

GI-MASK Automix New Formula

Coltène/Whaledent AG

Version No: 1.1

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

Issue Date: **21/04/2022**

Print Date: **02/12/2024**

L.REACH.GB.EN

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

1.1. Product Identifier

Product name	GI-MASK Automix New Formula
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	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

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Hazard statement(s)

H412	Harmful to aquatic life with long lasting effects.
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Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P273	Avoid release to the environment.
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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.
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Material contains octamethylcyclotetrasiloxane.

2.3. Other hazards

octamethylcyclotetrasiloxane	Listed in the European Chemicals Agency (ECHA) Candidate List of Substances of Very High Concern for Authorisation
octamethylcyclotetrasiloxane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
octamethylcyclotetrasiloxane	Determined to have endocrine-disrupting properties according to Europe Regulation (EU) 528/2012, Europe Regulation (EU) 2017/2100, and Europe Regulation (EU) 2018/605
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)
dodecamethylcyclohexasiloxane	Listed in the European Chemicals Agency (ECHA) Candidate List of Substances of Very High Concern for Authorisation
dodecamethylcyclohexasiloxane	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. 556-67-2 2. 209-136-7 3. 014-018-00-1 4. Not Available	<1	octamethylcyclotetrasiloxane ^[e]	Reproductive Toxicity Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H361f, H410 ^[1]	M = 10 Acute M factor: Not Applicable Chronic M factor: 10	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: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 540-97-6 2. 208-762-8 3. Not Available 4. Not Available	<1	dodecamethylcyclohexasiloxane	Not Classified ^[3]	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	

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

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

Treat symptomatically.

SECTION 5 Firefighting measures**5.1. Extinguishing media**

- ▶ 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	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. <p>May emit poisonous fumes.</p>

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

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid contact with skin and eyes.
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	<ul style="list-style-type: none"> ▶ 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	<p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment as required. ▶ Prevent spillage from entering drains or water ways. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. ▶ Wash area and prevent runoff into drains or waterways. ▶ If contamination of drains or waterways occurs, advise emergency services.

6.4. Reference to other sections

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

SECTION 7 Handling and storage**7.1. Precautions for safe handling**

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ Avoid contact with incompatible materials. ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	None known
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**

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Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
octamethylcyclotetrasiloxane	Inhalation 73 mg/m ³ (Systemic, Chronic) Inhalation 73 mg/m ³ (Local, Chronic) <i>Inhalation 0.013 mg/m³ (Systemic, Chronic) *</i> <i>Oral 3.7 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 13 mg/m³ (Local, Chronic) *</i>	0.0015 mg/L (Water (Fresh)) 0.00015 mg/L (Water (Marine)) 3 mg/kg sediment dw (Sediment (Fresh Water)) 0.3 mg/kg sediment dw (Sediment (Marine)) 0.84 mg/kg soil dw (Soil) 10 mg/L (STP) 41 mg/kg food (Oral)
decamethylcyclopentasiloxane	Inhalation 97.3 mg/m ³ (Systemic, Chronic) Inhalation 24.2 mg/m ³ (Local, Chronic) <i>Inhalation 0.0173 mg/m³ (Systemic, Chronic) *</i> <i>Oral 5 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 4.3 mg/m³ (Local, Chronic) *</i>	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)
dodecamethylcyclohexasiloxane	Inhalation 1.22 mg/m ³ (Local, Chronic) Inhalation 6.1 mg/m ³ (Local, Acute) <i>Inhalation 0.3 mg/m³ (Local, Chronic) *</i> <i>Inhalation 1.5 mg/m³ (Local, Acute) *</i>	13.5 mg/kg sediment dw (Sediment (Fresh Water)) 1.35 mg/kg sediment dw (Sediment (Marine)) 66.7 mg/kg food (Oral)

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

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

Not Applicable

Ingredient	Original IDLH	Revised IDLH
octamethylcyclotetrasiloxane	Not Available	Not Available
decamethylcyclopentasiloxane	Not Available	Not Available
dodecamethylcyclohexasiloxane	Not Available	Not Available

Occupational Exposure Banding


Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
octamethylcyclotetrasiloxane	E	≤ 0.1 ppm
decamethylcyclopentasiloxane	E	≤ 0.1 ppm
Notes:	<i>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.</i>	

MATERIAL DATA

8.2. Exposure controls

8.2.1. Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p> <table border="1"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air)</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>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)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min)</td> </tr> </tbody> </table>	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)
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)								

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	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	<ul style="list-style-type: none"> ▶ Safety glasses with side shields ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent] 	
Skin protection	See Hand protection below	
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber 	
Body protection	See Other protection below	
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash unit. 	

Respiratory protection

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

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

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	Not Available
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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)	>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/m ³)	Not Available	Enclosed Space Ignition Deflagration Density (g/m ³)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1. Reactivity	See section 7.2
10.2. Chemical stability	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	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material
Eye	

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	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	Exposure to the material may cause concerns for human fertility, generally on the basis that results in animal studies provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects.

GI-MASK Automix New Formula	TOXICITY	IRRITATION
	Not Available	Not Available
octamethylcyclotetrasiloxane	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2.5 ml/kg * ^[2]	Eye (Rodent - rabbit): 500mg/24H - Mild
	Dermal (rabbit) LD50: 794 uL/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
	dermal (rat) LD50: 1770 mg/kg ^[2]	Skin (Rodent - rabbit): 500mg/24H - Mild
	Inhalation (Rat) LC50: 2975 ppm/4h * ^[2]	Skin: adverse effect observed (irritating) ^[1]
	Inhalation (Rat) LC50: 36000 mg/m ³ /4H ^[2]	Skin: no adverse effect observed (not irritating) ^[1]
	Oral (Rat) LD50: >4800 mg/kg * ^[2]	
Oral (Rat) LD50: 1540 mg/kg ^[2]		
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]	
dodecamethylcyclohexasiloxane	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
	Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin: adverse effect observed (irritating) ^[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

octamethylcyclotetrasiloxane	Does not cause skin sensitization Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Remarks: Based on test data Test Type: Mutagenicity (in vitro mammalian cytogenetic test) Result: negative Remarks: Based on test data Test Type: Chromosome aberration test in vitro Result: negative Remarks: Based on test data Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative Remarks: Based on test data Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: negative Remarks: Based on test data Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Rat Application Route: inhalation (vapor) Result: negative Remarks: Based on test data Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: Ingestion Result: negative Remarks: Based on test data Germ cell mutagenicity - Assessment : Animal testing did not show any mutagenic effects Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat, male and female Application Route: inhalation (vapor) Symptoms: Effects on fertility. Remarks: Based on test data Effects on fetal development : Test Type: Prenatal development toxicity study (teratogenicity) Species: Rabbit Application Route: inhalation (vapor) Symptoms: No effects on fetal development. Remarks: Based on test data Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments. STOT-single exposure May cause damage to organs (Eyes, Central nervous system Routes of exposure: Skin contact Assessment: No significant health effects observed in animals at concentrations of 200 mg/kg bw or less. Results from a 2 year repeated vapor inhalation exposure study to rats of octamethylcyclotetrasiloxane (D4) indicate effects (benign uterine adenomas) in the uterus of female animals. This finding occurred at the highest exposure dose (700 ppm) only. Studies to date have not demonstrated if these effects occur through pathways that are relevant to humans. Repeated exposure in rats to D4 resulted in protoporphyrin accumulation in the liver. Without knowledge of the specific mechanism leading to the protoporphyrin accumulation the relevance of this finding to humans is unknown
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

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	<p>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. 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</p> <p>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.</p>
DODECAMETHYLCYCLOHEXASILOXANE	No significant acute toxicological data identified in literature search.
octamethylcyclotetrasiloxane & DECAMETHYLCYCLOPENTASILOXANE	<p>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.</p> <p>The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.</p>

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

Many chemicals may mimic or interfere with the body's hormones, known as the endocrine system. Endocrine disruptors are chemicals that can interfere with endocrine (or hormonal) systems. Endocrine disruptors interfere with the synthesis, secretion, transport, binding, action, or elimination of natural hormones in the body. Any system in the body controlled by hormones can be derailed by hormone disruptors. Specifically, endocrine disruptors may be associated with the development of learning disabilities, deformations of the body various cancers and sexual development problems. Endocrine disrupting chemicals cause adverse effects in animals. But limited scientific information exists on potential health problems in humans. Because people are typically exposed to multiple endocrine disruptors at the same time, assessing public health effects is difficult.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

GI-MASK Automix New Formula	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

octamethylcyclotetrasiloxane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	>0.022mg/L	2
	EC50	48h	Crustacea	>0.015mg/L	4
	NOEC(ECx)	96h	Algae or other aquatic plants	<0.001-0.029mg/L	4
	LC50	96h	Fish	>0.006mg/L	2

decamethylcyclopentasiloxane	Endpoint	Test Duration (hr)	Species	Value	Source

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	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
dodecamethylcyclhexasiloxane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>0.002mg/L	2
	NOEC(ECx)	72h	Algae or other aquatic plants	>=0.002mg/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

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
octamethylcyclotetrasiloxane	HIGH	HIGH
decamethylcyclopentasiloxane	HIGH	HIGH
dodecamethylcyclhexasiloxane	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
octamethylcyclotetrasiloxane	HIGH (BCF = 12400)
decamethylcyclopentasiloxane	HIGH (LogKOW = 5.2)
dodecamethylcyclhexasiloxane	HIGH (LogKOW = 6.3286)

12.4. Mobility in soil

Ingredient	Mobility
octamethylcyclotetrasiloxane	LOW (Log KOC = 17960)
decamethylcyclopentasiloxane	LOW (Log KOC = 145200)
dodecamethylcyclhexasiloxane	LOW (Log KOC = 1174000)

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

The evidence linking adverse effects to endocrine disruptors is more compelling in the environment than it is in humans. Endocrine disruptors profoundly alter reproductive physiology of ecosystems and ultimately impact entire populations. Some endocrine-disrupting chemicals are slow to break down in the environment. That characteristic makes them potentially hazardous over long periods of time. Some well established adverse effects of endocrine disruptors in various wildlife species include eggshell-thinning, displayed of characteristics of the opposite sex and impaired reproductive development. Other adverse changes in wildlife species that have been suggested, but not proven include reproductive abnormalities, immune dysfunction and skeletal deformities.

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

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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.) <ul style="list-style-type: none"> ▶ Recycle wherever possible or consult manufacturer for recycling options. ▶ Consult State Land Waste Management Authority for disposal. ▶ Bury residue in an authorised landfill. ▶ Recycle containers if possible, or dispose of in an authorised landfill.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

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

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14.2. UN proper shipping name		
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
octamethylcyclotetrasiloxane	Not Available
decamethylcyclopentasiloxane	Not Available
dodecamethylcyclohexasiloxane	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
octamethylcyclotetrasiloxane	Not Available
decamethylcyclopentasiloxane	Not Available
dodecamethylcyclohexasiloxane	Not Available

SECTION 15 Regulatory information

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

octamethylcyclotetrasiloxane is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

Great Britain GB mandatory classification and labelling list (GB MCL)

UK REACH Candidate List of substances of very high concern (SVHC) for Authorisation

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

dodecamethylcyclohexasiloxane 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

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Additional Regulatory Information

Not Applicable

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

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

Seveso Category	Not Available
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15.2. Chemical safety assessment

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

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (octamethylcyclotetrasiloxane; decamethylcyclopentasiloxane; dodecamethylcyclohexasiloxane)
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 (dodecamethylcyclohexasiloxane)
Vietnam - NCI	Yes
Russia - FBEPH	Yes
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	21/04/2022
Initial Date	27/01/2022

Full text Risk and Hazard codes

H361f	Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.

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

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- ▶ 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