

Pressure Spot Indicator Catalyst Coltène/Whaledent AG

Version No: 3.3

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: **02/10/2023**Print Date: **26/11/2024**L.REACH.GB.EN

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

1.1. Product Identifier

Product name	Pressure Spot Indicator Catalyst
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	Medical device, for dental use only	
Uses advised against	No specific uses advised against are identified.	

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

Registered company name	Coltène/Whaledent AG	
Address	Feldwiesenstrasse 20 Altstätten 9450 Switzerland	
Telephone	+41 (71) 75 75 300	
Fax	1) 75 75 301	
Website	w.coltene.com	
Email	sds@coltene.com	

1.4. Emergency telephone number

Association / Organisation	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone number(s)	+44 20 3901 3542
Other emergency telephone number(s)	+44 808 164 9592

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

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classified according to	H315 - Skin Corrosion/Irritation Category 2, H319 - Serious Eye Damage/Eye Irritation Category 2, H332 - Acute Toxicity
GB-CLP Regulation, UK SI	(Inhalation) Category 4, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H371 -
2019/720 and UK SI	Specific Target Organ Toxicity - Single Exposure Category 2, H373 - Specific Target Organ Toxicity - Repeated Exposure
2020/1567 ^[1]	Category 2, H413 - Hazardous to the Aquatic Environment Long-Term Hazard Category 4
Legend:	1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567

2.2. Label elements

Hazard pictogram(s)





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Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H371	May cause damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
H413	May cause long lasting harmful effects to aquatic life.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P260	Do not breathe mist/vapours/spray.	
P271	Use only outdoors or in a well-ventilated area.	
P270	Do not eat, drink or smoke when using this product.	
P273	P273 Avoid release to the environment.	
P280	Wear protective gloves, protective clothing, eye protection and face protection.	
P264	Wash all exposed external body areas thoroughly after handling.	

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.				
P308+P311	IF exposed or concerned: Call a POISON CENTER/doctor/physician/first aider.				
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.				
P337+P313	If eye irritation persists: Get medical advice/attention.				
P302+P352	P302+P352 IF ON SKIN: Wash with plenty of water and soap.				
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.				
P332+P313	If skin irritation occurs: Get medical advice/attention.				
P362+P364	Take off contaminated clothing and wash it before reuse.				

Precautionary statement(s) Storage

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

Precautionary statement(s) Disposal

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

Material contains Alkyl silicate, di-n-octyltin oxide, dioctyltin dinonanoate.

2.3. Other hazards

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

SECTION 3 Composition / information on ingredients

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1. CAS No 2.EC No 3.Index No 4.REACH No	% [weight]	Name	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	SCL / M- Factor	Nanoform Particle Characteristics
1. 870-08-6 2.212-791-1 3.Not Available 4.Not Available	5-10	di-n-octyltin oxide	Specific Target Organ Toxicity - Single Exposure Category 2; H371 [1]	SCL: Not Available Acute M factor: Not Applicable	Not Available

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1. CAS No 2.EC No 3.Index No 4.REACH No	% [weight]	Name	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	SCL / M- Factor	Nanoform Particle Characteristics
				Chronic M factor: Not Applicable	
Not Available Not Available Not Available Not Available A.Not Available	10-25	<u>Alkyl silicate</u>	Flammable Liquids Category 3, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Acute Toxicity (Inhalation) Category 3, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Specific Target Organ Toxicity - Repeated Exposure Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 4; H226, H315, H319, H331, H335, H373, H413 [1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 68299-15-0 2.269-595-4 3.Not Available 4.Not Available	5-10	dioctyltin dinonanoate	Specific Target Organ Toxicity - Single Exposure Category 2; H371 ^[1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available

SECTION 4 First aid measures

4.1. Description of first aid measures

= 000p	
Eye Contact	If this product comes in contact with the eyes: • Wash out immediately with fresh running water. • Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. • Seek medical attention without delay; if pain persists or recurs seek medical attention. • Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

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5.3. 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.
Fire/Explosion Hazard	 Non combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. May emit corrosive fumes.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

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

6.4. Reference to other sections

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

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Safe handling	 Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Fire and explosion protection	See section 5
Other information	 Store in original containers. Keep containers securely sealed. Store in a cool, dry, well-ventilated area.

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- ▶ Store away from incompatible materials and foodstuff containers.
- ▶ Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	Recommended storage temperature: 15 - 23 °C Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
di-n-octyltin oxide	Oral 0.002 mg/kg bw/day (Systemic, Chronic) *	Not Available
dioctyltin dinonanoate	Dermal 0.0175 mg/kg bw/day (Systemic, Chronic) Inhalation 0.0617 mg/m³ (Systemic, Chronic) Dermal 0.00625 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.0109 mg/m³ (Systemic, Chronic) * Oral 0.00625 mg/kg bw/day (Systemic, Chronic) *	Not Available

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs).	di-n-octyltin oxide	Tin compounds, organic, except Cyhexatin (ISO), (as Sn)	0.1 mg/m3	0.2 mg/m3	Not Available	Sk
UK Workplace Exposure Limits (WELs).	dioctyltin dinonanoate	Tin compounds, organic, except Cyhexatin (ISO), (as Sn)	0.1 mg/m3	0.2 mg/m3	Not Available	Sk

Ingredient	Original IDLH	Revised IDLH
di-n-octyltin oxide	25 mg/m3	Not Available
Alkyl silicate	Not Available	Not Available
dioctyltin dinonanoate	25 mg/m3	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
Alkyl silicate	Е	≤ 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.	

MATERIAL DATA

Exposure limits with "skin" notation indicate that vapour and liquid may be absorbed through intact skin. Absorption by skin may readily exceed vapour inhalation exposure. Symptoms for skin absorption are the same as for inhalation. Contact with eyes and mucous membranes may also contribute to overall exposure and may also invalidate the exposure standard.

The no/lowest-observed-adverse-effect levels (NOAELs or LOAELs) in inhalation studies involving tri-n-butyltin chloride and bromide are 0.3-0.4 ppm (2-4 mg/m3) based on changes in the lungs, heart, liver, kidneys, nervous system and reproductive system in rodents. Oral administration of organotin compounds has induced

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toxicity in a number of differing organ systems, organs and lungs. The LOAEL for triethyltin bromide was 0.4 mg triethyltin/kg/day as 5 ppm in drinking water. The LOAELs for the most critical organ sites in rats (i.e. the cellular immune response and CNS effects) are 0.15 and 0.23 mg/tin/kg body weight/day. Experience with ingested tri- and diethyltins in the treatment of staphylococcal infections, osteomyelitis, anthrax and acne suggests that humans react in a manner similar to rodents, but that the human is more sensitive to absorbed organic tin. The recommended TLV-TWA is thought to minimise the potential for adverse effects on immune function and the central nervous system. A STEL is also recommended to minimise acute symptoms such as eye and respiratory tract irritation, headaches and/or nausea. Based on an exposure to 0.1 mg/m3, a 70-kg worker breathing 10 m3 of air/8hr workday and assuming complete retention of the inhaled dose, would receive a daily exposure of 14.3 ug tin/kg body weight of an organotin compound. A skin notation was recommended based on animal data and the potential danger of enhanced absorption due to damaged skin present in many exposed workers.

8.2. Exposure controls

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

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The basic types of engineering controls are:

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

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

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.

An approved self contained breathing apparatus (SCBA) may be required in some situations.

Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the

8.2.1. Appropriate engineering controls

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

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range	
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents	
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity	
3: Intermittent, low production.	3: High production, heavy use	
4: Large hood or large air mass in motion	4: Small hood-local control only	

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal protective equipment











Eye and face protection

- Safety glasses with side shields.
- ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Skin protection

See Hand protection below

Hands/feet protection

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

Body protection

See Other protection below

Other protection

Overalls.

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- P.V.C apron.
- Barrier cream.
- Skin cleansing cream.
- ▶ Eye wash unit.

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 P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^{^ -} Full-face

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

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Green		
Physical state	Free-flowing Paste	Relative density (Water = 1)	1.0
Odour	Not Available	Partition coefficient n- octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	>150	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

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10.1.Reactivity	See section 7.2
10.2. Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Inhaled	
Ingestion	
Skin Contact	
Eye	
Chronic	

Pressure Spot Indicator	TOXICITY	IRRITATION
Catalyst	Not Available	Not Available
	TOXICITY	IRRITATION
di-n-octyltin oxide	Oral (Rat) LD50: 2500 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
		Skin: no adverse effect observed (not irritating) ^[1]
Alkyl silicate	TOXICITY	IRRITATION
	Not Available	Not Available
	TOXICITY	IRRITATION
dioctyltin dinonanoate	dermal (rat) LD50: >=2000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
	Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]

Legend:

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

dioctyltin dinonanoate

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 Carcinogenicity

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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 oliverol or acylolycerol.

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.

No significant acute toxicological data identified in literature search.

Pressure Spot Indicator Catalyst & di-n-octyltin oxide & dioctyltin dinonanoate 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

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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.

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

🗶 – Data either not available or does not fill the criteria for classification Legend:

Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

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

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

B O I b ii i	Endpoint	Test Duration (hr)	Species	Value	Source
Pressure Spot Indicator Catalyst	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>0.002mg/l	2
di-n-octyltin oxide	EC50	48h	Crustacea	>0.21mg/l	2
	NOEC(ECx)	24h	Crustacea	0.001mg/l	2
	LC50	96h	Fish	>0.09mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Source
Alkyl silicate	Not Available	Not Available	Not Available	Not Available	Not Availab
	Endpoint	Test Duration (hr)	Species	Value	Sourc
	EC50	96h	Algae or other aquatic plants	89mg/l	2
dia ataldia dia amana	EC50	72h	Algae or other aquatic plants	0.17mg/l	2
dioctyltin dinonanoate	EC10(ECx)	72h	Algae or other aquatic plants	>0.014mg/L	2
	LC50	96h	Fish	>5.8mg/l	2
	EC50	48h	Crustacea	0.17mg/l	2
Legend:		cotox database - Aquatic Toxicity D	e ECHA Registered Substances - Ecotoxicolo lata 5. ECETOC Aquatic Hazard Assessment centration Data 8. Vendor Data	,	

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
di-n-octyltin oxide	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
di-n-octyltin oxide	LOW (BCF = 100)
dioctyltin dinonanoate	LOW (LogKOW = 12.16)

12.4. Mobility in soil

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Ingredient	Mobility
di-n-octyltin oxide	LOW (Log KOC = 202700)

12.5. Results of PBT and vPvB assessment

	P	В	Т
Relevant available data	Not Available	Not Available	Not Available
PBT	×	×	×
vPvB	×	×	×
PBT Criteria fulfilled?	No		
vPvB	No		

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

•	
Marine Pollutant	NO
HAZCHEM	Not Applicable

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

Land transport (ADR). NO	I REGULATED FOR	INANSE	OKT OF DANGE	
14.1. UN number or ID number	Not Applicable	Not Applicable		
14.2. UN proper shipping name	Not Applicable			
14.3. Transport hazard	Class	Not Appli	cable	
class(es)	Subsidiary Hazard	Not Appli	cable	
14.4. Packing group	Not Applicable			
14.5. Environmental hazard	Not Applicable	Not Applicable		
	Hazard identification	(Kemler)	Not Applicable	
	Classification code		Not Applicable	
14.6. Special precautions	Hazard Label		Not Applicable	
for user	Special provisions		Not Applicable	
	Limited quantity		Not Applicable	
	Tunnel Restriction C	ode	Not Applicable	

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

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	ICAO/IATA Class	Not Applicable

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	ICAO / IATA Subsidiary Hazard	Not Applicable	
	ERG Code	Not Applicable	
14.4. Packing group	Not Applicable		
14.5. Environmental hazard	Not Applicable		
14.6. Special precautions for user	Special provisions	Not Applicable	
	Cargo Only Packing Instructions	Not Applicable	
	Cargo Only Maximum Qty / Pack	Not Applicable	
	Passenger and Cargo Packing Ir	Not Applicable	
	Passenger and Cargo Maximum	Not Applicable	
	Passenger and Cargo Limited Qu	Not Applicable	
	Passenger and Cargo Limited Ma	Not Applicable	

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

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

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

14.1. UN number	Not Applicable	Not Applicable		
14.2. UN proper shipping name	Not Applicable			
14.3. Transport hazard class(es)	Not Applicable No	Not Applicable Not Applicable		
14.4. Packing group	Not Applicable			
14.5. Environmental hazard	Not Applicable			
14.6. Special precautions for user	Classification code	Not Applicable		
	Special provisions	Not Applicable		
	Limited quantity	Not Applicable		
	Equipment required	Not Applicable		
	Fire cones number	Not Applicable		

14.7.1. 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
di-n-octyltin oxide	Not Available
Alkyl silicate	Not Available
dioctyltin dinonanoate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
di-n-octyltin oxide	Not Available
Alkyl silicate	Not Available

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Product name	Ship Type
dioctyltin dinonanoate	Not Available

SECTION 15 Regulatory information

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

di-n-octyltin oxide is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

Great Britain GB PIC List of Chemicals - Part 1 - Chemicals subject to export notification procedure (referred to in Article 8 of the PIC Regulation)

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

UK Workplace Exposure Limits (WELs).

Alkyl silicate is found on the following regulatory lists

Not Applicable

dioctyltin dinonanoate is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

Great Britain GB PIC List of Chemicals - Part 1 - Chemicals subject to export notification procedure (referred to in Article 8 of the PIC Regulation)

UK Workplace Exposure Limits (WELs).

Additional Regulatory Information

Not Applicable

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

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

Seveso Category Not Available

15.2. Chemical safety assessment

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

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (di-n-octyltin oxide; dioctyltin dinonanoate)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	All chemical substances in this product have been designated as TSCA Inventory 'Active'
Taiwan - TCSI	Yes
Mexico - INSQ	No (di-n-octyltin oxide; dioctyltin dinonanoate)
Vietnam - NCI	Yes
Russia - FBEPH	No (dioctyltin dinonanoate)
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

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Initial Date	12/01/2022

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H226	Flammable liquid and vapour.	
H331	Toxic if inhaled.	

SDS Version Summary

Version	Date of Update	Sections Updated
2.3	02/10/2023	Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (skin), Toxicological information - Acute Health (swallowed), First Aid measures - Advice to Doctor, Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (extinguishing media), Firefighting measures - Fire Fighter (fire/explosion hazard), Firefighting measures - Fire Fighter (fire incompatibility), First Aid measures - First Aid (swallowed), Composition / information on ingredients - Ingredients, Handling and storage - Storage (storage incompatibility), Handling and storage - Storage (suitable container), Identification of the substance / mixture and of the company / undertaking - Use

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.

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

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

- ▶ PC TWA: Permissible Concentration-Time Weighted Average
- ▶ PC STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ▶ ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ► TEEL: Temporary Emergency Exposure Limit。
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ► ES: Exposure Standard
- OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ▶ TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- ▶ OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ▶ DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- ► IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code
- ▶ 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

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▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Ciacomoanon ana procesa	orassinution and procedure used to derive the orassinution for inixtures according to regulation (ES) 12/22/00 [OLI]		
Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure		
Skin Corrosion/Irritation Category 2, H315	Expert judgement		
Serious Eye Damage/Eye Irritation Category 2, H319	Expert judgement		
Acute Toxicity (Inhalation) Category 4, H332	Expert judgement		
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, H335	Expert judgement		
Specific Target Organ Toxicity - Single Exposure Category 2, H371	Expert judgement		
Specific Target Organ Toxicity - Repeated Exposure Category 2, H373	Calculation method		
Hazardous to the Aquatic Environment Long-Term Hazard Category 4, H413	Calculation method		

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