	1,4-dioxane	1,4-Dioxane	10 ppm / 36 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	acetaldehyde	Acetaldehyde	20 ppm / 36 mg/m ³	91 mg/m ³ / 50 ppm	Not Available	Not Available
Australia Exposure Standards	ethylene oxide	Ethylene oxide	1 ppm / 1.8 mg/m ³	Not Available	Not Available	Not Available

Emergency Limits


Ingredient	TEEL-1	TEEL-2	TEEL-3
formaldehyde	Not Available	Not Available	Not Available
1,4-dioxane	Not Available	Not Available	Not Available
acetaldehyde	Not Available	Not Available	Not Available
ethylene oxide	5 ppm	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
sorbitan monooleate, ethoxylated	Not Available	Not Available
formaldehyde	20 ppm	Not Available
1,4-dioxane	500 ppm	Not Available
acetaldehyde	2,000 ppm	Not Available
ethylene oxide	800 ppm	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
sorbitan monooleate, ethoxylated	E ≤ 0.1 ppm	
Notes:	<i>Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.</i>	

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.</p>
Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none"> ▶ 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.
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber <p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the

computer-generated selection:

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Material	CPI
BUTYL	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
PE	C
PE/EVAL/PE	C
PVA	C
PVC	C

Respiratory protection

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

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.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	BAX-AUS / Class1 P2	-
up to 50	1000	-	BAX-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	BAX-2 P2
up to 100	10000	-	BAX-3 P2
100+			Airline**

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SARANEX-23 C	
TEFLON C	
VITON C	
VITON/NEOPRENE C	

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

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

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

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

* - Continuous Flow ** - Continuous-flow or positive pressure demand
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.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used
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SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Yellow oily liquid; mixes with water. Soluble in isopropanol, ethanol. Insoluble in mineral and vegetable oils. Viscosity @ 25 deg. Polysorbates are amphiphilic molecules, which are fatty esters of polyoxyethylated sorbitan or sorbitol. The polysorbates are, for the most part, viscous liquids to waxy solids that range in color from yellow to orange to tan.

They possess a faint, characteristic odor and a warm, somewhat bitter taste. Since the fatty acids used in the production of cosmetic ingredients frequently contain fatty acids other than the principal acid named (ie, a mixture), each of the polysorbates may contain a complex mixture of fatty acid moieties.

During the manufacturing process, the polysorbates are steam-stripped to remove unwanted water-soluble by-products such as 1,4-dioxane. Since polyethylene glycols (PEGs), used to produce these products, are the condensation products of ethylene oxide and water, with the chain length controlled by the number of moles of ethylene oxide that are polymerized, they may contain trace amounts of 1,4-dioxane, a by-product of ethoxylation.

Physical state	Liquid	Relative density (Water = 1)	1.080
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	-20.56 (pour point)	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	>100	Molecular weight (g/mol)	Not Available
Flash point (°C)	148	Taste	Not Available
Evaporation rate	Not Available	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)	Not Available
Vapour pressure (kPa)	Negligible	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	1059.48

SECTION 10 Stability and reactivity

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

Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Not normally a hazard due to non-volatile nature of product
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. Nonionic surfactants may produce localised irritation of the oral or gastrointestinal lining and induce vomiting and mild diarrhoea.
Skin Contact	The material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering. Repeated exposure may cause skin cracking, flaking or drying following normal handling and use. Non-ionic surfactants cause less irritation than other surfactants as they have less ability to denature protein in the skin. 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.
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals. Prolonged eye contact may cause inflammation characterised 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.
Chronic	Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Prolonged or repeated skin contact may cause degreasing, followed by drying, cracking and skin inflammation.

	TOXICITY	IRRITATION
sorbitan monooleate, ethoxylated	Oral (Mouse) LD50; 25000 mg/kg ^[2]	Eye (rabbit): 150 mg - mild Skin (rabbit): - slight
formaldehyde	Dermal (rabbit) LD50: 270 mg/kg ^[2] Inhalation(Rat) LC50: <463 ppm4h ^[1] Oral (Rat) LD50: 100 mg/kg ^[2]	Eye (human): 4 ppm/5m Eye (rabbit): 0.75 mg/24H SEVERE Eye: adverse effect observed (irritating) [1] Skin (human): 0.15 mg/3d-I mild Skin (rabbit): 2 mg/24H SEVERE Skin: adverse effect observed (corrosive) [1]
1,4-dioxane	Dermal (rabbit) LD50: 7600 mg/kg ^[2] Inhalation(Rat) LC50: 48.5-54.3 mg/14h ^[2] Oral (Rat) LD50: 4200 mg/kg ^[2]	Eye(human): 300 ppm/15m Eye(rabbit): 21 mg (int)-irritant Skin(rabbit): 515 mg (open)-mild
acetaldehyde	Dermal (rabbit) LD50: 3540 mg/kg ^[2] Inhalation(Mouse) LC50; 23 mg/L4h ^[2] Oral (Rat) LD50: 661 mg/kg ^[2]	Eye (human): 50 ppm/15min Eye (rabbit): 40 mg SEVERE Skin (rabbit): 500 mg open mild
ethylene oxide	TOXICITY	IRRITATION

Inhalation(Rat) LC50: 800 ppm4h[2]Eye (rabbit): 18 mg/6h - moderate

Oral (Rat) LD50: 72 mg/kg[2]Skin (human): 1%/7 sec - irritant

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 MONOOLEATE, ETHOXYLATED

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

The Cosmetic Ingredient Review (CIR) Expert Panel concluded that listed polysorbates are safe in cosmetics when formulated to be non-irritating. This conclusion supersedes the conclusion reached in the 1984, 2000, and 2001 CIR safety assessments. This safety assessment combines polysorbates reviewed in 3 previous safety assessments with other polysorbates that have not been reviewed by the CIR Panel into a group of 80 polyethoxylated sorbitan or sorbitol esters of fatty acid.

Following oral administration of polysorbate 20 to rats, ester bonds of polysorbates are hydrolyzed within the digestive tract by pancreatic lipase.²⁴ Free fatty acids were absorbed from the digestive tract and oxidized and excreted, mainly as carbon dioxide in exhaled breath. No migration of the polyoxyethylene sorbitan into the thymus lymph nodes has been demonstrated.

For sorbitan esters, ethoxylated (syn: polyoxyethylene sorbitan esters):

Some of the early short-term studies with these polyoxyethylene sorbitan esters in rats and hamsters showed deleterious effects. Subsequent work suggests that these were largely due to diarrhoea resulting from a large amount of unabsorbed polyglycol, possibly aggravated in some experiments by the use of an unsuitable basal diet. Since that time there has been considerable improvement in testing procedures, and more extensive long-term studies have been carried out. It seems reasonable therefore

to base the evaluation of these substances on the levels causing no adverse effects indicated by the results of the more recent investigations.

The significance of the local tumours which were produced by injection has been discussed at the meeting of the Scientific Group (1966).

Polyethers (such as ethoxylated surfactants and polyethylene glycols) are highly susceptible to being oxidized in the air. They then form complex mixtures of oxidation products.

Animal testing reveals that whole the pure, non-oxidised surfactant is non-sensitizing, many of the oxidation products are sensitizers. The oxidation products also cause irritation.

The sorbitan esters are agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products. They do not represent a toxicological concern since they are derived from naturally occurring materials and are ultimately metabolised back to these same natural constituents.

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

FORMALDEHYDE

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions.

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

The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.

Brain degenerative changes, kidney tubule changes, urine volume changes, lymphoma including Hodgkin's disease recorded.

1,4-DIOXANE

Acute toxic effects reported in animals are mainly central nervous system depression (including convulsions), kidney and liver damage, slight reddening of the skin and scaly skin irritation. There may also be reversible shrinkage of the pupils, and eye, nose and lung irritation. Skin absorption has been considered a potential route of exposure in case reports of human fatalities from short term exposures. Longer term effects of very high doses in animals include intoxication, behavioural changes, blood changes, heart problems and lesions in the kidneys, liver and brain.

ETHYLENE OXIDE	<p>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>Oxiranes (including glycidyl ethers and alkyl oxides, and epoxides) share many common characteristics with respect to animal toxicology. One such oxirane is ethyloxirane; data presented here may be taken as representative.</p> <p>For 1,2-butylene oxide (ethyloxirane):</p> <p>In animal testing, ethyloxirane increased the incidence of tumours of the airways in animals exposed via inhalation. However, tumours were not observed in mice chronically exposed via skin. Two structurally related substances, oxirane (ethylene oxide) and methyloxirane (propylene oxide), which are also direct-acting alkylating agents, have been classified as causing cancer. Ethylene oxide is very soluble in blood, so it can be quickly absorbed by the lung. It is also likely to be absorbed easily by skin. Human exposure mainly occurs through inhalation in sterilisation facilities and exposure can result from fumigated foods, pharmaceutical products, and sterilised medical equipment. Symptoms include nausea and vomiting.</p>
SORBITAN MONOOLEATE, ETHOXYLATED & ACETALDEHYDE	Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation.
SORBITAN MONOOLEATE, ETHOXYLATED & FORMALDEHYDE & 1,4-DIOXANE & ACETALDEHYDE & ETHYLENE OXIDE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia.
SORBITAN MONOOLEATE, ETHOXYLATED & FORMALDEHYDE	No significant acute toxicological data identified in literature search.
SORBITAN MONOOLEATE, ETHOXYLATED & FORMALDEHYDE & ETHYLENE OXIDE	WARNING: This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS.
SORBITAN MONOOLEATE, ETHOXYLATED & 1,4-DIOXANE & ACETALDEHYDE FORMALDEHYDE & ACETALDEHYDE & ETHYLENE OXIDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
1,4-DIOXANE & ACETALDEHYDE	Tenth Annual Report on Carcinogens: Substance anticipated to be Carcinogen [National Toxicology Program: U.S. Dep. of Health & Human Services 2002]
	WARNING: This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.

Acute Toxicity	✓	Carcinogenicity	✓
Skin Irritation/Corrosion	✓	Reproductivity	✗
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✓	Aspiration Hazard	✗

✗ – Data either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

Toxicity

sorbitan monooleate, ethoxylated	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	471mg/l	Not Available
formaldehyde	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	312h	Crustacea	0.005mg/l	4
	LC50	96h	Fish	0.727-9.193mg/l	4
	EC50	72h	Algae or other aquatic plants	1.034-1.984mg/l	4
	EC50	96h	Algae or other aquatic plants	0.375-0.579mg/l	4
EC50	48h	Crustacea	3.26mg/l	4	

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	Endpoint	Test Duration (hr)	Species	Value	Source
	1,4-dioxane	BCF	1008h	Fish	0.2-0.6
LC50		96h	Fish	6700mg/l	2
EC50		72h	Algae or other aquatic plants	>1000mg/l	2
EC50		48h	Crustacea	>1000mg/l	2
NOEC(ECx)		Not Available	Fish	20mg/l	1
	Endpoint	Test Duration (hr)	Species	Value	Source
	acetaldehyde	EC50(ECx)	48h	Algae or other aquatic plants	0.02mg/l
EC50		96h	Algae or other aquatic plants	236.6mg/l	4
EC50		72h	Algae or other aquatic plants	>100mg/l	2
LC50		96h	Fish	28-34mg/l	4
EC50		48h	Crustacea	39.4-59.1mg/l	4

BOD (28 d): 32% (OECD 301 C) COD 1.75 g O₂/g (OECD 301 C) DOC removal: 52% (OECD 301 C) Biodegradability: 100% (OECD static test method) Fish LC50 (96 h): rainbow trout 471 mg/l (static) Pseudomonas putida IC₀: >10000 mg/l Mysidopsis bahia LC50 (96 h): 165 mg/l

Surfactants are in general toxic to aquatic organisms due to their surface-active properties. Historically, synthetic surfactants were often composed of branched alkyl chains resulting in poor biodegradability which led to concerns about their environmental effects. Today however, many of them, for example those used in large amounts, globally, as detergents, are linear and therefore readily biodegradable and considered to be of rather low risk to the environment. A linear structure of the hydrophobic chain facilitates the approach of microorganism while branching, in particular at the terminal position, inhibits biodegradation.

For aliphatic fatty acids and alcohols:

Environmental fate:

Saturated fatty acids are very stable in air, whereas unsaturated (C=C bonds) fatty acids are susceptible to oxidation.

Unsaturation increases the rate of metabolism although the degree of unsaturation and positioning of double bonds is not highly significant.

The available data indicate all fatty acid salt chain lengths up to and including C18 can be metabolised under aerobic conditions and can be considered to be readily biodegradable

All tests showed that fatty acids and lipids are readily biodegradable

The aliphatic acids are of similar very weak acid strength (approximately pK_a 5), i.e., partially dissociate in aqueous solution; the salts of the aliphatic acids are highly dissociated in water solution such that the anion is the same for homologous salts and acids.

Slight (although inconsistent) effects on the trend for decreasing vapour pressure are also observed with the mono-, di- and tri-unsaturated substances as compared to the corresponding saturated substances.

For Group D Aliphatic Esters: (Sorbitan Fatty Esters):

Environmental Fate: The chain-length of the fatty acid in the sorbitan monoesters and the degree of esterification influences water solubility, boiling point and dissolvability in fats.

Biodegradation: The biodegradation of sorbitan monolaurate, sorbitan monooleate and sorbitan, fatty acid C6-10 tetraester (CAS 228573-47-5), has been reported. These three sorbitan esters undergo metabolism and degradation extensively in the aerobic environment. Sorbitan monooleate, as well as the other sorbitan esters, has also been shown to biodegrade.

For Surfactants: Kow cannot be easily determined due to hydrophilic/hydrophobic properties of the molecules in surfactants. BCF value: 1-350.

Aquatic Fate: Surfactants tend to accumulate at the interface of the air with water and are not extracted into one or the other liquid phases.

Terrestrial Fate: Anionic surfactants are not appreciably sorbed by inorganic solids.

For Formaldehyde:

Environmental Fate: Formaldehyde is common in the environment as a contaminant of smoke and as photochemical smog. Concentrated solutions containing formaldehyde are unstable and oxidize slowly. In the presence of air and moisture, polymerization takes place readily in concentrated solutions at room temperature to form paraformaldehyde.

Atmospheric Fate: In the atmosphere, formaldehyde both photolysis and reacts with reactive free radicals (primarily hydroxyl radicals).

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
formaldehyde	LOW (Half-life = 14 days)	LOW (Half-life = 2.97 days)
1,4-dioxane	HIGH (Half-life = 360 days)	LOW (Half-life = 3.38 days)
acetaldehyde	LOW	LOW
ethylene oxide	LOW (Half-life = 11.88 days)	HIGH (Half-life = 381.96 days)

Continued...

Bioaccumulative potential

Ingredient	Bioaccumulation
formaldehyde	LOW (LogKOW = 0.35)
1,4-dioxane	LOW (BCF = 0.7)
acetaldehyde	LOW (BCF = 1.2)
ethylene oxide	LOW (BCF = 0.35)

Mobility in soil

Ingredient	Mobility
formaldehyde	HIGH (KOC = 1)
1,4-dioxane	HIGH (KOC = 1)
acetaldehyde	HIGH (KOC = 1.498)
ethylene oxide	HIGH (KOC = 1.435)

SECTION 13 Disposal considerations**Waste treatment methods**

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. Otherwise: <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. 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: <ul style="list-style-type: none"> ▶ 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. ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible or consult manufacturer for recycling options. ▶ Consult State Land Waste Authority for disposal. ▶ Bury or incinerate residue at an approved site. ▶ Recycle containers if possible, or dispose of in an authorised landfill.
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SECTION 14 Transport information**Labels Required**

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): 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

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
sorbitan monooleate, ethoxylated	Not Available

Product name	Group
formaldehyde	Not Available
1,4-dioxane	Not Available
acetaldehyde	Not Available
ethylene oxide	Not Available

Transport in bulk in accordance with the IGC Code

Product name	Ship Type
sorbitan monooleate, ethoxylated	Not Available
formaldehyde	Not Available
1,4-dioxane	Not Available
acetaldehyde	Not Available
ethylene oxide	Not Available

SECTION 15 Regulatory information

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

sorbitan monooleate, ethoxylated is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

formaldehyde is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2

Australian Inventory of Industrial Chemicals (AIIC)

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans

1,4-dioxane is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6

Australian Inventory of Industrial Chemicals (AIIC)

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

acetaldehyde is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

ethylene oxide is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 7

Australian Inventory of Industrial Chemicals (AIIC)

Chemical Footprint Project - Chemicals of High Concern List

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 1: Carcinogenic to humans

United Nations List of Prior Informed Consent Chemicals

WHO Recommended Classification of Pesticides by Hazard - Table 7. Pesticides subject to the Rotterdam Convention

National Inventory Status

National Inventory Australia -	Status
AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (sorbitan monooleate, ethoxylated; formaldehyde; 1,4-dioxane; acetaldehyde; ethylene oxide)
China - IECSC	Yes

Continued...

National Inventory	Status
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes

Legend: Yes = All CAS declared ingredients are on the inventory
No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	07/09/2021
Initial Date	16/08/2006

SDS Version Summary

Version	Date of Update	Sections Updated
6.1	18/09/2019	CAS Number, Toxicological information - Chronic Health, Hazards identification - Classification, Ecological Information - Environmental, Exposure controls / personal protection - Personal Protection (hands/feet), Physical and chemical properties - Physical Properties, Handling and storage - Storage (storage incompatibility), Toxicological information - Toxicity and Irritation (Other)
7.1	07/09/2021	Toxicological information - Acute Health (skin), Toxicological information - Acute Health (swallowed), Physical and chemical properties - Appearance, Hazards identification - Classification, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, First Aid measures - First Aid (swallowed), Handling and storage - Storage (storage incompatibility), Toxicological information - Toxicity and Irritation (Other), Identification of the substance / mixture and of the company / undertaking - Use

Other information

Ingredients with multiple cas numbers

Name	CAS No
sorbitan monooleate, ethoxylated	9005-65-6, 1340-85-8, 141927-23-3, 178631-96-4, 209796-63-4, 253447-34-6, 361534-35-2, 37199-23-8, 37280-84-5, 51377-27-6, 541509-66-4, 61723-75-9, 8050-83-7, 9015-07-0, 9050-49-1, 9050-57-1, 1286269-72-4, 2137448-98-5, 900143-89-7
formaldehyde	50-00-0, 8005-38-7, 8006-07-3, 8013-13-6, 112068-71-0

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
 ES: Exposure Standard
 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
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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