TENA Plastic Free Wet Wipes

Essity Australasia

Chemwatch Hazard Alert Code: **1**

Chemwatch: **5689-38**
Version No: **2.1**
Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

Issue Date: **30/07/2024**
Print Date: **09/08/2024**
S.GHS.AUS.EN

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

Product Identifier

Product name	TENA Plastic Free Wet Wipes
Chemical Name	Not Applicable
Synonyms	product code: 9766
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	Wet wipes. NOTES: Hazard statements relates to the solution used to impregnate the wipe. Use according to manufacturer's directions. SDS are intended for use in the workplace ONLY. For domestic-use products, refer to consumer labels.

Details of the manufacturer or supplier of the safety data sheet

Registered company name	**Essity Australasia**	**Essity Australasia**
Address	30-32 Westall Road SPRINGVALE VIC 3171 Australia	Level 2, 103 Carlton Gore Road Newmarket Auckland 1023 New Zealand
Telephone	(03) 9550 2999	0800 523 565
Fax	1800 630 234	Not Available
Website	https://www.tork.com.au/	https://www.tork.co.nz/
Email	customerservice.anz@essity.com	customerservice.anz@essity.com

Emergency telephone number

Association / Organisation	**Essity Australasia**	**Essity Australasia**	**CHEMWATCH EMERGENCY RESPONSE (24/7)**
Emergency telephone numbers	1800 643 634	0800 523 565	+61 1800 951 288
Other emergency telephone numbers	Not Available	Not Available	+61 3 9573 3188

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

SECTION 2 Hazards identification

Classification of the substance or mixture

Poisons Schedule	Not Applicable
Classification [1]	Not Applicable

Label elements

Hazard pictogram(s)	Not Applicable
Signal word	**Not Applicable**

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
Not Available		wipe impregnated with
68-04-2	<1	sodium citrate
122-99-6	<1	ethylene glycol phenyl ether
9006-65-9	<1	dimethicone
5333-42-6	<1	2-octyldodecanol
532-32-1	<1	sodium benzoate
29806-73-3	<1	2-ethylhexyl palmitate
24634-61-5	<1	potassium sorbate
9005-64-5	<1	sorbitan monolaurate, ethoxylated
26590-05-6	<1	Polyquaternium-7
77-92-9	<0.1	citric acid
68439-49-6	<0.1	alcohols C16-18 ethoxylated
9004-95-9	<0.1	cetyl ether ethoxylated
540-10-3	<0.1	cetyl palmitate
31566-31-1	<0.1	glyceryl monostearate
65497-29-2	<0.1	guar hydroxypropyltrimonium chloride
56-81-5	<0.1	glycerol
94349-62-9	<0.01	Aloes, extract
110-17-8	<0.01	fumaric acid
1310-73-2	<0.01	sodium hydroxide
84082-60-0	<0.01	Chamomile recutica oil
7695-91-2	<0.01	DL-alpha-tocopherol acetate
Not Available	<1	parfum
7732-18-5	>90	water
Legend:	***1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available***	

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with eyes: ▸ Wash out immediately with water. ▸ If irritation continues, seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. ▸ Generally not applicable. ▸ If in eyes, hold eyelids apart and flush the eye continuously with running water. ▸ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▸ 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	▸ Generally not applicable. · Intended for application to skin. · Remove with soap and water if irritation occurs. · Seek medical advice if irritation persists.
Inhalation	▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary. ▸ Generally not applicable.
Ingestion	▸ Generally not applicable. If poisoning occurs, contact a doctor or Poisons Information Centre.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.
Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.
In such an event consider:

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

Special hazards arising from the substrate or mixture

Continued...

Fire Incompatibility	None known.

Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Use fire fighting procedures suitable for surrounding area. ▸ **DO NOT** approach containers suspected to be hot. ▸ Cool fire exposed containers with water spray from a protected location. ▸ If safe to do so, remove containers from path of fire. ▸ Equipment should be thoroughly decontaminated after use. Slight hazard when exposed to heat, flame and oxidisers.
Fire/Explosion Hazard	▸ Non combustible. ▸ Not considered to be a significant fire risk. ▸ Expansion or decomposition on heating may lead to violent rupture of containers. ▸ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). ▸ May emit acrid smoke. carbon dioxide (CO_2) nitrogen oxides (NOx) metal oxides other pyrolysis products typical of burning organic material. May emit corrosive fumes. Articles and manufactured articles may constitute a fire hazard where polymers form their outer layers or where combustible packaging remains in place. Certain substances, found throughout their construction, may degrade or become volatile when heated to high temperatures. This may create a secondary hazard.
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	▸ Clean up all spills immediately. ▸ Secure load if safe to do so. ▸ Bundle/collect recoverable product. ▸ Collect remaining material in containers with covers for disposal.
Major Spills	▸ Minor hazard. ▸ Clear area of personnel. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear physical protective gloves e.g. Leather. ▸ Contain spill/secure load if safe to do so. ▸ Bundle/collect recoverable product and label for recycling. ▸ Collect remaining product and place in appropriate containers for disposal. ▸ Clean up/sweep up area. ▸ Water may be required.

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	▸ Limit all unnecessary personal contact. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ When handling **DO NOT** eat, drink or smoke. ▸ Always wash hands with soap and water after handling. ▸ Avoid physical damage to containers. ▸ Use good occupational work practice. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS.
Other information	▸ Store away from incompatible materials.

Conditions for safe storage, including any incompatibilities

Suitable container	Generally packaging as originally supplied with the article or manufactured item is sufficient to protect against physical hazards. If repackaging is required ensure the article is intact and does not show signs of wear. As far as is practicably possible, reuse the original packaging or something providing a similar level of protection to both the article and the handler.
Storage incompatibility	None known

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Continued...

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	glyceryl monostearate	Stearates	10 mg/m3	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Australia Exposure Standards	glycerol	Glycerin mist	10 mg/m3	Not Available	Not Available	(a) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Australia Exposure Standards	sodium hydroxide	Sodium hydroxide	Not Available	Not Available	2 mg/m3	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
sodium citrate	9.3 mg/m3	100 mg/m3	610 mg/m3
ethylene glycol phenyl ether	1.5 ppm	16 ppm	97 ppm
sodium benzoate	61 mg/m3	680 mg/m3	810 mg/m3
Polyquaternium-7	30 mg/m3	330 mg/m3	2,000 mg/m3
alcohols C16-18 ethoxylated	3.8 mg/m3	42 mg/m3	250 mg/m3
glyceryl monostearate	0.66 mg/m3	7.2 mg/m3	43 mg/m3
glycerol	45 mg/m3	180 mg/m3	1,100 mg/m3
sodium hydroxide	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
sodium citrate	Not Available	Not Available
ethylene glycol phenyl ether	Not Available	Not Available
dimethicone	Not Available	Not Available
2-octyldodecanol	Not Available	Not Available
sodium benzoate	Not Available	Not Available
2-ethylhexyl palmitate	Not Available	Not Available
potassium sorbate	Not Available	Not Available
sorbitan monolaurate, ethoxylated	Not Available	Not Available
Polyquaternium-7	Not Available	Not Available
citric acid	Not Available	Not Available
alcohols C16-18 ethoxylated	Not Available	Not Available
cetyl ether ethoxylated	Not Available	Not Available
cetyl palmitate	Not Available	Not Available
glyceryl monostearate	Not Available	Not Available
guar hydroxypropyltrimonium chloride	Not Available	Not Available
glycerol	Not Available	Not Available
Aloes, extract	Not Available	Not Available
fumaric acid	Not Available	Not Available
sodium hydroxide	10 mg/m3	Not Available
Chamomile recutica oil	Not Available	Not Available
DL-alpha-tocopherol acetate	Not Available	Not Available
water	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
ethylene glycol phenyl ether	E	≤ 0.1 ppm
2-octyldodecanol	E	≤ 0.1 ppm
sodium benzoate	E	≤ 0.01 mg/m³
potassium sorbate	E	≤ 0.01 mg/m³
Polyquaternium-7	E	≤ 0.01 mg/m³
citric acid	E	≤ 0.01 mg/m³
alcohols C16-18 ethoxylated	E	≤ 0.1 ppm
cetyl ether ethoxylated	E	≤ 0.01 mg/m³
guar hydroxypropyltrimonium chloride	E	≤ 0.01 mg/m³
Aloes, extract	C	> 0.1 to ≤ milligrams per cubic meter of air (mg/m³)
fumaric acid	E	≤ 0.01 mg/m³
Chamomile recutica oil	D	> 0.1 to ≤ 1 ppm
DL-alpha-tocopherol acetate	E	≤ 0.1 ppm
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.***	

Exposure controls

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Appropriate engineering controls	Articles or manufactured items, in their original condition, generally don't require engineering controls during handling or in normal use. Exceptions may arise following extensive use and subsequent wear, during recycling or disposal operations where substances, found in the article, may be released to the environment.
Individual protection measures, such as personal protective equipment	
Eye and face protection	No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: ▸ Safety glasses with side shields. ▸ 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], [AS/NZS 1336 or national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	No special equipment needed when handling small quantities. **OTHERWISE**: Wear chemical protective gloves, e.g. PVC.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities **OTHERWISE:** ▸ Overalls ▸ Eyewash unit.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:
"Forsberg Clothing Performance Index".
The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection:
TENA Plastic Free Wet Wipes

Material	CPI
BUTYL	C
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
NITRILE+PVC	C
PE	C
PE/EVAL/PE	C
PVA	C
PVC	C
SARANEX-23	C
SARANEX-23 2-PLY	C
TEFLON	C
VITON	C
VITON/CHLOROBUTYL	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

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

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

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P3	-	A-PAPR-AUS / Class 1 P3
up to 50 x ES	-	A-AUS / Class 1 P3	-
up to 100 x ES	-	A-2 P3	A-PAPR-2 P3 ^

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

Respiratory protection not normally required due to the physical form of the product.

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	White wipe with perfume odour.

Physical state	Manufactured	**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 Applicable

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pH (as supplied)	4-7	**Decomposition temperature (°C)**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Not Applicable	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Not Applicable	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Applicable	**Surface Tension (dyn/cm or mN/m)**	Not Applicable
Lower Explosive Limit (%)	Not Applicable	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water	Miscible	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

SECTION 10 Stability and reactivity

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

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
Ingestion	The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence.
Skin Contact	Not considered an irritant through normal use. Discontinue use if irritation occurs
Eye	The liquid may produce eye discomfort causing temporary smarting and blinking.
Chronic	No adverse effects anticipated from normal use. Principal hazards are accidental eye contact and cleaner overuse. Overuse or obsessive cleaner use may lead to defatting of the skin and may cause irritation, drying, cracking, leading to dermatitis.

TENA Plastic Free Wet Wipes	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
sodium citrate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Mouse) LD50; 5000-6000 mg/kg[2]	Skin: no adverse effect observed (not irritating)[1]
ethylene glycol phenyl ether	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye (rabbit): 250 ug/24h - SEVERE
	Oral (Rat) LD50: 1260 mg/kg[2]	Eye (rabbit): 6 mg - moderate
		Eye: adverse effect observed (irreversible damage)[1]
		Eye: adverse effect observed (irritating)[1]
		Skin (rabbit): 500 mg/24h - mild
		Skin: adverse effect observed (irritating)[1]
		Skin: no adverse effect observed (not irritating)[1]
dimethicone	**TOXICITY**	**IRRITATION**
	Oral (Mouse) LD50; >20000 mg/kg[2]	Not Available
2-octyldodecanol	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >1700 mg/kg[1]	Eye (rabbit): 100 mg/24h mild
	Oral (Rat) LD50: >2000 mg/kg[1]	Eye (rabbit): 6/110 *(primary irritation index)
		Eye: no adverse effect observed (not irritating)[1]

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		Skin (rabbit): 0.6/8.0) *(primary irritation index)
		Skin (rabbit): 100 mg/24h severe
		Skin: no adverse effect observed (not irritating)[1]
sodium benzoate	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >2000 mg/kg[1]	Eye: adverse effect observed (irritating)[1]
	Inhalation (Rat) LC50: >12.2 mg/L4h[1]	Skin: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: 4070 mg/kg[2]	
2-ethylhexyl palmitate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye (rabbit): non-irritating *
	Inhalation (Rat) LC50: >5.3 mg/l4h[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: >5000 mg/kg[2]	Skin (rabbit): 500 mg/24h mild
		Skin (rabbit): slight irritant *
		Skin: no adverse effect observed (not irritating)[1]
potassium sorbate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye: adverse effect observed (irritating)[1]
	Oral (Rat) LD50: >6650 mg/kg[2]	Eyes (rabbit) (-) Irritant [Manufacturer]
		Skin (rabbit) (-) Irritant
		Skin: no adverse effect observed (not irritating)[1]
sorbitan monolaurate, ethoxylated	**TOXICITY**	**IRRITATION**
	Dermal (Guinea Pig) LD50: >3000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1]
	Inhalation (Rat) LC50: >5.1 mg/l4h[1]	Skin (human): 15 mg/3d mild
	Oral (Mouse) LD50; >33000 mg/kg[2]	Skin: no adverse effect observed (not irritating)[1]
Polyquaternium-7	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
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]	Eye: adverse effect observed (irritating)[1]
		Skin (rabbit): 500 mg/24h - mild
		Skin: adverse effect observed (irritating)[1]
		Skin: no adverse effect observed (not irritating)[1]
alcohols C16-18 ethoxylated	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >3000 mg/kg[1]	Eye : Severe (analogy) *
	Inhalation (Rat) LC50: >1.6 mg/l4h[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: 1260 mg/kg[2]	Skin: no adverse effect observed (not irritating)[1]
		Skin: not irritating * (analogy) *
cetyl ether ethoxylated	**TOXICITY**	**IRRITATION**
	Oral (Mouse) LD50; 2602 mg/kg[2]	Eye: no adverse effect observed (not irritating)[1]
		Skin: no adverse effect observed (not irritating)[1]
cetyl palmitate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: >5000 mg/kg[1]	Skin (rabbit): 500 mg/24h-mild
		Skin: no adverse effect observed (not irritating)[1]
glyceryl monostearate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Mouse) LD50; >5000 mg/kg[1]	Skin: no adverse effect observed (not irritating)[1]
guar hydroxypropyltrimonium chloride	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50: 3000 mg/kg[2]	Eye (rabbit): irritating *
glycerol	**TOXICITY**	**IRRITATION**
	Dermal (Guinea Pig) LD50: 58500 mg/kg[1]	Eye: no adverse effect observed (not irritating)[1]

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	Inhalation (Rat) LC50: >5.85 mg/L4h[1]	Skin: no adverse effect observed (not irritating)[1]
	Oral (Mouse) LD50; 4090 mg/kg[2]	
Aloes, extract	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
fumaric acid	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: 20000 mg/kg[2]	Eye (rabbit): 100 mg/24h-moderate *[Merck]
	Inhalation (Rat) LC50: >1.306 mg/l4h[1]	Eye: adverse effect observed (irritating)[1]
	Oral (Rat) LD50: 9300 mg/kg[2]	Skin (rabbit): 500 mg/24h - mild
		Skin: adverse effect observed (irritating)[1]
sodium hydroxide	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: 1350 mg/kg[2]	Eye (rabbit): 0.05 mg/24h SEVERE
	Oral (Rabbit) LD50; 325 mg/kg[1]	Eye (rabbit):1 mg/24h SEVERE
		Eye (rabbit):1 mg/30s rinsed-SEVERE
		Eye: adverse effect observed (irritating)[1]
		Skin (rabbit): 500 mg/24h SEVERE
		Skin: adverse effect observed (corrosive)[1]
Chamomile recutica oil	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50: >5000 mg/kg[1]	Eye: adverse effect observed (irritating)[1]
		Skin: adverse effect observed (irritating)[1]
DL-alpha-tocopherol acetate	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >3000 mg/kg[1]	Eye (rabbit): non-irritating *
	Oral (Mouse) LD50; >49700 mg/kg[2]	Eye: no adverse effect observed (not irritating)[1]
		Skin (rabbit): non-irritating * * [ROCHE]
		Skin: no adverse effect observed (not irritating)[1]
water	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50: >90000 mg/kg[2]	Not Available

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

ETHYLENE GLYCOL PHENYL ETHER	Bacterial cell mutagen The aryl alkyl alcohol (AAA) fragrance ingredients have diverse chemical structures, with similar metabolic and toxicity profiles. The AAA fragrances demonstrate low acute and subchronic toxicity by skin contact and swallowing. At concentrations likely to be encountered by consumers, AAA fragrance ingredients are non-irritating to the skin. The potential for eye irritation is minimal. With the exception of benzyl alcohol, phenethyl and 2-phenoxyethyl AAA alcohols, testing in humans indicate that AAA fragrance ingredients generally have no or low sensitization potential. Available data indicate that the potential for photosensitization is low. Testing suggests that at current human exposure levels, this group of chemicals does not cause maternal or developmental toxicity. Animal testing shows no cancer-causing evidence, with little or no genetic toxicity. It has been concluded that these materials would not present a safety concern at current levels of use, as fragrance ingredients.
DIMETHICONE	Substance has been investigated as a tumorigen and reproductive effector in rats.
2-OCTYLDODECANOL	Skin (rabbit): 100 mg/24 h - SEVERE Eye (rabbit): 100 mg/24 h - mild * Sasol SDS The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
SODIUM BENZOATE	NOTE: Oral doses of 8-10g may cause nausea and vomiting, though tolerance in human is 50 g/day. Use in food limited to 0.1%. [ICI] For benzoates: Benzyl alcohol, benzoic acid and its sodium and potassium salt have a common metabolic and excretion pathway. All but benzyl alcohol are considered to be unharmful and of low acute toxicity. They may cause slight irritation by oral, dermal or inhalation exposure except sodium benzoate which doesn't irritate the skin. Studies showed increased mortality, reduced weight gain, liver and kidney effects at higher doses, also, lesions of the brains, thymus and skeletal muscles may occur with benzyl alcohol. However, they do not cause cancer, genetic or reproductive toxicity. Developmental toxicity may occur but only at maternal toxic level.
2-ETHYLHEXYL PALMITATE	Non-sensitiser in guinea pig * *ISP MSDS
POTASSIUM SORBATE	Substance has been investigated as a mutagen by cytogenetis analysis in rodents.
SORBITAN MONOLAURATE, ETHOXYLATED	The Cosmetic Ingredient Review (CIR) Expert Panel concluded that listed polysorbates are safe in cosmetics when formulated to be non-irritating. This conclusion supersedes the conclusion reached in the 1984, 2000, and 2001 CIR safety assessments. This safety assessment combines polysorbates reviewed in 3 previous safety assessments with other polysorbates that have not been reviewed by the CIR Panel into a group of 80 polyethoxylated sorbitan or sorbitol esters of fatty acid. Following oral administration of polysorbate 20 to rats, ester bonds of polysorbates are hydrolyzed within the digestive tract by pancreatic lipase.24 Free fatty acids were absorbed from the digestive tract and oxidized and excreted, mainly as carbon dioxide in exhaled breath. No migration of the polyoxyethylene sorbitan into the thymus lymph nodes has been demonstrated. No sex difference has been detected in the disposition of polysorbates in rats. Following oral ingestion of polysorbate 20 in humans, 90% or more of the administered substance was excreted in the feces as metabolites, with the polyoxyethylene sorbitan structure maintained, and 2%-3% of these metabolites were excreted in the urine The Panel considered the data available to characterize the potential for polysorbates to cause systemic toxicity, irritation, sensitization, reproductive and developmental toxicity, and genotoxicity. They noted the lack of systemic toxicity at low and moderate doses in several acute and repeated-dose oral exposure studies, and low toxicity at high doses; little or

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	no irritation or sensitization in multiple tests of dermal and ocular exposure; the absence of genotoxicity in multiple Ames tests and chromosome aberration tests, and minimal irritation and lack of sensitization in tests of dermal exposure at concentration of use. The Panel recognizes that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used, concentrations of use and the similar pattern of use raise no safety concerns. The Panel note that polysorbate 20, polysorbate 65, and polysorbate 80 were shown to enhance dermal drug absorption. The Panel cautions that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption, or when dermal absorption was a concern. Especially, care should be taken when creating formulations intended for use on infants. To address the possible presence of 1,4-dioxane and ethylene oxide impurities in these ingredients, the Panel stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities from the PEG ingredients before blending them into cosmetic formulations. The Panel expressed concern about pesticide residues and heavy metals that may be present in botanical (ie, coconut-derived) ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities. Data from the 1984 safety assessment suggested that polysorbates caused a slight enhancement of tumor development caused by 7,12-dimethyl-benz[a]anthracene (DMBA) and N-methyl-N -nitro-N-nitrosoguanidine (MNNG); however, the data were not consistent. For other compounds, the tumorigenic properties of 3-methyl-cholanthrene (MCA) and 3,4-benz[a]pyrene (BP) were not enhanced by polysorbates. Since the tumor enhancement effects were inconsistent and depended on the simultaneous exposure to strong chemical carcinogens, which are not present in cosmetics, the Panel felt that the weak tumor enhancement effects were not relevant to cosmetic formulations. Because some studies showed minimal irritation at concentrations that are used in cosmetics, the Panel cautioned that products containing these ingredients should be formulated to be non-irritating. It was noted that at the time of the 2001 safety assessment on sorbeth beeswaxes, the Panel had recommended that cosmetic formulations containing PEGs not be used on damaged skin because of the possibility of renal toxicity when PEGs were applied to severely damaged skin, such as in burn patients. Since then, PEGs have been re-reviewed and the additional data demonstrated minimal dermal penetration of low-molecular weight PEGs. The amount of PEGs that would penetrate the stratum corneum barrier, even if damaged, from the use of cosmetics was well below the level of renal toxicity. Therefore, the Panel has removed the caveat that PEGs should not be used on damaged skin. The Panel strongly asserted that it is inappropriate to apply cosmetic products containing high concentrations of PEGs to individuals exhibiting barrier skin disruption through both the stratum corneum and the epidermis. The Panel discussed the issue of incidental inhalation exposure from spray products, including aerosol and pump hair sprays, spray deodorants, spray body and hand products, and spray moisturizing products. The limited acute exposure data available from 1 new inhalation study and 1 historical tracheal study suggest little potential for respiratory effects at relevant doses. These ingredients are reportedly used at concentrations up to 4% in cosmetic products that may be aerosolized. The Panel noted that 95%-99% of droplets/particles would not be respirable to any appreciable amount. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. Safety Assessment of Polysorbates as Used in CosmeticJuly 2015 https://www.cir-safety.org/sites/default/files/PSorba_062015_FR_0.pdf For sorbitan esters, ethoxylated (syn: polyoxyethylene sorbitan esters): Some of the early short-term studies with these polyoxyethylene sorbitan esters in rats and hamsters showed deleterious effects. Subsequent work suggests that these were largely due to diarrhoea resulting from a large amount of unabsorbed polyglycol, possibly aggravated in some experiments by the use of an unsuitable basal diet. Since that time there has been considerable improvement in testing procedures,and more extensive long-term studies have been carried out. It seems reasonable therefore to base the evaluation of these substances on the levels causing no adverse effects indicated by the results of the more recent investigations. The significance of the local tumours which were produced by injection has been discussed at the meeting of the Scientific Group (1966). No increase in tumour incidence has followed the oral intake of polyoxyethylene sorbitan esters. Furthermore, large doses of the oleate and stearate have been well tolerated by human subjects. Polyoxyethylene (20) sorbitan monoester of lauric, oleic, palmitic and stearic acid and triester of stearic acid Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. Techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53. The sorbitan esters are agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products. They do not represent a toxicological concern since they are derived from naturally occurring materials and are ultimately metabolised back to these same natural constituents.
POLYQUATERNIUM-7	Polyacrylamide is a polymer of controllable molecular weight formed by the polymerization of acrylamide monomers available in one of three forms: solid (powder or micro beads), aqueous solution, or inverse emulsions (in water droplets coated with surfactant and suspended in mineral oil). Residual acrylamide monomer is likely an impurity in most Polyacrylamide preparations, ranging from <1 ppm to 600 ppm. Higher levels of acrylamide monomers are present in the solid form compared to the other two forms. Residual levels of acrylamide in polyacrylamide can range from <.01% to 0.1%, although representative levels were reported at 0.02% to 0.03%. Because of the large sizes of polyacrylamide polymers, they do not penetrate the skin. Polyacrylamide itself is not significantly toxic. For example, an acute oral toxicity study of polyacrylamide in rats reported that a single maximum oral dose of 4.0 g/kg body weight was tolerated. In subchronic oral toxicity studies, rats and dogs treated with Polyacrylamide at doses up to 464 mg/kg body weight showed no signs of toxicity. Several 2-year chronic oral toxicity studies in rats and dogs fed diets containing up to 5% polyacrylamide had no significant adverse effects. Polyacrylamide was not an ocular irritant in animal tests. No compound-related lesions were noted in a three-generation reproductive study in which rats were fed 500 or 2000 ppm polyacrylamide in their diet. Polyacrylamide was not carcinogenic in several chronic animal studies. Human cutaneous tolerance tests performed to evaluate the irritation of 5% (w/w) polyacrylamide indicated that the compound was well tolerated. Amended final report on the safety assessment of polyacrylamide and acrylamide residues in cosmetics. Int J Toxicol. 2005;24 Suppl 2:21-50. As cationic polymers possess unique physical structures and surface properties, various kinds of cationic polymers have been developed over the past few decades for a wide spectrum of nanomedical applications in the central nervous system (CNS). Although cationic polymers could be successfully used for gene transfer, drug delivery, and diagnostic imaging, after entering into the CNS, they may cause neurotoxicity and induce CNS damage, which seriously limits their applications. The neurotoxic effects of cationic polymers on CNS are mostly studied in mice, and have not been examined in detail. While evaluating the neurotoxicity of cationic polymers, the surface charge, surface area, coating, size, shape, and the basic materials that cationic polymers are made up of are expected to show important roles, and should be carefully considered. Apoptosis, necrosis, autophagy, oxidative stress, inflammation, and inflammasome; which are expected to be the most important problems in the evaluation of cationic polymers-induced neurotoxicity. There is no data that exists regarding the health effects of cationic dialkyldimethylammonium (DADMA) salts, but they are expected to have similar properties to alkyltrimethylammonium (ATMA) salts, although they are generally less irritating than the corresponding ATMA salts For alkyltrimethylammonium chloride (ATMAC) Most undiluted cationic surfactants satisfy the criteria for classification as Harmful (Xn) with R22 and as Irritant (Xi) for skin and eyes with R38 and R41. In addition, certain surfactants will satisfy the criteria for classification as Corrosive with R34 in addition to the acute toxicity. According to Centre Europeen des Agents de Surface et de leurs Intermediaires Organiques (CESIO), C8-18 alkyltrimethylammonium chloride (ATMAC) (i.e., lauryl, coco, soya, and tallow) are classified as Corrosive (C) with the risk phrases R22 (Harmful if swallowed) and R34 (Causes burns). C16 ATMAC is classified as Harmful (Xn) with the risk phrases R22 (Harmful if swallowed), R38 (Irritating to skin), and R41 (Risk of serious damage to eyes). C20-22 ATMAC are classified as Irritant (Xi) with R36/38 (Irritating to eyes and skin). Acute toxicity: ATMAB (the bromide) is poorly absorbed through the skin or the digestive tract. Acute oral toxicity of alkyltrimethylammonium salts is somewhat higher than the toxicity of anionic and nonionic surfactants. This may be due to the strongly irritating effect which cationic surfactants have on the mucous membrane of the gastrointestinal tract. Cationic surfactants are generally about 10 times more toxic when given through a vein, compared to being given by mouth. Skin and eye irritation: Skin irritation depends on surfactant concentration. Concentrations above 1% generally cause pronounced irritation. Cationic surfactants are the most irritating surfactants to the eye. Many proteins in the skin are considerably more resistant to the denaturing effects of cationic surfactants compared to those of anionic surfactants. In contrast to the irreversible denaturing effect of sodium dodecyl sulfate, the adverse effects of some cationic surfactants on proteins may be reversible.

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	Sensitisation: A repeated patch test performed on human volunteers did not show sensitization. Sub-chronic toxicity: Animal testing over the long term resulted in no affects, except for reduced body weight at very high doses. Reproductive toxicity: Animal testing showed no effects toxic to the embryo or causing birth defects. Mild effects on the embryo were seen only at levels which were toxic to the mother. Mutation-causing potential: Animal testing showed no mutation-causing potential for C16 and C18 ATMAC. For quaternary ammonium compounds (QACs): Quaternary ammonium compounds (QACs) are cationic surfactants. They are in general more toxic than anionic and non-ionic surfactants. Because they can dissolve phospholipids and cholesterol in lipid membranes, QACs affect cell permeability which may lead to cell death. Further, QACs denature proteins as cationic materials precipitate protein and are accompanied by generalized tissue irritation. It has been suggested that the experimentally determined decrease in the acute toxicity of QAs with chain length above C16 is due to decreased water solubility. In general it appears that QACs with single long-chain alkyl groups are more toxic and irritating than those with two such substitutions. Animal testing shows that straight chain aliphathic QACs may cause lung tissue to release histamine. QACs may also show curare-like properties, causing limb paralysis and even life-threatening paralysis of the muscles of breathing, if they are injected. This paralysis seems to be transient. From human testing, it is concluded that all the compounds investigated to date show similar toxicological properties.
ALCOHOLS C16-18 ETHOXYLATED	Remarks: Patch test on human volunteers did not demonstrate sensitization properties. * Cognis MSDS for Ceteraeth -20 The skin sensitising potential was assessed with C16-18AE (CAS 68439-49-6) in a Buehler Test according to OECD Guideline 406. In this study 20 female guinea pigs were induced by an epicutaneous occlusive dressing with 100% test substance (in maize oil) for 6 h on Day 0, 7 and 14. Two weeks after the last induction animals were challenged by epicutaneous occlusive exposure for 6 h to 100% test substance (in maize oil). 24 and 48 h after patch removal the application site was assessed for signs of local irritation. No dermal reactions were observed in any test animal at any time point. Available oral toxicity studies provide a coherent picture on the subchronic and chronic oral toxicity of AE. Based on the described effects and argumentations, the dietary NOAEL of 500 mg/kg bw/day (Shell, 1982) representing an average of all NOAELs, was chosen for the risk assessment. The clastogenic potential was assessed in a chromosomal aberration test with C16-18AE (CAS 68439-49-6) in mammalian cells according to OECD Guideline 473. Chinese hamster ovary cells (CHO) were exposed to 313, 625, 1250, 2500 and 5000 µg/mL in the presence and 1.25, 2.5, 5, 10, 20, 39 and 78 µg/mL in the absence of metabolic activation. Positive and vehicle (1% ethanol) control cultures were included in each assay. No increases in the number of chromosome aberrations in the presence or absence of metabolic activation were seen at any concentration tested. Appropriate reference mutagens used as positive controls showed a significant increase in chromosome aberrations, thus indicating the sensitivity of the assay, and the efficacy of the S9-mix. Hence, the test substance can not be regarded as clastogenic. The mutagenic potential in mammalian cells was assessed with C16-18AE (CAS 68439-49-6) by a HPRT-assay according to OECD Guideline 476. Following pre-tests with the concentration ranging from 1-100 µg/mL, the latter being the solubility limit of the test substance, Chinese hamster ovary cells were exposed for 4 h to concentrations of 1.8, 6, 18, 60 and 100 µg/mL in the absence and presence of metabolic activation by rat liver S9-mix. No dose-related increases in mutant colony numbers were obtained in two independent experiments with the test substance in either the presence or absence of S9-mix. Appropriate reference mutagens used as positive controls produced highly significant increases in mutation frequency, thus indicating the sensitivity of the assay. Therefore, the test substance is regarded as not mutagenic in mammalian cells. In conclusion, C16AE (CAS 52609-19-5) is regarded as non-genotoxic a reproductive toxicity study on a structurally similar material, C14-15AE7 (CAS 68951-67-7) was conducted at dietary levels of 25, 50 and 250 mg/kg bw/day. The 2-generation study (Procter and Gamble Ltd., 1977: Long term reproduction and teratology study in rats with Neodol 45-7; unpublished report) did not show any potential for reproductive toxicity at the tested dose levels. The NOAEL for reproductive effects was greater than the highest tested dose of 250 mg/kg bw/day. Although the study was pre-GLP and not in full compliance with current OECD guidelines, the study provided sufficient information and was assessed to be scientifically reliable. The comparable toxicokinetic and metabolic profiles, as well as their toxicological similarities for this and other toxicological endpoints, support the conclusion that insights from the reproductive toxicity study on higher ethoxylated AE are applicable to AE with an ethoxylation degree of 1 - 2.5. * REACh Dossier Tri-ethylene glycol ethers undergo enzymatic oxidation to toxic alkoxy acids. They may irritate the skin and the eyes. At high oral doses, they may cause depressed reflexes, flaccid muscle tone, breathing difficulty and coma. Death may result in experimental animal. However, repeated exposure may cause dose dependent damage to the kidneys as well as reproductive and developmental defects.
CETYL PALMITATE	[Manufacturer]
GLYCERYL MONOSTEARATE	For group E aliphatic esters (polyol esters): The polyol esters, including trimethylolpropane (TMP). Pentaerythritol (PE) and dipentaerythritol (diPE) are unique in their chemical characteristics since they lack beta-tertiary hydrogen atoms, thus leading to stability against oxidation and elimination. Therefore their esters with C5-C10 fatty acids have applications as artificial lubricants. Because of their stability at high temperatures, they are also used in high temperature applications such as industrial oven chain oils, high temperature greases, fire resistant transformer coolants and turbine engines. Polyol esters that are extensively esterified also have greater polarity, less volatility and enhanced lubricating properties. Acute toxicity: Animal studies show relatively low toxicity by swallowing. These esters are hydrolysed in the gastrointestinal tract, and studies have not shown evidence of these accumulating in body tissues. Acute toxicity by skin contact was also found to be low. Repeat dose toxicity: According to animal testing, polyol esters show a low level of toxicity following repeated application, either by swallowing or by skin contact. Reproductive and developmental toxicity: This group should not produce profound reproductive effects in animals. Genetic toxicity: Tests have shown this group to be inactive. It is unlikely that these substances cause mutations. Cancer-causing potential: No association between this group of substances and cancer.
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE	* [Rhone-Poulenc]; ** [Canada Colors and Chemicals Ltd.] Most undiluted cationic surfactants satisfy the criteria for classification as Harmful (Xn) with R22 and as Irritant (Xi) for skin and eyes with R38 and R41. For quaternary ammonium compounds (QACs): Quaternary ammonium compounds are synthetically made surfactants. Studies show that its solubility, toxicity and irritation depend on chain length and bond type while effect on histamine depends on concentration. QACs may cause muscle paralysis with no brain involvement. There is a significant association between the development of asthma symptoms and the use of QACs as disinfectant.
GLYCEROL	At very high concentrations, evidence predicts that glycerol may cause tremor, irritation of the skin, eyes, digestive tract and airway. Otherwise it is of low toxicity. There is no significant evidence to suggest that it causes cancer, genetic, reproductive or developmental toxicity.
ALOES, EXTRACT	Aloe barbadensis Mill., extract **WARNING:** This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans. Whole leaf extract of Aloe vera was tested for carcinogenicity after oral administration in one 2-year study in mice, and one 2-year study in rats. In male and female rats, drinking-water containing whole leaf extract of Aloe vera caused significantly increased incidences of adenoma of the large intestine (colon and caecum) and carcinoma of the large intestine (colon and caecum), tumours rarely developed spontaneously in rats. In the 2-year study in mice, there was no significantly increased incidence of any type of tumours in males or females given drinking-water containing whole leaf extract of Aloe vera. In a study of photo-co-carcinogenesis with simulated sunlight, four articles were studied by skin application in hairless mice: three test articles containing Aloe vera that included gel, whole leaf extract, and decolourised whole leaf extract; and an aloe-emodin preparation. Almost all mice exposed to simulated sunlight developed skin neoplasms. No increase in the incidence of skin neoplasms was observed in the groups receiving any of the four test articles applied as a cream followed by simulated sunlight when compared with the group receiving control cream followed by simulated sunlight. There was a significant enhancing effect of Aloe vera gel cream or aloe-emodin cream on the photocarcinogenic activity of simulated sunlight in female mice based on an increase in the multiplicity of squamous cell papilloma, carcinoma or carcinoma in situ (combined). There was a significant enhancing effect of the whole leaf extract cream or decolourized whole leaf extract cream on the photocarcinogenic activity of simulated sunlight in both male and female mice, based on an increase in the multiplicity of squamous cell papilloma, carcinoma or carcinoma in situ (combined). Mechanistic and other relevant data

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	The C-glycosides aloin A and aloin B, which are components of Aloe vera latex, are converted to aloe-emodin-9-anthrone by bacteria present in the gastrointestinal tract of rats and humans. Aloe-emodin-9-anthrone undergoes sequential oxidation to aloe-emodin and rhein. Preparations of Aloe vera, acemannan, and aloin A, do not display genotoxic activity in assays for mutagenesis in bacteria and/or other assays for genotoxicity. In contrast, aloe-emodin has genotoxic activity. These data suggest that the neoplastic response observed with Aloe vera is a consequence of the conversion of the anthrone C-glycosides to aloe-emodin, which by itself or in combination with other components of Aloe vera is responsible for the adenomas and carcinomas in the large intestine of rats.
FUMARIC ACID	Fumaric acid is used in small amounts in the preparation of food, i.e. as an antioxidant. In the treatment of psoriasis, doses of several hundred mg are common. Among the side-effects are leucopenia and lymphopenia. Other adverse effects may include intolerable abdominal cramps and incoercible diarrhea, Other typical side effects of the fumaric acid esters were reversible elevation of transaminases, lymphocytopenia, and eosinophilia. These adverse effects were usually mild. Kidney damage caused either by acute renal injury or the Fanconi syndrome has been reported. A very rare, possible adverse effect of long-term therapy might be pneumonia, unresponsive to antibiotics, but responsive to prednisolone. Tolerance for the fetus has not been systematically studied, but the current experience on psoriasis treatment with fumaric acid dimethyl fumarate and ethyl hydrogen fumarate have given no indication of embryotoxic or teratogenic effects Fumaric acid derivatives are potent contact sensitizers and occupational contact dermatitis has been reported. Contact allergy related to newly acquired sofas and chairs is likely to have been due to dimethyl fumarate. A clinical study on humans (patch tests) with leather furniture and patches of pure dimethyl fumarate showed strong reactions in the most severe case down to 1 mg/kg. Dimethyl fumarate has been distributed in small pouches fixed inside the furniture or added to the footwear boxes. It thus evaporates and impregnates the product, protecting it from moulds. However, it then also affected consumers who were in contact with the products. Dimethyl fumarate penetrated through the clothes onto consumers skin where it caused painful skin contact dermatitis, including itching, irritation, redness, and burns; in some cases, acute respiratory troubles were reported. The dermatitis was particularly difficult to treat. Fumaric acid esters are substances of interest in dermatology. They exert various activities on cutaneous cells and cytokine networks. There is evidence that fumaric acid esters are not only effective and safe in psoriasis but granulomatous non-infectious diseases like granuloma annulare, necrobiosis lipoidica and sarcoidosis. In vitro and animal studies suggest some activity in malignant melanoma as well Fumaric acid esters can cause renal damage, including Fanconi syndrome. Patients developed reversible proteinuria during treatment with fumaric acid esters Both dimethyl fumarate and the active metabolite induce activation of the nuclear factor E2-related factor-2 pathway, which exerts neuroprotective effects and decreases myelin damage in the CNS. Antiinflammatory mechanisms have also been attributed to dimethyl fumarate. The most common side effects of dimethyl fumarate are flushing and gastrointestinal upset. In the postmarketing setting, several cases of progressive multifocal leukoencephalopathy (PML), a rare viral infection of the brain, were reported in patients who were taking dimethyl fumarate and had persistent lymphopenia. PML has also been reported as a complication of other dimethyl fumarate derivatives including fingolimod and, most notably, natalizumab. Fumaric acid appears to have neuroprotective and immunomodulatory (not immunosuppressive) properties through nuclear factor (erythroid derived-2)-like2 (NRF2) activation. NRF2 concentrates in the cell cytoplasm causing immunoregulatory as well as cytoprotective effects via upregulation of antioxidant proteins. Fumaric acid esters have been used in the treatment of psoriasis. They induce a shift from the T-helper 1 (Th-1) cytokine response to a Th-2 cytokine response and subsequent lymphopenia with low CD3 and CD4 counts. Low CD4 counts reflect the degree of immunosuppression and, in organ transplant recipients increase the risk of skin cancers, such as squamous cell carcinoma. For PFAE fumarates (Polyfunctional Aliphatic Esters) The toxicological properties show that all category members share similar toxicokinetic behaviour (i.e. hydrolysis of the ester bond before absorption followed by absorption and metabolism of the breakdown products) and that the constant pattern consists in a lack of potency change of properties across the category, explained by the common metabolic fate of aliphatic diesters, independent of the chain length of the dicarboxylic acid moiety (C4 unsaturated or C6) and the length/branching of the alcohol moiety. Thus, considering all available data from category members show no acute oral or dermal toxicity, no skin irritation,or eye irritation, no human hazard for systemic toxicity after repeated oral exposure, are not mutagenic or clastogenic, and have shown no relevant reproduction toxicity and have no effect on intrauterine development. Di-C12-15-alkyl fumarate (CAS RN: 142104-11-8)- at 100% induction concentration; 100% challenge concentration) was found to be a sensitiser in guinea pigs (Magnusson-Kligman method), with scattered mild redness noted in 10/20 and 8/20 animals at 24 and 48 hours after patch removal, respectively. In a second study in guinea pigs (Magnusson-Kligman method; 75% induction concentration; 75% challenge concentration), there was no evidence of reactions indicative of skin sensitisation to the chemical. The chemical (at 2.4%-15% concentration) was not a skin sensitiser in human repeat insult patch studies. Based on the above studies, and given the structural similarities between the notified chemical and chemicals that have also been shown to be skin sensitisers (e.g. dimethyl fumarate; CIR, 2009), there is insufficient evidence to indicate that the notified chemical is not a potential skin sensitiser. Therefore, for risk assessment purposes, the chemical is considered, by some *, to be a sensitiser. (* NICNAS Public Report my 2013) Oral toxicity: The smaller the molecule, the more easily it will be taken up. In general, molecular weights below 500 are favourable for oral absorption. Oral absorption of the molecule cannot be excluded for molecular weights less than 500 After oral ingestion, the members of the PFAE fumarates category undergo stepwise hydrolysis of the ester bonds by gastrointestinal enzymes. The respective alcohol as well as the fatty acid is formed. The physicochemical characteristics of the cleavage products (e.g. physical form, water solubility, molecular weight, log Kow, vapour pressure, etc.) are likely to be different from those of the parent substance before absorption into the blood takes place, and hence the predictions based upon the physicochemical characteristics of the parent substance do no longer apply. However, also for the resulting cleavage products with a high water solubility (i.e. fumaric acid), it is anticipated that they are absorbed in the gastrointestinal tract. In case of long carbon chains and thus rather low water solubility they are absorbed mainly by micellar solubilisation Dermal toxicity: The smaller the molecule, the more easily it may be taken up via the dermal route. In general, a molecular weight below 100 favours dermal absorption, above 500 the molecule may be too large to penetrate the skin. Dermal absorption of the molecule cannot be excluded for molecular weights less than 500. If the substance is a skin irritant or corrosive, damage to the skin surface may enhance penetration. As members of this category are not considered skin irritating based on the category approach, enhanced penetration of the substance due to local skin damage can be excluded. Based on a QSAR calculated dermal absorption a value < 0.00001 mg/cm²/event (very low) was predicted for 2-Butenedioic acid (E)-, di-C12-18-alkyl esters Based on this value the substance has a low potential for dermal absorption. For substances with a log Kow above 4, the rate of dermal penetration is limited by the rate of transfer between the stratum corneum and the epidermis, but uptake into the stratum corneum will be high. For substances with a log Kow above 6, the rate of transfer between the stratum corneum and the epidermis will be slow and will limit absorption across the skin, and the uptake into the stratum corneum itself is also slow. The substance must be sufficiently soluble in water to partition from the stratum corneum into the epidermis. Water solubility of category members is low so dermal uptake is likely to be (very) low.. Inhalation toxicity: Because of low vapour pressures, under normal use and handling conditions, inhalation exposure and thus availability for respiratory absorption of the substance in the form of vapours, gases, or mists is considered negligible. However, the substance may be available for respiratory absorption in the lung after inhalation of aerosols, if the substance is sprayed. In humans, particles with aerodynamic diameters below 100 µm have the potential to be inhaled. Particles with aerodynamic diameters below 50 µm may reach the thoracic region and those below 15 µm the alveolar region of the respiratory tract. Lipophilic compounds with a log Kow > 4, that are poorly soluble in water (1 mg/L or less) can be taken up by micellar solubilisation. Bioaccumulation Highly lipophilic substances tend in general to concentrate in adipose tissue, and depending on the conditions of exposure may accumulate. Although there is no direct correlation between the lipophilicity of a substance and its biological half-life, it is generally the case that substances with high log Kow values have long biological half-lives.High log Kow of >5 implies that family members have the potential to accumulate in adipose tissue. Distribution Distribution within the body through the circulatory system depends on the molecular weight, the lipophilic character and water solubility of a substance. In general, the smaller the molecule, the wider is the distribution. If the molecule is lipophilic, it is likely to distribute into cells

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	and the intracellular concentration may be higher than extracellular concentration particularly in fatty tissues. Family members undergo chemical changes as a result of enzymatic hydrolysis, leading to the cleavage products alcohol and fumaric acid. Aliphatic fatty alcohols are widely distributed within the body and efficiently eliminated. Due to its low molecular weight and moderate log Kow, fumaric acid will also be distributed within the body. Metabolism Dicarboxylic acid esters are expected have the same metabolic fate as fatty acid esters. Esters of carboxylic acids are hydrolysed to the corresponding alcohol and carboxylic acid by esterases. Depending on the route of exposure, esterase-catalysed hydrolysis takes place at different places in the organism: After oral ingestion, esters of alcohols and fatty acids undergo stepwise enzymatic hydrolysis already in the gastrointestinal fluids. In contrast, substances absorbed through the pulmonary alveolar membrane or through the skin enter the systemic circulation directly before entering the liver where hydrolysis will basically take place. In the first step of hydrolysis, the monoester is produced that is further hydrolysed to the alcohol and the dicarboxylic acid. During the first step of biotransformation the alcohols are oxidised to the corresponding carboxylic acids, followed by a stepwise elimination of C2-units in the mitochondrial beta-oxidation process. The second cleavage product fumaric acid is , as it is also an endogenous metabolite, incorporated into the citric acid cycle and rapidly degraded to CO2. In a publication on fumaric acid esters depletion of glutathione (GSH) after administration of dimethyl fumaric ester is described indicating conjugation with GSH catalyzed by GSH-transferases (GST) as Phase-II metabolism. The reason for this pathway is the double bond of the alpha,beta-unsaturated carbonyl group of fumaric acid as substrate for GST whereas saturated dicarboxylic acid esters like adipic acid diester are glucuronidated directly at the carbonyl group. Overall, family members are hydrolyzed and the cleavage products are metabolized by beta oxidation and/or conjugation with GSH. Excretion For family members and their cleavage products, the main route of excretion is expected to be by expired air as CO2 after metabolic degradation. Further routes of excretion might be via faeces and renal excretion after conjugation with GSH of the substance itself or its metabolites.
CHAMOMILE RECUTICA OIL	* Botanical Specialities MSDS Adverse reactions to fragrances in perfumes and fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, sensitivity to light, immediate contact reactions, and pigmented contact dermatitis. Airborne and connubial contact dermatitis occurs. Contact allergy is a lifelong condition, so symptoms may occur on re-exposure. Allergic contact dermatitis can be severe and widespread, with significant impairment of quality of life and potential consequences for fitness for work. If the perfume contains a sensitizing component, intolerance to perfumes by inhalation may occur. Symptoms may include general unwellness, coughing, phlegm, wheezing, chest tightness, headache, shortness of breath with exertion, acute respiratory illness, hayfever, asthma and other respiratory diseases. Perfumes can induce excess reactivity of the airway without producing allergy or airway obstruction. Breathing through a carbon filter mask had no protective effect. Occupational asthma caused 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. Prevention of contact sensitization to fragrances is an important objective of public health risk management. Hands: Contact sensitization may be the primary cause of hand eczema or a complication of irritant or atopic hand eczema. However hand eczema is a disease involving many factors, and the clinical significance of fragrance contact allergy in severe, chronic hand eczema may not be clear. Underarm: Skin inflammation of the armpits 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 skin specialist, a history of such first-time symptoms was significantly related to the later diagnosis of perfume allergy. Face: An important manifestation of fragrance allergy from the use of cosmetic products is eczema of the face. In men, after-shave products can cause eczema around the beard area and the adjacent part of the neck. Men using wet shaving as opposed to dry have been shown to have an increased risk of allergic to fragrances. Irritant reactions: Some individual fragrance ingredients, such as citral, are known to be irritant. Fragrances may cause a dose-related contact urticaria (hives) which is not allergic; cinnamal, cinnamic alcohol and Myroxylon pereirae are known to cause hives, but others, including menthol, vanillin and benzaldehyde have also been reported. Pigmentary anomalies: Type IV allergy is responsible for “pigmented cosmetic dermatitis”, referring to increased pigmentation on the face and neck. Testing showed a number of fragrance ingredients were associated, including jasmine absolute, ylang-ylang oil, cananga oil, benzyl salicylate, hydroxycitronellal, sandalwood oil, geraniol and geranium oil. Light reactions: Musk ambrette produced a number of allergic reactions mediated by light and was later banned from use in Europe. Furocoumarins (psoralens) in some plant-derived fragrances have caused phototoxic reactions, with redness. There are now limits for the amount of furocoumarins in fragrances. 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 the nose / airway. 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. A significant association was found between respiratory complaints related to fragrances and contact allergy to fragrance ingredients and hand eczema. Fragrance allergens act as haptens, which are small molecules that cause an immune reaction only when attached to a carrier protein. However, not all sensitizing fragrance chemicals are directly reactive, but some require previous activation. A prehapten is a chemical that itself causes little or no sensitization, but it is transformed into a hapten outside the skin by a chemical reaction (oxidation in air or reaction with light) without the requirement of an enzyme. For prehaptens, it is possible to prevent activation outside the body to a certain extent by different measures, for example, 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. Prehaptens: Most terpenes with oxidisable allylic positions can be expected to self-oxidise on air exposure. Depending on the stability of the oxidation products that are formed, the oxidized products will have differing levels of sensitization potential. Tests shows that air exposure of lavender oil increased the potential for sensitization. Prohaptens: Compounds that are bioactivated in the skin and thereby form haptens are referred to prohaptens. The possibility of a prohapten being activated cannot be avoided by outside measures. Activation processes increase the risk for cross-reactivity between fragrance substances. Various enzymes play roles in both activating and deactivating prohaptens. Skin-sensitizing prohaptens can be recognized and grouped into chemical classes based on knowledge of xenobiotic bioactivation reactions, clinical observations and/or studies of sensitization. QSAR prediction: Prediction of sensitization activity of these substances is complex, especially for those substances that can act both as pre- and prohaptens.
DL-ALPHA-TOCOPHEROL ACETATE	May cause skin and eye irritation * Reproductive and mutagenic effects have been observed in tests with laboratory animals * * Alfa Aeser MSDS Based on laboratory and animal testing, exposure to the material may result in irreversible effects and mutations in humans. alpha-Tocopherol was non-mutagenic and non-carcinogenic, and the results of reproduction/ teratology studies did not indicate that alpha-tocopherol had adverse effects on reproductive function. However, in a long-term study in rats, a no-effect level could not be established with respect to effects on blood clotting and liver histology, and there was evidence from human studies that excessive intakes of alpha-tocopherol could cause haemorrhage. Other adverse effects noted in clinical studies at doses of > 720 mg alpha-tocopherol/day included weakness, fatigue, creatinuria and effects on steroid hormone metabolism. Clinical studies indicate that, generally, intakes of below about 720 mg/day are without adverse effects in man, but one investigation in elderly patients showed an increase in serum cholesterol at doses of 300 mg alpha-tocopherol daily. Incidences of allergic reactions seem to be very rare. alpha-Tocopherol may be an essential nutrient. The U.S. National Academy of Sciences/National Research Council has recommended a dietary allowance of 0.15 mg/kg b.w./day. However, excessive intakes of alpha-tocopherol produce adverse clinical and biochemical effects, and self-medication with large doses of vitamin E preparations could present a hazard. The previously-allocated ADI was amended to include a lower value, which reflects the fact that alpha-tocopherol may be an essential nutrient. The upper value, which represents the maximum value for the AID, is based on clinical experience in man. IPCS Inchem: https://www.inchem.org/documents/jecfa/jecmono/v21je05.htm

Continued...

	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.
SODIUM CITRATE & CITRIC ACID	For citric acid (and its inorganic citrate salts) Based on extensive animal testing data and on human experience, citric acid has low acute toxicity. Citric acid is not suspected of causing cancer, birth defects or reproductive toxicity. Further, it does not cause mutations. Also, the sensitizing potential is considered low. In contrast, irritation, particularly of the eyes but also the airways and the skin, is the main hazard presented by citric acid.
ETHYLENE GLYCOL PHENYL ETHER & ALCOHOLS C16-18 ETHOXYLATED & SODIUM HYDROXIDE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
ETHYLENE GLYCOL PHENYL ETHER & 2-ETHYLHEXYL PALMITATE & SORBITAN MONOLAURATE, ETHOXYLATED & CITRIC ACID & ALCOHOLS C16-18 ETHOXYLATED & CETYL PALMITATE & FUMARIC ACID	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
DIMETHICONE & POLYQUATERNIUM-7 & GLYCERYL MONOSTEARATE & ALOES, EXTRACT & CHAMOMILE RECUTICA OIL & WATER	No significant acute toxicological data identified in literature search.
2-OCTYLDODECANOL & POTASSIUM SORBATE & POLYQUATERNIUM-7 & CITRIC ACID & GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE & GLYCEROL & SODIUM HYDROXIDE	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.
2-OCTYLDODECANOL & SODIUM HYDROXIDE	The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.
SODIUM BENZOATE & POTASSIUM SORBATE & CHAMOMILE RECUTICA OIL	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.
2-ETHYLHEXYL PALMITATE & CETYL PALMITATE	Group A aliphatic monoesters (fatty acid esters) cause very little or no injury and are considered safe for use in cosmetics.
SORBITAN MONOLAURATE, ETHOXYLATED & ALCOHOLS C16-18 ETHOXYLATED	Polyethers (such as ethoxylated surfactants and polyethylene glycols) are highly susceptible to being oxidized in the air. They then form complex mixtures of oxidation products. Animal testing reveals that whole the pure, non-oxidised surfactant is non-sensitizing, many of the oxidation products are sensitisers. The oxidization products also cause irritation.
ALCOHOLS C16-18 ETHOXYLATED & CETYL ETHER ETHOXYLATED	Humans have regular contact with alcohol ethoxylates through a variety of industrial and consumer products such as soaps, detergents and other cleaning products. Exposure to these chemicals can occur through swallowing, inhalation, or contact with the skin or eyes. Studies of acute toxicity show that relatively high volumes would have to occur to produce any toxic response. No death due to poisoning with alcohol ethoxylates has ever been reported. Studies show that alcohol ethoxylates have low toxicity through swallowing and skin contact. Animal studies show these chemicals may produce gastrointestinal irritation, stomach ulcers, hair standing up, diarrhea and lethargy. Slight to severe irritation occurred when undiluted alcohol ethyoxylates were applied to the skin and eyes of animals. These chemicals show no indication of genetic toxicity or potential to cause mutations and cancers. Toxicity is thought to be substantially lower than that of nonylphenol ethoxylates. Some of the oxidation products of this group of substances may have sensitizing properties. As they cause less irritation, nonionic surfactants are often preferred to ionic surfactants in topical products. However, their tendency to auto-oxidise also increases their irritation. Due to their irritating effect it is difficult to diagnose allergic contact dermatitis (ACD) by patch testing. Both laboratory and animal testing has shown that there is no evidence for alcohol ethoxylates (AEs) causing genetic damage, mutations or cancer. No adverse reproductive or developmental effects were observed.
CETYL PALMITATE & GLYCERYL MONOSTEARATE	For aliphatic fatty acids (and salts) 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. Skin and eye irritation potential, with a few stated exceptions, is chain length dependent and decreases with increasing chain length 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. 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. Animal eye irritation studies indicate that among the aliphatic acids, the C8-12 aliphatic acids are irritating to the eye while the 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 ug C16/cm2 and 91.84 ug 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

Continued...

	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. 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.
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE & CHAMOMILE RECUTICA OIL	Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins. Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated 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***

SECTION 12 Ecological information

Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
TENA Plastic Free Wet Wipes	Not Available	Not Available	Not Available	Not Available	Not Available

Continued...

sodium citrate

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	48h	Crustacea	>50mg/l	2
EC50(ECx)	48h	Crustacea	>50mg/l	2
EC50	96h	Algae or other aquatic plants	>18000-32000mg/l	1

ethylene glycol phenyl ether

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	>100mg/l	2
EC50	48h	Crustacea	460mg/l	2
NOEC(ECx)	24h	Fish	5mg/l	2
LC50	96h	Fish	154mg/l	2

dimethicone

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

2-octyldodecanol

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	100mg/l	1
EC50	48h	Crustacea	>0.035mg/l	2
LC50	96h	Fish	0.48mg/l	2
EC0(ECx)	72h	Algae or other aquatic plants	10mg/l	1

sodium benzoate

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	>30.5mg/l	2
EC50	48h	Crustacea	<650mg/l	1
LC50	96h	Fish	>100mg/l	2
NOEC(ECx)	72h	Algae or other aquatic plants	0.09mg/l	2

2-ethylhexyl palmitate

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	<100mg/l	2
EC50	48h	Crustacea	>3000mg/l	2
LC50	96h	Fish	>10000mg/l	2
EC50(ECx)	72h	Algae or other aquatic plants	<100mg/l	2

potassium sorbate

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96h	Fish	500mg/l	1
EC50	72h	Algae or other aquatic plants	24.1mg/l	2
EC50	48h	Crustacea	750mg/l	1
NOEC(ECx)	72h	Algae or other aquatic plants	6.47mg/l	2

sorbitan monolaurate, ethoxylated

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96h	Fish	383mg/l	2

Polyquaternium-7

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

citric acid

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	990mg/l	2
EC50	48h	Crustacea	>50mg/l	2
LC50	96h	Fish	>100mg/l	2
EC50(ECx)	48h	Crustacea	>50mg/l	2

alcohols C16-18 ethoxylated

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	>100mg/l	2
LC50	96h	Fish	>=0.423<=8.211mg/l	2
EC20(ECx)	72h	Algae or other aquatic plants	0.06mg/l	2

cetyl ether ethoxylated

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96h	Fish	>=0.423<=8.211mg/l	2

cetyl palmitate

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96h	Fish	<0.001mg/L	2
NOEC(ECx)	96h	Fish	<0.001mg/L	2

glyceryl monostearate

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	>0.01mg/L	2

Continued...

	EC50	48h	Crustacea	>0.01mg/l	2
	EC50(ECx)	48h	Crustacea	>0.01mg/l	2

guar hydroxypropyltrimonium chloride

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

glycerol

Endpoint	Test Duration (hr)	Species	Value	Source
LC50	96h	Fish	>11mg/L	2
EC0(ECx)	24h	Crustacea	>500mg/l	1

Aloes, extract

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

fumaric acid

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	41mg/l	1
EC10(ECx)	48h	Algae or other aquatic plants	6.7-228mg/l	4
EC50	48h	Crustacea	>100mg/l	2
LC50	96h	Fish	>100mg/l	2

sodium hydroxide

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	48h	Crustacea	34.59-47.13mg/l	4
EC50(ECx)	48h	Crustacea	34.59-47.13mg/l	4
LC50	96h	Fish	144-267mg/l	4

Chamomile recutica oil

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

DL-alpha-tocopherol acetate

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	>27.8mg/l	2
EC50	48h	Crustacea	>20.6mg/l	2
LC50	96h	Fish	>11mg/l	2
NOEC(ECx)	96h	Fish	11mg/l	2

water

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

Legend: ***Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data***

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
ethylene glycol phenyl ether	LOW	LOW
2-octyldodecanol	LOW	LOW
citric acid	LOW	LOW
cetyl ether ethoxylated	LOW	LOW
cetyl palmitate	LOW	LOW
glyceryl monostearate	LOW	LOW
glycerol	LOW	LOW
fumaric acid	LOW	LOW
sodium hydroxide	LOW	LOW
DL-alpha-tocopherol acetate	HIGH	HIGH
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
ethylene glycol phenyl ether	LOW (LogKOW = 1.16)
2-octyldodecanol	LOW (LogKOW = 8.6251)
citric acid	LOW (LogKOW = -1.64)
cetyl ether ethoxylated	HIGH (LogKOW = 6.4598)

Continued...

Ingredient	Bioaccumulation
cetyl palmitate	LOW (LogKOW = 14.615)
glyceryl monostearate	HIGH (LogKOW = 6.6162)
glycerol	LOW (LogKOW = -1.76)
fumaric acid	LOW (LogKOW = 0.46)
sodium hydroxide	LOW (LogKOW = -3.8796)
DL-alpha-tocopherol acetate	LOW (LogKOW = 11.9136)

Mobility in soil

Ingredient	Mobility
ethylene glycol phenyl ether	LOW (Log KOC = 12.12)
2-octyldodecanol	LOW (Log KOC = 40300)
citric acid	LOW (Log KOC = 10)
cetyl ether ethoxylated	LOW (Log KOC = 1292)
cetyl palmitate	LOW (Log KOC = 178500000)
glyceryl monostearate	LOW (Log KOC = 486.6)
glycerol	HIGH (Log KOC = 1)
fumaric acid	LOW (Log KOC = 6.314)
sodium hydroxide	LOW (Log KOC = 14.3)
DL-alpha-tocopherol acetate	LOW (Log KOC = 13870000)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	▸ Recycle wherever possible or consult manufacturer for recycling options. ▸ Consult State Land Waste Management Authority for disposal.

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

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

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

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

Not Applicable

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

Product name	Group
sodium citrate	Not Available
ethylene glycol phenyl ether	Not Available
dimethicone	Not Available
2-octyldodecanol	Not Available
sodium benzoate	Not Available
2-ethylhexyl palmitate	Not Available
potassium sorbate	Not Available
sorbitan monolaurate, ethoxylated	Not Available
Polyquaternium-7	Not Available
citric acid	Not Available
alcohols C16-18 ethoxylated	Not Available
cetyl ether ethoxylated	Not Available
cetyl palmitate	Not Available
glyceryl monostearate	Not Available
guar hydroxypropyltrimonium chloride	Not Available
glycerol	Not Available
Aloes, extract	Not Available
fumaric acid	Not Available
sodium hydroxide	Not Available
Chamomile recutica oil	Not Available

Continued...

Product name	Group
DL-alpha-tocopherol acetate	Not Available
water	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
sodium citrate	Not Available
ethylene glycol phenyl ether	Not Available
dimethicone	Not Available
2-octyldodecanol	Not Available
sodium benzoate	Not Available
2-ethylhexyl palmitate	Not Available
potassium sorbate	Not Available
sorbitan monolaurate, ethoxylated	Not Available
Polyquaternium-7	Not Available
citric acid	Not Available
alcohols C16-18 ethoxylated	Not Available
cetyl ether ethoxylated	Not Available
cetyl palmitate	Not Available
glyceryl monostearate	Not Available
guar hydroxypropyltrimonium chloride	Not Available
glycerol	Not Available
Aloes, extract	Not Available
fumaric acid	Not Available
sodium hydroxide	Not Available
Chamomile recutica oil	Not Available
DL-alpha-tocopherol acetate	Not Available
water	Not Available

SECTION 15 Regulatory information

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

sodium citrate is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

ethylene glycol phenyl ether is found on the following regulatory lists
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6
Australian Inventory of Industrial Chemicals (AIIC)

dimethicone is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

2-octyldodecanol is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

sodium benzoate is found on the following regulatory lists
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
Australian Inventory of Industrial Chemicals (AIIC)

2-ethylhexyl palmitate is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

potassium sorbate is found on the following regulatory lists
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
Australian Inventory of Industrial Chemicals (AIIC)

sorbitan monolaurate, ethoxylated is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

Polyquaternium-7 is found on the following regulatory lists
Australian Inventory of Industrial Chemicals (AIIC)

citric acid is found on the following regulatory lists
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australian Inventory of Industrial Chemicals (AIIC)

alcohols C16-18 ethoxylated is found on the following regulatory lists
Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Continued...

Australian Inventory of Industrial Chemicals (AIIC)

cetyl ether ethoxylated is found on the following regulatory lists

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

cetyl palmitate is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

glyceryl monostearate is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

guar hydroxypropyltrimonium chloride is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

glycerol is found on the following regulatory lists

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

Aloes, extract is found on the following regulatory lists

Australia Industrial Chemicals Introduction Scheme Comparable Chemicals Table
Australian Inventory of Industrial Chemicals (AIIC)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Group 2B: Possibly carcinogenic to humans

fumaric acid is found on the following regulatory lists

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

sodium hydroxide is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 10 / Appendix C
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5
Australian Inventory of Industrial Chemicals (AIIC)

Chamomile recutica oil is found on the following regulatory lists

Australia Industrial Chemicals Introduction Scheme Comparable Chemicals Table

DL-alpha-tocopherol acetate is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

water is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (Chamomile recutica oil)
Canada - NDSL	No (ethylene glycol phenyl ether; dimethicone; 2-octyldodecanol; sodium benzoate; 2-ethylhexyl palmitate; potassium sorbate; sorbitan monolaurate, ethoxylated; Polyquaternium-7; citric acid; alcohols C16-18 ethoxylated; cetyl ether ethoxylated; cetyl palmitate; glyceryl monostearate; guar hydroxypropyltrimonium chloride; glycerol; Aloes, extract; fumaric acid; sodium hydroxide; Chamomile recutica oil; DL-alpha-tocopherol acetate; water)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (dimethicone; Polyquaternium-7; guar hydroxypropyltrimonium chloride)
Japan - ENCS	No (dimethicone; guar hydroxypropyltrimonium chloride; Aloes, extract; Chamomile recutica oil)
Korea - KECI	No (dimethicone; Aloes, extract; Chamomile recutica oil)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (Chamomile recutica oil)
USA - TSCA	No (dimethicone; Aloes, extract; Chamomile recutica oil)
Taiwan - TCSI	Yes
Mexico - INSQ	No (alcohols C16-18 ethoxylated; Chamomile recutica oil)
Vietnam - NCI	Yes
Russia - FBEPH	No (dimethicone; sorbitan monolaurate, ethoxylated; Polyquaternium-7; alcohols C16-18 ethoxylated; cetyl ether ethoxylated; guar hydroxypropyltrimonium chloride; Aloes, extract; Chamomile recutica oil)
Legend:	***Yes = All CAS declared ingredients are on the inventory*** ***No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.***

SECTION 16 Other information

Revision Date	30/07/2024
Initial Date	30/07/2024

Continued...

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit。
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration

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