

# **Jasco Pty Limited**

Chemwatch: **5684-92** Version No: **2.1** Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements Chemwatch Hazard Alert Code: 4

Issue Date: **18/06/2024** Print Date: **28/06/2024** L.GHS.AUS.EN

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

## **Product Identifier**

Product name	FLEXIBLE MODELLING PASTE	
Chemical Name	Not Applicable	
Synonyms	ms 0123500 JASART BYRON FLEXIBLE MODELLING PASTE 250ML; 0123510 JASART BYRON FLEXIBLE MODELLING PASTE 500ML	
Chemical formula	Not Applicable	
Other means of identification	Not Available	

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

Relevant identified uses	Use according to manufacturer's directions.
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## Details of the manufacturer or supplier of the safety data sheet

Registered company name	Jasco Pty Limited		
Address	1-5 Commercial Road Kingsgrove NSW 2208 Australia		
Telephone	+61 2 9807 1555		
Fax	Not Available		
Website	www.jasco.com.au		
Email	quickinfo@jasco.com.au		

## **Emergency telephone number**

Association / Organisation	Australian Poisons Centre	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	13 11 26 (24/7)	+61 1800 951 288
Other emergency telephone numbers	Not Available	+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

Poisons Schedule	Not Applicable
Classification <sup>[1]</sup>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Acute Hazard 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)



## Hazard statement(s)

H315	Causes skin irritation.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H402	Harmful to aquatic life.

## Precautionary statement(s) Prevention

Signal word

Danger

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.
P273	Avoid release to the environment.
P264	Wash all exposed external body areas thoroughly after handling.

#### Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
P310	Immediately call a POISON CENTER/doctor/physician/first aider.	
P302+P352	2302+P352         IF ON SKIN: Wash with plenty of water.	
P304+P340	P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.	
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

See section below for composition of Mixtures

## Mixtures

CAS No	%[weight]	Name
471-34-1	50.6	calcium carbonate
25085-34-1	19.5	styrene/ acrylic acid copolymer
57-55-6	3.9	propylene glycol
25212-88-8	0.432	methacrylic acid/ ethyl acrylate copolymer
84133-50-6	0.5	alcohols C12-14 secondary ethoxylated
124-68-5	0.352	monoisobutanolamine
8050-83-7	0.4	sorbitan monooleate, ethoxylated
52-51-7	0.05	2-bromo-2-nitropropan-1,3-diol
7732-18-5	balance	water
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		

## **SECTION 4 First aid measures**

## Description of first aid measures

Eye Contact

If this product comes in contact with the eyes:

• Immediately hold eyelids apart and flush the eye continuously with running water.

	<ul> <li>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.</li> <li>Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>Transport to hospital or doctor without delay.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
Skin Contact	<ul> <li>If skin contact occurs:</li> <li>Immediately remove all contaminated clothing, including footwear.</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>
Inhalation	<ul> <li>If fumes or combustion products are inhaled remove from contaminated area.</li> <li>Lay patient down. Keep warm and rested.</li> <li>Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>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.</li> <li>Transport to hospital, or doctor, without delay.</li> </ul>
Ingestion	<ul> <li>If swallowed do NOT induce vomiting.</li> <li>If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>Observe the patient carefully.</li> <li>Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>Seek medical advice.</li> </ul>

## Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## **SECTION 5 Firefighting measures**

## Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

#### 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

Fire Fighting	<ul> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>Prevent, by any means available, spillage from entering drains or water courses.</li> <li>Use fire fighting procedures suitable for surrounding area.</li> <li>DO NOT approach containers suspected to be hot.</li> <li>Cool fire exposed containers with water spray from a protected location.</li> <li>If safe to do so, remove containers from path of fire.</li> <li>Equipment should be thoroughly decontaminated after use.</li> </ul>
Fire/Explosion Hazard	carbon dioxide (CO2) nitrogen oxides (NOx) metal oxides other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes. Heating calcium carbonate at high temperatures( 825 C.) causes decomposition, releases carbon dioxide gas and leaves a residue of alkaline lime
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

Clean up all spills immediately.Avoid contact with skin and eyes.

	<ul> <li>Wear impervious gloves and safety goggles.</li> <li>Trowel up/scrape up.</li> <li>Place spilled material in clean, dry, sealed container.</li> <li>Flush spill area with water.</li> </ul>
Major Spills	<ul> <li>Clear area of personnel and move upwind.</li> <li>Alert Fire Brigade and tell them location and nature of hazard.</li> <li>Wear breathing apparatus plus protective gloves.</li> <li>Prevent, by any means available, spillage from entering drains or water course.</li> <li>Stop leak if safe to do so.</li> <li>Contain spill with sand, earth or vermiculite.</li> <li>Collect recoverable product into labelled containers for recycling.</li> <li>Neutralise/decontaminate residue (see Section 13 for specific agent).</li> <li>Collect solid residues and seal in labelled drums for disposal.</li> <li>Wash area and prevent runoff into drains.</li> <li>After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.</li> <li>If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

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

## **SECTION 7 Handling and storage**

## Precautions for safe handling

Safe handling	<ul> <li>Avoid all personal contact, including inhalation.</li> <li>Wear protective clothing when risk of exposure occurs.</li> <li>Use in a well-ventilated area.</li> <li>Prevent concentration in hollows and sumps.</li> <li>DO NOT enter confined spaces until atmosphere has been checked.</li> <li>DO NOT allow material to contact humans, exposed food or food utensils.</li> <li>Avoid contact with incompatible materials.</li> <li>When handling, DO NOT eat, drink or smoke.</li> <li>Keep containers securely sealed when not in use.</li> <li>Avoid physical damage to containers.</li> <li>Always wash hands with soap and water after handling.</li> <li>Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>Use good occupational work practice.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
Other information	<ul> <li>Store in original containers.</li> <li>Keep containers securely sealed.</li> <li>Store in a cool, dry, well-ventilated area.</li> <li>Store away from incompatible materials and foodstuff containers.</li> <li>Protect containers against physical damage and check regularly for leaks.</li> <li>Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

## Conditions for safe storage, including any incompatibilities

Suitable container	<ul> <li>Polyethylene or polypropylene container.</li> <li>Packing as recommended by manufacturer.</li> <li>Check all containers are clearly labelled and free from leaks.</li> </ul>
Storage incompatibility	<ul> <li>Calcium carbonate:</li> <li>is incompatible with acids, ammonium salts, fluorine, germanium, lead diacetate, magnesium, mercurous chloride, silicon, silver nitrate, titanium.</li> <li>Contact with acid generates carbon dioxide gas, which may pressurise and then rupture closed containers</li> <li>Formaldehyde:</li> <li>is a strong reducing agent</li> <li>may polymerize in air unless properly inhibited (usually with methanol up to 15%) and stored at controlled temperatures</li> <li>will polymerize with active organic material such as phenol</li> <li>reacts violently with strong oxidisers, hydrogen peroxide, potassium permanganate, acrylonitrile, caustics (sodium hydroxide, yielding formic acid and flammable hydrogen), magnesium carbonate, nitromethane, nitrogen oxides (especially a elevated temperatures), peroxyformic acid</li> <li>is incompatible with strong acids (hydrochloric acid forms carcinogenic bis(chloromethyl)ether*), amines, ammonia, aniline, bisulfides, gelatin, iodine, magnesite, phenol, some monomers, tannins, salts of copper, iron, silver.</li> <li>acid catalysis can produce impurities: methylal, methyl formate</li> <li>Aqueous solutions of formaldehyde:</li> <li>slowly oxidise in air to produce formic acid</li> <li>attack carbon steel</li> <li>Concentrated solutions containing formaldehyde are:</li> <li>unstable, both oxidising slowly to form formic acid and polymerising; in dilute aqueous solutions formaldehyde appears as monomeric hydrate (methylene glycol) - the more concentrated the solution the more polyoxymethylene glycol occurs as oligomers and polymers (methanol and amine-containing compounds inhibit polymer formation)</li> <li>readily subject to polymerisation, at room temperature, in the presence of air and moisture, to form paraformaldehyde (8-100 units of formaldehyde), a solid mixture of linear polyoxymethylene glycol scontaining 90-99% formaldehyde; a cyclic trimer,</li> </ul>

trioxane (CH2O3), may also form Flammable and/or toxic gases are generated by the combination of aldehydes with azo, diazo compounds, dithiocarbamates, nitrides, and strong reducing agents \*The empirical equation may be used to determine the concentration of bis(chloromethyl)ether (BCME) formed by reaction with HCI: log(BCME)ppb = -2.25 + 0.67 · log(HCHO) ppm + 0.77 · log(HCI)ppm Assume values for formaldehyde, in air, of 1 ppm and for HCl of 5 ppm, resulting BCME concentration, in air, would be 0.02 ppb. • Avoid strong acids, acid chlorides, acid anhydrides and chloroformates. • Avoid reaction with oxidising agents

## **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	calcium carbonate	Calcium carbonate	10 mg/m3	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Australia Exposure Standards	propylene glycol	Propane-1,2-diol total: (vapour & particulates)	150 ppm / 474 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	propylene glycol	Propane-1,2-diol: particulates only	10 mg/m3	Not Available	Not Available	Not Available

#### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
calcium carbonate	45 mg/m3	210 mg/m3	1,300 mg/m3
propylene glycol	30 mg/m3	1,300 mg/m3	7,900 mg/m3
monoisobutanolamine	17 mg/m3	190 mg/m3	570 mg/m3

Ingredient	Original IDLH	Revised IDLH
calcium carbonate	Not Available	Not Available
styrene/ acrylic acid copolymer	Not Available	Not Available
propylene glycol	Not Available	Not Available
methacrylic acid/ ethyl acrylate copolymer	Not Available	Not Available
alcohols C12-14 secondary ethoxylated	Not Available	Not Available
monoisobutanolamine	Not Available	Not Available
sorbitan monooleate, ethoxylated	Not Available	Not Available
2-bromo-2-nitropropan-1,3- diol	Not Available	Not Available
water	Not Available	Not Available

#### **Occupational Exposure Banding**

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit		
alcohols C12-14 secondary ethoxylated	E	≤ 0.1 ppm		
monoisobutanolamine	E	≤ 0.01 mg/m³		
sorbitan monooleate, ethoxylated	E	≤ 0.1 ppm		
2-bromo-2-nitropropan-1,3- diol	E	≤ 0.01 mg/m³		
Notes:	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.

#### MATERIAL DATA

Tenth Annual Report on Carcinogens: Substance anticipated to be Carcinogen [National Toxicology Program: U.S. Dep. of Health & Human Services 2002] For calcium carbonate:

The TLV-TWA is thought to be protective against the significant risk of physical irritation associated with exposure.

for propylene glycol:

Saturated vapour concentration @ 20 deg C.= 65.8 ppm, 204.6 mg/m3; i.e higher concentrations can only occur as aerosols or at higher temperatures. Odour Threshold: Practically odourless.

A small number of individuals show skin irritation or sensitisation from repeated or prolonged exposure to propylene glycol. A workplace environmental exposure limit (WEEL) has been established by AIHA and is thought to be protective against systemic effects.

## Exposure controls

Appropriate engineering	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. engineering controls can be highly effective in protecting workers and will typically be independent of work 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 v that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an ai designed properly. The design of a ventilation system must match the particular process and chemical or Employers may need to use multiple types of controls to prevent employee overexposure. Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct obtain adequate protection. Supplied-air type respirator may be required in some situations. Provide adequate protection. An approved self contained breathing apparatus (SCBA) may be required in some situations. Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the wor "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effect 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 nickling (released at low velocity into zone of active generation)			
controls	welding, spray drift, plating acid fumes, pickling (released a direct spray, spray painting in shallow booths, drum filling, o	at low velocity into zone of active generation) conveyer loading, crusher dusts, gas	200 f/min.) 1-2.5 m/s (200-	
	discharge (active generation into zone of rapid air motion) 	500 f/min.) 2.5-10 m/s (500-		
	into zone of very high rapid air motion).		2000 f/min.)	
	Within each range the appropriate value depends on:			
	Lower end of the range	Upper end of the range		
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents		
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity		
	3: Intermittent, low production.	3: High production, heavy use		
	4: Large hood or large air mass in motion	4: Small hood-local control only		
	Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.			
Individual protection measures, such as personal protective equipment				
Eye and face protection	<ul> <li>Safety glasses with side shields.</li> <li>Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]</li> <li>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 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].</li> </ul>			
Skin protection	See Hand protection below			
Hands/feet protection	<ul> <li>Wear chemical protective gloves, e.g. PVC.</li> <li>Wear safety footwear or safety gumboots, e.g. Rubber</li> <li>NOTE:</li> <li>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.</li> <li>Contaminated leather items, such as shoes, bolts and worksh bonds should be removed and destroyed.</li> </ul>			

Body protection	See Other protection below
Other protection	<ul> <li>Overalls.</li> <li>P.V.C apron.</li> <li>Barrier cream.</li> <li>Skin cleansing cream.</li> <li>Eye wash unit.</li> </ul>

#### 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:

LEXIBLE MODELLING PASTE

Material	CPI
BUTYL	С
NATURAL RUBBER	С
NEOPRENE	С
PE/EVAL/PE	С
PVA	С
VITON	С

\* 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.

#### Respiratory protection

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

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	AK-AUS P2	-	AK-PAPR-AUS / Class 1 P2
up to 50 x ES	-	AK-AUS / Class 1 P2	-
up to 100 x ES	-	AK-2 P2	AK-PAPR-2 P2 ^

#### ^ - Full-face

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

• Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.

• The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

 $\cdot$  Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.

 $\cdot$  Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.

 $\cdot$  Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

 $\cdot$  Use approved positive flow mask if significant quantities of dust becomes airborne.

 $\cdot$  Try to avoid creating dust conditions.

Class P2 particulate filters are used for protection against mechanically and thermally generated particulates or both.

P2 is a respiratory filter rating under various international standards, Filters at least 94% of airborne particles

Suitable for:

 $\cdot$  Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.

 $\cdot$  Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.

 $\cdot$  Biologically active airborne particles under specified infection control

applications e.g. viruses, bacteria, COVID-19, SARS

## **SECTION 9** Physical and chemical properties

## Information on basic physical and chemical properties

Appearance Ointment.

Physical state	Non Slump Paste	Relative density (Water = 1)	Not Available
Odour	Ammonia - like	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)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	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)	Not Available	Gas group	Not Available
Solubility in water	Not Available	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	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system. Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Ingestion of propylene glycol produced reversible central nervous system depression in humans following ingestion of 60 ml. Symptoms included increased heart-rate (tachycardia), excessive sweating (diaphoresis) and grand mal seizures in a 15 month child who ingested large doses (7.5 ml/day for 8 days) as an ingredient of vitamin preparation. Excessive repeated ingestions may cause hypoglycaemia (low levels of glucose in the blood stream) among susceptible individuals; this may result in muscular weakness, incoordination and mental confusion. Very high doses given during feeding studies to rats and dogs produce central nervous system depression (although one-third of that produced by ethanol), haemolysis and insignificant kidney changes. In humans propylene glycol is partly excreted unchanged in the urine and partly metabolised as lactic and pyruvic acid. Lactic acidosis may result.

Skin Contact	<ul> <li>The material produces moderate skin irritation; evidence exists, or practical experience predicts, that the material either</li> <li>produces moderate inflammation of the skin in a substantial number of individuals following direct contact, and/or</li> <li>produces significant, but moderate, inflammation when applied to the healthy intact skin of animals (for up to four hours), such inflammation being present twenty-four hours or more after the end of the exposure period.</li> <li>Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</li> <li>Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.</li> <li>Open cuts, abraded or irritated skin should not be exposed to this material</li> <li>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.</li> </ul>
Eye	When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.
Chronic	On the basis, primatily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic defects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment. Respected or tog-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contlact with skin and if swallowed. Serious damage (clear functional disturbance or morphological change which may have toxicological significance) is likely to be caused by repeated or prolonged exposure. As a rule the material produces, or contains a substance which produces servere leaions. Such damage may become apparent following direct application in subchronic (90 day) toxicity studies or following sub-acute (28 day) or chronic (two-year) toxicity tests. There exists limited evidence that shows that shin contact with the material in acquest frammes in <i>advisional as an produce presense in experimental animals</i> . Pure calcium carbonate does not produce preumoconicis probably being eliminated from the lungs slowly by solution. As mined, number of individuals, and/or of producing positive response in experimental animals. If the blood concentrations of calcium in marging vier ties to vasodilation and depress cardiac function leading to hypotension and syncope. Calciulin in the site or based and any precisite digital to the heat and may precisite digital to the lange. Specing of use and the sociation. Calcium salts also reduce the absorption of tetracyclines to reason the vasodialation and depress cardiac function leading to hypotension and syncope. Calciulin instant be associated with normal or reason free theorem failer can al failure can also develop into chronic forms of the disease. Hy

LEXIBLE	MODELLING	•
	PASTE	

TOXICITY	IRRITATION
Not Available	Not Available

	ΤΟΧΙCΙΤΥ	IRRITATION	
	dermal (rat) LD50: >2000 mg/kg <sup>[1]</sup>	Eye (rabbit): 0.75 mg/24h - SEVERE	
calcium carbonate	Inhalation (Rat) LC50: >3 mg/l4h <sup>[1]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>	
	Oral (Rat) LD50: >2000 mg/kg <sup>[1]</sup>	Skin (rabbit): 500 mg/24h-moderate	
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>	
styrene/ acrylic acid	ΤΟΧΙΟΙΤΥ	IRRITATION	
copolymer	Not Available	Not Available	
	ΤΟΧΙĊΙΤΥ	IRRITATION	
	Dermal (rabbit) LD50: 11890 mg/kg <sup>[2]</sup>	Eye (rabbit): 100 mg - mild	
	Inhalation (Rat) LC50: >44.9 mg/l4h <sup>[1]</sup>	Eye (rabbit): 500 mg/24h - mild	
propylene glycol	Oral (Rat) LD50: 20000 mg/kg <sup>[2]</sup>	Eye: no adverse effect observed (not irritating) <sup>[1]</sup>	
		Skin(human):104 mg/3d Intermit Mod	
		Skin(human):500 mg/7days mild	
		Skin: no adverse effect observed (not irritating) <sup>[1]</sup>	
methacrylic acid/ ethyl	ΤΟΧΙCΙΤΥ	IRRITATION	
acrylate copolymer	Not Available	Not Available	
alcohols C12-14 secondary	ΤΟΧΙΟΙΤΥ	IRRITATION	
ethoxylated	Not Available	Not Available	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
monoisobutanolamine	Dermal (rabbit) LD50: >2000 mg/kg <sup>[1]</sup>	Eye: adverse effect observed (irreversible damage) <sup>[1]</sup>	
	Oral (Mouse) LD50; 2150 mg/kg <sup>[2]</sup>	Skin: adverse effect observed (irritating) <sup>[1]</sup>	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
sorbitan monooleate, ethoxvlated	Oral (Mouse) LD50; 25000 mg/kg <sup>[2]</sup>	Eye (rabbit): 150 mg - mild	
		Skin (rabbit): - slight	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
	dermal (rat) LD50: ~1600 mg/kg <sup>[1]</sup>	Eye (rabbit): 5 mg	
	Inhalation (Rat) LC50: >0.12<1.14 mg/l4h <sup>[1]</sup>	Eye: adverse effect observed (irreversible damage) <sup>[1]</sup>	
2-bromo-2-nitropropan-1,3- diol	Oral (Rat) LD50: 180 mg/kg <sup>[2]</sup>	Skin (human): 10 mg moderate	
		Skin (rabbit): 500 mg/24h mild	
		Skin (rabbit): 80 mg moderate	
		Skin: adverse effect observed (irritating) <sup>[1]</sup>	
	ΤΟΧΙΟΙΤΥ	IRRITATION	
water	Oral (Rat) LD50: >90000 mg/kg <sup>[2]</sup>	Not Available	
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		

CALCIUM CARBONATE ALCOHOLS C12-14

SECONDARY ETHOXYLATED No evidence of carcinogenic properties. No evidence of mutagenic or teratogenic effects.

Human beings have regular contact with alcohol ethoxylates through a variety of industrial and consumer products such as soaps, detergents, and other cleaning products . Exposure to these chemicals can occur through ingestion, inhalation, or contact with the skin or eyes. Studies of acute toxicity show that volumes well above a reasonable intake level would have to occur to produce any toxic response. Moreover, no fatal case of poisoning with alcohol ethoxylates has ever been reported. Multiple studies investigating the acute toxicity of alcohol ethoxylates have shown that the use of these compounds is of low concern in terms of oral and dermal toxicity .
Clinical animal studies indicate these chemicals may produce gastrointestinal irritation such as ulcerations of the stomach, pilo-

erection, diarrhea, and lethargy. Similarly, slight to severe irritation of the skin or eye was generated when undiluted alcohol ethoxylates were applied to the skin and eyes of rabbits and rats. The chemical shows no indication of being a genotoxin, carcinogen, or mutagen (HERA 2007). No information was available on levels at which these effects might occur, though toxicity is thought to be substantially lower than that of nonylphenol ethoxylates.

Polyethers, for example, ethoxylated surfactants and polyethylene glycols, are highly susceptible towards air oxidation as the ether oxygens will stabilize intermediary radicals involved. Investigations of a chemically well-defined alcohol (pentaethylene glycol mono-n-dodecyl ether) ethoxylate, showed that polyethers form complex mixtures of oxidation products when exposed to air.

Sensitization studies in guinea pigs revealed that the pure nonoxidized surfactant itself is nonsensitizing but that many of the investigated oxidation products are sensitizers. Two hydroperoxides were identified in the oxidation mixture, but only one (16-hydroperoxy-3,6,9,12,15-pentaoxaheptacosan-1-ol) was stable enough to be isolated. It was found to be a strong sensitizer in LLNA (local lymph node assay for detection of sensitization capacity). The formation of other hydroperoxides was indicated by the detection of their corresponding aldehydes in the oxidation mixture .

On the basis of the lower irritancy, nonionic surfactants are often preferred to ionic surfactants in topical products. However, their susceptibility towards autoxidation also increases the irritation. Because of their irritating effect, it is difficult to diagnose allergic contact dermatitis (ACD) to these compounds by patch testing

Overall, alcohol alkoxylates (AAs) are not expected to be systemically toxic, although some short chain ethylene glycol ethers, e.g. methyl and ethyl homologues are of concern for a range of adverse health effects. They include skin and eye irritation, liver and kidney damage, bone marrow and central nervous system (CNS) depression, testicular atrophy, developmental toxicity, and immunotoxicity. For higher propyl and butyl homologues, the toxicity involves haemolysis (anaemia) with secondary effects relating to haemosiderin accumulation in the spleen, liver and kidney, and compensatory haematopoiesis in the bone marrow. Systemic toxicity was shown to decrease with increasing alkyl chain lengths and/or alkoxylation degrees (ECETOC, 2005; US EPA, 2010). The chemicals ethylene glycol hexyl ether (with a longer alkyl chain length, CAS No. 112-25-4) and diethylene glycol butyl ether (with a higher ethoxylation degree, CAS No. 112-34-5) have no evidence of systemic effects including haemolysis. Commercially available AAs are mixtures of homologues of varying carbon chain lengths and it is possible that some of the chemicals with an average alkyl chain length C >=6 may also contain shorter alkyl chain lengths may not be present at all. The available data suggest a lack of systemic toxicity for the AE chemicals with potential short alkyl chain presence (NICNASa); therefore, the toxicity of the chemicals in this assessment is unlikely to be significantly affected by the presence of shorter chain alkyl groups.

Alcohol ethoxylates are according to CESIO (2000) classified as Irritant or Harmful depending on the number of EO-units: EO < 5 gives Irritant (Xi) with R38 (Irritating to skin) and R41 (Risk of serious damage to eyes)

EO > 5-15 gives Harmful (Xn) with R22 (Harmful if swallowed) - R38/41

EO > 15-20 gives Harmful (Xn) with R22-41

>20 EO is not classified (CESIO 2000)

Oxo-AE, C13 EO10 and C13 EO15, are Irritating (Xi) with R36/38 (Irritating to eyes and skin) .

AE are not included in Annex 1 of the list of dangerous substances of the Council Directive 67/548/EEC

In general, alcohol ethoxylates (AE) are readily absorbed through the skin of guinea pigs and rats and through the gastrointestinal mucosa of rats. AE are quickly eliminated from the body through the urine, faeces, and expired air (CO2).Orally dosed AE was absorbed rapidly and extensively in rats, and more than 75% of the dose was absorbed. When applied to the skin of humans, the doses were absorbed slowly and incompletely (50% absorbed in 72 hours). Half of the absorbed surfactant was excreted promptly in the urine and smaller amounts of AE appeared in the faeces and expired air (CO2) ). The metabolism of C12 AE yields PEG, carboxylic acids, and CO2 as metabolites. The LD50 values after oral administration to rats range from about 1-15 g/kg body weight indicating a low to moderate acute toxicity.

The ability of nonionic surfactants to cause a swelling of the stratum corneum of guinea pig skin has been studied. The swelling mechanism of the skin involves a combination of ionic binding of the hydrophilic group as well as hydrophobic interactions of the alkyl chain with the substrate. 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. A substantial amount of toxicological data and information in vivo and in vitro demonstrates that there is no evidence for alcohol ethoxylates (AEs) being genotoxic, mutagenic or carcinogenic. No adverse reproductive or developmental effects were observed. The majority of available toxicity studies revealed NOAELs in excess of 100 mg/kg bw/d but the lowest NOAEL for an individual AE was established to be 50 mg/kg bw/day. This value was subsequently considered as a conservative, representative value in the risk assessment of AE. The effects were restricted to changes in organ weights with no histopathological organ changes with the exception of liver hypertrophy (indicative of an adaptive response to metabolism rather than a toxic effect). It is noteworthy that there was practically no difference in the NOAEL in oral studies of 90day or 2 years of duration in rats. A comparison of the aggregate consumer exposure and the systemic NOAEL (taking into account an oral absorption value of 75%) results in a Margin of Exposure of 5,800. Taking into account the conservatism in the exposure assessment and the assigned systemic NOAEL, this margin of exposure is considered more than adequate to account for the inherent uncertainty and variability of the hazard database and inter and intra-species extrapolations.

AEs are not contact sensitisers. Neat AE are irritating to eyes and skin. The irritation potential of aqueous solutions of AEs depends on concentrations. Local dermal effects due to direct or indirect skin contact in certain use scenarios where the products are diluted are not of concern as AEs are not expected to be irritating to the skin at in-use concentrations. Potential irritation of the respiratory tract is not a concern given the very low levels of airborne AE generated as a consequence of spray cleaner aerosols or laundry powder detergent dust.

In summary, the human health risk assessment has demonstrated that the use of AE in household laundry and cleaning detergents is safe and does not cause concern with regard to consumer use.

For high boiling ethylene glycol ethers (typically triethylene- and tetraethylene glycol ethers):

Skin absorption: Available skin absorption data for triethylene glycol ether (TGBE), triethylene glycol methyl ether (TGME), and triethylene glycol ethylene ether (TGEE) suggest that the rate of absorption in skin of these three glycol ethers is 22 to 34 micrograms/cm2/hr, with the methyl ether having the highest permeation constant and the butyl ether having the lowest. The rates of absorption of TGBE, TGEE and TGME are at least 100-fold less than EGME, EGEE, and EGBE, their ethylene glycol monoalkyl ether counterparts, which have absorption rates that range from 214 to 2890 micrograms/ cm2/hr . Therefore, an increase in either the chain length of the alkyl substituent or the number of ethylene glycol moieties appears to lead to a decreased rate of percutaneous absorption. However, since the ratio of the change in values of the ethylene glycol to the diethylene glycol series is larger than that

of the diethylene glycol to triethylene glycol series, the effect of the length of the chain and number of ethylene glycol moieties on absorption diminishes with an increased number of ethylene glycol moieties. Therefore, although tetraethylene glycol methyl; ether (TetraME) and tetraethylene glycol butyl ether (TetraBE) are expected to be less permeable to skin than TGME and TGBE, the differences in permeation between these molecules may only be slight. **Metabolism:** The main metabolic pathway for metabolism of ethylene glycol monoalkyl ethers (EGME, EGEE, and EGBE) is

oxidation via alcohol and aldehyde dehydrogenases (ALD/ADH) that leads to the formation of an alkoxy acids. Alkoxy acids are the only toxicologically significant metabolites of glycol ethers that have been detected *in vivo*. The principal metabolite of TGME is believed to be 2-[2-(2-methoxyethoxy)ethoxy] acetic acid. Although ethylene glycol, a known kidney toxicant, has been identified as an impurity or a minor metabolite of glycol ethers in animal studies it does not appear to contribute to the toxicity of glycol ethers.

The metabolites of category members are not likely to be metabolized to any large extent to toxic molecules such as ethylene glycol or the mono alkoxy acids because metabolic breakdown of the ether linkages also has to occur

Acute toxicity: Category members generally display low acute toxicity by the oral, inhalation and dermal routes of exposure. Signs of toxicity in animals receiving lethal oral doses of TGBE included loss of righting reflex and flaccid muscle tone, coma, and heavy breathing. Animals administered lethal oral doses of TGEE exhibited lethargy, ataxia, blood in the urogenital area and piloerection before death.

Irritation: The data indicate that the glycol ethers may cause mild to moderate skin irritation. TGEE and TGBE are highly irritating to the eyes. Other category members show low eye irritation.

Repeat dose toxicity: Results of these studies suggest that repeated exposure to moderate to high doses of the glycol ethers in this category is required to produce systemic toxicity

In a 21-day dermal study, TGME, TGEE, and TGBE were administered to rabbits at 1,000 mg/kg/day. Erythema and oedema were observed. In addition, testicular degeneration (scored as trace in severity) was observed in one rabbit given TGEE and one rabbit given TGME. Testicular effects included spermatid giant cells, focal tubular hypospermatogenesis, and increased cytoplasmic vacuolisation. Due to a high incidence of similar spontaneous changes

in normal New Zealand White rabbits , the testicular effects were considered not to be related to treatment . Thus, the NOAELs for TGME, TGEE and TGBE were established at 1000 mg/kg/day. Findings from this report were considered unremarkable.

A 2-week dermal study was conducted in rats administered TGME at doses of 1,000, 2,500, and 4,000 mg/kg/day . In this study, significantly-increased red blood cells at 4,000 mg/kg/day and significantly-increased urea concentrations in the urine at 2,500 mg/kg/day were observed. A few of the rats given 2,500 or 4,000 mg/kg/day had watery caecal contents and/or haemolysed blood in the stomach These gross pathologic observations were not associated with any histologic abnormalities in these tissues or alterations in haematologic and clinical chemistry parameters. A few males and females treated with either 1,000

these tissues or alterations in haematologic and clinical chemistry parameters. A few males and females treated with either 1,000 or 2,500 mg/kg/day had a few small scabs or crusts at the test site. These alterations were slight in degree and did not adversely affect the rats

In a 13-week drinking water study, TGME was administered to rats at doses of 400, 1,200, and 4,000 mg/kg/day. Statisticallysignificant changes in relative liver weight were observed at 1,200 mg/kg/day and higher. Histopathological effects included hepatocellular cytoplasmic vacuolisation (minimal to mild in most animals) and hypertrophy (minimal to mild) in males at all doses and hepatocellular hypertrophy (minimal to mild) in high dose females. These effects were statistically significant at 4,000 mg/kg/day. Cholangiofibrosis was observed in 7/15 high-dose males; this effect was observed in a small number of bile ducts and was of mild severity. Significant, small decreases in total test session motor activity were observed in the high-dose animals, but no other neurological effects were observed. The changes in motor activity were secondary to systemic toxicity **Mutagenicity**: Mutagenicity studies have been conducted for several category members. All in vitro and in vivo studies were

negative at concentrations up to 5,000 micrograms/plate and 5,000 mg/kg, respectively, indicating that the category members are not genotoxic at the concentrations used in these studies. The uniformly negative outcomes of various mutagenicity studies performed on category members lessen the concern for carcinogenicity.

**Reproductive toxicity:** Although mating studies with either the category members or surrogates have not been performed, several of the repeated dose toxicity tests with the surrogates have included examination of reproductive organs. A lower molecular weight glycol ether, ethylene glycol methyl ether (EGME), has been shown to be a testicular toxicant. In addition, results of repeated dose toxicity tests with TGME clearly show testicular toxicity at an oral dose of 4,000 mg/kg/day four times greater that the limit dose of 1,000 mg/kg/day recommended for repeat dose studies. It should be noted that TGME is 350 times less potent for testicular effects than EGME. TGBE is not associated with testicular toxicity, TetraME is not likely to be metabolised by any large extent to 2-MAA (the toxic metabolite of EGME), and a mixture containing predominantly methylated glycol ethers in the C5-C11 range does not produce testicular toxicity (even when administered intravenously at 1,000 mg/kg/day).

**Developmental toxicity**: The bulk of the evidence shows that effects on the foetus are not noted in treatments with . 1,000 mg/kg/day during gestation. At 1,250 to 1,650 mg/kg/day TGME (in the rat) and 1,500 mg/kg/day (in the rabbit), the developmental effects observed included skeletal variants and decreased body weight gain.

MONOISOBUTANOLAMINE

For tris(hydroxymethyl)aminomethane (TRIS AMINO; CAS 77-88-1) and its surrogates 2-amino-2-methyl-1,3-propanediol (AMPD; CAS 115-69-5) and monoisobutanolamine (AMP; CAS 124-68-5)

TRIS AMINO and the surrogate chemicals have displayed little if any toxicity to humans during their long history of use as human drugs and/or in personal care products and cosmetics. TRIS AMINO has found use as an IV drug for the management of acidosis in humans for many years and the toxicity of AMPD and AMP have been reviewed by the Cosmetic Ingredient Review Expert Panel which concluded that these materials are safe as used in cosmetic formulations up to 1%

Acute toxicity: Mammalian toxicity studies have displayed similar results. The oral LD50 value for TRIS AMINO is 5500 mg/kg in the mouse, and its surrogates range from 2150 to greater than 5000 mg/kg in the rat and mouse. TRIS AMINO was non-irritating to eyes when a 40% aqueous solution was applied to the eyes of rabbits (pH 10.4 for 0.1M aqueous solution). In contrast, 95% AMP in water was severely irritating to the eyes, presumably due to the severely alkaline pH of the test solution used (pH 11.3 for 0.1M aqueous solution); however, more neutral cosmetic formulations containing lower concentrations of AMP are only minimally irritating. There is no sensitisation data available for TRIS AMINO; however, based on the following data, TRIS AMINO is not expected to be a sensitiser. Laboratory animal test samples of AMP did not cause allergic skin reactions when tested in guinea pigs following topical or intradermal administration. In patch tests with humans, AMP and cosmetic formulations containing either AMP or AMPD were negative for dermal sensitisation.

**Repeated dose toxicity**: Repeated-dose mammalian toxicity studies conducted on TRIS AMINO and the two surrogate chemicals indicate that the compounds are generally well-tolerated at concentrations as high as 500 mg/kg/day via IV infusion for TRIS AMINO and ingestion of up to 3200 ppm in the rodent diet (250-750 mg/kg/day for rats and mice, estimated). A number of human clinical trials of the IV infusion of TRIS AMINO have also been successfully conducted. In all studies, the only target tissue, when observed at all, has been the liver with AMP. Human clinical studies with Keterolac(a major component of which is

TRIS AMINO) have suggested that patients with decreased liver function not be given the drug over extended treatment periods based upon changes in several clinical chemistry parameters. Ingestion of relatively high dosages of AMP has caused liver histopathological changes in rats and dogs. The most significant toxicological activity has been a foetotoxic effect of AMP when ingested at relatively high levels by pregnant rats. Subsequent dermal exposure to comparable dosages failed to elicit a developmental effect in rats. Overall, there have been no consistently-noted observations or treatment-related findings among the numerous repeated-dose mammalian toxicity studies that have been conducted over at last 50 years on these compounds that would indicate long-term significant toxicity of either compound at typical human exposure levels. Reflective of these findings is the fact that both TRIS AMINO and AMP display similar patterns of excretion from the body, being primarily eliminated unchanged via the urine over a relatively short period of time. Further, no evidence of either direct reactivity or metabolism to reactive species toward genetic material has been observed. **Genetic toxicity:** Studies conducted on the TRIS AMINO and the surrogate substances in the presence or absence of mammalian metabolic enzymes have all been negative.

#### 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. Maternal relative water intake was comparable among treatment groups throughout gestation. 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 .

Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of

appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.

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. No sex difference has been detected in the disposition of polysorbates in rats. Following oral ingestion of polysorbate 20 in humans, 90% or more of the administered substance was excreted in the feces as metabolites, with the polyoxyethylene sorbitan structure maintained, and 2%-3% of these metabolites were excreted in the urine The Panel considered the data available to characterize the potential for polysorbates to cause systemic toxicity, irritation, sensitization, reproductive and developmental toxicity, and genotoxicity. They noted the lack of systemic toxicity at low and moderate doses in several acute and repeated-dose oral exposure studies, and low toxicity at high doses; little or no irritation or sensitization in multiple tests of dermal and ocular exposure; the absence of genotoxicity in multiple Ames tests and chromosome aberration tests, and minimal irritation and lack of sensitization in tests of dermal exposure at concentration of use. The Panel recognizes that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used, concentrations of use and the similar pattern of use raise no safety concerns. The Panel note that polysorbate 20, polysorbate 65, and polysorbate 80 were shown to enhance dermal drug absorption. The Panel cautions that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption, or when dermal absorption was a concern. Especially, care should be taken when creating formulations intended for use on infants

To address the possible presence of 1,4-dioxane and ethylene oxide impurities in these ingredients, the Panel stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities from the PEG ingredients before blending them into cosmetic formulations. The Panel expressed concern about pesticide residues and heavy metals that may be present in botanical (ie, coconut-derived) ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities. Data from the 1984 safety assessment suggested that polysorbates caused a slight enhancement of tumor development caused by 7,12-dimethyl-benz[a]anthracene (DMBA) and N-methyl-N -nitro-N-nitrosoguanidine (MNNG); however, the data were not consistent. For other compounds, the tumorigenic properties of 3-methyl-cholanthrene (MCA) and 3,4-benz[a]pyrene (BP) were not enhanced by polysorbates. Since the tumor enhancement effects were inconsistent and depended on the simultaneous exposure to strong chemical carcinogens, which are not present in cosmetics, the Panel felt that the weak tumor enhancement effects were not relevant to cosmetic formulations. Because some studies showed minimal irritation at concentrations that are used in cosmetics, the Panel cautioned that products containing these ingredients should be formulated to be non-irritating. It was noted that at the time of the 2001 safety assessment on sorbeth beeswaxes, the Panel had recommended that

cosmetic formulations containing PEGs not be used on damaged skin because of the possibility of renal toxicity when PEGs were applied to severely damaged skin, such as in burn patients. Since then, PEGs have been re-reviewed and the additional data demonstrated minimal dermal penetration of low-molecular weight PEGs. The amount of PEGs that would penetrate the stratum corneum barrier, even if damaged, from the use of cosmetics was well below the level of renal toxicity. Therefore, the

Panel has removed the caveat that PEGs should not be used on damaged skin. The Panel strongly asserted that it is inappropriate to apply cosmetic products containing high concentrations of PEGs to individuals exhibiting barrier skin disruption through both the stratum corneum and the epidermis.

The Panel discussed the issue of incidental inhalation exposure from spray products, including aerosol and pump hair sprays, spray deodorants, spray body and hand products, and spray moisturizing products. The limited acute exposure

data available from 1 new inhalation study and 1 historical tracheal study suggest little potential for respiratory effects at relevant doses. These ingredients are reportedly used at concentrations up to 4% in cosmetic products that may be aerosolized. The Panel noted that 95%-99% of droplets/particles would not be respirable to any appreciable amount. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects.

Safety Assessment of Polysorbates as Used in CosmeticJuly 2015

http://www.cir-safety.org/sites/default/files/PSorba\_062015\_FR\_0.pdf

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). No increase in tumour incidence has followed the oral intake of polyoxyethylene sorbitan esters. Furthermore, large doses of the oleate and stearate have been well tolerated by human subjects.

Polyoxyethylene (20) sorbitan monoester of lauric, oleic, palmitic and stearic acid and triester of stearic acid

Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. Techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.

For Group D aliphatic esters:(sorbitan fatty esters)

Sorbitan fatty acid esters are mono-, di-, and triesters of fatty acids and sorbitol-derived hexitol anhydrides.

Sorbitan fatty acid esters were relatively nontoxic via ingestion in acute and long-term studies. They were generally minimal to mild skin irritants in animal studies, except that sorbitan isostearate applied to the skin was a moderate irritant in one rabbit study and when injected intradermally caused mild to severe irritation in guinea pigs. Sorbitan fatty acid esters did not sensitise guinea pigs. The fatty acid component, tested alone, typically caused only slight irritation and sensitisation, and was not photosensitising. Sorbitan fatty acid esters were not ocular irritants. Fatty acids are normal components of diet for which no data were available concerning reproductive or developmental toxicity, but Sorbitol had no adverse effects on the reproduction of CD rats during a multigeneration feeding study and was not a reproductive toxin at doses of 3000 to 7000 mg/kg/day for 2 years. 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. In clinical tests, Sorbitan fatty acid esters were generally minimal to mild skin irritants and were nonsensitizing, 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. Careful consideration was made of the data on the cocarcinogenesis of sorbitan laurate and sorbitan trioleate, but the high exposure levels, high frequency of exposure, and absence of a dose-response led to the conclusion that there was not a cocarcinogenesis risk with the use of these ingredients in cosmetic formulations. Accordingly, these ingredients were considered safe for use in cosmetic formulations under the present practices of use.

Final report on the safety assessment of sorbitan caprylate, sorbitan cocoate, sorbitan diisostearate, sorbitan dioleate, sorbitan distearate, sorbitan isostearate, sorbitan olivate, sorbitan sesquiisostearate, sorbitan sesquistearate, and sorbitan triisostearate Lanigan et al Int J. Toxicol 2002, pp 93-112

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 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, 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. 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

ETHOXYLATED & 2-

#### LEXIBLE MODELLING PASTE

	sorbitan sesquioleate to the components of a fragrance mix used in patch testing increased both irritant and allergic reactions to
	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 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 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.
	The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (ervithema) and swelling epidermis. Histologically there may be
	intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.
2-BROMO-2- NITROPROPAN-1,3-DIOL	The European Union has reclassified several formaldehyde-releasing agents (FRAs) such as methylenedimorpholine (MBM), oxazolidine (MBO) and hydroxypropylamine (HPT) as category IB carcinogens. Previously, formaldehyde itself was classed as a carcinogen - but formaldehyde-releasing agents were not. This is no longer the case. Based on this regulation, formulations for which the maximum theoretical concentration of releasable formaldehyde is more than > 1000 ppm (>0.1%), have to be labelled as carcinogenic. Water mix metalworking fluids are subject to contamination by bacteria and fungi, and the control of this is an essential part of good fluid maintenance. The use of preservatives both within the formulation and tank-side treatment plays a significant contribution in the protection of potentially hamful microbes that could cause health problems for workers. A large proportion of bactericides on the market today are classed as formaldehyde releasing blocides which means that under specific conditions they release small amounts of formaldehyde – this is their mode of action in the presence of bacteria. Although they are effective as a blocide their use may become restricted or unfavourable due to potential changes in legislation. A decision by the ECHA (European Chemicals Agency) was made to re-classify formaldehyde release blocides should be classified the same as formaldehyde because formaldehyde is released when these substances come into contact under favorable conditions (i.e. interaction with microorganisms). Formaldehyde generators (releasers) are often used as preservatives (antimicrobials, blocides, microbiodies). Formaldehyde may be generated following hydrolysis. The most widely used antimicrobial compounds function by releasing formaldehyde more linkid the microbe cell. Some release detectable levels of formaldehyde into the air space, above working solutions, especially when pH has dropped. Many countries are placing regulatory pressure on suppliers and users to replace formaldehyde
LEXIBLE MODELLING	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-
PASTE & CALCIUM CARBONATE & SORBITAN MONOOLEATE,	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

Continued...

BROMO-2-NITROPROPAN- 1,3-DIOL	bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.
LEXIBLE MODELLING PASTE & STYRENE/ ACRYLIC ACID COPOLYMER & METHACRYLIC ACID/ ETHYL ACRYLATE COPOLYMER & ALCOHOLS C12-14 SECONDARY ETHOXYLATED & SORBITAN MONOOLEATE, ETHOXYLATED & WATER	No significant acute toxicological data identified in literature search.
LEXIBLE MODELLING PASTE & PROPYLENE GLYCOL	The acute oral toxicity of propylene glycol is very low, and large quantities are required to cause perceptible health damage in humans. Serious toxicity generally occurs only at plasma concentrations over 1 g/L, which requires extremely high intake over a relatively short period of time. It would be nearly impossible to reach toxic levels by consuming foods or supplements, which contain at most 1 g/R of PG. Cases of propylene glycol poisoning are usually related to either inappropriate intravenous administration or accidental ingestion of large quantities by children. The potential for long-term oral toxicity is also low. Because of its low chronic oral toxicity, propylene glycol as easerffeed by the U. S. Food and Drug Administration as "generally recognized as safe" (GRAS) for use as a direct food additive.
LEXIBLE MODELLING PASTE & SORBITAN MONOOLEATE, ETHOXYLATED	WARNING: This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS.
LEXIBLE MODELLING PASTE & CALCIUM CARBONATE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
LEXIBLE MODELLING PASTE & CALCIUM CARBONATE & PROPYLENE GLYCOL & 2- BROMO-2-NITROPROPAN- 1,3-DIOL	The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

Acute Toxicity	×	Carcinogenicity	×		
ALCOHOLS C12-14 SECONDARY ETHOXYLATED & SORBITAN MONOOLEATE, ETHOXYLATED	I yeol mono-n-dodecyl ether) ethoxylate, showed that polyethers form complex mixtures of oxidation products when exposed to air. Sensitization studies in guinea pigs revealed that the pure nonoxidized surfactant itself is nonsensitizing but that many of the investigated oxidation products are sensitizers. Two hydroperoxides were identified in the oxidation mixture, but only one (16-hydroperoxy-36,9,12,15-pentaoxaheptacosan-1-ol) was stable enough to be isolated. It was found to be a strong sensitizer in LLNA (local lymph node assay for detection of sensitization capacity). The formation of other hydroperoxides was indicated by the detection of their corresponding aldehydes in the oxidation mixture. On the basis of the lower irritancy, nonionic surfactants are often preferred to ionic surfactants in topical products. However, their succeptibility towards autoxidation also increases the irritation. Because of their irritating effect, it is difficult to diagnose ACD to these compounds by patch testing. Anr-Theres Kartberg et al; Chem. Res. Toxicol.2008.21,53-69 Polyethylene glycols (PEGs) have a wide variety of PEG-derived mixtures due to their readily linkable terminal primary hydroxyl groups in combination with many possible compounds and complexes such as ethers, fatty acids, castor oils, amines, propylene glycols, suong other derivatives. PEGs and their derivatives are broadly utilized in cosmetic products as surfactants, emulsifiers cleansing agents, humectants, and skin conditioners. Refs and PEG derivatives were generally regulated as safe for use in cosmetics, with the conditions that impurities and by-products, such as ethylene oxides and 1,4-dioxane, which are known carcinogenic materials, should be removed before they are mixed in cosmetic formulation. Most PEGs are commonly available commercially as mixtures of different oligomer size in broadly- or narrowly-defined molecular weight MW of 10,000. PEG is also known as polyethylene oxide (PEO) or polyoxyethyle				
	Polyethers, for example, ethoxylated surfactants and polyethylene glycols, are highly susceptible towards air oxidation as the ether oxygens will stabilize intermediary radicals involved. Investigations of a chemically well-defined alcohol (pentaethylene glycol mono-n-dodecyl ether) ethoxylate, showed that polyethers form complex mixtures of oxidation products when exposed to				

Acute Toxicity	<b>^</b>	Carcinogenicity	<b>^</b>
Skin Irritation/Corrosion	×	Reproductivity	×
Serious Eye Damage/Irritation	*	STOT - Single Exposure	*
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×
	Le	gend: 🛛 🗙 – Data either not ava	ilable or does not fill the criteria for classification

X − Data either not available or does not fill the criteria for classification
 ✓ − Data available to make classification

# **SECTION 12 Ecological information**

## Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
LEXIBLE MODELLING PASTE	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
a dalama a aka wata	NOEC(ECx)	1h	Fish	4-320mg/l	4
calcium carbonate	EC50	72h	Algae or other aquatic plants	>14mg/l	2
	LC50	96h	Fish	>165200mg/L	4
styrene/ acrylic acid copolymer	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
propylene glycol	NOEC(ECx)	336h	Algae or other aquatic plants	<5300mg/l	1
	EC50	96h	Algae or other aquatic plants	19000mg/l	2
	EC50	72h	Algae or other aquatic plants	19300mg/l	2
	EC50	48h	Crustacea	>114.4mg/L	4
	1.050	96h	Fish	710mg/l	4

methacrylic acid/ ethyl acrylate copolymer	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
alaahala C12 11 aasaa damu	Endpoint	Test Duration (hr)	Species	Value	Source
ethoxylated	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	100mg/l	1
	EC50	72h	Algae or other aquatic plants	>103mg/l	2
monoisobutanolamine	EC50	48h	Crustacea	193mg/l	1
	EC0(ECx)	48h	Crustacea	100mg/l	1
	EC50	96h	Algae or other aquatic plants	>103mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Source
sorbitan monooleate, ethoxylated	LC50	96h	Fish	471mg/l	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC10(ECx)	72h	Algae or other aquatic plants	0.013mg/l	2
	EC50	72h	Algae or other aquatic plants	0.026mg/l	2
2-bromo-2-nitropropan-1,3- diol	EC50	96h	Algae or other aquatic plants	0.02- 0.025mg/L	4
	EC50	48h	Crustacea	1.1- 3.52mg/L	4
	LC50	96h	Fish	10.274- 14.454mg/L	4
water	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity				

4. US EPA, Ecotox database - Aquatic Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicit
 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

Calcium provides an important link between tectonics, climate and the carbon cycle. In the simplest terms, uplift of mountains exposes Ca-bearing rocks to chemical weathering and releases Ca2+ into surface water. This Ca2+ eventually is transported to the ocean where it reacts with dissolved CO2 to form limestone. Some of this limestone settles to the sea floor where it is incorporated into new rocks. Dissolved CO2, along with carbonate and bicarbonate ions, are referred to as dissolved inorganic carbon (DIC).

Propylene glycol is known to exert high levels of biochemical oxygen demand (BOD) during degradation in surface waters. This process can adversely affect aquatic life by consuming oxygen needed by aquatic organisms for survival. Large quantities of dissolved oxygen (DO) in the water column are consumed when microbial populations decompose propylene glycol.

Sufficient dissolved oxygen levels in surface waters are critical for the survival of fish, macro-invertebrates, and other aquatic organisms. If oxygen concentrations drop below a minimum level, organisms emigrate, if able and possible, to areas with higher oxygen levels or eventually die. This effect can drastically reduce the amount of usable aquatic habitat. Reductions in DO levels can reduce or eliminate bottom-feeder populations, create conditions that favour a change in a community's species profile, or alter critical food-web interactions.

log Kow : -1.41- -0.3 Half-life (hr) air : 32 Henry's atm m3 /mol: 1.20E-08 BOD 5: 0.995,2.2% ThOD : 1.685 BCF : <1 Bioaccumulation : not sig processes Abiotic: photoxid For 2-bromo-2-nitropropan-1,3-diol (Bronopol)

#### Environmental fate:

One hydrolysis study indicates that bronopol appears to hydrolyse slowly at acidic or neutral pH conditions. Bronopol decomposes in aqueous solution on exposure to light. Increases in temperature increase decomposition.

#### Ecotoxicity:

Bird LD50: mallard duck 510 mg/kg Bird dietary LC50: quail 4488 ppm Daphnia magna EC50 (48 h): 1.4 mg/l

## Fish LC50: trout 41.5 ppm DO NOT discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
propylene glycol	LOW	LOW
monoisobutanolamine	LOW	LOW
2-bromo-2-nitropropan-1,3- diol	LOW	LOW
water	LOW	LOW

## **Bioaccumulative potential**

Ingredient	Bioaccumulation
propylene glycol	LOW (BCF = 1)
monoisobutanolamine	LOW (BCF = 330)
2-bromo-2-nitropropan-1,3- diol	LOW (LogKOW = -0.6408)

## Mobility in soil

Ingredient	Mobility
propylene glycol	HIGH (Log KOC = 1)
monoisobutanolamine	MEDIUM (Log KOC = 2.196)
2-bromo-2-nitropropan-1,3- diol	HIGH (Log KOC = 1)

## **SECTION 13 Disposal considerations**

Waste treatment methods	
Product / Packaging disposal	<ul> <li>Containers may still present a chemical hazard/ danger when empty.</li> <li>Return to supplier for reuse/ recycling if possible.</li> <li>Otherwise:</li> <li>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.</li> <li>Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>DO NOT allow wash water from cleaning or process equipment to enter drains.</li> <li>It may be necessary to collect all wash water for treatment before disposal.</li> <li>In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>Where in doubt contact the responsible authority.</li> <li>Recycle wherever possible or consult manufacturer for recycling options.</li> <li>Consult State Land Waste Authority for disposal.</li> <li>Bury or incinerate residue at an approved site.</li> <li>Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>

## **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

# 14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

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

Product name	Group
calcium carbonate	Not Available

Bijoolius/tanapije acid	Group Not Available
copolymer	Norwalable
propylene glycol	Not Available
methacrylic acid/ ethyl acrylate copolymer	Not Available
alcohols C12-14 secondary ethoxylated	Not Available
monoisobutanolamine	Not Available
sorbitan monooleate, ethoxylated	Not Available
2-bromo-2-nitropropan-1,3- diol	Not Available
water	Not Available

## 14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
calcium carbonate	Not Available
styrene/ acrylic acid copolymer	Not Available
propylene glycol	Not Available
methacrylic acid/ ethyl acrylate copolymer	Not Available
alcohols C12-14 secondary ethoxylated	Not Available
monoisobutanolamine	Not Available
sorbitan monooleate, ethoxylated	Not Available
2-bromo-2-nitropropan-1,3- diol	Not Available
water	Not Available

## **SECTION 15 Regulatory information**

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

#### calcium carbonate is found on the following regulatory lists

#### Australian Inventory of Industrial Chemicals (AIIC)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

#### styrene/ acrylic acid copolymer is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

#### propylene glycol is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

## methacrylic acid/ ethyl acrylate copolymer is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

#### alcohols C12-14 secondary ethoxylated is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals Australian Inventory of Industrial Chemicals (AIIC)

#### monoisobutanolamine is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals Australian Inventory of Industrial Chemicals (AIIC)

#### sorbitan monooleate, ethoxylated is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

#### 2-bromo-2-nitropropan-1,3-diol is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

water is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

## Additional Regulatory Information

Not Applicable

#### **National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (styrene/ acrylic acid copolymer; propylene glycol; methacrylic acid/ ethyl acrylate copolymer; alcohols C12-14 secondary ethoxylated; monoisobutanolamine; sorbitan monooleate, ethoxylated; 2-bromo-2-nitropropan-1,3-diol; water)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (styrene/ acrylic acid copolymer; methacrylic acid/ ethyl acrylate copolymer; alcohols C12-14 secondary ethoxylated)
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	No (methacrylic acid/ ethyl acrylate copolymer; alcohols C12-14 secondary ethoxylated)
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	18/06/2024
Initial Date	18/06/2024

#### 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.

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
- 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
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- 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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TEL (+61 3) 9572 4700.