



Pressed to Fresh - Bed & Mattress Freshener

Western Paradise Limited

Part Number: X001933S09

Version No: 1.2

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Issue Date: 01/12/2023

L.REACH.GBR.EN

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

1.1. Product Identifier

Product name	Pressed to Fresh - Bed & Mattress Freshener
Synonyms	Not Available
Other means of identification	Not Available

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

Relevant identified uses	Mattress Cleaner
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Western Paradise Limited
Address	6 Ambleside Avenue Beckenham London BR3 3RW
Telephone	02039185633
Fax	Not Available
Website	www.Pressedtofresh.co.uk
Email	support@pressedtofresh.co.uk

1.4. Emergency telephone number

Association / Organisation	Western Paradise Limited
Emergency telephone numbers	02039185633
Other emergency telephone numbers	111

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	Not Applicable
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2.2. Label elements

Hazard pictogram(s)	Not Applicable
Signal word	Not Applicable

Hazard statement(s)

Not Applicable

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

Material contains citric acid, sodium lauryl sulfate, lavender oil, orange, sweet, Valencia extract.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients**3.1. Substances**

See 'Composition on ingredients' in Section 3.2

3.2. Mixtures

1. CAS No 2. EC No 3. Index No 4. REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 8000-28-0 2. Not Available 3. Not Available 4. Not Available	<0.5	<u>lavender oil</u>	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H317, H319, H335, H336, H411, EUH018, EUH019 ^[1]	Not Available	Not Available
1. 97766-30-8 2.307-891-8 3. Not Available 4. Not Available	<0.5	<u>orange, sweet, Valencia extract</u>	Flammable Liquids Category 3, Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H226, H315, H317, H319, H335, H336, H410, EUH019 ^[1]	Not Available	Not Available
1. 35812-01-2 2.252-737-4 3. Not Available 4. Not Available	<0.1	<u>N-bromosaccharin</u>	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , Germ Cell Mutagenicity Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H317, H319, H335, H341, H411 ^[1]	Not Available	Not Available
1. 61789-30-8 2.263-049-9 3. Not Available 4. Not Available	5	<u>Castille Soap</u> <u>coconut oil,</u> <u>potassium salts</u>	Not Classified ^[1]	Not Available	Not Available
1. 2682-20-4 2.220-239-6 3.613-326-00-9 4. Not Available	<0.1	<u>2-methyl-4-isothiazolin-3-one</u>	Acute Toxicity (Oral) Category 3, Acute Toxicity (Dermal) Category 3, Skin Corrosion/Irritation Category 1B, Sensitisation (Skin) Category 1A, Serious Eye Damage/Eye Irritation Category 1, Acute Toxicity (Inhalation) Category 2, Hazardous to the Aquatic Environment Acute Hazard Category	Skin Sens. 1A; H317: C ≥ 0,0015 % M=10 M=1	Not Available

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1. CAS No 2. EC No 3. Index No 4. REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
			1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H301, H311, H314, H317, H318, H330, H400, H410 [2]		
1. 72561-05-8 2.276-716-4 3.647-014-00-9 4.Not Available	<0.1	<u>endoproteinase</u> <u>Lys-C</u>	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H317, H319, H334, H335 [1]	Not Available	Not Available
1. 8049-47-6 2.232-468-9 3.Not Available 4.Not Available	<0.1	<u>pancreatin</u>	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H317, H319, H334, H335 [1]	Not Available	Not Available
1. 37288-54-3 2.253-446-5 3.Not Available 4.Not Available	<0.1	<u>mannanase</u>	Sensitisation (Respiratory) Category 1; H334 [1]	Not Available	Not Available
1. 77-92-9 2.201-069-1 3.607-750-00-3 4.Not Available	<0.5	<u>citric acid</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H318, H335 [1]	Not Available	Not Available
1. 151-21-3 2.205-788-1 3. Not Available 4. Not Available	0.1	<u>sodium lauryl sulfate</u>	Flammable Solids Category 1, Acute Toxicity (Oral, Dermal and Inhalation) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H228, H302+H312+H332, H315, H318, H335 [1]	Not Available	Not Available
Legend:		1. Classification by vendor; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties			

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ 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.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

5.2. Special hazards arising from the substrate or mixture

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

Fire Fighting	<ul style="list-style-type: none"> ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear full body protective clothing with breathing apparatus. ▸ Prevent, by any means available, spillage from entering drains or water course. ▸ Use water delivered as a fine spray to control fire and cool adjacent area. ▸ Avoid spraying water onto liquid pools. ▸ 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.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▸ Combustible. ▸ Slight fire hazard when exposed to heat or flame. ▸ Heating may cause expansion or decomposition leading to violent rupture of containers. ▸ On combustion, may emit toxic fumes of carbon monoxide (CO). ▸ May emit acrid smoke. ▸ Mists containing combustible materials may be explosive. <p>Combustion products include: carbon dioxide (CO₂) hydrogen cyanide nitrogen oxides (NO_x) other pyrolysis products typical of burning organic material. May emit corrosive fumes.</p>

SECTION 6 Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▸ Remove all ignition sources. ▸ Clean up all spills immediately. ▸ Avoid breathing vapours and contact with skin and eyes. ▸ Control personal contact with the substance, by using protective equipment. ▸ 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>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. ▸ No smoking, naked lights or ignition sources. ▸ Increase ventilation. ▸ Stop leak if safe to do so. ▸ Contain spill with sand, earth or vermiculite. ▸ Collect recoverable product into labelled containers for recycling. ▸ Absorb remaining product with sand, earth or vermiculite. ▸ Collect solid residues and seal in labelled drums for disposal. ▸ Wash area and prevent runoff into drains. ▸ If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections

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

SECTION 7 Handling and storage

7.1. 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.▸ Avoid smoking, naked lights or ignition sources.▸ 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.▸ 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.
Fire and explosion protection	See section 5
Other information	<ul style="list-style-type: none">▸ Store in original containers.▸ Keep containers securely sealed.▸ No smoking, naked lights or ignition sources.▸ Store in a cool, dry, well-ventilated area.▸ Store away from incompatible materials and foodstuff containers.▸ Protect containers against physical damage and check regularly for leaks.▸ Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none">▸ Metal can or drum▸ Packaging as recommended by manufacturer.▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<p>It is suggested that crystalline proteins are explosive as evidenced by the easily induced shattering of microcrystals. This may be a consequence of the implosive collapse of a metastable ordering of molecules (Bretherick's Handbook of Reactive Chemical Hazards).</p> <p>A study was performed to obtain quantitative data on the nature and yields of oxidation products formed by a prototypic oxidant system (HO• /O2) on small peptides, including Val-Gly-Val-Ala-Pro-Gly. Study results indicated that hydroperoxide formation occurred nonrandomly (Pro > Val > Ala > Gly) and that the formation of hydroperoxide was inversely related to carbonyl yields (both peptide-bound and released). Multiple alcohols were generated at both side-chain and backbone sites. Summation of the product concentrations provided clear evidence for the occurrence of chain reactions in peptides exposed to HO• /O2, with the overall product yields exceeding that of the initial HO• generated.</p> <ul style="list-style-type: none">▸ Avoid reaction with oxidising agents
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available



X — Must not be stored together
0 — May be stored together with specific preventions
+ — May be stored together

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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.

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
orange, sweet, Valencia extract	Dermal 8.89 mg/kg bw/day (Systemic, Chronic) Inhalation 31.1 mg/m³ (Systemic, Chronic) Dermal 185.8 µg/cm² (Local, Acute) <i>Dermal 4.44 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 7.78 mg/m³ (Systemic, Chronic) *</i> <i>Oral 4.44 mg/kg bw/day (Systemic, Chronic) *</i> <i>Dermal 92.9 µg/cm² (Local, Acute) *</i>	5.4 µg/L (Water (Fresh)) 5.77 µg/L (Water - Intermittent release) 0.54 µg/L (Water (Marine)) 1.3 mg/kg sediment dw (Sediment (Fresh Water)) 0.13 mg/kg sediment dw (Sediment (Marine)) 0.261 mg/kg soil dw (Soil) 2.1 mg/L (STP)
2-methyl-4-isothiazolin-3-one	Inhalation 0.02 mg/m³ (Local, Chronic) Inhalation 0.04 mg/m³ (Local, Acute) <i>Oral 0.027 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.02 mg/m³ (Local, Chronic) *</i> <i>Oral 0.053 mg/kg bw/day (Systemic, Acute) *</i> <i>Inhalation 0.04 mg/m³ (Local, Acute) *</i>	3.39 µg/L (Water (Fresh)) 3.39 µg/L (Water - Intermittent release) 3.39 µg/L (Water (Marine)) 0.047 mg/kg soil dw (Soil) 0.23 mg/L (STP)
mannanase	Not Available	55.5 µg/L (Water (Fresh)) 555 µg/L (Water - Intermittent release) 5.55 µg/L (Water (Marine)) 6.64 µg/kg soil dw (Soil) 65000 µg/L (STP)
sodium lauryl sulfate	Dermal 0.625 mg/kg bw/day (Systemic, Chronic) Inhalation 1.102 mg/m³ (Systemic, Chronic) <i>Dermal 0.312 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.272 mg/m³ (Systemic, Chronic) *</i> <i>Oral 0.156 mg/kg bw/day (Systemic, Chronic) *</i>	0.012 mg/L (Water (Fresh)) 0.013 mg/L (Water - Intermittent release) 0.001 mg/L (Water (Marine)) 0.179 mg/kg sediment dw (Sediment (Fresh Water)) 0.018 mg/kg sediment dw (Sediment (Marine)) 0.028 mg/kg soil dw (Soil) 1.35 mg/L (STP)

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

Not Applicable

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
sodium lauryl sulfate	3.9 mg/m3	43 mg/m3	260 mg/m3

Ingredient	Original IDLH	Revised IDLH
lavender oil	Not Available	Not Available
orange, sweet, Valencia extract	Not Available	Not Available
N-bromosaccharin	Not Available	Not Available
coconut oil, potassium salts	Not Available	Not Available
2-methyl-4-isothiazolin-3-one	Not Available	Not Available
endoproteinase Lys-C	Not Available	Not Available
pancreatin	Not Available	Not Available
mannanase	Not Available	Not Available
citric acid	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
sodium lauryl sulfate	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
lavender oil	E	≤ 0.1 ppm
orange, sweet, Valencia extract	E	≤ 0.1 ppm
N-bromosaccharin	E	≤ 0.01 mg/m³
2-methyl-4-isothiazolin-3-one	D	> 0.01 to ≤ 0.1 mg/m³
endoproteinase Lys-C	E	≤ 0.01 mg/m³
pancreatin	E	≤ 0.01 mg/m³
mannanase	C	> 0.1 to ≤ milligrams per cubic meter of air (mg/m³)
citric acid	E	≤ 0.01 mg/m³
sodium lauryl sulfate	E	≤ 0.01 mg/m³

Notes:

Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

CEL Ceiling: 0.00006 mg/m3 (sensitiser)
(compare TLV-C subtilisins; proteolytic enzymes - 100% crystalline)
Exposure at or below the recommended TLV-C is thought to minimise the potential for allergic respiratory sensitization for the majority of immunologically normal persons and to minimise skin irritation and sensitization. TLV compliance is contingent on measurement of workplace air concentrations with a high volume sampler appropriate to capture these proteins for at least 60 minutes.
Although the recommended TLV-C is specifically prescribed for subtilisins, the Chemwatch recommendation (CEL) recognizes that all proteins have the potential to produce allergic responses. It should be noted, however, that proteins are typically poorly absorbed through the skin and after inhalation. Literature reports indicate that protein bioavailability, via the lung, is as low as 2%.
Fragrance substance with is an established contact allergen in humans.
Scientific Committee on Consumer Safety SCCS OPINION on Fragrance allergens in cosmetic products 2012

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.


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

Type of Contaminant:	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

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	<table><tr><td>3: Intermittent, low production.</td><td>3: High production, heavy use</td></tr><tr><td>4: Large hood or large air mass in motion</td><td>4: Small hood-local control only</td></tr></table>	3: Intermittent, low production.	3: High production, heavy use	4: Large hood or large air mass in motion	4: Small hood-local control only	
3: Intermittent, low production.	3: High production, heavy use					
4: Large hood or large air mass in motion	4: Small hood-local control only					
	<p>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.</p>					
8.2.2. Individual protection measures, such as personal protective equipment						
Eye and face protection	<ul style="list-style-type: none">▸ Safety glasses with side shields.▸ Chemical goggles. [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	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. 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> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none">· frequency and duration of contact,· chemical resistance of glove material,· glove thickness and· dexterity <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none">· 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.· 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> <ul style="list-style-type: none">▸ Wear chemical protective gloves, e.g. PVC.▸ Wear safety footwear or safety gumboots, e.g. Rubber					
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 A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

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

* - Continuous Flow ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

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

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	<ul style="list-style-type: none"> ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 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.
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	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. There is a possibility that unintended contact with this product (such as through a cut, needle stick, eye or mucous membrane, or inhalation) could result in allergic or hypersensitivity reactions. Such reactions are more likely following repeated exposures or in persons with a pre-existing allergy to certain proteins. Dusts produced by proteins are capable, under certain conditions, of sensitising workers by virtue of the bodies reaction to foreign proteins. Typical allergic asthma may be rapidly produced after exposure, with symptoms may include chronic cough, sputum production, fever, myalgia, fatigue, airway obstruction; chest radiographs may show a generalised reticulonodular pattern, or basal or apical fibrosis. In addition there may be retrosternal discomfort, headache, stomach-ache and general severe dyspnoea may develop giving a clinical picture similar to that of farmer's lung and allied conditions of extrinsic allergic alveolitis. No irritation is likely after brief skin contact, but prolonged contact in the presence of moisture may result in soreness, redness, inflammation and possible ulceration of the skin. Repeated attacks may lead to permanent impairment of lung function due to fibrotic change.

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	Not Available	Not Available
lavender oil	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
	Oral (Rat) LD50: 4250 mg/kg ^[2]	Skin (rabbit): 500 mg/24h mild
		Skin: adverse effect observed (irritating) ^[1]
orange, sweet, Valencia extract	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
	Oral (Rabbit) LD50: >5000 mg/kg ^[2]	Skin: no adverse effect observed (not irritating) ^[1]
N-bromosaccharin	TOXICITY	IRRITATION
	Not Available	Not Available
coconut oil, potassium salts	TOXICITY	IRRITATION
	Not Available	Not Available
2-methyl-4-isothiazolin-3-one	TOXICITY	IRRITATION
	dermal (rat) LD50: 242 mg/kg ^[1]	Eye: adverse effect observed (irreversible damage) ^[1]
	Inhalation (Rat) LC50: 0.1 mg/4h ^[1]	Skin: adverse effect observed (corrosive) ^[1]
	Oral (Rat) LD50: 120 mg/kg ^[1]	
endoproteinase Lys-C	TOXICITY	IRRITATION
	Not Available	Not Available
pancreatin	TOXICITY	IRRITATION
	Oral (Rat) LD50: >10000 mg/kg ^[2]	Not Available
mannanase	TOXICITY	IRRITATION
	Inhalation (Rat) LC50: >0.45 mg/4h ^[1]	Eye : Mild
	Oral (Rat) LD50: >3320 mg/kg ^[1]	Skin : Mild
citric acid	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit): 0.75 mg/24h-SEVERE
	Oral (Rat) LD50: 3000 mg/kg ^[2]	Skin (rabbit): 500 mg/24h - mild
sodium lauryl sulfate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit):100 mg/24 hr-moderate
	Oral (Rat) LD50: 1288 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Skin (human): 25 mg/24 hr - mild
		Skin: adverse effect observed (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

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Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A prehapten is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems. A prohaptens is a chemical that itself is non- or low-sensitising but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis. It is not always possible to know whether a particular allergen that is not directly reactive acts as a prehapten or as a prohaptens, or both, because air oxidation and bioactivation can often give the same product (geraniol is an example). Some chemicals might act by all three pathways.

Prohaptens

Compounds that are bioactivated in the skin and thereby form haptens are referred to as prohaptens.

In the case of prohaptens, the possibility to become activated is inherent to the molecule and activation cannot be avoided by

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	<p>extrinsic measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Crossreactivity has been shown for certain alcohols and their corresponding aldehydes, i.e. between geraniol and geranial (citral) and between cinnamyl alcohol and cinnamal.</p> <p>The human skin expresses enzyme systems that are able to metabolise xenobiotics, modifying their chemical structure to increase hydrophilicity and allow elimination from the body. Xenobiotic metabolism can be divided into two phases: phase I and phase II. Phase I transformations are known as activation or functionalisation reactions, which normally introduce or unmask hydrophilic functional groups. If the metabolites are sufficiently polar at this point they will be eliminated. However, many phase I products have to undergo subsequent phase II transformations, i.e. conjugation to make them sufficiently water soluble to be eliminated. Although the purpose of xenobiotic metabolism is detoxification, it can also convert relatively harmless compounds into reactive species. Cutaneous enzymes that catalyse phase I transformations include the cytochrome P450 mixed-function oxidase system, alcohol and aldehyde dehydrogenases, monoamine oxidases, flavin-containing monooxygenases and hydrolytic enzymes. Acyltransferases, glutathione S-transferases, UDP-glucuronosyltransferases and sulfotransferases are examples of phase II enzymes that have been shown to be present in human skin. These enzymes are known to catalyse both activating and deactivating biotransformations, but the influence of the reactions on the allergenic activity of skin sensitisers has not been studied in detail. Skin sensitising prohaptens can be recognised and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or in vivo and in vitro studies of sensitisation potential and chemical reactivity.</p> <p>QSAR prediction: The relationships between molecular structure and reactivity that form the basis for structural alerts are based on well established principles of mechanistic organic chemistry. Examples of structural alerts are aliphatic aldehydes (alerting to the possibility of sensitisation via a Schiff base reaction with protein amino groups), and alpha,beta-unsaturated carbonyl groups, C=C-CO- (alerting to the possibility of sensitisation via Michael addition of protein thiol groups). Prediction of the sensitisation potential of compounds that can act via abiotic or metabolic activation (pre- or prohaptens) is more complex compared to that of compounds that act as direct haptens without any activation. The autoxidation patterns can differ due to differences in the stability of the intermediates formed, e.g. it has been shown that autoxidation of the structural isomers linalool and geraniol results in different major haptens/allergens. Moreover, the complexity of the prediction increases further for those compounds that can act both as pre- and prohaptens. In such cases, the impact on the sensitisation potency depends on the degree of abiotic activation (e.g. autoxidation) in relation to the metabolic activation</p>
<p>LAVENDER OIL</p>	<p>For monoterpenes:</p> <p>The chemical category designated terpenoid hydrocarbons includes three simple C10 isomeric monocyclic terpene hydrocarbons (<i>d</i>-limonene, <i>d</i>-limonene, and terpinolene) two simple C10 acyclic terpene hydrocarbons (<i>beta</i>-myrcene and dihydromyrcene) and mixtures composed primarily of <i>d</i>-limonene, <i>d</i>-limonene (dipentene), terpinolene, myrcene, and <i>alpha</i> and <i>beta</i>-pinene. Monoterpene hydrocarbons are mainly released by coniferous woodland such as pine trees, cedars, redwood and firs. To a lesser extent, they are also produced and released by deciduous plants. They are common components of traditional foods occurring in essentially all fruits and vegetables.</p> <p>Members of this chemical category are of very low acute toxicity</p> <p>Studies of terpene hydrocarbons indicate that they are rapidly absorbed, distributed, metabolised and excreted. The principal metabolic pathway involves side chain oxidation to yield monocyclic terpene alcohols and carboxylic acids. These metabolites are mainly conjugated with glucuronic acid and excreted in the urine, or to a lesser extent in the feces. A secondary pathway involves epoxidation of either the exocyclic or endocyclic double bond yielding an epoxide that is subsequently detoxicated via formation of the corresponding diol or conjugation with glutathione. Although some species- and sex-specific differences exist, studies for <i>d</i>-limonene and <i>beta</i>-myrcene indicate that the monoterpene hydrocarbons in this chemical category will participate in common pathways of absorption, distribution, metabolism and excretion.</p> <p>Genotoxicity: Based on the results of this <i>in vivo</i> genotoxicity assay and the numerous <i>in vitro</i> genotoxicity assays, it is unlikely that any of these materials would exhibit a significant genotoxic potential <i>in vivo</i>.</p> <p>Carcinogenicity: Under the conditions of 2-year gavage studies, conducted by NTP, there was clear evidence of carcinogenic activity of <i>d</i>-limonene for male F344/N rats as shown by increased incidences in tubular cell hyperplasia, adenomas, and adenocarcinomas of the kidney. There was no evidence of carcinogenic activity of <i>d</i>-limonene for female rats receiving 300 or 600 mg/kg bw/d. It has been demonstrated that renal lesions, which were observed in the NTP study, resulted from the accumulation of aggregates of <i>alpha</i>-2 microglobulin (a low molecular-weight protein synthesised in the liver) and limonene-1,2-epoxide in the P2 segment of the renal proximal tubule. While humans produce low molecular weight serum proteins, which are reabsorbed by the kidney, there is no evidence that a similar <i>alpha</i>-2 microglobulin is produced.</p> <p>The kidney changes seen in male rats administered limonene have been well characterized, and are known to be specific to the male rat and of no significance in human risk assessment.</p> <p>Reproductive toxicity: Substances within this chemical category exhibit low reproductive toxicity potential. This is based on the results of three reproductive toxicity assays. using sweet orange peel oil predominantly composed of <i>d</i>-limonene and <i>beta</i>-myrcene.</p> <p>Developmental toxicity: Given the results of six developmental toxicity assays using limonene, sweet orange oil and <i>beta</i>-myrcene, it may be concluded that the substances within this chemical category exhibit low developmental toxicity potential</p> <p>Cross-reactivity is also expected between ester derivatives and their parent alcohols, as the esters will be hydrolysed by esterases in the skin. Esters of important contact allergens that can be activated by hydrolysis in the skin are isoeugenol acetate, eugenyl acetate and geranyl acetate all of which are known to be used as fragrance ingredients.</p>
<p>ORANGE, SWEET, VALENCIA EXTRACT</p>	<p>The essential oils, oleoresins (solvent-free), and natural extractives (including distillates) derived from citrus fruits are generally recognized as safe (GRAS) for their intended use in foods for human consumption.</p> <p>Botanicals such as citrus are comprised of hundreds of constituents, some of which have the potential to cause toxic effects; for example, bergapten (aka 5-methoxysporalen or 5-MOP) is a naturally occurring furanocoumarin (psoralen) in bergamot oil that causes phototoxicity. Under the rules governing cosmetic products in the European Union, citrus-derived ingredients must have furocoumarin content below 1 mg/kg in sun-protection and bronzing products.</p> <p>Acute toxicity:</p> <p>The dermal LD50 of undiluted either bitter orange or citrus reticulata (tangerine) leaf oil (described as "petitgrain bigarade oil") was reported as greater than 2000 mg/kg in rabbits. The dermal LD50 of undiluted mandarin peel oil (Citrus reticulata) was greater than 5000 mg/kg in rabbits</p>

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	<p>Dermal irritation: Varying degrees of irritation were observed in animals treated with undiluted citrus aurantium amara (bitter orange) flower wax, unreported concentrations of either bitter orange or citrus reticulata (tangerine) leaf oil (described as "petitgrain bigarade oil"), or unreported concentrations of mandarin peel oil. In human subjects, no irritation was observed after topical exposure to citrus aurantium dulcis (orange) peel wax (100%), bergamot oil (up to 15%), either bitter orange or citrus reticulata (tangerine) leaf oil (described as "petitgrain bigarade oil"; up to 8%), lemon oil (up to 20%), or mandarin peel oil (8%).</p> <p>Ocular irritation: The eye tolerance of citrus aurantium amara (bitter orange) flower wax (> 50%) was tested in vitro using the SIRC cell strain. Tolerance was evaluated by measuring cytotoxicity. Negative controls solutions were physiological serum or sample diluent and the positive control solutions were 0.01% to 0.2% SDS. Negligible cytotoxicity was observed.</p> <p>Sensitisation: Bitter orange or citrus reticulata (tangerine) leaf oil (described as "petitgrain bigarade oil") and mandarin peel oil were not sensitising in human maximization tests. In studies of 250 dermatitis patients, less than 2.5% had positive reactions to bergamot oil, bitter orange oil, lemon oil, or sweet orange oil tested at 2% in paraffin. In a retrospective study (2001-2010) of professional food handlers in Denmark, 8.5% (16/188) of the patients had positive reactions to orange peel and 7.9% (15/191) of the patients had positive reactions to lemon peel</p> <p>Phototoxicity and Photosensitisation: Citrus aurantium dulcis (orange) peel wax (100%) was not photosensitising in a human study. Mixed results were observed in non-human and human phototoxicity and photosensitisation studies of diluted and undiluted bergamot oil, either bitter orange or citrus reticulata (tangerine) leaf oil (described as "petitgrain bigarade oil"), lime oil, lemon oil, lemon fruit and peel juice, grapefruit oil, mandarin oil, tangerine oil, bitter orange oil, bitter orange peel oil, orange peel, orange mesocarp, and orange fruit. Many of the citrus-derived ingredients contain constituents that are photoactive agents, although those noted to be furocoumarin free tended not to induce photosensitisation.</p> <p>Phototoxicity and photosensitisation were noted in several patients exposed to bergamot oil or limes/lime juice</p> <p>Carcinogenicity: Tumour-promoting activity was observed in mouse skin exposed to essential oils of orange (sweet), lemon, grapefruit, or lime. Groups of mice received weekly applications of 0.25 ml of the test substances 3 weeks after the application of 9,10-dimethyl-1,2-benzanthracene (DMBA) a tumour initiator. By the fifth week, papillomas were observed in mice exposed to lemon oil, grapefruit oil, and lime oil. Papillomas were observed in the orange oil group by the 12 th week. After 33 weeks, 10/20 mice in the lemon oil and lime oil treatment groups and 13/20 mice in the grapefruit oil and orange oil groups had papillomas. No malignant skin tumours were observed in the orange oil group: treatment was stopped after 42 weeks. Squamous cell carcinomas of the skin were observed in 2 mice from the lemon oil group and 2 mice of the grapefruit oil group between weeks 36 and 55. Non-dermal tumors during the treatment period were observed in 1 mouse of the orange oil group (a haemangioma of the subcutaneous tissue starting at week 7) and in 1 mouse of the grapefruit oil group (a spindle cell sarcoma of the subcutaneous tissues). No tumours of the internal organs were observed. The survival of all the mice in this experiment was poor due to a very high incidence of renal disease.</p>
<p>N-BROMOSACCHARIN</p>	<p>Acute toxicity data show that 1,2-benzisothiazoline-3-one (BIT) is moderately toxic by the oral and dermal routes but that this chemical is a severe eye irritant. Irritation to the skin from acute data show only mild skin irritation, but repeated dermal application indicated a more significant skin irritation response.</p> <p>The neurotoxicity observed in the rat acute oral toxicity study (piloerection and upward curvature of the spine at 300 mg/kg and above; decreased activity, prostration, decreased abdominal muscle tone, reduced righting reflex, and decreased rate and depth of breathing at 900 mg/kg) and the acute dermal toxicity study (upward curvature of the spine was observed in increased incidence, but this was absent after day 5 post-dose at a dose of 2000 mg/kg) were felt to be at exposures in excess of those expected from the use pattern of this pesticide and that such effects would not be observed at estimated exposure doses.</p> <p>Subchronic oral toxicity studies showed systemic effects after repeated oral administration including decreased body weight, increased incidence of forestomach hyperplasia, and non-glandular stomach lesions in rats. In dogs, the effects occurred at lower doses than in rats, and included alterations in blood chemistry (decreased plasma albumin, total protein, and alanine aminotransferase) and increased absolute liver weight.</p> <p>Developmental toxicity studies were conducted in rats with maternal effects including decreased body weight gain, decreased food consumption, and clinical toxicity signs (audible breathing, haircoat staining of the anogenital region, dry brown material around the nasal area) as well as increased mortality. Developmental effects consisted of increases in skeletal abnormalities (extra sites of ossification of skull bones, unossified sternebrae) but not external or visceral abnormalities.</p> <p>Reproductive toxicity: In a two-generation reproduction study, parental toxicity was observed at 500 ppm and was characterized by lesions in the stomach. In pups, toxic effects were reported at 1000 ppm and consisted of preputial separation in males and impaired growth and survival in both sexes. The reproduction study did not show evidence of increased susceptibility of offspring.</p>
<p>COCONUT OIL, POTASSIUM SALTS</p>	<p>Reproductive effector in mice.</p> <p>For aliphatic fatty acids (and salts)</p> <p>Acute oral (gavage) toxicity: The acute oral LD50 values in rats for both were greater than >2000 mg/kg bw Clinical signs were generally associated with poor condition following administration of high doses (salivation, diarrhoea, staining, piloerection and lethargy). There were no adverse effects on body weight in any study. In some studies, excess test substance and/or irritation in the gastrointestinal tract was observed at necropsy.</p> <p>Skin and eye irritation potential, with a few stated exceptions, is chain length dependent and decreases with increasing chain length</p> <p>According to several OECD test regimes the animal skin irritation studies indicate that the C6-10 aliphatic acids are severely irritating or corrosive, while the C12 aliphatic acid is irritating, and the C14-22 aliphatic acids generally are not irritating or mildly irritating.</p> <p>Human skin irritation studies using more realistic exposures (30-minute, 1-hour or 24-hours) indicate that the aliphatic acids have sufficient, good or very good skin compatibility.</p> <p>Animal eye irritation studies indicate that among the aliphatic acids, the C8-12 aliphatic acids are irritating to the eye while the</p>

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C14-22 aliphatic acids are not irritating.

Eye irritation potential of the ammonium salts does not follow chain length dependence; the C18 ammonium salts are corrosive to the eyes.

Dermal absorption:

The in vitro penetration of C10, C12, C14, C16 and C18 fatty acids (as sodium salt solutions) through rat skin decreases with increasing chain length. At 86.73 µg C16/cm² and 91.84 µg C18/cm², about 0.23% and less than 0.1% of the C16 and C18 soap solutions is absorbed after 24 h exposure, respectively.

Sensitisation:

No sensitisation data were located.

Repeat dose toxicity:

Repeated dose oral (gavage or diet) exposure to aliphatic acids did not result in systemic toxicity with NOAELs greater than the limit dose of 1000 mg/kg bw. .

Mutagenicity

Aliphatic acids do not appear to be mutagenic or clastogenic in vitro or in vivo

Carcinogenicity

No data were located for carcinogenicity of aliphatic fatty acids.

Reproductive toxicity

No effects on fertility or on reproductive organs, or developmental effects were observed in studies on aliphatic acids and the NOAELs correspond to the maximum dose tested. The weight of evidence supports the lack of reproductive and developmental toxicity potential of the aliphatic acids category.

Given the large number of substances in this category, their closely related chemical structure, expected trends in physical chemical properties, and similarity of toxicokinetic properties, both mammalian and aquatic endpoints were filled using read-across to the closest structural analogue, and selecting the most conservative supporting substance effect level.

Structure-activity relationships are not evident for the mammalian toxicity endpoints. That is, the low mammalian toxicity of this category of substances limits the ability to discern structural effects on biological activity. Regardless, the closest structural analogue with the most conservative effect value was selected for read across. Irritation is observed for chain lengths up to a cut-off" at or near 12 carbons).

Metabolism:

The aliphatic acids share a common degradation pathway in which they are metabolized to acetyl-CoA or other key metabolites in all living systems. Common biological pathways result in structurally similar breakdown products, and are, together with the physico-chemical properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.

Differences in metabolism or biodegradability of even and odd numbered carbon chain compounds or saturated/ unsaturated compounds are not expected; even-and odd-numbered carbon chain compounds, and the saturated and unsaturated compounds are naturally occurring and are expected to be metabolized and biodegraded in the same manner.

The acid and alkali salt forms of the homologous aliphatic acid are expected to have many similar physicochemical and toxicological properties when they become bioavailable; therefore, data read across is used for those instances where data are available for the acid form but not the salt, and vice versa. In the gastrointestinal tract, acids and bases are absorbed in the undissociated (non-ionised) form by simple diffusion or by facilitated diffusion. It is expected that both the acids and the salts will be present in (or converted to) the acid form in the stomach. This means that for both aliphatic acid or aliphatic acid salt, the same compounds eventually enter the small intestine, where equilibrium, as a result of increased pH, will shift towards dissociation (ionised form).

Hence, the situation will be similar for compounds originating from acids and therefore no differences in uptake are anticipated

Note that the saturation or unsaturation level is not a factor in the toxicity of these substances and is not a critical component of the read across process..

Toxicokinetics:

The turnover of the [14C] surfactants in the rat showed that there was no significant difference in the rate or route of excretion of 14C given by intraperitoneal or subcutaneous administration. The main route of excretion was as 14CO₂ in the expired air at 6 h after administration. The remaining material was incorporated in the body. Longer fatty acid chains are more readily incorporated than shorter chains. At ca. 1.55 and 1.64 mg/kg bw, 71% of the C16:0 and 56% of the C18:0 was incorporated and 21% and 38% was excreted as 14CO₂, respectively.

Glycidyl fatty acid esters (GEs), one of the main contaminants in processed oils, are mainly formed during the deodorisation step in the refining process of edible oils and therefore occur in almost all refined edible oils. GEs are potential carcinogens, due to the fact that they readily hydrolyze into the free form glycidol in the gastrointestinal tract, which has been found to induce tumours in various rat tissues. Therefore, significant effort has been devoted to inhibit and eliminate the formation of GEs

GEs contain a common terminal epoxide group but exhibit different fatty acid compositions. This class of compounds has been reported in edible oils after overestimation of 3-monochloropropane-1,2-diol (3-MCPD) fatty acid esters analysed by an indirect method, 3-MCPD esters have been studied as food processing contaminants and are found in various food types and food ingredients, particularly in refined edible oils. 3-Monochloropropane-1,2-diol (3-MCPD) and 2-monochloropropane-1,3-diol (2-MCPD) are chlorinated derivatives of glycerol (1,2,3-propanetriol). 3- and 2-MCPD and their fatty acid esters are among non-volatile chloropropanols. Glycidol is associated with the formation and decomposition of 3- and 2-MCPD. It forms monoesters with fatty acids (GE) during the refining of vegetable oils. Chloropropanols are formed in HVP during the hydrochloric acid-mediated hydrolysis step of the manufacturing process. In food production, chloropropanols form from the reaction of endogenous or added chloride with glycerol or acylglycerol.

Although harmful effects on humans and animals have not been demonstrated, the corresponding hydrolysates, 3-MCPD and glycidol, have been identified as rodent genotoxic carcinogens, ultimately resulting in the formation of kidney tumours (3-MCPD) and tumours at other tissue sites (glycidol). Therefore, 3-MCPD and glycidol have been categorised as "possible human carcinogens (group 2B) and "probably carcinogenic to humans (group 2A), respectively, by the International Agency for Research on Cancer (IARC).

Diacylglyceride (DAG) based oils produced by one company were banned from the global market due to "high levels" of GEs.

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Several reports have also suggested that a bidirectional transformation process may occur not only between glycidol and 3-MCPD but also their esterified forms in the presence of chloride ions. The transformation rate of glycidol to 3-MCPD was higher than that of 3-MCPD to glycidol under acidic conditions in the presence of chloride ion.

Precursors of GEs in refined oils have been identified as partial acylglycerols, that is, DAGs and monoacylglycerides (MAGs); however, whether they also originate from triacylglycerides (TAGs) is still a topic of controversial debates. Several authors noted that pure TAGs were stable during heat treatment (such as 235 deg C) for 3 h and were therefore not involved in the formation of GEs. However, experimental results have shown that small amounts of GEs are present in a heat-treated oil model consisting of almost 100% TAGs. The formation of GEs from TAGs can be attributed to the pyrolysis of TAGs to DAGs and MAGs. In contrast, 3-MCPD esters in refined oils can be obtained from TAG. Presently, the mechanism for the formation of GE intermediates and the relationship between GEs and 3-MCPD esters are still unknown.

Fatty acid salts are of low acute toxicity. Their skin and eye irritation potential is chain length dependent and decreases with increasing chain length - they are poorly absorbed through the skin nor are they skin sensitisers. The available repeated dose toxicity data demonstrate the low toxicity of the fatty acids and their salts. Also, they are not considered to be mutagenic, genotoxic or carcinogenic, and are not reproductive or developmental toxicants. Accidental ingestion of fatty acid salt containing detergent products is not expected to result in any significant adverse health effects. This assessment is based on toxicological data demonstrating the low acute oral toxicity of fatty acid salts and the fact that not a single fatality has been reported in the UK following accidental ingestion of detergents containing fatty acid salts. Also in a report published by the German Federal Institute for Health Protection of Consumers and Veterinary Medicine, detergent products were not mentioned as dangerous products with a high incidence of poisoning. The estimated total human exposure to fatty acid salts, from the different exposure scenarios for the handling and use of detergent products containing fatty acid salts, showed a margin of exposure (MOE) of 258,620. This extremely large MOE is large enough to be reassuring with regard to the relatively small variability of the hazard data on which it is based. Also, in the UK, the recommended dietary fatty acid intake by the Department of Health is about 100 g of fatty acids per day or 1.7 g (1700 mg) of fatty acids per kilogram body weight per day. This exposure is several orders of magnitude above that resulting from exposure to fatty acid salts in household cleaning products. Based on the available data, the use of fatty acid salts in household detergent and cleaning products does not raise any safety concerns with regard to consumer

Considered to be a minor sensitiser in Kathon CG (1) (1). Bruze et al - Contact Dermatitis 20: 219-39, 1989
In light of potential adverse effects, and to ensure a harmonised risk assessment and management, the EU regulatory framework for biocides has been established with the objective of ensuring a high level of protection of human and animal health and the environment. To this aim, it is required that risk assessment of biocidal products is carried out before they can be placed on the market. A central element in the risk assessment of the biocidal products are the utilization instructions that defines the dosage, application method and amount of applications and thus the exposure of humans and the environment to the biocidal substance. Humans may be exposed to biocidal products in different ways in both occupational and domestic settings. Many biocidal products are intended for industrial sectors or professional uses only, whereas other biocidal products are commonly available for private use by non-professional users. In addition, potential exposure of non-users of biocidal products (i.e. the general public) may occur indirectly via the environment, for example through drinking water, the food chain, as well as through atmospheric and residential exposure. Particular attention should be paid to the exposure of vulnerable sub-populations, such as the elderly, pregnant women, and children. Also pets and other domestic animals can be exposed indirectly following the application of biocidal products. Furthermore, exposure to biocides may vary in terms of route (inhalation, dermal contact, and ingestion) and pathway (food, drinking water, residential, occupational) of exposure, level, frequency and duration. The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The European Union has reclassified several formaldehyde-releasing agents (FRAs) such as methylenedimorpholine (MBM), oxazolidine (MBO) and hydroxypropylamine (HPT) as category 1B carcinogens. Previously, formaldehyde itself was classed as a carcinogen – but formaldehyde-releasing agents were not. This is no longer the case. Based on this regulation, formulations for which the maximum theoretical concentration of releasable formaldehyde is more than > 1000 ppm (>0.1%), have to be labelled as carcinogenic.

Water mix metalworking fluids are subject to contamination by bacteria and fungi, and the control of this is an essential part of good fluid maintenance. The use of preservatives both within the formulation and tank-side treatment plays a significant contribution in the protection of potentially harmful microbes that could cause health problems for workers. A large proportion of bactericides on the market today are classed as formaldehyde releasing biocides which means that under specific conditions they release small amounts of formaldehyde – this is their mode of action in the presence of bacteria. Although they are effective as a biocide their use may become restricted or unfavourable due to potential changes in legislation. A decision by the ECHA (European Chemicals Agency) was made to re-classify formaldehyde as a category 1b H350 carcinogen and category 2 mutagen in June 2015.

It has also been proposed by the ECHA Risk Assessment Committee (RAC) that formaldehyde release biocides should be classified the same as formaldehyde because formaldehyde is released when these substances come into contact under favorable conditions (i.e. interaction with microorganisms).

Formaldehyde generators (releasers) are often used as preservatives (antimicrobials, biocides, microbiocides). Formaldehyde may be generated following hydrolysis. The most widely used antimicrobial compounds function by releasing formaldehyde once inside the microbe cell. Some release detectable levels of formaldehyde into the air space, above working solutions, especially when pH has dropped.

Many countries are placing regulatory pressure on suppliers and users to replace formaldehyde generators.

Formaldehyde generators are a diverse group of chemicals that can be recognised by a small, easily detachable formaldehyde moiety, prepared by reacting an amino alcohol with formaldehyde ("formaldehyde-condensates"),

There is concern that when formaldehyde-releasing preservatives are present in a formulation that also includes amines, such as triethanolamine (TEA), diethanolamine (DEA), or monoethanolamine (MEA), nitrosamines can be formed,; nitrosamines are carcinogenic substances that can potentially penetrate skin.

One widely-discussed hypothesis states that formaldehyde-condensate biocides, such as triazines and oxazolidines, may cause an imbalance in the microbial flora of in-use metalworking fluids (MWFs).The hypothesis further asserts that this putative

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	<p>microbial imbalance favours the proliferation of certain nontuberculosis mycobacteria (NTM) in MWFs and that the subsequent inhalation of NTM-containing aerosols can cause hypersensitivity pneumonitis (HP), also known as extrinsic allergic alveolitis, in a small percentage of susceptible workers. Symptoms of HP include flu-like illness accompanied by chronic dyspnea, i.e., difficult or laboured respiration</p> <p>According to Annex VI of the Cosmetic Directive 76/768/EC, the maximum authorised concentration of free formaldehyde is 0.2% (2000 ppm). In addition, the provisions of Annex VI state that,</p> <p><i>All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.</i></p> <p>Formaldehyde-releasing preservatives have the ability to release formaldehyde in very small amounts over time. The use of formaldehyde-releasing preservatives ensures that the actual level of free formaldehyde in the products is always very low but at the same time sufficient to ensure absence of microbial growth. The formaldehyde reacts most rapidly with organic and inorganic anions, amino and sulfide groups and electron-rich groups to disrupt metabolic processes, eventually causing death of the organism.</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>
MANNANASE	May be irritating to eye, skin and by inhalation (Genencor MSDS)
CITRIC ACID	<p>for citric acid (and its inorganic citrate salts)</p> <p>Based on many experimental data in animals and on human experience, citric acid is of low acute toxicity. The NOAEL for repeated dose toxicity for rats is 1200 mg/kg/d. The major, reversible (sub)chronic toxic effects seem to be limited to changes in blood chemistry and metal absorption/excretion kinetics. Citric acid is not suspected of being a carcinogen nor a reprotoxic or teratogenic agent. The NOAEL for reproductive toxicity for rats is 2500 mg/kg/d. Further, it is not mutagenic <i>in vitro</i> and <i>in vivo</i>. Also, the sensitising potential is seen as low. In contrast, irritation, in particular of the eyes but also of the respiratory pathways and the skin, is the major toxicological hazard presented by citric acid</p> <p>The CIR Expert Panel (Panel) assessed the safety of citric acid, 12 inorganic citrate salts, and 20 alkyl citrate esters as used in cosmetics, concluding that these ingredients are safe in the present practices of use and concentration. Citric acid is reported to function as a pH adjuster, chelating agent, or fragrance ingredient. Some of the salts are also reported to function as chelating agents, and a number of the citrates are reported to function as skin-conditioning agents but other functions are also reported. The Panel reviewed available animal and clinical data, but because citric acid, calcium citrate, ferric citrate, manganese citrate, potassium citrate, sodium citrate, diammonium citrate, isopropyl citrate, stearyl citrate, and triethyl citrate are generally recognized as safe direct food additives, dermal exposure was the focus for these ingredients in this cosmetic ingredient safety assessment.</p>
SODIUM LAURYL SULFATE	<p>Eye (None) None: None None rabbit None 250 ugSkin (rabbit):25 mg/24 hr-moderate Skin (None) None: None rabbit None 50 mg/24Eye (rabbit) 10: mg-</p> <p>Alkyl sulfates (AS) anionic surfactants are generally classified according to Comité Européen des Agents de Surface et leurs Intermédiaires Organiques (CESIO) as Irritant (Xi) with the risk phrases R38 (Irritating to skin) and R41 (Risk of serious damage to eyes). An exception has been made for C12 AS which is classified as Harmful (Xn) with the risk phrases R22 (Harmful if swallowed) and R38 and R41 (CESIO 2000). AS are not included in Annex 1 of list of dangerous substances of Council Directive 67/548/EEC.</p> <p>AS are readily absorbed from the gastrointestinal tract after oral administration. Penetration of AS through intact skin appears to be minimal. AS are extensively metabolized in various species resulting in the formation of several metabolites. The primary metabolite is butyric acid-4-sulfate. The major site of metabolism is the liver. AS and their metabolites are primarily eliminated via the urine and only minor amounts are eliminated via the faeces. In rats about 70-90% of the dose was eliminated via the urine within 48 hours after oral, intravenous or intraperitoneal administration of 1 mg of AS per rat. The acute toxicity of AS in animals is considered to be low after skin contact or oral intake.</p> <p>For a homologous series of AS (C8 to C16), maximum swelling of stratum corneum (the outermost layer of epidermis) of the skin was produced by the C12 homologue. This is in accordance with the fact that the length of the hydrophobic alkyl chain influences the skin irritation potential. Other studies have shown that especially AS of chain lengths C11, C12 and C13 remove most amino acids and soluble proteins from the skin during washing.</p> <p>Concentrated samples of AS are skin irritants in rabbits and guinea pigs. AS are non-irritant to laboratory animals at a 0.1% concentration. C12 AS is used in research laboratories as a standard substance to irritate skin and has been shown to induce an irritant eczema. AS were found, by many authors, to be the most irritating of the anionic surfactants, although others have judged the alkyl sulfates only as irritant as laurate (fatty acid soap).</p> <p>A structure/effect relationship with regard to the length of the alkyl chain can also be observed on mucous membranes. The maximum eye irritation occurs at chain lengths of C10 to C14 . In acute ocular tests, 10% C12 AS caused corneal damage to the rabbit eyes if not irrigated. Another study showed that a 1.0% aqueous C12 AS solution only had a slight effect on rabbit eyes, whereas 5% C12 AS caused temporary conjunctivitis, and 25% C12 AS resulted in corneal damage.</p> <p>In a 13-week feeding study, rats were fed dietary levels of 0, 40, 200, 1,000 or 5,000 ppm of C12 AS. The only test material related effect observed was an increase in absolute organ weights in the rats fed with the highest concentration which was 5,000 ppm. The organ weights were not further specified and no other abnormalities were found.</p> <p>In a mutagenicity study, rats were fed 1.13 and 0.56% C12 AS in the diet for 90 days. This treatment did not cause chromosomal aberrations in the bone marrow cells.</p> <p>Mutagenicity studies with <i>Salmonella typhimurium</i> strains (Ames test) indicate no mutagenic effects of C12 AS). The available long-term studies in experimental animals (rats and mice) are inadequate to evaluate the carcinogenic potential of AS. However, in studies in which animals were administered AS in the diet at levels of up to 4% AS, there was no indication of increased risk of cancer after oral ingestion.</p> <p>No specific teratogenic effects were observed in rabbits, rats or mice when pregnant animals were dosed with 0.2, 2.0, 300 and 600 mg C12 AS/kg body weight/day by gavage during the most important period of organogenesis (day 6 to 15 of pregnancy for mice and rats and day 6 to 18 of pregnancy for rabbits). Reduced litter size, high incidence of skeletal abnormalities and foetal loss were observed in mice at 600 mg C12 AS/kg/day, a dose level which also caused severe toxic effects in the parent animals in all three species . An aqueous solution of 2% AS was applied (0.1 ml) once daily to the dorsal skin (2 x 3 cm) of pregnant mice from day 1 to day 17 of gestation. A solution of 20% AS was tested likewise from day 1 to day 10 of gestation. The</p>

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mice were killed on days 11 and 18, respectively. A significant decrease in the number of implantations was observed when mice were treated with 20% AS compared to a control group which was dosed with water. No evidence of teratogenic effects was noted.

When aqueous solutions of 2% and 20% AS (0.1 ml) were applied once per day to the dorsal skin (2 x 3 cm) of pregnant ICR/Jc1 mice from day 12 to day 17 of gestation no effects on pregnancy outcome were detected. Treatment with 20% AS resulted in growth retardation of suckling mice, but this effect disappeared after weaning. A 10% AS solution (0.1 ml) was applied twice daily to the dorsal skin (2 x 3 cm) of pregnant ICR/Jc1 mice during the preimplantation period (days 0-3 of gestation). A significant number of embryos collected on day 3 as severely deformed or remained at the morula stage. The number of embryos in the oviducts was significantly greater for the mice dosed with AS as compared to the control mice. No pathological changes were detected in the major organs of the dams

The category consists of alkyl sulfates with a predominantly linear alkyl chain length of C8-C18. Most chemicals of this category are not defined substances, but mixtures of homologues with different alkyl chain lengths (UVCBs). The most important common structural feature of the category members is the presence of a predominantly linear aliphatic hydrocarbon chain with a polar sulfate group, neutralized with a counter ion (i.e., Na⁺, K⁺, NH₄⁺, or an alkanolamine cation). The hydrophobic hydrocarbon chain (with a length between C8 and C18) and the polar sulfate group confer surfactant properties and enable the commercial use of these substances as anionic surfactants. Common physical and biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health. The counter ion will not influence chemical reactivity and classification for the purpose of this assessment is not expected to be affected by the difference in counter ion. In aqueous environments the salts will dissociate, so that the counter ions will not fundamentally alter pathways of tissue disposition, metabolism, excretion, or target organs of toxicity. Accordingly no major differences were found in most of the endpoints between the compounds with different counter ions

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Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.

Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation. The patient's earlier symptoms were verified; breathing through the carbon filter had no protective effect. The symptoms were not transmitted via the olfactory nerve but they may have been induced by trigeminal reflex via the respiratory tract or by the eyes.

Cases of occupational asthma induced by perfume substances such as isoamyl acetate, limonene, cinnamaldehyde and benzaldehyde, tend to give persistent symptoms even though the exposure is below occupational exposure limits. Inhalation intolerance has also been produced in animals. The emissions of five fragrance products, for one hour, produced various combinations of sensory irritation, pulmonary irritation, decreases in expiratory airflow velocity as well as alterations of the functional observational battery indicative of neurotoxicity in mice. Neurotoxicity was found to be more severe after mice were repeatedly exposed to the fragrance products, being four brands of cologne and one brand of toilet water.

Contact allergy to fragrances is relatively common, affecting 1 to 3% of the general population, based on limited testing with eight common fragrance allergens and about 16 % of patients patch tested for suspected allergic contact dermatitis.

Contact allergy to fragrance ingredients occurs when an individual has been exposed, on the skin, to a sufficient degree of fragrance contact allergens. Contact allergy is a life-long, specifically altered reactivity in the immune system. This means that once contact allergy is developed, cells in the immune system will be present which can recognise and react towards the allergen. As a consequence, symptoms, i.e. allergic contact dermatitis, may occur upon re-exposure to the fragrance allergen(s) in question. Allergic contact dermatitis is an inflammatory skin disease characterised by erythema, swelling and vesicles in the acute phase. If exposure continues it may develop into a chronic condition with scaling and painful fissures of the skin. Allergic contact dermatitis to fragrance ingredients is most often caused by cosmetic products and usually involves the face and/or hands. It may affect fitness for work and the quality of life of the individual. Fragrance contact allergy has long been recognised as a frequent and potentially disabling problem. Prevention is possible as it is an environmental disease and if the environment is modified (e.g. by reduced use concentrations of allergens), the disease frequency and severity will decrease. Fragrance contact allergy is mostly non-occupational and related to the personal use of cosmetic products. Allergic contact dermatitis can be severe and widespread, with a significant impairment of quality of life and potential consequences for fitness for work. Thus, prevention of contact sensitisation to fragrances, both in terms of primary prevention (avoiding sensitisation) and secondary prevention (avoiding relapses of allergic contact dermatitis in those already sensitised), is an important objective of public health risk management measure.

Hands: Contact sensitisation may be the primary cause of hand eczema, or may be a complication of irritant or atopic hand eczema. The number of positive patch tests has been reported to correlate with the duration of hand eczema, indicating that long-standing hand eczema may often be complicated by sensitisation. Fragrance allergy may be a relevant problem in patients with hand eczema; perfumes are present in consumer products to which their hands are exposed. A significant relationship between hand eczema and fragrance contact allergy has been found in some studies based on patients investigated for contact allergy. However, hand eczema is a multi-factorial disease and the clinical significance of fragrance contact allergy in (severe) chronic hand eczema may not be clear.

Axillae Bilateral axillary (underarm) dermatitis may be caused by perfume in deodorants and, if the reaction is severe, it may spread down the arms and to other areas of the body. In individuals who consulted a dermatologist, a history of such first-time symptoms was significantly related to the later diagnosis of perfume allergy.

Face Facial eczema is an important manifestation of fragrance allergy from the use of cosmetic products (16). In men, after-shave products can cause an eczematous eruption of the beard area and the adjacent part of the neck and men using wet shaving as opposed to dry have been shown to have an increased risk of being fragrance allergic.

Irritant reactions (including contact urticaria): Irritant effects of some individual fragrance ingredients, e.g. citral are known. Irritant contact dermatitis from perfumes is believed to be common, but there are no existing investigations to substantiate this,

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Many more people complain about intolerance or rashes to perfumes/perfumed products than are shown to be allergic by testing. This may be due to irritant effects or inadequate diagnostic procedures. Fragrances may cause a dose-related contact urticaria of the non-immunological type (irritant contact urticaria). Cinnamal, cinnamic alcohol, and Myroxylon pereirae are well recognised causes of contact urticaria, but others, including menthol, vanillin and benzaldehyde have also been reported. The reactions to Myroxylon pereirae may be due to cinnamates. A relationship to delayed contact hypersensitivity was suggested, but no significant difference was found between a fragrance-allergic group and a control group in the frequency of immediate reactions to fragrance ingredients in keeping with a nonimmunological basis for the reactions seen.

Pigmentary anomalies: The term "pigmented cosmetic dermatitis" was introduced in 1973 for what had previously been known as melanosis faciei feminae when the mechanism (type IV allergy) and causative allergens were clarified. It refers to increased pigmentation, usually on the face/neck, often following sub-clinical contact dermatitis. Many cosmetic ingredients were patch tested at non-irritant concentrations and statistical evaluation showed that a number of fragrance ingredients were associated: jasmine absolute, ylang-ylang oil, cananga oil, benzyl salicylate, hydroxycitronellal, sandalwood oil, geraniol, geranium oil.

Photo-reactions Musk ambrette produced a considerable number of allergic photocontact reactions (in which UV-light is required) in the 1970s and was later banned from use in the EU. Nowadays, photoallergic contact dermatitis is uncommon. Furocoumarins (psoralens) in some plant-derived fragrance ingredients caused phototoxic reactions with erythema followed by hyperpigmentation resulting in Berloque dermatitis. There are now limits for the amount of furocoumarins in fragrance products. Phototoxic reactions still occur but are rare.

General/respiratory: Fragrances are volatile and therefore, in addition to skin exposure, a perfume also exposes the eyes and naso-respiratory tract. It is estimated that 2-4% of the adult population is affected by respiratory or eye symptoms by such an exposure. It is known that exposure to fragrances may exacerbate pre-existing asthma. Asthma-like symptoms can be provoked by sensory mechanisms. In an epidemiological investigation, a significant association was found between respiratory complaints related to fragrances and contact allergy to fragrance ingredients, in addition to hand eczema, which were independent risk factors in a multivariate analysis.

for alkyl sulfates; alkane sulfonates and alpha-olefin sulfonates

Most chemicals of this category are not defined substances, but mixtures of homologues with different alkyl chain lengths. Alpha-olefin sulfonates are mixtures of alkene sulfonate and hydroxyl alkane sulfonates with the sulfonate group in the terminal position and the double bond, or hydroxyl group, located at a position in the vicinity of the sulfonate group.

Common physical and/or biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.

Acute toxicity: These substances are well absorbed after ingestion; penetration through the skin is however poor. After absorption, these chemicals are distributed mainly to the liver.

Acute oral LD50 values of alkyl sulfates in rats and/or mice were (in mg/kg):

C10-; 290-580

C10-16-, and C12-; 1000-2000

C12-14, C12-15, C12-16, C12-18 and C16-18-; >2000

C14-18, C16-18-; >5000

The clinical signs observed were non-specific (piloerection, lethargy, decreased motor activity and respiratory rate, diarrhoea). At necropsy the major findings were irritation of the gastrointestinal tract and anemia of inner organs.

Based on limited data, the acute oral LD50 values of alkane sulfonates and alpha-olefin sulfonates of comparable chain lengths are assumed to be in the same range.

The counter ion does not appear to influence the toxicity in a substantial way.

Acute dermal LD50 values of alkyl sulfates in rabbits (mg/kg):

C12-; 200

C12-13 and C10-16-; >500

Apart from moderate to severe skin irritation, clinical signs included tremor, tonic-clonic convulsions, respiratory failure, and body weight loss in the study with the C12- alkyl sulfate and decreased body weights after administration of the C10-16- alkyl sulfates. No data are available for alkane sulfonates but due to a comparable metabolism and effect concentrations in long-term studies effect concentrations are expected to be in the same range as found for alkyl sulfates.

There are no data available for acute inhalation toxicity of alkyl sulfates, alkane sulfonates or alpha-olefin sulfonates.

In skin irritation tests using rabbits (aqueous solutions, OECD TG 404):

C8-14 and C8-16 (30%), C12-14 (90%), C14-18 (60%)- corrosive

Under occlusive conditions:

C12, and C12-14 (25%), C12-15-, C13-15 and C15-16 (5-7%) - moderate to strong irritants

Comparative studies investigating skin effects like transepidermal water loss, epidermal electrical conductance, skin swelling, extraction of amino acids and proteins or development of erythema in human volunteers consistently showed a maximum of effects with C12-alkyl sulfate, sodium; this salt is routinely used as a positive internal control giving borderline irritant reactions in skin irritation studies performed on humans. As the most irritant alkyl sulfate it can be concluded that in humans 20% is the threshold concentration for irritative effects of alkyl sulfates in general. No data were available with regard to the skin irritation potential of alkane sulfonates. Based on the similar chemical structure they are assumed to exhibit similar skin irritation properties as alkyl sulfates or alpha-olefin sulfonates of comparable chain lengths.

In eye irritation tests, using rabbits, C12-containing alkyl sulfates (>10% concentration) were severely irritating and produced irreversible corneal effects. With increasing alkyl chain length, the irritating potential decreases, and C16-18 alkyl sulfate sodium, at a concentration of 25%, was only a mild irritant.

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Concentrated C14-16- alpha-olefin sulfonates were severely irritating, but caused irreversible effects only if applied as undiluted powder. At concentrations below 10% mild to moderate, reversible effects, were found. No data were available for alkane sulfonates

Alkyl sulfates and C14-18 alpha-olefin sulfonates were not skin sensitisers in animal studies. No reliable data were available for alkane sulfonates. Based on the similar chemical structure, no sensitisation is expected.

However anecdotal evidence suggests that sodium lauryl sulfate causes pulmonary sensitisation resulting in hyperactive airway dysfunction and pulmonary allergy accompanied by fatigue, malaise and aching. Significant symptoms of exposure can persist for more than two years and can be activated by a variety of non-specific environmental stimuli such as a exhaust, perfumes and passive smoking.

Absorbed sulfonates are quickly distributed through living systems and are readily excreted. Toxic effects may result from the effects of binding to proteins and the ability of sulfonates to translocate potassium and nitrate (NO₃-) ions from cellular to interstitial fluids. Airborne sulfonates may be responsible for respiratory allergies and, in some instances, minor dermal allergies. Repeated skin contact with some sulfonated surfactants has produced sensitisation dermatitis in predisposed individuals

Repeat dose toxicity: After repeated oral application of alkyl sulfates with chain lengths between C12 and C18, the liver was the only target organ for systemic toxicity. Adverse effects on this organ included an increase in liver weight, enlargement of liver cells, and elevated levels of liver enzymes. The LOAEL for liver toxicity (parenchymal hypertrophy and an increase in comparative liver weight) was 230 mg/kg/day (in a 13 week study with C16-18 alkyl sulfate, sodium). The lowest NOAEL in rats was 55 mg/kg/day (in a 13 week study with C12-alkyl sulfate, sodium).

C14- and C14-16-alpha-olefin sulfonates produced NOAELs of 100 mg/kg/day (in 6 month- and 2 year studies). A reduction in body weight gain was the only adverse effect identified in these studies.

No data were available with regard to the repeated dose toxicity of alkane sulfonates. Based on the similarity of metabolic pathways between alkane sulfonates, alkyl sulfates and alkyl-olefin sulfonates, the repeated dose toxicity of alkane sulfonates is expected to be similar with NOAEL and LOAEL values in the same range as for alkyl sulfates and alpha-olefin sulfonates, i.e. 100 and 200-250 mg/kg/day, respectively, with the liver as potential target organ.

Genotoxicity: Alkyl sulfates of different chain lengths and with different counter ions were not mutagenic in standard bacterial and mammalian cell systems both in the absence and in the presence of metabolic activation. There was also no indication for a genotoxic potential of alkyl sulfates in various in vivo studies on mice (micronucleus assay, chromosome aberration test, and dominant lethal assay).

alpha-Olefin sulfonates were not mutagenic in the Ames test, and did not induce chromosome aberrations in vitro. No genotoxicity data were available for alkane sulfonates. Based on the overall negative results in the genotoxicity assays with alkyl sulfates and alpha-olefin sulfonates, the absence of structural elements indicating mutagenicity, and the overall database on different types of sulfonates, which were all tested negative in mutagenicity assays, a genotoxic potential of alkane sulfonates is not expected.

Carcinogenicity: Alkyl sulfates were not carcinogenic in feeding studies with male and female Wistar rats fed diets with C12-15 alkyl sulfate sodium for two years (corresponding to doses of up to 1125 mg/kg/day).

alpha-Olefin sulfonates were not carcinogenic in mice and rats after dermal application, and in rats after oral exposure.

No carcinogenicity studies were available for the alkane sulfonates.

Reproductive toxicity: No indication for adverse effects on reproductive organs was found in various oral studies with different alkyl sulfates. The NOAEL for male fertility was 1000 mg/kg/day for sodium dodecyl sulfate. In a study using alpha-olefin sulfonates in male and female rats, no adverse effects were identified up to 5000 ppm.

Developmental toxicity: In studies with various alkyl sulfates (C12 up to C16-18- alkyl) in rats, rabbits and mice, effects on litter parameters were restricted to doses that caused significant maternal toxicity (anorexia, weight loss, and death).

The principal effects were higher foetal loss and increased incidences of total litter losses. The incidences of malformations and visceral and skeletal anomalies were unaffected apart from a higher incidence of delayed ossification or skeletal variation in mice at > 500 mg/kg bw/day indicative of a delayed development. The lowest reliable NOAEL for maternal toxicity was about 200 mg/kg/day in rats, while the lowest NOAELs in offspring were 250 mg/kg/day in rats and 300 mg/kg/day for mice and rabbits. For alpha-olefin sulfonates (C14-16-alpha-olefin sulfonate, sodium) the NOAEL was 600 mg/kg/day both for maternal and developmental toxicity.

No data were available for the reproductive and developmental toxicity of alkane sulfonates. Based on the available data, the similar toxicokinetic properties and a comparable metabolism of the alkyl sulfates and alkane sulfonates, alkane sulfonates are not considered to be developmental toxicants.

Although the database for category members with C<12 is limited, the available data are indicating no risk as the substances have comparable toxicokinetic properties and metabolic pathways. In addition, longer-term studies gave no indication for adverse effects on reproductive organs with different alkyl sulfates

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ORANGE, SWEET,
VALENCIA EXTRACT &
N-BROMOSACCHARIN &
2-METHYL-
4-ISOTHIAZOLIN-3-ONE &
ENDOPROTEINASE LYS-C
& PANCREATIN**

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.

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<p>LAVENDER OIL & ORANGE, SWEET, VALENCIA EXTRACT & N-BROMOSACCHARIN & 2-METHYL- 4-ISOTHIAZOLIN-3-ONE & ENDOPROTEINASE LYS-C & PANCREATIN & CITRIC ACID & SODIUM LAURYL SULFATE</p>	<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>
<p>LAVENDER OIL & ORANGE, SWEET, VALENCIA EXTRACT & N-BROMOSACCHARIN & COCONUT OIL, POTASSIUM SALTS & 2-METHYL- 4-ISOTHIAZOLIN-3-ONE & ENDOPROTEINASE LYS-C & MANNANASE</p>	<p>No significant acute toxicological data identified in literature search.</p>
<p>LAVENDER OIL & ORANGE, SWEET, VALENCIA EXTRACT</p>	<p>For linalool: Linalool gradually breaks down when in contact with oxygen, forming an oxidized by-product that may cause allergic reactions such as eczema in susceptible individuals. Between 5 and 7% of patients undergoing patch testing in Sweden were found to be allergic to the oxidized form of linalool.[Linalool has an acute oral mammalian LD50 close to 3,000 mg/kg bw; the acute dermal toxicity is ~ 2,000 mg/kg bw. After inhalation exposure of mice and man, slight sedative effects were observed; however a dose response characteristic could not be determined. Linalool is irritating to the skin, based on animal studies, and is a mild irritant from human experience. It may be moderately irritant to the eyes at the same concentration where it produces nasal pungency. Linalool is considered not to be a sensitiser. The incidence of dermal reaction to linalool is below 1% in naïve probands (not knowingly pre-sensitised) while in subjects pre-sensitised to fragrances it is up to 10%. In a 28-day oral rat study (72.9% linalool) findings were increased liver and kidney weight, thickened liver lobes and pale areas on the kidneys and in females only hepatocellular cytoplasmic vacuolisation. Other findings were related to local irritation of the gastro-intestinal tract. Based on the effects on liver and kidney a NOAEL of 160 mg/kg bw/d (equivalent to 117 mg/kg bw/d linalool) was derived. In this study no effects on male and female gonads were found. Linalool was not mutagenic in seven out of eight bacterial tests nor in two (one <i>in vitro</i> and one <i>in vivo</i>) mammalian tests; the one positive bacterial result is estimated to be a chance event. Linalool (72.9%) was tested in a reproduction screening test (non-OECD). The NOAEL for maternal toxicity based on clinical signs and effects on body weight and food consumption was 500 mg/kg bw/d (equivalent to 365 mg/kg bw/d linalool). The NOAEL on reproduction toxicity and developmental toxicity is 500 mg/kg bw/d (equivalent to 365 mg/kg bw linalool), based on the decreased litter size at birth and pup morbidity/mortality thereafter. Linalool seems not to be an immunotoxicant according to one animal study. For terpenoid tertiary alcohols and their related esters: Substances assigned to this category, as part of the HPV Challenge Program, possess close structural relationships, similar physicochemical properties and participate in the same pathways of metabolic detoxification and have similar toxicologic potential. Acute Toxicity: Oral and dermal LD50 values for members of this chemical category indicate a low order of both oral and dermal toxicity. All rabbit dermal, and mouse and rat oral LD50 values exceed 2000 mg/kg with the majority of values greater than 5000 mg/kg Repeat dose toxicity: In a safety evaluation study, a 50/50 mixture of linalool and citronellol was fed to male and female rats (number and strain not specified) in the diet. The daily intake was calculated to be 50 mg/kg bw of each. Measurements of haematology, clinical chemistry, and urinalysis at weeks 6 and 12 showed no statistically significant differences between test and control groups. Histopathology revealed no dose-related lesions. A slight retardation of growth was observed in males only, but was concluded by the authors to be biologically insignificant Reproductive toxicity: Four groups of 10 virgin CrI CD rats were administered 0,250,500, or 1000 mg/kg bw of an essential oil (coriander oil) known to contain 73% linalool by mass. The test material was given by gavage once daily, 7 days prior to cohabitation, through cohabitation (maximum of 7 days), gestation, delivery, and a 4-day post-parturition period. The duration of the study was 39 days. Maternal effects reported included increased body weight and increased food consumption at 250 mg/kg/d, a non-statistically significant decrease in body weight and food consumption and decreased gestation index and decreased length of gestation at 500 mg/kg/d, and a statistically significant decrease in body weight and food consumption, statistically significant decrease in gestation index, length of gestation, and litter size at 1000 mg/kg/d. The only effect on pups was a decrease in viability of pups at the highest dose level. The authors concluded that there were no effects observed in the dams at the low dose of 250 mg/kg bw/d or in the offspring at the 250 and 500 mg/kg bw/d levels. The authors concluded that the maternal NOAEL was 250 mg/kg/d and the developmental NOAEL was 500 mg/kg/d. Four groups of 10 virgin CrI CD rats were administered 0,375,750, or 1500 mg/kg bw of an essential oil (cardamom oil) known to contain greater than 65 % tertiary terpenoid alcohols with 5 1% alpha-terpineol acetate by mass. Maternal observations included a non-statistically significant decrease in body weight gain and food consumption at 375 mg/kg/d. Mortality, clinical signs, a statistically significant decrease in body weight gain and food consumption, and gross lesions at necropsy were seen at 750 and 1500 mg/kg/d. The only effects on pups were a reduced body weight gain in pups at 750 and 1500 mg/kg/d and increased mortality at 1500 mg/kg/d. The authors concluded that there were no significant adverse effects in the dams or offspring at the 375 mg/kg/d dose. A maternal NOEL was reported to be less than 375 mg/kg/d based on reduced body weight gain and food consumption at 375 mg/kg/d and a developmental NOAEL was reported to be 375 mg/kg/d Developmental toxicity: A range finding study and follow-up teratology study was performed with pine oil. Pregnant CrI:CD(SD)</p>

BR rats were given 0, 50, 100, 500, 750, or 1000 mg/kg/d by gavage in corn oil on days 6 to 20 of gestation. Laparotomies were performed, corpora lutea were counted, and the uterus of each rat was removed, weighed and then examined for number, placement and viability of implantations. Live fetuses were weighed, sexed and gross external alterations were identified. There were no deaths or abortions during the course of this study. Necropsy revealed no gross lesions. Maternal effects included local alopecia, decreased body weight gain and food consumption for the 3 highest dose levels. At 750 and 1000 mg/kg, average gravid uterine weight was reduced. In fetuses, decreased body weight was observed at dose levels of 100 mg/kg and above, and at dose levels of 500 and above there was a slight increase in average number of resorptions/litter.

In the follow-up teratology study, pregnant Crl:CD(SD) BR rats were given 0, 50, 600, or 1200 mg/kg/d by gavage in corn oil on days 6 to 20 of gestation. Six of the 25 rats in 1200 mg/kg dose group died and necropsies revealed that adrenal weights were significantly increased in these rats. At 1200 mg/kg/d, fetuses exhibited increased incidences of delayed ossification, delayed brain development, decreased weights, increased embryo-foetal mortality, and sunken eye bulge with associated soft and hard tissue findings, a dose that also resulted in maternal death and a low incidence of embryo-foetal death (resorption). The maternal and developmental NOEL for pine oil was greater than 50 mg/kg/d but less than 600 mg/kg/d.

Genotoxicity: Mutagenicity/genotoxicity testing has been performed on six members of this chemical category, including a complete battery of in vitro genotoxicity tests using linalool. In nineteen separate in vitro tests on the mutagenicity and genotoxicity of terpenoid tertiary alcohols and related esters, all but two were negative. One of the positive results for linalool was observed in a rec assay using differences in growth rates in two strains of *Bacillus subtilis* as a measure of DNA changes. In contrast, no evidence of mutagenicity was observed in the same test at a higher concentration nor was DNA damage observed in a rat hepatocyte UDS assay. The authors of the mouse lymphoma assay which gave a weak positive result for linalool, emphasized that positive results in this assay are commonly observed for polar substances in the absence of S-9 and may be associated with changes in physiologic culture conditions (pH and osmolality).

Based on a weight of evidence evaluation of the available in vitro and in vivo mutagenicity and genotoxicity assays on terpenoid tertiary alcohols and related esters, this group of flavouring substances would not be expected to exhibit a low genotoxic potential in vivo.

Metabolic fate: Based on the results of hydrolysis, the reactivity of linalool in aqueous media, and data on metabolism it is concluded that members of this chemical category exhibit similar chemical and biochemical fate. The esters are readily hydrolyzed to the corresponding alcohols, linalool and alpha-terpineol. Linalool is then partially converted to alpha-terpineol mainly under acidic conditions. Alicyclic and aliphatic tertiary alcohols are efficiently detoxicated by two principal pathways: conjugation primarily with glucuronic acid and excretion primarily in urine, and omega-oxidation to eventually yield diacids and their reduced or hydrated analogs. These polar metabolites will be efficiently excreted primarily in the urine either unchanged or as the glucuronic acid conjugates. The physicochemical and toxicological properties of these substances are consistent with their known reactivity and common metabolic fate.

Esters belonging to this category can be hydrolysed to their corresponding terpenoid alcohol and organic acid. Hydrolysis can also be catalysed by a class of esters known as carboxylesterases or B-type esterases that predominated in hepatocytes. Esters of tertiary terpenoid alcohols are readily hydrolyzed in animals, including fish. Once hydrolysed, the resulting alcohols undergo excretion unchanged or as the glucuronic acid conjugate. To a minor extent, CYP-450 mediated oxidation at the omega or omega-1 position yields polar oxidized metabolites capable of excretion primarily in the urine. Terpenoid alcohols formed in the gastrointestinal tract are readily absorbed. During hydrolysis under acidic condition cyclisation may occur.

In humans and animals, terpenoid tertiary alcohols primarily conjugate with glucuronic acid and are excreted in the urine and feces. Terpenoid alcohols with unsaturation may also undergo allylic oxidation to form polar diol metabolites that may be excreted either free or conjugated. If the diol contains a primary alcohol function, it may undergo further oxidation to the corresponding carboxylic acid. In a minor pathway, the endocyclic alkene of alpha-terpineol is epoxidised and then hydrolyzed to yield a triol metabolite 1,2,8-trihydroxy--p-menthane which also has been reported in humans following inadvertent oral ingestion of a pine oil disinfectant containing alpha-terpineol.

Bicyclic tertiary alcohols are conjugated with glucuronic acid and excreted primarily in the urine. In rabbits the structurally related bicyclic tertiary alcohols thujyl alcohol (4-methyl-1-(1-methylethyl)bicyclo[3.1.0]-hexan-3-ol) and beta-santenol (2,3,7-trimethylbicyclo[2.2.1]-heptan-2-ol) are conjugated with glucuronic acid. In a metabolism study using the terpenoid tertiary alcohol trans-sobrerol, in humans, dogs, and rats, ten metabolites were isolated in urine, eight of which were characterised in humans. Two principle modes of metabolism were observed, allylic oxidation of the ring positions and alkyl substituents, and conjugation of the tertiary alcohol fractions with glucuronic acid. These metabolic patterns are common modes of converting tertiary and secondary terpenoid alcohols to polar metabolites, which are easily excreted in the urine and faeces. Menthol forms similar conjugation products in rats.

Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A **prehapten** is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems.

In the case of prehapten, it is possible to prevent activation outside the body to a certain extent by different measures, e.g. prevention of air exposure during handling and storage of the ingredients and the final product, and by the addition of suitable antioxidants. When antioxidants are used, care should be taken that they will not be activated themselves and thereby form new sensitisers.

Prehapten

Most terpenes with oxidisable allylic positions can be expected to autoxidise on air exposure due to their inherent properties. Depending on the stability of the oxidation products that are formed, a difference in the sensitisation potency of the oxidised terpenes can be seen.

Autoxidation is a free radical chain reaction in which hydrogen atom abstraction in combination with addition of oxygen forms peroxy radicals. The reaction shows selectivity for positions where stable radicals can be formed. So far, all fragrance substances that have been investigated with regard to the influence of autoxidation on the allergenic potential, including identification of formed oxidation products, have oxidisable allylic positions that are able to form hydroperoxides and/or hydrogen peroxide as primary oxidation products upon air exposure. Once the hydroperoxides have been formed outside the skin they form specific antigens and act as skin sensitisers. Secondary oxidation products such as aldehydes and epoxides can also be allergenic, thus further increasing the sensitisation potency of the autoxidation mixture. The process of photoactivation may also play a role, but further research is required to establish whether this activation route is currently underestimated in importance.

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due to insufficient knowledge of the true haptens in this context.

It should be noted that activation of substances via air oxidation results in various haptens that might be the same or cross-reacting with other haptens (allergens). The main allergens after air oxidation of linalool and linalyl acetate are the hydroperoxides. If linalyl acetate is chemically hydrolysed outside the skin it can thereafter be oxidised to the same haptens as seen for linalool. A corresponding example is citronellol and citronellyl acetate. In clinical studies, concomitant reactions to oxidised linalool and oxidised linalyl acetate have been observed. Whether these reactions depend on cross-reactivity or are due to exposure to both fragrance substances cannot be elucidated as both have an allergenic effect themselves. Linalool and linalyl acetate are the main components of lavender oil. They autoxidise on air exposure also when present in the essential oil, and form the same oxidation products found in previous studies of the pure synthetic terpenes. Experimental sensitisation studies showed that air exposure of lavender oil increased the sensitisation potency. Patch test results in dermatitis patients showed a connection between positive reactions to oxidised linalool, linalyl acetate and lavender oil.

Prohaptens

Compounds that are bioactivated in the skin and thereby form haptens are referred to as prohaptens.

In the case of prohaptens, the possibility to become activated is inherent to the molecule and activation cannot be avoided by extrinsic measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Crossreactivity has been shown for certain alcohols and their corresponding aldehydes, i.e. between geraniol and geranial (citral) and between cinnamyl alcohol and cinnamal.

The human skin expresses enzyme systems that are able to metabolise xenobiotics, modifying their chemical structure to increase hydrophilicity and allow elimination from the body. Xenobiotic metabolism can be divided into two phases: phase I and phase II. Phase I transformations are known as activation or functionalisation reactions, which normally introduce or unmask hydrophilic functional groups. If the metabolites are sufficiently polar at this point they will be eliminated. However, many phase I products have to undergo subsequent phase II transformations, i.e. conjugation to make them sufficiently water soluble to be eliminated. Although the purpose of xenobiotic metabolism is detoxification, it can also convert relatively harmless compounds into reactive species. Cutaneous enzymes that catalyse phase I transformations include the cytochrome P450 mixed-function oxidase system, alcohol and aldehyde dehydrogenases, monoamine oxidases, flavin-containing monooxygenases and hydrolytic enzymes. Acyltransferases, glutathione S-transferases, UDP-glucuronosyltransferases and sulfotransferases are examples of phase II enzymes that have been shown to be present in human skin. These enzymes are known to catalyse both activating and deactivating biotransformations, but the influence of the reactions on the allergenic activity of skin sensitisers has not been studied in detail. Skin sensitising prohaptens can be recognised and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or in vivo and in vitro studies of sensitisation potential and chemical reactivity.

QSAR prediction: The relationships between molecular structure and reactivity that form the basis for structural alerts are based on well established principles of mechanistic organic chemistry. Examples of structural alerts are aliphatic aldehydes (alerting to the possibility of sensitisation via a Schiff base reaction with protein amino groups), and alpha,beta-unsaturated carbonyl groups, C=C-CO- (alerting to the possibility of sensitisation via Michael addition of protein thiol groups). Prediction of the sensitisation potential of compounds that can act via abiotic or metabolic activation (pre- or prohaptens) is more complex compared to that of compounds that act as direct haptens without any activation. The autoxidation patterns can differ due to differences in the stability of the intermediates formed, e.g. it has been shown that autoxidation of the structural isomers linalool and geraniol results in different major haptens/allergens. Moreover, the complexity of the prediction increases further for those compounds that can act both as pre- and prohaptens. In such cases, the impact on the sensitisation potency depends on the degree of abiotic activation (e.g. autoxidation) in relation to the metabolic activation.

d-Limonene is readily absorbed by inhalation and ingestion. Dermal absorption is reported to be lower than by the inhalation route. d-Limonene is rapidly distributed to different tissues in the body, readily metabolised and eliminated primarily through the urine.

Limonene exhibits low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans. Limited data are available on the potential to cause eye and respiratory irritation. Autooxidised products of d-limonene have the potential to be skin sensitisers. Limited data are available in humans on the potential to cause respiratory sensitisation. Autooxidation of limonene occurs readily in the presence of light and air forming a variety of oxygenated monocyclic terpenes.

Risk of skin sensitisation is high in situations where contact with oxidation products of limonene occurs.

Renal tumours induced by limonene in male rats is thought to be sex and species specific and are not considered relevant to humans. Repeated exposure affects the amount and activity of liver enzymes, liver weight, blood cholesterol levels and bile flow in animals. Increase in liver weight is considered a physiological adaption as no toxic effects on the liver have been reported. From available data it is not possible to identify an NOAEL for these effects. Limonene is neither genotoxic or teratogenic nor toxic to the reproductive system.

<p>2-METHYL-4-ISOTHIAZOLIN-3-ONE & SODIUM LAURYL SULFATE</p>	<p>Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies with similar materials using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.</p>
<p>2-METHYL-4-ISOTHIAZOLIN-3-ONE & CITRIC ACID</p>	<p>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.</p>
<p>ENDOPROTEINASE LYS-C & PANCREATIN & MANNANASE</p>	<p>Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive. Factors which increase the sensitivity of the mucosa may play a role in predisposing a person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens). Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated</p>

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reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.

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

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Pressed to Fresh Bed & Mattress Freshener	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
lavender oil	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
orange, sweet, Valencia extract	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	0.45mg/l	2
	EC50	72h	Algae or other aquatic plants	0.36mg/l	2
	EC50(ECx)	72h	Algae or other aquatic plants	0.36mg/l	2
	LC50	96h	Fish	0.32mg/l	2
N-bromosaccharin	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
coconut oil, potassium salts	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
2-methyl-4-isothiazolin-3-one	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	0.189-0.257mg/L	4
	EC50	96h	Algae or other aquatic plants	0.061mg/L	2
	EC50	72h	Algae or other aquatic plants	0.057mg/L	2
	LC50	96h	Fish	0.081-0.122mg/L	4
	NOEC(ECx)	96h	Algae or other aquatic plants	0.01mg/l	2
endoproteinase Lys-C	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
pancreatin	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

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mannanase	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	>105.8mg/l	2
	EC50	72h	Algae or other aquatic plants	>105.8mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	26.5mg/l	2
	LC50	96h	Fish	>105.8mg/l	2
citric acid	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	>50mg/l	2
	EC50	72h	Algae or other aquatic plants	990mg/l	2
	EC50(ECx)	48h	Crustacea	>50mg/l	2
	LC50	96h	Fish	>100mg/l	2
sodium lauryl sulfate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	0.939mg/l	1
	EC50	72h	Algae or other aquatic plants	4.8mg/l	2
	EC50	96h	Algae or other aquatic plants	0.4-3.7mg/l	4
	EC0(ECx)	72h	Algae or other aquatic plants	30mg/l	1
	LC50	96h	Fish	0.59mg/l	4
Legend: <i>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</i>					

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

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

Terrestrial Fate: Anionic surfactants are not appreciably sorbed by inorganic solids. Cationic surfactants are strongly sorbed by solids, particularly clays. Significant sorption of anionic and non-ionic surfactants has been observed in activated sludge and organic river sediments. Surfactants have been shown to improve water infiltration into soils with moderate to severe hydrophobic or water-repellent properties.

Ecotoxicity: Some surfactants are known to be toxic to animals, ecosystems and humans, and can increase the diffusion of other environmental contaminants. The acute aquatic toxicity generally is considered to be related to the effects of the surfactant properties on the organism and not to direct chemical toxicity. Surfactants should be considered to be toxic to aquatic species under conditions that allow contact of the chemicals with the organisms. Surfactants are expected to transfer slowly from water into the flesh of fish. During this process, readily biodegradable surfactants are expected to be metabolized rapidly during the process of bioaccumulation. Surfactants are not to be considered to show bioaccumulation potential if they are readily biodegradable.

Proteins are generally easily biodegradable.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
orange, sweet, Valencia extract	HIGH	HIGH
2-methyl-4-isothiazolin-3-one	HIGH	HIGH
citric acid	LOW	LOW
sodium lauryl sulfate	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
orange, sweet, Valencia extract	HIGH (LogKOW = 5.6842)
2-methyl-4-isothiazolin-3-one	LOW (LogKOW = -0.8767)
citric acid	LOW (LogKOW = -1.64)
sodium lauryl sulfate	LOW (BCF = 7.15)

12.4. Mobility in soil

Ingredient	Mobility
orange, sweet, Valencia extract	LOW (Log KOC = 2899)
2-methyl-4-isothiazolin-3-one	LOW (Log KOC = 27.88)
citric acid	LOW (Log KOC = 10)
sodium lauryl sulfate	LOW (Log KOC = 10220)

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12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✗	✗	✗
vPvB	✗	✗	✗
PBT Criteria fulfilled?	No		
vPvB	No		

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

One or more ingredients within this SDS has the potential of causing ozone depletion and/or photochemical ozone creation.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	<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 or consult manufacturer for recycling options. ▸ Consult State Land Waste Authority for disposal. ▸ Bury or incinerate residue at an approved site. ▸ Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number or ID number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Class	Not Applicable
	Subsidiary Hazard	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	

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14.6. Special precautions for user	Hazard identification (Kemler)	Not Applicable
	Classification code	Not Applicable
	Hazard Label	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Tunnel Restriction Code	Not Applicable

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	ICAO/IATA Class	Not Applicable
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Special provisions	Not Applicable
	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	IMDG Class	Not Applicable
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	EMS Number	Not Applicable
	Special provisions	Not Applicable
	Limited Quantities	Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Not Applicable	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable

	Equipment required	Not Applicable
	Fire cones number	Not Applicable

14.7. Maritime transport in bulk according to IMO instruments

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
lavender oil	Not Available
orange, sweet, Valencia extract	Not Available
N-bromosaccharin	Not Available
coconut oil, potassium salts	Not Available
2-methyl-4-isothiazolin-3-one	Not Available
endoproteinase Lys-C	Not Available
pancreatin	Not Available
mannanase	Not Available
citric acid	Not Available
sodium lauryl sulfate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
lavender oil	Not Available
orange, sweet, Valencia extract	Not Available
N-bromosaccharin	Not Available
coconut oil, potassium salts	Not Available
2-methyl-4-isothiazolin-3-one	Not Available
endoproteinase Lys-C	Not Available
pancreatin	Not Available
mannanase	Not Available
citric acid	Not Available
sodium lauryl sulfate	Not Available

SECTION 15 Regulatory information

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

lavender oil is found on the following regulatory lists

Europe EC Inventory
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

orange, sweet, Valencia extract is found on the following regulatory lists

Europe EC Inventory
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

N-bromosaccharin is found on the following regulatory lists

Europe EC Inventory
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

coconut oil, potassium salts is found on the following regulatory lists

Europe EC Inventory
European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

2-methyl-4-isothiazolin-3-one is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

endoproteinase Lys-C is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

pancreatin is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

mannanase is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

citric acid is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

sodium lauryl sulfate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category	Not Available
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15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (N-bromosaccharin; endoproteinase Lys-C)
Canada - DSL	No (N-bromosaccharin; endoproteinase Lys-C; pancreatin)
Canada - NDSL	No (lavender oil; orange, sweet, Valencia extract; N-bromosaccharin; 2-methyl-4-isothiazolin-3-one; endoproteinase Lys-C; pancreatin; citric acid)
China - IECSC	No (N-bromosaccharin; endoproteinase Lys-C)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (lavender oil; orange, sweet, Valencia extract; N-bromosaccharin; endoproteinase Lys-C; pancreatin; mannanase)
Korea - KECI	No (N-bromosaccharin; endoproteinase Lys-C)
New Zealand - NZIoC	No (N-bromosaccharin; endoproteinase Lys-C)
Philippines - PICCS	No (N-bromosaccharin; endoproteinase Lys-C)
USA - TSCA	No (orange, sweet, Valencia extract; N-bromosaccharin; endoproteinase Lys-C)
Taiwan - TCSI	Yes
Mexico - INSQ	No (lavender oil; N-bromosaccharin; coconut oil, potassium salts; endoproteinase Lys-C; mannanase)
Vietnam - NCI	No (N-bromosaccharin; endoproteinase Lys-C)
Russia - FBEPH	No (N-bromosaccharin; coconut oil, potassium salts; endoproteinase Lys-C)

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

SECTION 16 Other information

Revision Date	01/12/2023
Initial Date	01/12/2023

Full text Risk and Hazard codes

H226	Flammable liquid and vapour.
H228	Flammable solid.
H301	Toxic if swallowed.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Other information

Ingredients with multiple cas numbers

Name	CAS No
lavender oil	8000-28-0, 8016-78-2, 97722-12-8
orange, sweet, Valencia extract	97766-30-8, 8028-48-6
coconut oil, potassium salts	61789-30-8, 68783-34-6, 769136-44-9
2-methyl-4-isothiazolin-3-one	2682-20-4, 125794-71-0, 1610617-47-4, 184720-17-0
citric acid	77-92-9, 1192555-95-5, 12262-73-6, 136108-93-5, 245654-34-6, 43136-35-2, 623158-96-3, 856568-15-5, 878903-72-1, 890704-54-8, 896506-46-0, 906507-37-7
sodium lauryl sulfate	151-21-3, 1335-72-4, 3088-31-1, 9004-82-4, 90583-28-1, 1231880-35-5, 85586-07-8, 90583-11-2, 73296-89-6, 68955-19-1, 85049-86-1, 90583-10-1, 85665-45-8, 85586-38-5, 1268005-68-0, 90583-18-9, 68585-47-7, 68081-96-9, 68081-97-0, 68890-70-0, 91783-23-2

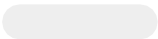
Classification of the preparation and its individual components has drawn on official and authoritative sources using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks 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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

Definitions and abbreviations

▸ PC—TWA: Permissible Concentration-Time Weighted Average



- PC—STEL: Permissible Concentration-Short Term Exposure Limit
 - IARC: International Agency for Research on Cancer
 - ACGIH: American Conference of Governmental Industrial Hygienists
 - STEL: Short Term Exposure Limit
 - TEEL: Temporary Emergency Exposure Limit.
 - IDLH: Immediately Dangerous to Life or Health Concentrations
 - ES: Exposure Standard
 - OSF: Odour Safety Factor
 - NOAEL: No Observed Adverse Effect Level
 - LOAEL: Lowest Observed Adverse Effect Level
 - TLV: Threshold Limit Value
 - LOD: Limit Of Detection
 - OTV: Odour Threshold Value
 - BCF: BioConcentration Factors
 - BEI: Biological Exposure Index
 - DNEL: Derived No-Effect Level
 - PNEC: Predicted no-effect concentration
-
- AIIC: Australian Inventory of Industrial Chemicals
 - DSL: Domestic Substances List
 - NDSL: Non-Domestic Substances List
 - IECSC: Inventory of Existing Chemical Substance in China
 - EINECS: European INventory of Existing Commercial chemical Substances
 - ELINCS: European List of Notified Chemical Substances
 - NLP: No-Longer Polymers
 - ENCS: Existing and New Chemical Substances Inventory
 - KECI: Korea Existing Chemicals Inventory
 - NZIoC: New Zealand Inventory of Chemicals
 - PICCS: Philippine Inventory of Chemicals and Chemical Substances
 - TSCA: Toxic Substances Control Act
 - TCSI: Taiwan Chemical Substance Inventory
 - INSQ: Inventario Nacional de Sustancias Químicas
 - NCI: National Chemical Inventory
 - FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances