

Bugalugs No Rinse Dog & Cat Shampoos

Adeval Group Pty Ltd

Part Number: BSNRBF200; BCATPCNR200

Version No: 2.3

Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

Issue Date: 16/09/2024

Print Date: 16/09/2024

L.GHS.AUS.EN

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

Product Identifier

Product name	Bugalugs No Rinse Dog & Cat Shampoos
Synonyms	Not Available
Other means of identification	BSNRBF200; BCATPCNR200

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

Relevant identified uses	Leave in dog & cat shampoos
--------------------------	-----------------------------

Details of the manufacturer or supplier of the safety data sheet

Registered company name	Adeval Group Pty Ltd
Address	276 Proximity Drive Sunshine West Victoria 3020 Australia
Telephone	03 8566 7660
Fax	Not Available
Website	www.garth.com.au
Email	info@garth.com.au

Emergency telephone number

Association / Organisation	Poisons Information Centre
Emergency telephone numbers	13 11 26
Other emergency telephone numbers	000


SECTION 2 Hazards identification

Classification of the substance or mixture

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

Poisons Schedule	Not Applicable
Classification [1]	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 1, Hazardous to the Aquatic Environment Acute Hazard Category 2
Legend:	1. Classification by vendor; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	
Signal word	Danger

Bugalugs No Rinse Dog & Cat Shampoos

Hazard statement(s)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H401	Toxic to aquatic life.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

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.
P272	Contaminated work clothing should not be allowed out of the workplace.

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	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
------	--

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
7732-18-5	87	<u>water</u>
56-81-5	5	<u>glycerol</u>
9005-64-5	2.5	<u>sorbitan monolaurate, ethoxylated</u>
41444-55-7	2.2	<u>decyl D-glucoside</u>
2163-42-0	0.8	<u>2-methyl-1,3-propanediol</u>
61789-40-0	0.7	<u>cocamidopropylbetaine</u>
112-02-7	0.6	<u>cetyltrimethylammonium chloride</u>
1117-86-8	0.1	<u>1,2-octanediol</u>
7647-14-5	0.1	<u>sodium chloride</u>
Legend:	1. Classification by vendor; 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	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold eyelids apart and flush the eye continuously with running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay.
--------------------	---

Bugalugs No Rinse Dog & Cat Shampoos

	<ul style="list-style-type: none"> ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures**Extinguishing media**

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- ▶ foam.
- ▶ dry chemical powder.
- ▶ carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
-----------------------------	-------------

Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ The material is not readily combustible under normal conditions. ▶ However, it will break down under fire conditions and the organic component may burn. ▶ Not considered to be a significant fire risk. ▶ Heat may cause expansion or decomposition with violent rupture of containers. ▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). ▶ May emit acrid smoke. <p>Decomposes on heating and produces toxic fumes of: carbon dioxide (CO₂) other pyrolysis products typical of burning organic material. May emit corrosive fumes.</p>
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures**Personal precautions, protective equipment and emergency procedures**

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<p>Environmental hazard - contain spillage.</p> <ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment.
---------------------	--

Bugalugs No Rinse Dog & Cat Shampoos

	<ul style="list-style-type: none"> ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. ▶ Place in a suitable, labelled container for waste disposal.
Major Spills	<p>Environmental hazard - contain spillage. Moderate hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▶ If contamination of drains or waterways occurs, advise emergency services.

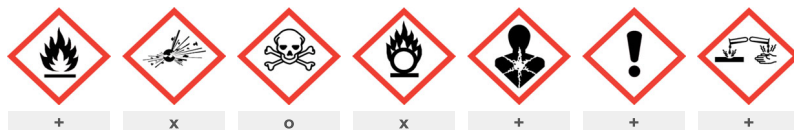
Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage**Precautions for safe handling**

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ DO NOT enter confined spaces until atmosphere has been checked. ▶ DO NOT allow material to contact humans, exposed food or food utensils. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. ▶ DO NOT allow clothing wet with material to stay in contact with skin
Other information	

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known



X — Must not be stored together

0 — May be stored together with specific preventions

+ — May be stored together

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

SECTION 8 Exposure controls / personal protection**Control parameters**

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Bugalugs No Rinse Dog & Cat Shampoos

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	glycerol	Glycerin mist	10 mg/m ³	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
glycerol	45 mg/m ³	180 mg/m ³	1,100 mg/m ³
cetyltrimethylammonium chloride	1.1 mg/m ³	12 mg/m ³	70 mg/m ³
sodium chloride	0.5 ppm	2 ppm	20 ppm

Ingredient	Original IDLH	Revised IDLH
water	Not Available	Not Available
glycerol	Not Available	Not Available
sorbitan monolaurate, ethoxylated	Not Available	Not Available
decyl D-glucoside	Not Available	Not Available
2-methyl-1,3-propanediol	Not Available	Not Available
cocamidopropylbetaine	Not Available	Not Available
cetyltrimethylammonium chloride	Not Available	Not Available
1,2-octanediol	Not Available	Not Available
sodium chloride	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
decyl D-glucoside	E	≤ 0.01 mg/m ³
cocamidopropylbetaine	E	≤ 0.1 ppm
cetyltrimethylammonium chloride	E	≤ 0.01 mg/m ³
sodium chloride	E	≤ 0.01 mg/m ³

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

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- ▶ cause inflammation
- ▶ cause increased susceptibility to other irritants and infectious agents
- ▶ lead to permanent injury or dysfunction
- ▶ permit greater absorption of hazardous substances and
- ▶ acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

Exposure controls

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

Bugalugs No Rinse Dog & Cat Shampoos

General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or 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

- ▶ Safety glasses with side shields.
- ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
- ▶ 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].

Skin protection

See Hand protection below

Hands/feet protection

- ▶ Wear chemical protective gloves, e.g. PVC.
- ▶ Wear safety footwear or safety gumboots, e.g. Rubber

NOTE:

- ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
- ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.

Bugalugs No Rinse Dog & Cat Shampoos

	<ul style="list-style-type: none"> · Contaminated gloves should be replaced. <p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash unit.

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

SECTION 9 Physical and chemical properties**Information on basic physical and chemical properties**

Appearance	Coloured		
Physical state	Liquid	Relative density (Water = 1)	Not Available

Bugalugs No Rinse Dog & Cat Shampoos

Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable
pH (as supplied)	4.5-5.5	Decomposition temperature (°C)	Not Applicable
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Available
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 Applicable
Vapour pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant 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. 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

Bugalugs No Rinse Dog & Cat Shampoos

	<p>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.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>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.</p>
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	<p>Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.</p> <p>Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.</p> <p>Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers</p> <p>Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.</p> <p>Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.</p>

Bugalugs No Rinse Dog & Cat Shampoos	TOXICITY	IRRITATION
	Not Available	Not Available
water	TOXICITY	IRRITATION
	Oral (Rat) LD50: >90000 mg/kg ^[2]	Not Available
glycerol	TOXICITY	IRRITATION
	Dermal (Guinea Pig) LD50: 58500 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
	Inhalation (Rat) LC50: >5.85 mg/L4h ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
sorbitan monolaurate, ethoxylated	TOXICITY	IRRITATION
	Dermal (Guinea Pig) LD50: >3000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
	Inhalation (Rat) LC50: >5.1 mg/l4h ^[1]	Skin (human): 15 mg/3d mild
decyl D-glucoside	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[2]	Not Available
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	
	Oral (Rat) LD50: >2000 mg/kg ^[1]	
2-methyl-1,3-propanediol	TOXICITY	IRRITATION
	Oral (Rat) LD50: >5000 mg/kg ^[2]	
	Dermal (rabbit) LD50: >2000 mg/kg ^[2]	Eye (rabbit): Non Irritant [ARCO]
	Inhalation (Rat) LC50: >5.1 mg/l4h ^[1]	Skin (rabbit): Non Irritant
cocamidopropylbetaine	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye: adverse effect observed (irreversible damage) ^[1]
	Oral (Rat) LD50: 2700 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Eye: primary irritant *
		Skin: adverse effect observed (irritating) ^[1]
		Skin: no adverse effect observed (not irritating) ^[1]
	Skin: primary irritant *	

Bugalugs No Rinse Dog & Cat Shampoos

	TOXICITY	IRRITATION
cetyltrimethylammonium chloride	Dermal (rabbit) LD50: 4300 mg/kg ^[2]	Eye: adverse effect observed (irreversible damage) ^[1]
	Oral (Rat) LD50: 250 mg/kg ^[2]	Skin: adverse effect observed (corrosive) ^[1]
1,2-octanediol	Inhalation (Rat) LC50: >7.015 mg/l4h ^[1]	Eye: adverse effect observed (irritating) ^[1]
	Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
sodium chloride	Dermal (rabbit) LD50: >10000 mg/kg ^[1]	Eye (rabbit): 10 mg - moderate
	Inhalation (Rat) LC50: >10.5 mg/l4h ^[1]	Eye (rabbit): 100 mg/24h - moderate
	Oral (Rat) LD50: 3000 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Skin (rabbit): 500 mg/24h - mild
		Skin: no adverse effect observed (not irritating) ^[1]
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	

GLYCEROL	<p>For glycerol:</p> <p>Acute toxicity: Glycerol is of a low order of acute oral and dermal toxicity with LD50 values in excess of 4000 mg/kg bw. At very high dose levels, the signs of toxicity include tremor and hyperaemia of the gastro-intestinal tract. Skin and eye irritation studies indicate that glycerol has low potential to irritate the skin and the eye. The available human and animal data, together with the very widespread potential for exposure and the absence of case reports of sensitisation, indicate that glycerol is not a skin sensitiser.</p> <p>Repeat dose toxicity: Repeated oral exposure to glycerol does not induce adverse effects other than local irritation of the gastro-intestinal tract. The overall NOEL after prolonged treatment with glycerol is 10,000 mg/kg bw/day (20% in diet). At this dose level no systemic or local effects were observed. For inhalation exposure to aerosols, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/m³ and 662 mg/m³ for systemic effects.</p> <p>Genotoxicity: Glycerol is free from structural alerts, which raise concern for mutagenicity. Glycerol does not induce gene mutations in bacterial strains, chromosomal effects in mammalian cells or primary DNA damage <i>in vitro</i>. Results of a limited gene mutation test in mammalian cells were of uncertain biological relevance. <i>In vivo</i>, glycerol produced no statistically significant effect in a chromosome aberrations and dominant lethal study. However, the limited details provided and the absence of a positive control, prevent any reliable conclusions to be drawn from the <i>in vivo</i> data. Overall, glycerol is not considered to possess genotoxic potential.</p> <p>Carcinogenicity: The experimental data from a limited 2 year dietary study in the rat does not provide any basis for concerns in relation to carcinogenicity. Data from non-guideline studies designed to investigate tumour promotion activity in male mice suggest that oral administration of glycerol up to 20 weeks had a weak promotion effect on the incidence of tumour formation.</p> <p>Reproductive and developmental toxicity: No effects on fertility and reproductive performance were observed in a two generation study with glycerol administered by gavage (NOAEL 2000 mg/kg bw/day). No maternal toxicity or teratogenic effects were seen in the rat, mouse or rabbit at the highest dose levels tested in a guideline comparable teratogenicity study (NOEL 1180 mg/kg bw/day).</p>
SORBITAN MONOLAURATE, ETHOXYLATED	<p>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.</p> <p>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</p> <p>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.</p> <p>To address the possible presence of 1,4-dioxane and ethylene oxide impurities in these ingredients, the Panel</p>

Bugalugs No Rinse Dog & Cat Shampoos

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-dimethylbenz[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 Cosmetic July 2015

https://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.

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-pentaosaheptacosan-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 ACD to these compounds by patch testing.

Allergic Contact Dermatitis—Formation, Structural Requirements, and Reactivity of Skin Sensitizers.

Ann-Therese Karlberg 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, among other derivatives. PEGs and their derivatives are broadly utilized in cosmetic products as surfactants, emulsifiers, cleansing agents, humectants, and skin conditioners.

PEGs 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 formulations.

Most PEGs are commonly available commercially as mixtures of different oligomer sizes in broadly- or narrowly-defined molecular weight (MW) ranges. For instance, PEG-10,000 typically designates a mixture of PEG molecules (n = 195 to 265) having an average MW of 10,000. PEG is also known as polyethylene oxide (PEO) or polyoxyethylene (POE), with the three names being chemical synonyms. However, PEGs mainly refer to oligomers and polymers with molecular masses below 20,000 g/mol, while PEOs are polymers with molecular masses above 20,000 g/mol, and POEs are polymers of any molecular mass. Relatively small molecular weight PEGs are produced by the chemical reaction between ethylene oxide and water or ethylene glycol (or other ethylene glycol oligomers), as catalyzed by acidic or basic catalysts. To produce PEO or high-molecular weight PEGs, synthesis is performed by suspension polymerization. It is necessary to hold the growing polymer chain in solution during the course of the poly-condensation process. The reaction is catalyzed by magnesium-, aluminum-, or calcium-organoelement compounds. To prevent coagulation of polymer chains in the solution, chelating additives such as dimethylglyoxime are used.

Safety Evaluation of Polyethylene Glycol (PEG) Compounds for Cosmetic Use: Toxicol Res 2015; 31:105-136 The Korean Society of Toxicology

<https://doi.org/10.5487/TR.2015.31.2.105>

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 sesquiosostearate, sorbitan sesquisteate, and sorbitan trisostearate 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 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 and the chemistry of the sorbitan esters (i.e., sorbitan/ sorbitol, natural fatty acids) does not suggest the likelihood that the sorbitan esters are electrophilic or reactive in nature. Thus, it is not likely that the substances in Group D cause mutagenic effects.

Sorbitan monostearate did not transform primary Syrian golden hamster embryo cells. As discussed above for point mutation, the chemistry of the sorbitan esters does not suggest the likelihood that these substances, or their constituent substructures (i.e., sorbitol, fatty acids) are reactive or electrophilic in nature.

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

DECYL D-GLUCOSIDE

A high molecular weight polyglycoside was found to have a NOAEL of 250 mg/kg/day in a 90 day oral study in rats. Adverse treatment related effects were limited to the site of contact (forestomach) in animals treated at higher doses.

Bugalugs No Rinse Dog & Cat Shampoos

Alcohols with a chain length C18-C22 are of low acute toxicity and did not cause adverse effects when dosed at 1000 mg/bw/day in a 28 day study.

Absorption by oral route is expected to be good. For the substance per se, absorption by respiratory route is undetermined and absorption by dermal exposure is most probably limited; furthermore for both routes, absorption is virtually null for workers at the manufacturing steps as the substance is in the form of pearls.

-

The components of the UVCB may undergo acido-basic, oxidoreductive reactions and deglycosylation, leading to the same endogenous metabolism as that of fatty acids and glucose. Elimination is expected to be mainly faecal (fatty acids and metabolites) and to a minor extent expiratory (organic volatiles and carbon dioxide). No urinary excretion is expected, notably as the putative metabolite glucose, due to regulation of glycemia. The possibility of excretion into milk is undetermined.

REACH Dossier; Acetalization product between glucose and C16-18 (even numbered)- alcohol (EC Number 927-870-2)

Alkyl glycosides (syn: alkyl polyglucosides, alkyl polyglycosides, APGs) are considered non-irritating to skin, but irritating to eyes at very high concentrations. A general classification of a 65% C8 alkyl glycoside solution according to the Substance Directive 67/548/EEC is Irritating (Xi) with the risk phrase R41 (Risk of serious damage to the eyes) or R36 (Irritating to the eyes) (Akzo Nobel 1998).

Acute toxicity:

In single dose dermal studies with caprylyl/capryl glucoside and C10-16 alkyl glucoside (both 50% a.i., n:1.6) in rabbits, the LD50 was greater than the 2000 mg/kg dose administered. In oral studies with the same test substances, none of the mice dosed with 2000 mg/kg caprylyl glucoside and none of the rats dosed with 5000 mg/kg C10-16 alkyl glucoside died during the study.

Ocular:

In system studies for ocular irritation, the ocular irritation potential of decyl, lauryl, C10-16 alkyl, and coco-glucosides was not to slightly irritating and of caprylyl/capryl glucoside was highly irritating. In a HET-CAM study with APG of varying proportions of alkyl chain length, the ocular irritation potential increased with the increased proportion of shorter-chain APGs. In studies using rabbits, neutralized lauryl glucoside produced slight ocular reactions. Caprylyl/capryl glucoside was severely irritating to rabbit eyes when tested undiluted; the irritation threshold value was 10% for 30% a.i. caprylyl/capryl glucoside and 5% for 60% a.i. caprylyl/capryl glucoside.

Dermal:

In an in vitro dermal absorption study using human skin samples, the mean absorbed dose of 10% caprylyl/capryl glucoside was 0.01%.

APGs of varying chain length (C8/10 to C12/16; 15-70% a.i.) are potentially irritating with irritation potential decreasing with increasing chain length, and, independent of the degree of polymerisation, the irritation was concentration-dependent. The primary dermal irritation indices (PDII) ranged from 0.0 to 4.6 in rabbits. (A PDII of 2 was considered a positive responder). In clinical studies, the dermal irritation of decyl, lauryl, and coco-glucosides was evaluated in epicutaneous patch (2.0% a.i.) and soap chamber tests (1.0% a.i.), and decyl glucoside was evaluated in a single insult occlusive patch test SIOPT (0.5% a.i.). At most, these ingredients were slightly irritating

Ingestion:

In an oral study in which female mice were dosed by gavage with a 5% aq. solution of caprylyl [U-14C]glucoside, the highest levels of radioactivity at 2 h after dosing were found in the stomach, intestines, liver, and kidney. The radioactivity in the stomach was primarily unchanged substrate, while only a trace amount found in the liver was unchanged. Labeled glucose was found in all of these organs. In a feeding study in rats in which dietary sucrose was replaced with 10 or 20% ethyl glucoside for 39 days, 60-90% of the ingested ethyl glucoside was recovered in the urine.

Repeat dose toxicity:

In 2-wk repeated dose dermal studies in rabbits with 60% active caprylyl/capryl glucoside, occlusive applications produced testicular effects, while non-occlusive application did not. In the two occlusive studies, one with 0.09 and 1.8 g a.i./kg and the other with 0.14-1.25 g a.i./kg, an NOEL for testicular effects could not be established. In the non-occlusive study, the NOEL for systemic toxicity was 0.18 g a.i./kg caprylyl/capryl glucoside. Severe dermal irritation was observed in both occlusive studies, while slight to moderate irritation was reported in the non-occlusive study.

Dermal application of 60% active caprylyl/capryl glucoside, 0.9-1.8 g a.i./kg, under occlusive conditions may affect the testes and accessory sex glands of rabbits; however, it was not clear if the effects were test-article related or due to stress of the occlusive procedure and resulting irritation and weight loss. Lauryl glucoside, 100-1000 mg/kg by gavage, did not produce adverse reproductive or developmental effects. Lauryl glucoside, 0.1-10,000 nmol, did not have any effects in in vitro oestrogenicity assays

In oral repeated dose toxicity studies, moderately-dilated renal tubules were observed in 3 of 6 rats fed 20% ethyl glucoside for 39 days, but in none of the rats fed 10% ethyl glucoside. Kidney weights were statistically significantly increased in the test animals. In rats dosed orally with 250-1000 mg/kg C12/16 APG for 13 wks, reversible irritation and ulceration of the stomach mucosa was observed, but there was no systemic toxicity reported for any group.

Mutagenicity:

Alkyl polyglucosides (polyglycoses; APGs) (chain length not specified), tested at 8-500 ug/l and 11-900 ug/plate in distilled water, were not mutagenic in Ames tests with or without metabolic activation. C10-16 APG, tested at concentrations of <= 160 ug/ml with and without metabolic activation, was not clastogenic.

Sensitisation:

Glucosides with alkyl chain lengths ranging from C8-C10 to >C18, as well as a C18 branched glucoside, were evaluated in both the guinea pig maximisation test (GPMT), at concentrations of 1.25-10% for intradermal induction, 5-100% for epidermal induction, and 2.5-50% for challenge, and the local lymph node assay (LLNA) at concentrations of 1.25-50%. None of the glucosides tested were irritants or sensitisers in the GPMT, but the LLNA indicated that one C12-C18 glucoside, C14 glucoside, and C18 branched glucoside may cause skin sensitization at concentrations of 8.4%, 5.9%, and 0.43%, respectively. The sensitization potential of C12/16 APG was evaluated in studies in guinea pigs using the Buehler method (test concentrations of 20%) and the Magnusson-Kligman protocol (1, 60, and 10% used for intracutaneous induction, epidermal induction, and epidermal challenge respectively). C12/16 APG was not a sensitiser in the Buehler or Magnusson-Kligman studies. In clinical testing, the sensitization potential of 0.5, 0.75, and 1.8% a.i. decyl glucoside (in formulation), 5% a.i. aq. decyl and lauryl glucoside, and 1% a.i. aq. coco-glucoside was evaluated in Human Repeat Insult Patch Tests (HRIPTs). These ingredients were not irritating or sensitising.

CIR Expert Panel Meeting, September 2011

COCAMIDOPROPYLBETAINE

* [Van Waters and Rogers] ** [Canada Colors and Chemicals Ltd.] Toxicokinetics, metabolism and distribution. Absorption of the chemical across dermal and gastrointestinal membranes is possible based on the relatively low molecular weight of the chemical (500 Da) and given that it is a surfactant (EC, 2003). Acute toxicity. Acute oral toxicity studies in rats and mice

Bugalugs No Rinse Dog & Cat Shampoos

indicated that the LD50 values of the chemical (at 30-35.61% concentration) ranged from 1800 mg/kg bw (male rats) up to 5000 mg/kg bw, with mortalities noted in most studies (CIR, 2010). Of note is an acute oral toxicity study conducted in Sprague-Dawley rats (5/sex) at a single dose of 1800 mg/kg bw (formulation containing 35.61% of the chemical), where no males but all five females died. Overall, the data suggests that mortality occurs following oral administration of the chemical and that it may be an acute oral toxicant. Therefore, based on these data the chemical may be harmful if swallowed. An acute dermal toxicity study in rats was conducted using 2000 mg/kg bw of a 31% formulation of the chemical (CIR, 2010). Irritation was observed, but there were no clinical signs of systemic toxicity or mortalities. The lack of effects in this study suggests that the chemical is likely to be of low acute dermal toxicity. Irritation. The chemical has a quaternary ammonium functional group, which is a structural alert for corrosion. Numerous skin irritation studies, conducted with formulations containing 7.5-30% of the chemical, indicated that the chemical has irritant properties. The studies were, in-general, conducted under occlusive conditions, with exposure times of up to 24 hours (7.5-10%). Based on the information available, the chemical is likely to be a skin irritant. Eye irritation studies with the chemical showed that corrosive and necrotic effects occurred at 30% whereas less severe effects were observed at lower concentrations of 2.3-10%. The chemical is classified with the risk phrase R36: Irritating to eyes, however, based on studies conducted on the chemical it may be a severe eye irritant. Sensitisation. The chemical has a quaternary ammonium functional group, which is a structural alert for sensitisation (Conflicting results have been obtained with the chemical in animal studies. Positive results were reported in an LLNA study (an EC3 value was not reported). In addition, positive results were obtained in two guinea pig maximisation studies conducted by a single laboratory, the first at 3% induction and 3% challenge, and the second at 0.15% induction and 0.015% challenge. However, there was no sensitisation in a guinea pig maximisation test when the chemical was tested at 6% induction and 1% challenge. In addition, no sensitisation was observed in another test in guinea pigs at 0.75% induction and 0.02% challenge. No evidence of sensitisation was reported in a HRIPT on a formulation containing the chemical at 0.6% concentration (a 10% dilution of a ~6% formulation) with 110 volunteers. In HRIPT studies on formulations containing the chemical, no evidence of sensitisation was reported at concentrations of 1.87% (88 subjects), 0.93% (93 subjects), 0.3% (100 subjects), 1.5-3.0% (141 subjects), 6.0% (210 subjects), 0.018% (27 subjects). However, positive results were observed in provocative studies conducted on formulations containing the chemical (at 0.3-1% concentration), conducted in subjects diagnosed with various forms of contact dermatitis, suggesting that the chemical may cause reactions in sensitive individuals. In one study authors note that sensitisation effects of the chemical (and related compounds) are most likely due to the impurities, including DMAPA and amidopropyl dimethylamines, however, they do not exclude the possibility of the causing the sensitisation. The potential for skin sensitisation, due to the presence of the above impurities in the chemical, will be limited by their reported low concentration. In summary, a definitive conclusion cannot be made on the skin sensitisation potential of the chemical. The available information suggests that skin sensitisation is possible. Although there are some inconsistencies in the results reported for studies conducted on the chemical, the scientific data points towards the positive findings being caused by impurities, in particular DMAPA and amidopropyl dimethylamines, which are present in the chemical at low concentrations. Repeated Dose Toxicity. In a 28-day repeated dose oral toxicity study, rats were administered a 30.6% solution of the chemical at 0, 100, 500 or 1000 mg/kg bw/day. Inflammation of the non-glandular stomach was noted in animals of the high-dose group, although this effect was attributed to the irritant properties of the test material. Mortality was also observed in this study at all treatment levels but there was no dose-response relationship. In another 28-day repeated dose oral toxicity study, rats were administered a solution containing the chemical (concentration not stated) at 0, 250, 500 or 1000 mg/kg bw/day. The NOEL was reported as 500 mg/kg bw/day, which appears to be based on non-systemic irritant effects on the non-glandular stomach. No mortalities were observed. In a 90-day repeated dose oral toxicity study, rats were administered a solution containing the chemical (concentration not stated) at 0, 250, 500 or 1000 mg/kg bw/day. There were no mortalities and the noted effects are isolated to the stomach region and appear to be irritant in nature. The NOEL established by the study authors was 250 mg/kg bw/day, based on these effects. Mutagenicity. The chemical was not mutagenic in numerous bacterial reverse mutation assays. Negative results were also obtained for the chemical in a mouse lymphoma test and a micronucleus test in mice. Carcinogenicity. No signs of carcinogenicity were noted in a 20 month dermal study in mice (3 applications/week) for a hair dye formulation containing the chemical at a concentration of 0.09%. The formation of nitrosamines is possible. Secondary amides (and the identified impurities) may serve as substrates for N-nitrosation, therefore formulation with N-nitrosating agents should be avoided. Possible cross-reactions to several fatty acid amidopropyl dimethylamines were observed in patients that were reported to have allergic contact dermatitis to a baby lotion that contained 0.3% oleamidopropyl dimethylamine. Stearamidopropyl dimethylamine at 2% in hair conditioners was not a contact sensitizer when tested neat or diluted to 30%. However, irritation reactions were observed. A 10-year retrospective study found that out of 46 patients with confirmed allergic eyelid dermatitis, 10.9% had relevant reactions to oleamidopropyl dimethylamine and 4.3% had relevant reactions to cocamidopropyl dimethylamine. Several cases of allergic contact dermatitis were reported in patients from the Netherlands that had used a particular type of body lotion that contained oleamidopropyl dimethylamine. In 12 patients tested with their personal cosmetics, containing the fatty acid amidopropyl dimethylamine cocamidopropyl betaine (CAPB), 9 had positive reactions to at least one dilution and 5 had irritant reactions. All except 3 patients, who were not tested, had 2 or 3+ reaction to the 3,3-dimethylaminopropylamine (DMAPA, the reactant used in producing fatty acid amidopropyl dimethylamines) at concentrations as low as 0.05%. The presence of DMAPA was investigated via thin-layer chromatography in the personal cosmetics of 4 of the patients that had positive reactions. DMAPA was measured in the products at 50 - 150 ppm suggesting that the sensitising agent in CAPB-induced allergy is DMAPA. The sensitisation potential of a 4% aqueous liquid fabric softener formulation containing 0.5% stearyl/palmitylamidopropyl dimethylamine was investigated using. The test material caused some irritation in most volunteers. After a rest period of 2 weeks, the subjects received challenge patches with the same concentration of test material on both arms. Patch sites were graded 48 and 96 h after patching. Eight subjects reacted at challenge, and 7 of the eight submitted to rechallenge with 4% and 0.4% aqueous formulations. No reactions indicative of sensitisation occurred at rechallenge. The test formulation containing stearyl/palmitylamidopropyl dimethylamine had no significant sensitisation potential. Most undiluted cationic surfactants satisfy the criteria for classification as Harmful (Xn) with R22 and as Irritant (Xi) for skin and eyes with R38 and R41. 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 of the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. For betaines: Several sources revealing data on skin irritation, skin sensitisation and dermal absorption in humans are available for CAS 683-10-3, the C12-alkyldimethyl betaine, which is the most frequently occurring betaine because it is one of the components of most of the substances of the alkyldimethyl betaine group, among those also Betaines, C12-14 (even numbered)-

Buglugs No Rinse Dog & Cat Shampoos

alkyldimethyl. Therefore, read-across of exposure-related observations in humans from CAS 683-10-3 is justified. Data from several human closed patch tests demonstrate skin irritation in humans ranging from mild to strong under occlusive conditions even with concentrations as low as 1%. In contrast, exposure to 0.1% under open conditions did not induce any positive skin reactions.

Information on skin sensitisation in humans is available from a closed human patch test with CAS 683-10-3. After an induction period of 6 days with 0.1% of active ingredient, followed by a treatment-free period of 10 days, the volunteers were challenged under occlusive conditions for 24 hours. No reactions were observed immediately after challenge; during the next 4 days only irritation reactions were observed.

This finding was further supported by industrial medical monitoring data. Workers involved in the production of CAS 683-10-3 are routinely checked every 3 years for signs of skin sensitisation, respiratory irritation, skin irritation and eye irritation. During these examinations no signs of the aforementioned disorders were observed which were related to the test substance.

Moreover, a study focusing on dermal uptake of C12-alkyldimethyl betaine into human skin and the effects of surfactants on skin barrier function demonstrated that only up to 0.4% of the applied dose was absorbed within 30 minutes of exposure, with absorbance being dependent on the concentration applied. Tape stripping of the skin revealed that the administered test substance was primarily located in the outer stratum corneum layer

Test material does not demonstrate mutagenic or clastogenic effects in bacteria or mammalian cells *in vitro*

" REACH Dossier

Amphoteric surfactants are easily absorbed in the intestine and are excreted partly unchanged via the faeces. Metabolisation to CO₂ and short-chained fatty acids also occur. No tendency to accumulation in the organism or storage of betaines in certain organs has been detected. Betaines generally have a low acute toxicity. E.g., LD50 values for cocoamidopropylbetaine (30% solution) by oral administration have been determined to 4,910 mg/kg body weight in rats.

Betaines do not carry any net charge, and, therefore, they can only form hydrophobic bonds with proteins in the skin. This may be the explanation for the low protein denaturation potential of betaines as the ion-binding of other surfactants contributes to denaturation. In combination with anionic surfactants a positive synergistic effect with regard to skin compatibility is often found. Compared to a 20% solution of C12 alkyl sulfate (AS; sodium lauryl sulfate) alone, decreased erythema was observed for the combination of 20% C12 AS and 10% cocoamidopropyl betaine one hour after the removal of patches. The combination of cocoamidopropyl betaine and C12 AS also reduced swelling of the skin, and generally interactions between amphoteric and AS produce less swelling and result in milder skin reactions. Concentrated betaines are expected to be irritant to skin and eyes. Diluted solutions (3-10%) are not irritant to skin, but they are mildly irritant to the eyes (4.5%)

No evidence of delayed contact hypersensitivity was found in guinea pigs after topically administered solutions of 10% cocoamidopropyl betaine by using the Magnusson-Kligman maximization test. Various instances of contact allergy to cocoamidopropyl betaine have been reported. In all of the reports it was concluded that the observed skin reactions were due to the presence of 3-dimethylaminopropylamine which is an impurity in cocoamidopropyl betaine. This impurity is an intermediate in the synthesis of alkylamidopropyldimethylamines that are intermediates in the synthesis of the corresponding alkylamido betaines.

Cocoamidopropyl betaine was proven to be non-mutagenic to *Salmonella typhimurium* in the Ames *Salmonella*/microsome reverse mutation assay. Short-term genotoxicity tests have shown negative results of mutagenicity for lauryl betaine in various strains of *Salmonella typhimurium*.

**CETYLTRIMETHYLAMMONIUM
CHLORIDE**

Changes in motor activity ** Akzo * for hexadecylammonium chloride Cetyltrimethylammonium chloride is expected to produce similar toxic effects

for acid mists, aerosols, vapours

Data from assays for genotoxic activity *in vitro* suggest that eukaryotic cells are susceptible to genetic damage when the pH falls to about 6.5. Cells from the respiratory tract have not been examined in this respect. Mucous secretion may protect the cells of the airways from direct exposure to inhaled acidic mists, just as mucous plays an important role in protecting the gastric epithelium from its auto-secreted hydrochloric acid. In considering whether pH itself induces genotoxic events *in vivo* in the respiratory system, comparison should be made with the human stomach, in which gastric juice may be at pH 1-2 under fasting or nocturnal conditions, and with the human urinary bladder, in which the pH of urine can range from <5 to="7" and normally averages 6.2. Furthermore, exposures to low pH *in vivo* differ from exposures *in vitro* in that, *in vivo*, only a portion of the cell surface is subjected to the adverse conditions, so that perturbation of intracellular homeostasis may be maintained more readily than *in vitro*.

For alkytrimethylammonium chloride (ATMAC)

Most undiluted cationic surfactants satisfy the criteria for classification as Harmful (Xn) with R22 and as Irritant (Xi) for skin and eyes with R38 and R41. In addition, certain surfactants will satisfy the criteria for classification as Corrosive with R34 in addition to the acute toxicity.

According to Centre Europeen des Agents de Surface et de leurs Intermediaires Organiques (CESIO), C8-18 alkytrimethylammonium chloride (ATMAC) (i.e., lauryl, coco, soya, and tallow) are classified as Corrosive (C) with the risk phrases R22 (Harmful if swallowed) and R34 (Causes burns). C16 ATMAC is classified as Harmful (Xn) with the risk phrases R22 (Harmful if swallowed), R38 (Irritating to skin), and R41 (Risk of serious damage to eyes). C20-22 ATMAC are classified as Irritant (Xi) with R36/38 (Irritating to eyes and skin).

Toxicokinetics and Acute Toxicity: The few available absorption studies conducted with cationic surfactants indicate that absorption occurs in small amounts through the skin. Percutaneous absorption of radiolabelled C12 alkytrimethylammonium bromide (ATMAB) in 3% aqueous solution (applied to an 8 cm² area with occlusion) in the rat was low and corresponded to 0.6% of the applied 14C activity in 72 hours. Most of the absorbed surfactant was excreted in the urine, i.e. 0.35% of the applied 14C activity within the first 24 hours, whereas 13.2% remained on the skin after rinsing. Cutaneous application of the surfactant without rinsing resulted in a greater degree of percutaneous absorption (3.15%) in 48 hours. In the rat elimination after parenteral administration was rapid and was effected primarily via the urine, - more than 80% of the radioactivity was eliminated within 24 hours of application. About 80% of the 14C activity was found in the gastrointestinal tract 8 hours after oral administration of 14C-labelled C16 ATMAB. Only small amounts of the applied radioactivity were found in the urine and in the blood plasma. This indicates poor intestinal absorption. Similar small amounts of 14C were found in the liver, kidneys, spleen, heart, lungs and skeletal muscles. Within 3 days of ingestion, 92% of the administered radioactivity had been excreted in the faeces and 1% in the urine. No appreciable enterohepatic circulation of the radioactivity was found.

The acute oral toxicity of alkytrimethylammonium salts is somewhat higher than the toxicity of anionic and nonionic surfactants. This may be due to the strongly irritating effect which cationic surfactants exhibit on the mucous membrane of the gastrointestinal tract (SFT 1991). Cationic surfactants are generally about 10 times more toxic when administered by the intravenous route compared to oral administration.

Buglugs No Rinse Dog & Cat Shampoos

Skin and Eye Irritation: Skin irritation depends on surfactant concentration. Regardless of the structure, cationic surfactants lead to serious destruction of the skin at high concentrations. Solutions of approximately 0.1% are rarely irritating, whereas irritation is usually pronounced at concentrations between 1.0 and 10.0% surfactant. C16 ATMAC was severely irritating to rabbit skin in a concentration of 2.5%. The surfactant was applied to intact and abraded sites and scored after 34 hours. Then the skin was rinsed and then scored again after 48 hours. The erythema and Eschar Index was 3.75 (maximum 4) and the edema Index was 2.0 (maximum 4).

With regard to eye irritation, cationic surfactants are the most irritating of the surfactants. The longer chained alkyltrimethylammonium salts are less irritating to the rabbit eye than the shorter alkyl chain homologues. C10 ATMAC, C12 ATMAC, and C16 ATMAC were tested in concentrations between 0.1 and 1.0% in water and were found to be significantly irritating or injurious to the rabbit eye. A 5% solution of C18 ATMAC was instilled into the eyes of guinea pigs, and this concentration was very irritating with a total PII (The Primary Irritation Index) score of 96 (maximum 110).

A homologous series of ATMAC produced very little swelling of the stratum corneum and some homologues produced a shrinkage of the stratum corneum after prolonged exposure.

Many proteins in the skin are considerably more resistant to the denaturing effects of cationic surfactants compared to those of anionic surfactants. As cationic surfactants frequently have a lower critical micelle concentration than the anionic surfactants, a saturation of the surfactant/protein complex is prevented by the formation of micelles.

Compared to a representative anionic surfactant, the cooperative binding with subsequent protein denaturation requires about a tenfold higher concentration of a cationic surfactant. Contrary to the irreversible denaturing effect of sodium dodecyl sulfate, the adverse effects of some cationic surfactants on proteins may be reversible. Cationic surfactants can interact with proteins or peptides by polar and hydrophobic binding. Polar interactions result in electrostatic bonds between the negatively charged groups of the protein molecule and the positively charged surfactant molecule.

Sensitisation: A repeated insult patch test of C16 ATMAC was conducted with 114 volunteers. Seventeen days after the last induction of 0.25% surfactant, a challenge patch of 0.25% was applied. No sensitization was observed.

Sub-chronic toxicity: C16 ATMAC was administered at concentrations of 10, 20, and 45 mg/kg/day via the drinking water to rats for one year. The only effect observed was a decrease in body weight gain in the 45 mg/day dose group.

Reproductive Toxicity: No embryo toxic effects were seen, when C18 ATMAC was applied dermally to pregnant rats during the period of major organogenesis (day 6-15 of gestation). The concentrations of C18 ATMAC were 0.9, 1.5 and 2.5%. There was no increase in the incidence of fetal malformations. C16 ATMAC was not teratogenic in rats after oral doses. Mild embryonic effects were observed with 50 mg/kg/day, but these effects were attributed to maternal toxicity rather than to a primary embryonic effect. Lower doses of C16 ATMAC showed no embryo toxic or teratogenic effects.

Mutagenicity: C16 ATMAC was studied in in vitro short-term tests to detect potential mutagenic effects. Cultures of Syrian golden hamster embryo cells were used for an in vitro bioassay. No in vitro transformation of hamster embryo cells was induced, and C16 ATMAC was not mutagenic in *Salmonella typhimurium* (Inoue and Sunakawa 1980). No mutagenic effects or genetic damages were indicated in a survey of nine short-term genotoxicity tests with C16 and C18 ATMAC (Yam *et al.* 1984).

Environmental and Health Assessment of Substances in Household Detergents and Cosmetic Detergent Products, Environment Project, 615, 2001. Torben Madsen *et al.*: Miljøministeriet (Danish Environmental Protection Agency)

For quaternary ammonium compounds (QACs):

Quaternary ammonium compounds (QACs) are cationic surfactants. They are synthetic organically tetra-substituted ammonium compounds, where the R substituents are alkyl or heterocyclic radicals. A common characteristic of these synthetic compounds is that one of the R s is a long-chain hydrophobic aliphatic residue.

The cationic surface active compounds are in general more toxic than the anionic and non-ionic surfactants. The positively-charged cationic portion is the functional part of the molecule and the local irritation effects of QACs appear to result from the quaternary ammonium cation.

Due to their relative ability to solubilise phospholipids and cholesterol in lipid membranes, QACs affect cell permeability which may lead to cell death. Further QACs denature proteins as cationic materials precipitate protein and are accompanied by generalised tissue irritation.

It has been suggested that the experimentally determined decrease in acute toxicity of QACs with chain lengths above C16 is due to decreased water solubility.

In general it appears that QACs with a single long-chain alkyl groups are more toxic and irritating than those with two such substitutions,

The straight chain aliphatic QACs have been shown to release histamine from minced guinea pig lung tissue. However, studies with benzalkonium chloride have shown that the effect on histamine release depends on the concentration of the solution. When cell suspensions (11% mast cells) from rats were exposed to low concentrations, a decrease in histamine release was seen. When exposed to high concentrations the opposite result was obtained.

In addition, QACs may show curare-like properties (specifically benzalkonium and cetylpyridinium derivatives, a muscular paralysis with no involvement of the central nervous system. This is most often associated with lethal doses. Parenteral injections in rats, rabbits and dogs have resulted in prompt but transient limb paralysis and sometimes fatal paresis of the respiratory muscles. This effect seems to be transient.

From human testing of different QACs the generalised conclusion is obtained that all the compounds investigated to date exhibit similar toxicological properties.

for Fatty Nitrogen-Derived Cationics (FND Cationics):

Overall, the available data support the conclusion that, because of their closely-related structures, FND Cationics possess similar environmental fate and ecotoxicity across the category.

Environmental fate:

FND Cationics are considered to be essentially nonvolatile. Water solubility estimates varied from insoluble to slightly soluble, with higher solubility predictions tending to occur for lower molecular weight chemicals. Log Kow values less than 5 were predicted for all of the chemicals that could be modeled.

Measurement and prediction of physical/chemical properties for surfactants are complicated by their behavior in test systems and the environment, and the Kow is not an appropriate hydrophobicity parameter for reliably predicting environmental behavior. Although predictions vary, the overall data and knowledge of the chemicals support the conclusion that the FND Cationics have closely related structures and behave similarly from the perspective of physical/chemical properties.

Fugacity models predict virtually no occurrence of the FND Cationics in air. Nonetheless, modeling of these and similar substances indicates that these chemicals would be expected to degrade relatively rapidly upon exposure to light (t1/2 values ranging from approximately 2.8 to 5.9 hours).

Predicted distribution of the chemicals in the environment was to water and/or sediment compartments based on the assumption that release of the chemicals to the environment is exclusively via water. For chemicals with higher predicted

Bugalugs No Rinse Dog & Cat Shampoos

	<p>water solubility (lower Kow), the water compartment was favoured. Measured biodegradation rates were variable and frequently confounded by adsorption. Overall, the FND Cationic Category chemicals are biodegradable.</p> <p>Cationic substances in the environment instantaneously form complexes with naturally occurring negatively charged constituents in sewage, soils, sediments, and with dissolved humic substances in surface waters. This complexation behavior results in reduced bioavailability in actual environmental conditions that is not adequately represented by standard laboratory assays and/or predictions by various QSAR models.</p> <p>Ecotoxicity:</p> <p>These chemicals, by the nature of their surfactant properties, are toxic to aquatic organisms at low concentrations. Measured aquatic toxicity values indicated acute LC50 and EC50 values generally less than approximately 25 mg/l for fish, daphnid and algae. Other species may be less sensitive to the toxicity of these surfactants with acute LC50 values of 36 and > 50 mg/l recorded for shrimp and crabs, respectively. Chronic toxicity to aquatic organisms varied considerably, with NOECs ranging from 4.15 ug/l to 12.7 mg/l. These studies of aquatic toxicity, many of which were conducted in natural waters with and without added effluents, indicate that the source and composition of the test water dramatically affects the toxicity of the test substance.</p> <p>NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.</p> <p>Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).</p>
Bugalugs No Rinse Dog & Cat Shampoos & DECYL D-GLUCOSIDE & COCAMIDOPROPYL BETAINE	<p>The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p>
WATER & DECYL D-GLUCOSIDE & 1,2-OCTANEDIOL	No significant acute toxicological data identified in literature search.
GLYCEROL & CETYLTRIMETHYLAMMONIUM CHLORIDE & SODIUM CHLORIDE	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. 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.</p>
SORBITAN MONOLAURATE, ETHOXYLATED & SODIUM CHLORIDE	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 epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.
COCAMIDOPROPYL BETAINE & SODIUM CHLORIDE	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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

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

SECTION 12 Ecological information

Toxicity

Bugalugs No Rinse Dog & Cat Shampoos	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
water	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
glycerol	Endpoint	Test Duration (hr)	Species	Value	Source

Bugalugs No Rinse Dog & Cat Shampoos

	LC50	96h	Fish	>11mg/L	2
	EC0(ECx)	24h	Crustacea	>500mg/l	1
sorbitan monolaurate, ethoxylated	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	383mg/l	2
decyl D-glucoside	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	12.43mg/l	2
	EC50	48h	Crustacea	31.62mg/l	2
	LC50	96h	Fish	96.64mg/l	2
	NOEC(ECx)	672h	Fish	1mg/l	2
2-methyl-1,3-propanediol	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	>1000mg/l	2
	EC50	72h	Algae or other aquatic plants	>1000mg/l	2
	EC50	48h	Crustacea	>1000mg/l	2
	NOEC(ECx)	504h	Crustacea	100mg/l	2
cocamidopropylbetaine	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	1-10mg/l	1
	EC50	48h	Crustacea	6.5mg/l	1
	EC0(ECx)	96h	Algae or other aquatic plants	0.09mg/l	1
	LC50	96h	Fish	1-10mg/l	Not Available
cetyltrimethylammonium chloride	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	0.115mg/l	2
	EC50	48h	Crustacea	0.067mg/L	5
	LC50	96h	Fish	0.06-0.15mg/L	4
	NOEC(ECx)	504h	Crustacea	>=0.005mg/L	2
1,2-octanediol	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	35mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	15mg/l	2
	EC50	48h	Crustacea	176mg/l	2
	LC50	96h	Fish	>2.2<22mg/l	2
sodium chloride	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	20.76-36.17mg/L	4
	EC50	48h	Crustacea	0.004-0.006mg/L	4
	LC50	96h	Fish	1000mg/L	4
	EC50	96h	Algae or other aquatic plants	1110.36mg/L	4
	NOEC(ECx)	6h	Fish	0.001mg/L	4
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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				

Toxic 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.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
water	LOW	LOW

Bugalugs No Rinse Dog & Cat Shampoos

Ingredient	Persistence: Water/Soil	Persistence: Air
glycerol	LOW	LOW
decyl D-glucoside	LOW	LOW
2-methyl-1,3-propanediol	LOW	LOW
1,2-octanediol	LOW	LOW
sodium chloride	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
glycerol	LOW (LogKOW = -1.76)
decyl D-glucoside	LOW (LogKOW = 1.916)
2-methyl-1,3-propanediol	LOW (LogKOW = -0.2909)
1,2-octanediol	LOW (LogKOW = 1.6735)
sodium chloride	LOW (LogKOW = 0.5392)

Mobility in soil

Ingredient	Mobility
glycerol	HIGH (Log KOC = 1)
decyl D-glucoside	LOW (Log KOC = 10)
2-methyl-1,3-propanediol	HIGH (Log KOC = 1)
1,2-octanediol	LOW (Log KOC = 10)
sodium chloride	LOW (Log KOC = 14.3)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. <p>Otherwise:</p> <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
-------------------------------------	--

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
water	Not Available
glycerol	Not Available
sorbitan monolaurate, ethoxylated	Not Available
decyl D-glucoside	Not Available
2-methyl-1,3-propanediol	Not Available
cocamidopropylbetaine	Not Available
cetyltrimethylammonium chloride	Not Available
1,2-octanediol	Not Available
sodium chloride	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
water	Not Available
glycerol	Not Available
sorbitan monolaurate, ethoxylated	Not Available
decyl D-glucoside	Not Available
2-methyl-1,3-propanediol	Not Available
cocamidopropylbetaine	Not Available
cetyltrimethylammonium chloride	Not Available
1,2-octanediol	Not Available
sodium chloride	Not Available

SECTION 15 Regulatory information

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

water is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

glycerol is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
Australian Inventory of Industrial Chemicals (AIIC)

sorbitan monolaurate, ethoxylated is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

decyl D-glucoside is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

2-methyl-1,3-propanediol is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

cocamidopropylbetaine is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6

Australian Inventory of Industrial Chemicals (AIIC)

cetyltrimethylammonium chloride is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

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

Australian Inventory of Industrial Chemicals (AIIC)

1,2-octanediol is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

sodium chloride is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

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 (water; glycerol; sorbitan monolaurate, ethoxylated; decyl D-glucoside; 2-methyl-1,3-propanediol; cocamidopropylbetaine; cetyltrimethylammonium chloride; 1,2-octanediol; sodium chloride)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	No (decyl D-glucoside)
Vietnam - NCI	Yes
Russia - FBEPH	No (sorbitan monolaurate, ethoxylated; cetyltrimethylammonium chloride; 1,2-octanediol)
Legend:	<i>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.</i>

SECTION 16 Other information

Revision Date	16/09/2024
Initial Date	16/09/2024

Other information

Ingredients with multiple cas numbers

Name	CAS No
glycerol	56-81-5, 29796-42-7, 30049-52-6, 37228-54-9, 75398-78-6, 78630-16-7, 8013-25-0, 8043-29-6, 1400594-62-8
sorbitan monolaurate, ethoxylated	9005-64-5, 118955-39-8, 122304-31-8, 1242241-45-7, 129428-64-4, 1341-06-6, 1646144-25-3, 194879-92-0, 37310-96-6, 54174-54-8, 60318-54-9, 62229-28-1, 8036-82-6, 851015-03-7, 861842-35-5, 9011-30-7, 9015-57-0, 93037-36-6
decyl D-glucoside	41444-55-7, 58846-77-8, 59947-99-8, 68515-73-1, 54549-25-6, 141464-42-8, 197236-02-5, 6801-91-8
cocamidopropylbetaine	61789-40-0, 83138-08-3, 86438-79-1, 97862-59-4, 61789-70-6
cetyltrimethylammonium chloride	112-02-7, 53023-95-3, 79728-63-5, 139272-33-6
sodium chloride	7647-14-5, 14762-51-7, 16887-00-6, 8028-77-1

Classification of the preparation and its individual components has drawn on official and authoritative sources 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

- AIC: 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