AFFINIS PRECIOUS light body / PRECIOUS regular body

Coltène/Whaledent AG

Version No: **3.4**
Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: **10/09/2024**
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SECTION 1 Identification of the substance / mixture and of the company / undertaking

1.1. Product Identifier

Product name	AFFINIS PRECIOUS light body / PRECIOUS regular body
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 Use according to manufacturer's directions.
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	+41 (71) 75 75 301
Website	www.coltene.com
Email	msds@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 GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 [1]	H412 - Hazardous to the Aquatic Environment Long-Term Hazard Category 3
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)	Not Applicable
Signal word	**Not Applicable**

Hazard statement(s)

H412	Harmful to aquatic life with long lasting effects.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P273	Avoid release to the environment.

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

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

Material contains cristobalite, silica amorphous, Silanamine, 1,1,1-trimethyl-N- (trimethylsilyl)-, hydrolysis products with silica, heptamethyltrisiloxane, ethoxylated, propyl ether.

2.3. Other hazards

decamethylcyclopentasiloxane	Listed in the European Chemicals Agency (ECHA) Candidate List of Substances of Very High Concern for Authorisation
decamethylcyclopentasiloxane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)

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. 112945-52-5 2.231-545-4 3.Not Available 4.Not Available	1-5	silica amorphous	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure Category 3; H315, H319, H335, EUH210 [3]	SCL: Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 541-02-6 2.208-764-9 3.Not Available 4.Not Available	<1	decamethylcyclopentasiloxane	Not Classified [3]	SCL: Not Available Acute M factor: 100 Chronic M factor: 10	Not Available
1. 27306-78-1 2.Not Available 3.Not Available 4.Not Available	<2	heptamethyltrisiloxane, ethoxylated, propyl ether	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1]	SCL: Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 14464-46-1 2.238-455-4 3.Not Available 4.Not Available	15-25	cristobalite	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373 [1]	SCL: Not Available Acute M factor: Not	Not Available

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
				Available Chronic M factor: Not Available	
1. 68909-20-6 2.Not Available 3.Not Available 4.Not Available	1-5	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Specific Target Organ Toxicity - Repeated Exposure Category 2; H373, EUH066 [1]	SCL: Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 128-37-0 2.204-881-4 3.Not Available 4.None	<0.2	2,6-di-tert-butyl-4-methylphenol*	Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H410 [1]	SCL: Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available

Legend:	***1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties***

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	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, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary.
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.

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. silicon dioxide (SiO2) 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

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 full body protective clothing with breathing apparatus. ▸ Prevent, by all means available, spillage from entering drains or water courses. ▸ Consider evacuation (or protect in place). ▸ No smoking, naked lights or ignition sources. ▸ Increase ventilation. ▸ Stop leak if safe to do so. ▸ Water spray or fog may be used to disperse / absorb vapour. ▸ Contain or absorb spill with sand, earth or vermiculite. ▸ Collect recoverable product into labelled containers for recycling. ▸ 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. ▸ 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	▸ Avoid strong acids, bases.
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
silica amorphous	Inhalation 0.3 mg/m³ (Local, Chronic)	Not Available
decamethylcyclopentasiloxane	Inhalation 97.3 mg/m³ (Systemic, Chronic) Inhalation 24.2 mg/m³ (Local, Chronic) ***Inhalation 0.0173 mg/m³ (Systemic, Chronic) **** ***Oral 5 mg/kg bw/day (Systemic, Chronic) **** ***Inhalation 4.3 mg/m³ (Local, Chronic) ****	0.0012 mg/L (Water (Fresh)) 0.00012 mg/L (Water (Marine)) 11 mg/kg sediment dw (Sediment (Fresh Water)) 1.1 mg/kg sediment dw (Sediment (Marine)) 2.54 mg/kg soil dw (Soil) 10 mg/L (STP) 16 mg/kg food (Oral)
2,6-di-tert-butyl-4-methylphenol*	Dermal 0.5 mg/kg bw/day (Systemic, Chronic) Inhalation 1.76 mg/m³ (Systemic, Chronic) ***Dermal 0.25 mg/kg bw/day (Systemic, Chronic) **** ***Inhalation 0.000435 mg/m³ (Systemic, Chronic) **** ***Oral 0.25 mg/kg bw/day (Systemic, Chronic) ****	0.000199 mg/L (Water (Fresh)) 0.00199 mg/L (Water - Intermittent release) 0.00002 mg/L (Water (Marine)) 0.458 mg/kg sediment dw (Sediment (Fresh Water)) 0.046 mg/kg sediment dw (Sediment (Marine)) 0.054 mg/kg soil dw (Soil) 0.017 mg/L (STP) 16.67 mg/kg food (Oral)

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs).	silica amorphous	Diatomaceous earth, natural, respirable dust	1.2 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	silica amorphous	Silica, fused respirable dust	0.08 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	cristobalite	Silica, respirable crystalline (respirable fraction)	0.1 mg/m3	Not Available	Not Available	Carc (where generated as a result of a work process)
UK Workplace Exposure Limits (WELs).	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Silica, amorphous: inhalable dust	6 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Silica, amorphous: respirable dust	2.4 mg/m3	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	2,6-di-tert-butyl-4-methylphenol*	2,6-Di-tert-butyl-p-cresol	10 mg/m3	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
silica amorphous	3,000 mg/m3	Not Available

Ingredient	Original IDLH	Revised IDLH
decamethylcyclopentasiloxane	Not Available	Not Available
heptamethyltrisiloxane, ethoxylated, propyl ether	Not Available	Not Available
cristobalite	Not Available	Not Available
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not Available	Not Available
2,6-di-tert-butyl-4-methylphenol*	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
decamethylcyclopentasiloxane	E	≤ 0.1 ppm
heptamethyltrisiloxane, ethoxylated, propyl ether	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.***	

MATERIAL DATA

For amorphous crystalline silica (precipitated silicic acid):
Amorphous crystalline silica shows little potential for producing adverse effects on the lung and exposure standards should reflect a particulate of low intrinsic toxicity. Mixtures of amorphous silicas/ diatomaceous earth and crystalline silica should be monitored as if they comprise only the crystalline forms.
The dusts from precipitated silica and silica gel produce little adverse effect on pulmonary functions and are not known to produce significant disease or toxic effect.
IARC has classified silica, amorphous as Group 3: **NOT** classifiable as to its carcinogenicity to humans.
Evidence of carcinogenicity may be inadequate or limited in animal testing.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

- Employees exposed to confirmed human carcinogens should be authorized to do so by the employer, and work in a regulated area.
- Work should be undertaken in an isolated system such as a "glove-box" . Employees should wash their hands and arms upon completion of the assigned task and before engaging in other activities not associated with the isolated system.
- Within regulated areas, the carcinogen should be stored in sealed containers, or enclosed in a closed system, including piping systems, with any sample ports or openings closed while the carcinogens are contained within.
- Open-vessel systems are prohibited.
- Each operation should be provided with continuous local exhaust ventilation so that air movement is always from ordinary work areas to the operation.
- Exhaust air should not be discharged to regulated areas, non-regulated areas or the external environment unless decontaminated. Clean make-up air should be introduced in sufficient volume to maintain correct operation of the local exhaust system.
- For maintenance and decontamination activities, authorized employees entering the area should be provided with and required to wear clean, impervious garments, including gloves, boots and continuous-air supplied hood. Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- Except for outdoor systems, regulated areas should be maintained under negative pressure (with respect to non-regulated areas).
- Local exhaust ventilation requires make-up air be supplied in equal volumes to replaced air.
- Laboratory hoods must be designed and maintained so as to draw air inward at an average linear face velocity of 0.76 m/sec with a minimum of 0.64 m/sec. Design and construction of the fume hood requires that insertion of any portion of the employees body, other than hands and arms, be disallowed.

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. ‣ 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	Coloured

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

		(g/m3)	
Nanoform Solubility	Not Available	**Nanoform Particle Characteristics**	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	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	

AFFINIS PRECIOUS light body / PRECIOUS regular body	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
silica amorphous	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Eye (Rodent - rabbit): 25mg/24H - Mild
	Inhalation (Rat) LC50: >0.09<0.84 mg/l4h[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: >1000 mg/kg[1]	Skin: no adverse effect observed (not irritating)[1]
decamethylcyclopentasiloxane	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >15248 mg/kg[2]	Eye (Rodent - rabbit): 500mg/24H - Mild
	Inhalation (Rat) LC50: 8.67 mg/l4h[1]	Eye: no adverse effect observed (not irritating)[1]
	Oral (Rat) LD50: >5000 mg/kg[1]	Skin (Rodent - rabbit): 500mg/24H - Mild
		Skin: adverse effect observed (irritating)[1]
		Skin: no adverse effect observed (not irritating)[1]
heptamethyltrisiloxane, ethoxylated, propyl ether	**TOXICITY**	**IRRITATION**
	Inhalation (Rat) LC50: 2 mg/L4h[2]	Not Available
	Oral (Rat) LD50: 4929.84 mg/kg[2]	
cristobalite	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50: >5000 mg/kg[2]	Not Available
2,6-di-tert-butyl-4-methylphenol*	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >2000 mg/kg *[2]	Eye (Rodent - rabbit): 100mg/24H - Moderate
	Oral (Rat) LD50: >2000 mg/kg *[2]	Eye: no adverse effect observed (not irritating)[1]

	Oral (Rat) LD50: 890 mg/kg[2]	Skin (Human): 500mg/48H - Mild
	Oral (woman) TDLo: 80 mg/kg[2]	Skin (Rodent - rabbit): 500mg/48H - Moderate
		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***

SILICA AMORPHOUS	Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]
DECAMETHYLCYCLOPENTASILOXANE	Liver changes, spleen changes recorded. Carcinogenicity: Animal testing showed no carcinogenic effects. Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on test data Genotoxicity in vivo: Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo Species: Rat Application Route: inhalation (vapor) Result: negative Remarks: Based on test data Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effect. Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Inhalation Symptoms: No effects on fertility. Remarks: Based on test data Effects on fetal development : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Inhalation Symptoms: No effects on fetal development. Remarks: Based on test data Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments Routes of exposure: Assessment: No significant health effects observed in animals at concentrations of 200 mg/kg bw or less. Routes of exposure: Ingestion Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less. Routes of exposure: inhalation (vapor) Assessment: No significant health effects observed in animals at concentrations of 1 mg/l/6h/d or less. Results from a 2 year repeated vapour inhalation exposure study to rats of decamethylcyclopentasiloxane (D5) indicate effects (uterine endometrial tumours) in female animals. This finding occurred at the highest exposure dose (160 ppm) only. Studies to date have not demonstrated if this effect occurs through a pathway that is relevant to humans The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.
HEPTAMETHYLTRISILOXANE, ETHOXYLATED, PROPYL ETHER	For siloxanes: Effects which based on the reviewed literature do not seem to be problematic are acute toxicity, irritant effects, sensitization and genotoxicity. Some studies indicate that some of the siloxanes may have endocrine disrupting properties, and reproductive effects have caused concern about the possible effects of the siloxanes on humans and the environment. Only few siloxanes are described in the literature with regard to health effects, and it is therefore not possible to make broad conclusions and comparisons of the toxicity related to short-chained linear and cyclic siloxanes based on the present evaluation. Data are primarily found on the cyclic siloxanes D4 (octamethylcyclotetrasiloxane) and D5 (decamethylcyclopentasiloxane) and the short-linear HMDS (hexamethyldisiloxane). These three siloxanes have a relatively low order of acute toxicity by oral, dermal and inhalatory routes and do not require classification for this effect. They are not found to be irritating to skin or eyes and are also not found sensitizing by skin contact. Data on respiratory sensitization have not been identified. Subacute and subchronic toxicity studies show that the liver is the main target organ for D4 which also induces liver cell enzymes. This enzyme induction contributes to the elimination of the substance from the tissues. Primary target organ for D5 exposure by inhalation is the lung. D5 has an enzyme induction profile similar to that of D4. Subacute and subchronic inhalation of HMDS affect in particular the lungs and kidneys in rats. None of the investigated siloxanes show any signs of genotoxic effects ***in vitro*** or ***in vivo***. Preliminary results indicate that D5 has a potential carcinogenic effect. D4 is considered to impair fertility in rats by inhalation and is classified as a substance toxic to reproduction in category 3 with the risk phrase R62 ('Possible risk of impaired fertility'). The results of a study to screen for oestrogen activity indicate that D4 has very weak oestrogenic and antioestrogenic activity and is a partial agonist (enhances the effect of the estrogen). It is not uncommon for compounds that are weakly oestrogenic to also have antioestrogenic properties. Comparison of the oestrogenic potency of D4 relative to ethinyloestradiol (steroid hormone) indicates that D4 is 585,000 times less potent than ethinyloestradiol in the rat stain Sprague- Dawley and 3.7 million times less potent than ethinyloestradiol in the Fisher-344 rat strain. Because of the lack of effects on other endpoints designated to assess oestrogenicity, the oestrogenicity as mode of action for the D4 reproductive effects has been questioned. An indirect mode of action causing a delay of the LH (luteinising hormone) surge necessary for optimal timing of ovulation has been suggested as the mechanism. Based on the reviewed information, the critical effects of the siloxanes are impaired fertility (D4) and potential carcinogenic effects (uterine tumours in females). Furthermore there seem to be some effects on various organs following repeated exposures, the liver (D4), kidney (HMDS) and lung (D5 and HMDS) being the target organs. A possible oestrogenic effect contributing to the reproductive toxicity of D4 is debated. There seems however to be some indication that this toxicity may be caused by another mechanism than oestrogen activity. Studies are available for linear siloxanes from an analogue group comprising di- to hexa- siloxanes, as well as key physicochemical properties, The results of the acute toxicity studies for this analogue group are in agreement: there is no evidence from any of the available studies that the substances in this group have any potential for acute toxicity (in terms of either lethality or adverse clinical effects) by any route up to and exceeding the maximum dose

	levels tested according to current OECD guidelines. It is therefore valid to read-across the lack of acute toxicity between the members of the group where there are data gaps The metabolism of silanes and siloxanes is influenced by the chemistry of silicon, and it is fundamentally different from that of carbon compounds. These differences are due to the fact that silicon is more electropositive than carbon; Si-Si bonds are less stable than C-C bonds and Si-O bonds form very readily, the latter due to their high bond energy. Functional groups such as -OH, -CO2H, and -CH2OH are commonly seen in organic drug metabolites. If such functionalities are formed from siloxane metabolism, they will undergo rearrangement with migration of the Si atom from carbon to oxygen. Consequently, alpha hydroxysilanes may isomerise to silanols and this provides a mechanism by which very polar metabolites may be formed from highly hydrophobic alkylsiloxanes in relatively few metabolic steps
cristobalite	Inhalation (human) TCLo: 16 mppcf*/8H/17.9y-I * Millions of particles per cubic foot **WARNING:** For inhalation exposure ONLY: This substance has been classified by the IARC as Group 1: **CARCINOGENIC TO HUMANS** The International Agency for Research on Cancer (IARC) has classified occupational exposures to **respirable** (<5 um) crystalline silica as being carcinogenic to humans . This classification is based on what IARC considered sufficient evidence from epidemiological studies of humans for the carcinogenicity of inhaled silica in the forms of quartz and cristobalite. Crystalline silica is also known to cause silicosis, a non-cancerous lung disease. Intermittent exposure produces; focal fibrosis, (pneumoconiosis), cough, dyspnoea, liver tumours. * Millions of particles per cubic foot (based on impinger samples counted by light field techniques). NOTE : the physical nature of quartz in the product determines whether it is likely to present a chronic health problem. To be a hazard the material must enter the breathing zone as respirable particles.
2,6-di-tert-butyl-4-methylphenol*	* Degussa SDS Effects such as behavioral changes, reduction in body weight gain, and decrement in body weight have been observed after long-term administration of BHT to mice and rats. Toxic effects may be attributed more to BHT metabolites than to their parent compound, only a few studies have focused on their carcinogenicity and toxicity, and not only on that of BHT. The metabolite BHT-QM (syn: 2,6-di-tert-butyl-1,4-methylene-2,5-cyclohexadien-1-one, CAS RN: 2607-52-5) is a very reactive compound which is considered to play a significant role in hepatoxicity, pneumotoxicity, and skin tumor promotion in mice. In addition, it was reported that another quinone derivative, BHT-OH(t)QM (syn 2-tert-butyl-6-(2-hydroxy-tert-butyl-4-methylene-2,5-cyclohexadien-1-one, CAS RN: 124755-19-7), is chemically more reactive than BHT-QM, and it has been recognized as the principal metabolite responsible for lung tumor promotion activity of BHT in mice. BHT has been reported to exert prooxidant effects under certain conditions. Thus, when BHT was added in excess to a wheat seedling medium in aerobic conditions, an enhancement of the generation rate of superoxide anion was observed. This is a reactive particle that may damage cellular structures at high concentrations In addition, an increase in hepatic microsomal lipid peroxidation was observed in rats fed with diets containing 0.2% of BHT for 30 days. Due to this ability of BHT to exert prooxidant effects at high concentrations, it has been used to induce experimental models of oxidative stress in several animals and fungi in order to study the protective effects of other compounds. Quinone methide derivatives form adducts with several proteins, including enzymes that protect cells from oxidative stress; this prooxidant state can also lead to cell oxidative damage. It must be noted that relationships between chronic oxidative stress and tumor promotion are well known Some authors have reported that at high aeration rate, BHT can react with molecular oxygen rather than with the reactive oxygen species present, yielding BHT-phenoxyl radical and superoxide anion. In addition, the phenolic radical itself may undergo redox recycling which can be a critical factor depending on the reductant involved However, it has to be noted that BHT-phenoxyl radical has been reported to be relatively stable. Furthermore, the potential reactivity of BHT-derived metabolites should be taken into account; some studies reported that not only BHT but also its metabolites, such as BHT-Q and BHT-QM, can act as prooxidant. As BHT undergoes several reactions during biotransformation, a large number of intermediate metabolites have been identified. However, their nature and concentration depend on the environmental conditions and on the animal species. Although the changes undergone by BHT during in vivo digestion processes have not been studied, after submission of a fluid deep-frying fat containing BHT and BHT-QM to an in vitro gastrointestinal digestion model, both these were detected in the digested samples. These results indicate that BHT and its toxic metabolite could remain bioaccessible for intestinal absorption. Studies concerning BHT metabolism have shown that, unlike other synthetic antioxidants, BHT is a potent inducer of the microsomal monooxygenase system and its major route of degradation is oxidation catalyzed by cytochrome P450. Studies have reported potential toxicity derived from the ingestion or administration of BHT. As for acute oral toxicity, although this is considered low in animals, it must be noted that 2 clinical cases were reported in patients who suffered acute neurotoxicity and gastritis after ingesting a high dose of BHT (4 and 80 g without medical prescription) to cure recurrent genital herpes. Regarding short-term subchronic toxicity studies, it has been reported that BHT causes dose-related increase in the incidence and severity of toxic nephrosis in mice, nephrotoxicity and pneumotoxicity in rats, and in chicken a marked congestion of the liver and kidney, as well as diffuse enlargement of the liver with rounded borders and rupture with hemorrhaging . It has to be noted that the EFSA Panel (2012) pointed out certain inconsistencies in the findings obtained from the short-term and subchronic toxicity studies. Several genotoxicity studies on BHT concluded that BHT does not represent a genotoxic risk, because most of the studies carried out to that date had shown BHT was not able to induce mutations or to damage deoxyribonucleic acid (DNA). Nevertheless, it must be mentioned that other studies reported contrary results. The effect of BHT and 7 of its metabolites on in vitro DNA cleavage was studied and the metabolites BHT-Q (syn: 2,6-di-tert-butyl-2,5-cyclohexadiene-1,4-dione, CAS RN: 719-22-2), BHT-CHO (syn: 3,5-di-tert-butyl-4-hydroxybenzaldehyde, CAS RN: 1620-98-0 and BHT-OOH (syn: 2,6-di-tert-butyl-4-methyl-4-hydroperoxy-2,5-cyclohexadien-1-one, CAS RN: 6485-57-0) were able to cleave DNA.. The Panel on Food Additives and Nutrient Sources Added to Food of the European Food Safety Authority (EFSA) recognized that these positive genotoxicity results may be due to the prooxidative chemistry of BHT, which gives rise to reactive metabolites. Some studies addressed the carcinogenicity and chronic toxicity of BHT and its metabolites in rodents with contradictory results. Thus, mice-fed dietary BHT for a year developed marked hyperplasia of the hepatic bile ducts with an associated subacute cholangitis Moreover, after 104 wk of administration of BHT, the formation of hepatocellular tumors in male mice was observed. After 10 months of feeding mice with a diet containing different amounts of BHT, an increased incidence of liver tumors in male, but not female, animals was also reported . However, in a similar study no evidence of the carcinogenicity of

	BHT administered to mice was observed. Studies performed in rats also reported dose-related increases in hepatocellular adenomas and carcinomas; nevertheless, other studies carried out with rats showed no consistent carcinogenic effects. Several studies have demonstrated the potential of BHT to act either as a tumor promotor or as a tumor suppressor, modulating the carcinogenicity of some well-known carcinogens. Barbara Nieva-Echevarria etal: Comprehensive reviews in Food Science and Food Safety, Vol 14, Dec 2014 https://onlinelibrary.wiley.com/doi/10.1111/1541-4337.12121/pdf Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies. The 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. for bridged alkyl phenols: **Acute toxicity:** Acute oral and dermal toxicity data are available for all but two of the substances in the group. The data show that acute toxicity of these substances is low. The testing for acute toxicity spans five decades **Repeat dose toxicity:** Repeat dose studies on the members of this category include both subchronic and chronic exposures. The liver is identified as the target organ in rats for all of the substances tested. NOAEL s or NOEL s in rats for 13- week studies ranged from 100 ppm (approximately 5 mg/kg/day) to 500 ppm (approximately 25 mg/kg/day) while NOAEL s or NOEL s in rats for chronic studies were the same, 25 mg/kg/day (500 ppm). **Reproductive toxicity:** Evaluation of effects on reproduction for the bridged alkyl phenols is supplemented by histopathological data on male and female reproductive organs in repeated dose studies. The data on the effects of bridged alkyl phenols on reproduction and reproductive organs span the range of structures and molecular weights. While not all of the data for reproductive effects are from reproduction studies, microscopic evaluations of reproductive organs along with other short-term tests for reproductive effects provide adequate data to evaluate the effects of these bridged alkyl phenols on reproduction It can be concluded that reproductive toxicity is low. Typically a two-year chronic feeding study provides data for 4,4'-thiobis-6-(t-butyl-m-cresol) (96-69-5). No adverse effects were noted on reproductive organs **Genotoxicity:** Data from bacterial reverse mutation assays and in vitro and in vivo chromosome aberration studies were reviewed. Adequate bacterial gene mutation assays have been conducted with all of the category chemicals except two. Chromosome aberration studies, in vitro and/or in vivo, are available for all but two substances. The mutagenicity data span the range of structures and molecular weights and data can be bridged from other members of the group to meet any outstanding requirements. The weight of evidence for mutagenic potential for this category indicates these substances are not mutagenic. **Carcinogenicity:** The mutagenicity data combined with the animal data plus the long historical use of BHT (128-37-0) indicate that the chemicals in this class are not expected to exhibit any significant potential to cause cancer. The weight of the evidence indicates that these chemicals are not genotoxic. The Bridged Alkyl Phenols Category consists of a group of chemicals in which two molecules of mono or di-substituted alkyl (C1, C4, and/or C9) phenols are “bridged” or linked by a single atom (carbon or sulfur). The carbon atom linking the alkyl phenol groups contains hydrogen, propyl, or methyl substitutions. CAS No. 128-37-0 (BHT) is included in this category for data purposes because it is an alkyl phenol with a single carbon group such as the ones that link the phenol groups ferroptosis inhibitors are currently being treated systemically rather than specifically, which may have multiple side effects. For example,Desferoxamin (DFO), an iron chelating agent, is known to have a short half-life, need long-term subcutaneous infusions, and provoke ototoxicity and neurotoxicity. Deferasirox (DFX), an iron chelator, is associated with gastrointestinal and renal toxicity . The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. For hindered phenols: Available data shows that acute toxicity of these substances is low. **Mutagenicity.** Data from bacterial reverse mutation assays and ***in vitro*** and ***in vivo*** chromosome aberration studies were reviewed. All assays, with and without metabolic activation, were negative. The weight of evidence for mutagenic potential for this category indicates these substances are not mutagenic. **In Vitro Chromosome Aberration Studies.** In vitro chromosome aberration studies are available for several members All except 2,6-di-tert-butyl-p-cresol were negative **In Vivo Chromosome Aberration Studies.** In vivo studies evaluating chromosome damage are available for six of the hindered phenols. All in vivo evaluations were negative. **Repeated Dose Toxicity.** Repeated dose toxicity data of approximately three months (90-day, 12- and 13-week) are available for some of the substances in this group. The liver was the target organ in rats for almost all of the substances with subchronic toxicity data in that species. Other target organs included thyroid and kidney and mesenteric lymph nodes. NOAELs in rats ranged from 100 ppm (approximately 5 mg/kg/day) to 10,000 ppm (500 mg/kg/day **Carcinogenicity:** Data is available for 2,6-di-tert-butyl-p-cresol (128-37-0); and 4,4'-thiobis-6-(t-butyl-m-cresol) (96-69-5). Liver adenomas were reported for 2,6-di-tert-butyl-p-cresol (128-37-0) and a NOAEL was established for the study at 25 mg/kg/day. 4,4'-Thiobis-6-(t-butyl-m-cresol) (96-69-5) was not carcinogenic in rats or mice, but the kidney was identified as a target organ in female rats
AFFINIS PRECIOUS light body / PRECIOUS regular body & SILICA	For silica amorphous: Derived No Adverse Effects Level (NOAEL) in the range of 1000 mg/kg/d.

AMORPHOUS	In humans, synthetic amorphous silica (SAS) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin. When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals. After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification. Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser. Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact. Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure. Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m3 to 150 mg/m3. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m3. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m3. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/LOAEL. Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected. For Synthetic Amorphous Silica (SAS) Repeated dose toxicity Oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet. Inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) =1.3 mg/m3 based on mild reversible effects in the lungs. Inhalation (rat), 90 days, LOEL = 1 mg/m3 based on reversible effects in the lungs and effects in the nasal cavity. For silane treated synthetic amorphous silica: Repeated dose toxicity: oral (rat), 28-d, diet, no significant treatment-related adverse effects at the doses tested. There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS.
SILICA AMORPHOUS & 2,6-di-tert-butyl-4-methylphenol*	The substance is classified by IARC as Group 3: **NOT** classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.
DECAMETHYLCYCLOPENTASILOXANE & HEPTAMETHYLTRISILOXANE, ETHOXYLATED, PROPYL ETHER & 2,6-di-tert-butyl-4-methylphenol*	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.

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

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

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

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

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

AFFINIS PRECIOUS light body / PRECIOUS regular body

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

silica amorphous

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	72h	Algae or other aquatic plants	14.1mg/l	2
EC50	96h	Algae or other aquatic plants	217.576mg/l	2
EC0(ECx)	24h	Crustacea	>=10000mg/l	1
EC50	48h	Crustacea	>86mg/l	2
LC50	96h	Fish	1033.016mg/l	2

decamethylcyclopentasiloxane

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	96h	Algae or other aquatic plants	>0.012mg/L	2
EC50	48h	Crustacea	>0.003mg/L	2
NOEC(ECx)	48h	Crustacea	>=0.003mg/L	2
LC50	96h	Fish	>0.016mg/L	2

heptamethyltrisiloxane, ethoxylated, propyl ether

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

cristobalite

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

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica

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

2,6-di-tert-butyl-4-methylphenol*

Endpoint	Test Duration (hr)	Species	Value	Source
EC50	96h	Algae or other aquatic plants	0.758mg/l	2
BCF	1344h	Fish	220-2800	7
EC50	72h	Algae or other aquatic plants	>0.42mg/l	1
EC0(ECx)	48h	Crustacea	>=0.31mg/l	1
EC50	48h	Crustacea	>0.17mg/l	2
ErC50	72h	Algae or other aquatic plants	>0.42mg/l	1
LC50	96h	Fish	0.199mg/l	2

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.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
silica amorphous	LOW	LOW
decamethylcyclopentasiloxane	HIGH	HIGH
heptamethyltrisiloxane, ethoxylated, propyl ether	HIGH	HIGH
2,6-di-tert-butyl-4-methylphenol*	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
silica amorphous	LOW (LogKOW = 0.5294)
decamethylcyclopentasiloxane	HIGH (LogKOW = 5.2)
heptamethyltrisiloxane, ethoxylated, propyl ether	HIGH (LogKOW = 5.2897)
2,6-di-tert-butyl-4-methylphenol*	HIGH (BCF = 2500)

12.4. Mobility in soil

Ingredient	Mobility
silica amorphous	LOW (Log KOC = 23.74)
decamethylcyclopentasiloxane	LOW (Log KOC = 145200)
heptamethyltrisiloxane, ethoxylated, propyl ether	LOW (Log KOC = 736.1)
2,6-di-tert-butyl-4-methylphenol*	LOW (Log KOC = 23030)

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✗	✗	✗
vPvB	✗	✗	✗

PBT Criteria fulfilled?	No
vPvB	No

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

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

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

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

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

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

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

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

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

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

14.7.1. 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
silica amorphous	Not Available
decamethylcyclopentasiloxane	Not Available
heptamethyltrisiloxane, ethoxylated, propyl ether	Not Available
cristobalite	Not Available
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not Available
2,6-di-tert-butyl-4-methylphenol*	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
silica amorphous	Not Available
decamethylcyclopentasiloxane	Not Available
heptamethyltrisiloxane, ethoxylated, propyl ether	Not Available
cristobalite	Not Available
Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	Not Available
2,6-di-tert-butyl-4-methylphenol*	Not Available

SECTION 15 Regulatory information

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

silica amorphous is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
Great Britain GB Biocidal Active Substances
Great Britain GB mandatory classification and labelling (GB MCL) technical reports
Great Britain GB mandatory classification and labelling list (GB MCL)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
UK Workplace Exposure Limits (WELs).

decamethylcyclopentasiloxane is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
UK REACH Candidate List of substances of very high concern (SVHC) for Authorisation

heptamethyltrisiloxane, ethoxylated, propyl ether is found on the following regulatory lists

Not Applicable

cristobalite is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
UK Workplace Exposure Limits (WELs).

Silanamine, 1,1,1-trimethyl-N- (trimethylsilyl)-, hydrolysis products with silica is found on the following regulatory lists

Great Britain GB Biocidal Active Substances
Great Britain GB mandatory classification and labelling (GB MCL) technical reports
Great Britain GB mandatory classification and labelling list (GB MCL)
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
UK Workplace Exposure Limits (WELs).

2,6-di-tert-butyl-4-methylphenol* is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic
International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)
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 (decamethylcyclopentasiloxane; heptamethyltrisiloxane, ethoxylated, propyl ether; cristobalite; Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; 2,6-di-tert-butyl-4-methylphenol*)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (heptamethyltrisiloxane, ethoxylated, propyl ether)
Japan - ENCS	No (Silanamine, 1,1,1-trimethyl-N- (trimethylsilyl)-, hydrolysis products with silica)
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 (heptamethyltrisiloxane, ethoxylated, propyl ether; Silanamine, 1,1,1-trimethyl-N- (trimethylsilyl)-, hydrolysis products with silica)
Vietnam - NCI	Yes
Russia - FBEPH	No (heptamethyltrisiloxane, ethoxylated, propyl ether; Silanamine, 1,1,1-trimethyl-N- (trimethylsilyl)-, hydrolysis products with silica)
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	10/09/2024
Initial Date	17/12/2021

Full text Risk and Hazard codes

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.

SDS Version Summary

Version	Date of Update	Sections Updated
2.4	10/09/2024	Toxicological information - Acute Health (skin), Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (fire/explosion hazard), Composition / information on ingredients - Ingredients, Exposure controls / personal protection - Personal Protection (Respirator), Handling and storage - Storage (storage incompatibility)

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
- 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]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Hazardous to the Aquatic Environment Long-Term Hazard Category 3, H412	Calculation method