

GI-MASK Universal Separator

Coltène/Whaledent AG

Version No: 2.2

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

Issue Date: 24/11/2022

Print Date: 22/01/2025

L.REACH.GB.EN

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

1.1. Product Identifier

Product name	GI-MASK Universal Separator
Chemical Name	Not Applicable
Synonyms	Not Available
Proper shipping name	AEROSOLS
Chemical formula	Not Applicable
Other means of identification	UFI: EGP7-W3MX-0N4M-MSM5

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

Relevant identified uses	For dental use only Application is by spray atomisation from a hand held aerosol pack
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	
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

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]	H222+H229 - Aerosols, Hazard Category 1, H304 - Aspiration Hazard Category 1, H315 - Skin Corrosion/Irritation Category 2, H336 - Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, H411 - Hazardous to the Aquatic Environment Long-Term Hazard Category 2
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)	   
---------------------	---

GI-MASK Universal Separator

Signal word	Danger
-------------	--------

Hazard statement(s)

H222+H229	Extremely flammable aerosol. Pressurized container: may burst if heated.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H336	May cause drowsiness or dizziness.
H411	Toxic to aquatic life with long lasting effects.

Supplementary statement(s)

EUH044	Risk of explosion if heated under confinement.
--------	--

Precautionary statement(s) Prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211	Do not spray on an open flame or other ignition source.
P251	Do not pierce or burn, even after use.
P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves and protective clothing.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
P331	Do NOT induce vomiting.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P391	Collect spillage.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

P405	Store locked up.
P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

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

Material contains 2-methylpentane, isopropyl acetate.

2.3. Other hazards

Inhalation may produce health damage*.

Cumulative effects may result following exposure*.

May produce discomfort of the respiratory system*.

Repeated exposure potentially causes skin dryness and cracking*.

2-methylpentane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
isopropyl acetate	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
propane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
propane	The material within this SDS meets the criteria for persistent, bioaccumulative and toxic in accordance with Annex XIII.
butane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
iso-butane	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)

GI-MASK Universal Separator

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. 107-83-5 2.203-523-4 3.601-007-00-7 4.Not Available	45-55	<u>2-methylpentane</u>	Flammable Liquids Category 2, Aspiration Hazard Category 1, Skin Corrosion/Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H225, H304, H315, H336, H411 [2]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 108-21-4 2.203-561-1 3.607-024-00-6 4.Not Available	<1	<u>isopropyl acetate</u>	Flammable Liquids Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3; H225, H319, H336 [2]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 74-98-6 2.200-827-9 3.601-003-00-5 4.Not Available	15-30	<u>propane</u>	Flammable gases, Hazard Category 1, Gases Under Pressure; H220, H280 [2]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 106-97-8. 2.Not Available 3.Not Available 4.Not Available	15-30	<u>butane</u>	Flammable gases, Hazard Category 1A, Gases Under Pressure (Liquefied Gas); H220, H280, EUH044 [1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	Not Available
1. 75-28-5. 2.Not Available 3.Not Available 4.Not Available	5-15	<u>iso-butane</u>	Flammable gases, Hazard Category 1A, Gases Under Pressure (Liquefied Gas); H220, H280, EUH044 [1]	SCL: Not Available Acute M factor: Not Applicable Chronic M factor: Not Applicable	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	<p>If aerosols come in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold the eyelids apart and flush the eye with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If solids or aerosol mists are deposited upon the skin:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available).

GI-MASK Universal Separator

	<ul style="list-style-type: none"> ▶ Remove any adhering solids with industrial skin cleansing cream. ▶ DO NOT use solvents. ▶ Seek medical attention in the event of irritation.
Inhalation	<p>If aerosols, fumes or combustion products are inhaled:</p> <ul style="list-style-type: none"> ▶ Remove to fresh air. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ If breathing is shallow or has stopped, ensure clear airway and apply resuscitation, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▶ Transport to hospital, or doctor.
Ingestion	<ul style="list-style-type: none"> ▶ Not considered a normal route of entry. ▶ If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus. ▶ Avoid giving milk or oils. ▶ Avoid giving alcohol.

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

SMALL FIRE:

- ▶ Water spray, dry chemical or CO₂

LARGE FIRE:

- ▶ Water spray or fog.

5.2. Special hazards arising from the substrate or mixture

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

5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ If safe, switch off electrical equipment until vapour fire hazard removed. ▶ Use extinguishing foam delivered as a fine spray to control fire and cool adjacent area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with extinguishing foam 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"> ▶ Liquid and vapour are highly flammable. ▶ Severe fire hazard when exposed to heat or flame. ▶ Vapour forms an explosive mixture with air. ▶ Severe explosion hazard, in the form of vapour, when exposed to flame or spark. ▶ Aerosol cans may explode on exposure to naked flames. ▶ May emit acrid, poisonous or corrosive fumes. ▶ On combustion, may emit toxic fumes of carbon monoxide (CO). <p>Combustion products include: carbon monoxide (CO) carbon dioxide (CO₂) other pyrolysis products typical of burning organic material.</p> <p>Contains low boiling substance: Closed containers may rupture due to pressure buildup under fire conditions.</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

GI-MASK Universal Separator

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Wear protective clothing, impervious gloves and safety glasses. ▶ Shut off all possible sources of ignition and increase ventilation. ▶ Wipe up. ▶ If safe, damaged cans should be placed in a container outdoors, away from all ignition sources, until pressure has dissipated. ▶ Undamaged cans should be gathered and stowed safely.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of all unprotected personnel and move upwind. ▶ Alert Emergency Authority and advise them of the location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear full body clothing with breathing apparatus. ▶ Prevent by any means available, spillage from entering drains and water-courses. ▶ Consider evacuation. ▶ Shut off all possible sources of ignition and increase ventilation. ▶ No smoking or naked lights within area. ▶ Use extreme caution to prevent violent reaction. ▶ Stop leak only if safe to so do. ▶ DO NOT enter confined space where gas may have collected. ▶ Keep area clear until gas has dispersed.

6.4. Reference to other sections

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

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ DO NOT enter confined spaces until atmosphere has been checked. ▶ Avoid smoking, naked lights or ignition sources. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ DO NOT incinerate or puncture aerosol cans. ▶ DO NOT spray directly on humans, exposed food or food utensils. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. ▶ DO NOT allow clothing wet with material to stay in contact with skin
Fire and explosion protection	See section 5
Other information	<ul style="list-style-type: none"> ▶ Keep dry to avoid corrosion of cans. Corrosion may result in container perforation and internal pressure may eject contents of can ▶ Store in original containers in approved flammable liquid storage area. ▶ DO NOT store in pits, depressions, basements or areas where vapours may be trapped. ▶ No smoking, naked lights, heat or ignition sources. ▶ Keep containers securely sealed. Contents under pressure. ▶ Store away from incompatible materials. ▶ Store in a cool, dry, well ventilated area. ▶ Avoid storage at temperatures higher than 40 deg C. ▶ Store in an upright position. ▶ Protect containers against physical damage. ▶ Check regularly for spills and leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<p>Recommended storage temperature: 15 - 23 °C</p> <ul style="list-style-type: none"> ▶ Aerosol dispenser. ▶ Check that containers are clearly labelled.
Storage incompatibility	<p>Butane / isobutane:</p> <ul style="list-style-type: none"> ▶ reacts violently with strong oxidisers, acetylene, halogens, and nitrous oxides ▶ does not mix with chlorine dioxide, nitric acid and some plastics ▶ may generate electrostatic charges, due to low conductivity, which may ignite vapours. <p>Propane:</p> <ul style="list-style-type: none"> ▶ reacts violently with strong oxidisers, barium peroxide, chlorine dioxide, dichlorine oxide, fluorine etc. ▶ liquid attacks some plastics, rubber and coatings

GI-MASK Universal Separator

	<ul style="list-style-type: none">▶ may accumulate static charges which may ignite its vapours▶ Avoid reaction with oxidising agents▶ Compressed gases may contain a large amount of kinetic energy over and above that potentially available from the energy of reaction produced by the gas in chemical reaction with other substances
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	P3b: Flammable Aerosols, E2: Hazardous to the Aquatic Environment in Category Chronic 2
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	P3b Lower- / Upper-tier requirements: 5 000 (net) / 50 000 (net) E2 Lower- / Upper-tier requirements: 200 / 500

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
isopropyl acetate	Dermal 27 mg/kg bw/day (Systemic, Chronic) Inhalation 275 mg/m³ (Systemic, Chronic) Inhalation 227 mg/m³ (Local, Chronic) Inhalation 558 mg/m³ (Systemic, Acute) <i>Dermal 16 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.168 mg/m³ (Systemic, Chronic) *</i> <i>Oral 16 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 136 mg/m³ (Local, Chronic) *</i> <i>Inhalation 335 mg/m³ (Systemic, Acute) *</i>	0.22 mg/L (Water (Fresh)) 1.1 mg/L (Water - Intermittent release) 0.022 mg/L (Water (Marine)) 1.25 mg/kg sediment dw (Sediment (Fresh Water)) 0.125 mg/kg sediment dw (Sediment (Marine)) 0.35 mg/kg soil dw (Soil) 190 mg/L (STP)

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs).	isopropyl acetate	Isopropyl acetate	Not Available	849 mg/m3 / 200 ppm	Not Available	Not Available
UK Workplace Exposure Limits (WELs).	butane	Butane	600 ppm / 1450 mg/m3	1810 mg/m3 / 750 ppm	Not Available	Carc, (only applies if Butane contains more than 0.1% of buta-1,3-diene)

Ingredient	Original IDLH	Revised IDLH
2-methylpentane	Not Available	Not Available
isopropyl acetate	1,800 ppm	Not Available
propane	Not Available	Not Available
butane	Not Available	Not Available
iso-butane	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
2-methylpentane	C	> 1 to ≤ 10 parts per million (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

for: hexane, isomers (excluding n-hexane)
The TLV-TWA is thought to be protective against nausea, headache, upper respiratory tract irritation and CNS depression. The STEL is added to prevent objective depression of the CNS. The lower value ascribed to n-hexane is due to the neurotoxicity of its metabolites, principally 5-hydroxy-2-hexanone and 2,5-hexanedione. It is considered unlikely that other hexanes follow the same metabolic route. It should be noted however that the n-hexane TLV-TWA also applies to commercial hexane having a concentration of greater than 5% n-hexane.

For isopropyl acetate:

GI-MASK Universal Separator

Odour Threshold Value: 0.50-34 ppm (detection), 0.91-41 ppm (recognition)

The TLV-TWA is thought to be protective against ocular and upper respiratory tract irritation. It must be noted however that one study demonstrated that the majority of subjects exposed at 200 ppm for 15 minutes experienced eye irritation.

Odour Safety Factor(OSF)

OSF=74 (ISOPROPYL ACETATE)

Exposed individuals are **NOT** reasonably expected to be warned, by smell, that the Exposure Standard is being exceeded.

Odour Safety Factor (OSF) is determined to fall into either Class C, D or E.

The Odour Safety Factor (OSF) is defined as:

OSF= Exposure Standard (TWA) ppm/ Odour Threshold Value (OTV) ppm

Classification into classes follows:

Class	OSF	Description
A	550	Over 90% of exposed individuals are aware by smell that the Exposure Standard (TLV-TWA for example) is being reached, even when distracted by working activities
B	26-550	As "A" for 50-90% of persons being distracted
C	1-26	As "A" for less than 50% of persons being distracted
D	0.18-1	10-50% of persons aware of being tested perceive by smell that the Exposure Standard is being reached
E	<0.18	As "D" for less than 10% of persons aware of being tested

For butane:

Odour Threshold Value: 2591 ppm (recognition)

Butane in common with other homologues in the straight chain saturated aliphatic hydrocarbon series is not characterised by its toxicity but by its narcosis-inducing effects at high concentrations. The TLV is based on analogy with pentane by comparing their lower explosive limits in air. It is concluded that this limit will protect workers against the significant risk of drowsiness and other narcotic effects.

Odour Safety Factor(OSF)

OSF=0.22 (n-BUTANE)

For propane

Odour Safety Factor(OSF)

OSF=0.16 (PROPANE)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

The basic types of engineering controls are:

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

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

General exhaust is adequate under normal 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.






Type of Contaminant:	Speed:
aerosols, (released at low velocity into zone of active generation)	0.5-1 m/s
direct spray, spray painting in shallow booths, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 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.

GI-MASK Universal Separator

8.2.2. Individual protection measures, such as personal protective equipment	    
Eye and face protection	<ul style="list-style-type: none"> ▶ No special equipment for minor exposure i.e. when handling small quantities. ▶ OTHERWISE: For potentially moderate or heavy exposures: ▶ Safety glasses with side shields. ▶ NOTE: Contact lenses pose a special hazard; soft lenses may absorb irritants and ALL lenses concentrate them.
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ No special equipment needed when handling small quantities. ▶ OTHERWISE: ▶ For potentially moderate exposures: ▶ Wear general protective gloves, eg. light weight rubber gloves. ▶ For potentially heavy exposures: ▶ Wear chemical protective gloves, eg. PVC. and safety footwear.
Body protection	See Other protection below
Other protection	<p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ Skin cleansing cream. ▶ Eyewash unit. ▶ Do not spray on hot surfaces.

Respiratory protection

Type AX 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 5 x ES	Air-line*	AX-2	AX-PAPR-2 ^
up to 10 x ES	-	AX-3	-
10+ x ES	-	Air-line**	-

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

^ - 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	Colourless		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	<0	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	HIGHLY FLAMMABLE.	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available

GI-MASK Universal Separator

Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

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

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Inhaled	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>WARNING:Intentional misuse by concentrating/inhaling contents may be lethal.</p> <p>Material is highly volatile and may quickly form a concentrated atmosphere in confined or unventilated areas. The vapour may displace and replace air in breathing zone, acting as a simple asphyxiant. This may happen with little warning of overexposure.</p>
Ingestion	Not normally a hazard due to physical form of product.
Skin Contact	<p>Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p>
Eye	<p>Although the liquid 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).</p> <p>Direct contact with the eye may not cause irritation because of the extreme volatility of the gas; however concentrated atmospheres may produce irritation after brief exposures..</p>
Chronic	<p>Repeated or prolonged exposure to mixed hydrocarbons may produce narcosis with dizziness, weakness, irritability, concentration and/or memory loss, tremor in the fingers and tongue, vertigo, olfactory disorders, constriction of visual field, paraesthesias of the extremities, weight loss and anaemia and degenerative changes in the liver and kidney. Chronic exposure by petroleum workers, to the lighter hydrocarbons, has been associated with visual disturbances, damage to the central nervous system, peripheral neuropathies (including numbness and paraesthesias), psychological and neurophysiological deficits, bone marrow toxicities (including hypoplasia possibly due to benzene) and hepatic and renal involvement. Chronic dermal exposure to petroleum hydrocarbons may result in defatting which produces localised dermatoses. Surface cracking and erosion may also increase susceptibility to infection by microorganisms. One epidemiological study of petroleum refinery workers has reported elevations in standard mortality ratios for skin cancer along with a dose-response relationship indicating an association between routine workplace exposure to petroleum or one of its constituents and skin cancer, particularly melanoma. Other studies have been unable to confirm this finding.</p>

GI-MASK Universal Separator

Hydrocarbon solvents are liquid hydrocarbon fractions derived from petroleum processing streams, containing only carbon and hydrogen atoms, with carbon numbers ranging from approximately C5-C20 and boiling between approximately 35-370 deg C. Many of the hydrocarbon solvents have complex and variable compositions with constituents of 4 types, alkanes (normal paraffins, isoparaffins, and cycloparaffins) and aromatics (primarily alkylated one- and two-ring species). Despite the compositional complexity, most hydrocarbon solvent constituents have similar toxicological properties, and the overall toxicological hazards can be characterized in generic terms. Hydrocarbon solvents can cause chemical pneumonitis if aspirated into the lung, and those that are volatile can cause acute CNS effects and/or ocular and respiratory irritation at exposure levels exceeding occupational recommendations. Otherwise, there are few toxicologically important effects. The exceptions, n-hexane and naphthalene, have unique toxicological properties

Animal studies:

No deaths or treatment related signs of toxicity were observed in rats exposed to light alkylate naphtha (paraffinic hydrocarbons) at concentrations of 668, 2220 and 6646 ppm for 6 hrs/day, 5 days/wk for 13 weeks. Increased liver weights and kidney toxicity (male rats) was observed in high dose animals. Exposure to pregnant rats at concentrations of 137, 3425 and 6850 ppm did not adversely affect reproduction or cause maternal or foetal toxicity. Lifetime skin painting studies in mice with similar naphthas have shown weak or no carcinogenic activity following prolonged and repeated exposure. Similar naphthas/distillates, when tested at nonirritating dose levels, did not show any significant carcinogenic activity indicating that this tumorigenic response is likely related to chronic irritation and not to dose. The mutagenic potential of naphthas has been reported to be largely negative in a variety of mutagenicity tests. The exact relationship between these results and human health is not known. Some components of this product have been shown to produce a species specific, sex hormonal dependent kidney lesion in male rats from repeated oral or inhalation exposure. Subsequent research has shown that the kidney damage develops via the formation of a alpha-2u-globulin, a mechanism unique to the male rat. Humans do not form alpha-2u-globulin, therefore, the kidney effects resulting from this mechanism are not relevant in human.

Principal route of occupational exposure to the gas is by inhalation.

GI-MASK Universal Separator	TOXICITY	IRRITATION
	Not Available	Not Available
2-methylpentane	TOXICITY	IRRITATION
	Oral (Rat) LD50: ~15.84 mg/kg ^[1]	Not Available
isopropyl acetate	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >20000 mg/kg ^[2]	Eye (Human): 200ppm/15M
	Oral (Rabbit) LD50: 6946 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Eye: no adverse effect observed (not irritating) ^[1]
		Skin (Rodent - rabbit): 500mg/24H - Mild
		Skin: no adverse effect observed (not irritating) ^[1]
propane	TOXICITY	IRRITATION
	Inhalation (Rat) LC50: 364726.819 ppm4h ^[2]	Not Available
butane	TOXICITY	IRRITATION
	Inhalation (Rat) LC50: 658 mg/l4h ^[2]	Not Available
iso-butane	TOXICITY	IRRITATION
	Inhalation (Rat) LC50: >13023 ppm4h ^[1]	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

Studies indicate that normal, branched and cyclic paraffins are absorbed from the mammalian gastrointestinal tract and that the absorption of n-paraffins is inversely proportional to the carbon chain length, with little absorption above C30. With respect to the carbon chain lengths likely to be present in mineral oil, n-paraffins may be absorbed to a greater extent than iso- or cyclo-paraffins.

The major classes of hydrocarbons have been shown to be well absorbed by the gastrointestinal tract in various species. In many cases, the hydrophobic hydrocarbons are ingested in association with dietary lipids. The dependence of hydrocarbon absorption on concomitant triglyceride digestion and absorption is known as the "hydrocarbon continuum hypothesis", and asserts that a series of solubilising phases in the intestinal lumen, created by dietary triglycerides and their digestion products, afford hydrocarbons a route to the lipid phase of the intestinal absorptive cell (enterocyte) membrane. While some hydrocarbons may traverse the mucosal epithelium unmetabolised and appear as solutes in lipoprotein particles in intestinal lymph, there is evidence that most hydrocarbons partially separate from nutrient lipids and undergo metabolic transformation in the enterocyte. The enterocyte may play a major role in determining the proportion of an absorbed hydrocarbon that, by escaping initial biotransformation, becomes available for deposition in its unchanged form in peripheral tissues such as adipose tissue, or in the liver.

Acute Toxicity

✗

Carcinogenicity

✗

GI-MASK Universal Separator

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

GI-MASK Universal Separator	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
2-methylpentane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	4.321mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	4.321mg/l	2
isopropyl acetate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	37.1mg/l	2
	EC50	72h	Algae or other aquatic plants	250mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	37.1mg/l	2
	EC50	48h	Crustacea	110mg/l	1
	LC50	96h	Fish	400mg/l	2
propane	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
butane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	7.71mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	7.71mg/l	2
	LC50	96h	Fish	24.11mg/l	2
iso-butane	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	96h	Algae or other aquatic plants	7.71mg/l	2
	EC50(ECx)	96h	Algae or other aquatic plants	7.71mg/l	2
	LC50	96h	Fish	24.11mg/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				

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

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
2-methylpentane	LOW	LOW
isopropyl acetate	LOW	LOW
propane	LOW	LOW
butane	LOW	LOW

GI-MASK Universal Separator

Ingredient	Persistence: Water/Soil	Persistence: Air
iso-butane	HIGH	HIGH

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
2-methylpentane	LOW (LogKOW = 3.2145)
isopropyl acetate	LOW (BCF = 1.8)
propane	LOW (LogKOW = 2.36)
butane	LOW (LogKOW = 2.89)
iso-butane	LOW (BCF = 1.97)

12.4. Mobility in soil

Ingredient	Mobility
2-methylpentane	LOW (Log KOC = 124.9)
isopropyl acetate	LOW (Log KOC = 9.479)
propane	LOW (Log KOC = 23.74)
butane	LOW (Log KOC = 43.79)
iso-butane	LOW (Log KOC = 35.04)

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	Product disposal Waste code number: 16 05 04* Gases in pressurized containers containing hazardous substances Product and product residues must not be disposed of together with household waste and must be disposed of in accordance with the applicable laws. In Switzerland, the Ordinance on the Prevention and Disposal of Waste (Waste Ordinance, VVEA; SR 814.600), the Ordinance on the Movement of Waste (VeVA; SR 814.610) and the DETEC Ordinance on Lists on the Movement of Waste (SR 814.610.1) apply.
	Disposal of contaminated packaging Waste code number: 15 01 10* Packaging containing residues of substances or special wastes with particularly hazardous properties or contaminated by substances or special wastes with particularly hazardous properties.
	Disposal of empty packaging Waste code number: 15 01 04 Metal packaging. If packaging is not completely empty, it is not subject to waste code 15 01 04 and must be disposed of properly and without damage by the end user in accordance with the disposal of contaminated packaging and waste code 15 01 10*.
	Waste treatment options Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

	
--	---

GI-MASK Universal Separator

Marine Pollutant	
HAZCHEM	Not Applicable

Land transport (ADR-RID)

14.1. UN number or ID number	1950												
14.2. UN proper shipping name	AEROSOLS												
14.3. Transport hazard class(es)	<table> <tr> <td>Class</td><td>2.1</td></tr> <tr> <td>Subsidiary Hazard</td><td>Not Applicable</td></tr> </table>	Class	2.1	Subsidiary Hazard	Not Applicable								
Class	2.1												
Subsidiary Hazard	Not Applicable												
14.4. Packing group	Not Applicable												
14.5. Environmental hazard	Environmentally hazardous												
14.6. Special precautions for user	<table> <tr> <td>Hazard identification (Kemler)</td><td>Not Applicable</td></tr> <tr> <td>Classification code</td><td>5F</td></tr> <tr> <td>Hazard Label</td><td>2.1</td></tr> <tr> <td>Special provisions</td><td>190 327 344 625</td></tr> <tr> <td>Limited quantity</td><td>1 L</td></tr> <tr> <td>Tunnel Restriction Code</td><td>D</td></tr> </table>	Hazard identification (Kemler)	Not Applicable	Classification code	5F	Hazard Label	2.1	Special provisions	190 327 344 625	Limited quantity	1 L	Tunnel Restriction Code	D
Hazard identification (Kemler)	Not Applicable												
Classification code	5F												
Hazard Label	2.1												
Special provisions	190 327 344 625												
Limited quantity	1 L												
Tunnel Restriction Code	D												

Air transport (ICAO-IATA / DGR)

14.1. UN number	1950														
14.2. UN proper shipping name	Aerosols, flammable (engine starting fluid)														
14.3. Transport hazard class(es)	<table> <tr> <td>ICAO/IATA Class</td><td>2.1</td></tr> <tr> <td>ICAO / IATA Subsidiary Hazard</td><td>Not Applicable</td></tr> <tr> <td>ERG Code</td><td>10L</td></tr> </table>	ICAO/IATA Class	2.1	ICAO / IATA Subsidiary Hazard	Not Applicable	ERG Code	10L								
ICAO/IATA Class	2.1														
ICAO / IATA Subsidiary Hazard	Not Applicable														
ERG Code	10L														
14.4. Packing group	Not Applicable														
14.5. Environmental hazard	Environmentally hazardous														
14.6. Special precautions for user	<table> <tr> <td>Special provisions</td><td>A1 A145 A167 A802</td></tr> <tr> <td>Cargo Only Packing Instructions</td><td>203</td></tr> <tr> <td>Cargo Only Maximum Qty / Pack</td><td>150 kg</td></tr> <tr> <td>Passenger and Cargo Packing Instructions</td><td>Forbidden</td></tr> <tr> <td>Passenger and Cargo Maximum Qty / Pack</td><td>Forbidden</td></tr> <tr> <td>Passenger and Cargo Limited Quantity Packing Instructions</td><td>Forbidden</td></tr> <tr> <td>Passenger and Cargo Limited Maximum Qty / Pack</td><td>Forbidden</td></tr> </table>	Special provisions	A1 A145 A167 A802	Cargo Only Packing Instructions	203	Cargo Only Maximum Qty / Pack	150 kg	Passenger and Cargo Packing Instructions	Forbidden	Passenger and Cargo Maximum Qty / Pack	Forbidden	Passenger and Cargo Limited Quantity Packing Instructions	Forbidden	Passenger and Cargo Limited Maximum Qty / Pack	Forbidden
Special provisions	A1 A145 A167 A802														
Cargo Only Packing Instructions	203														
Cargo Only Maximum Qty / Pack	150 kg														
Passenger and Cargo Packing Instructions	Forbidden														
Passenger and Cargo Maximum Qty / Pack	Forbidden														
Passenger and Cargo Limited Quantity Packing Instructions	Forbidden														
Passenger and Cargo Limited Maximum Qty / Pack	Forbidden														

Sea transport (IMDG-Code / GGVSee)

14.1. UN number	1950						
14.2. UN proper shipping name	AEROSOLS						
14.3. Transport hazard class(es)	<table> <tr> <td>IMDG Class</td><td>2.1</td></tr> <tr> <td>IMDG Subsidiary Hazard</td><td>Not Applicable</td></tr> </table>	IMDG Class	2.1	IMDG Subsidiary Hazard	Not Applicable		
IMDG Class	2.1						
IMDG Subsidiary Hazard	Not Applicable						
14.4. Packing group	Not Applicable						
14.5. Environmental hazard	Marine Pollutant						
14.6. Special precautions for user	<table> <tr> <td>EMS Number</td><td>F-D , S-U</td></tr> <tr> <td>Special provisions</td><td>63 190 277 327 344 381 959</td></tr> <tr> <td>Limited Quantities</td><td>1000 ml</td></tr> </table>	EMS Number	F-D , S-U	Special provisions	63 190 277 327 344 381 959	Limited Quantities	1000 ml
EMS Number	F-D , S-U						
Special provisions	63 190 277 327 344 381 959						
Limited Quantities	1000 ml						

GI-MASK Universal Separator

Inland waterways transport (ADN)

14.1. UN number	1950	
14.2. UN proper shipping name	AEROSOLS	
14.3. Transport hazard class(es)	2.1	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Environmentally hazardous	
14.6. Special precautions for user	Classification code	5F
	Special provisions	190; 327; 344; 625
	Limited quantity	1 L
	Equipment required	PP, EX, A
	Fire cones number	1

14.7. Maritime transport in bulk according to IMO instruments

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

Not Applicable

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

Product name	Group
2-methylpentane	Not Available
isopropyl acetate	Not Available
propane	Not Available
butane	Not Available
iso-butane	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
2-methylpentane	Not Available
isopropyl acetate	Not Available
propane	Not Available
butane	Not Available
iso-butane	Not Available

SECTION 15 Regulatory information

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

2-methylpentane is found on the following regulatory lists

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

isopropyl acetate is found on the following regulatory lists

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

UK Workplace Exposure Limits (WELs).

propane is found on the following regulatory lists

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

butane 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 Workplace Exposure Limits (WELs).

iso-butane 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)

GI-MASK Universal Separator

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	P3b, E2
-----------------	---------

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 (2-methylpentane; isopropyl acetate; propane; butane; iso-butane)
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	Yes
Vietnam - NCI	Yes
Russia - FBEPH	Yes
Legend:	<p>Yes = All CAS declared ingredients are on the inventory</p> <p>No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.</p>

SECTION 16 Other information

Revision Date	24/11/2022
Initial Date	08/02/2022

Full text Risk and Hazard codes

H220	Extremely flammable gas.
H225	Highly flammable liquid and vapour.
H280	Contains gas under pressure; may explode if heated.
H319	Causes serious eye irritation.

SDS Version Summary

Version	Date of Update	Sections Updated
1.2	24/11/2022	Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (swallowed), Hazards identification - Classification, Ecological Information - Environmental, First Aid measures - First Aid (swallowed), Composition / information on ingredients - Ingredients, Transport Information

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

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

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 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

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	If this product comes in contact with eyes: <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	If skin or hair contact occurs: <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.
----------------------	-------------

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. May emit poisonous 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	<ul style="list-style-type: none">▶ Clean up all spills immediately.▶ Avoid contact with skin and eyes.
--------------	--

GI-MASK Automix New Formula

	<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**

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
octamethylcyclotetrasiloxane	Inhalation 73 mg/m³ (Systemic, Chronic) Inhalation 73 mg/m³ (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/m³ (Systemic, Chronic) Inhalation 24.2 mg/m³ (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/m³ (Local, Chronic) Inhalation 6.1 mg/m³ (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: 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

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><tr><td>Type of Contaminant:</td><td>Air Speed:</td></tr><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></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)								

GI-MASK Automix New Formula

	<p>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</p> <p>2.5-10 m/s (500-2000 f/min.)</p> <p>Within each range the appropriate value depends on:</p> <table> <tr> <th>Lower end of the range</th><th>Upper end of the range</th></tr> <tr> <td>1: Room air currents minimal or favourable to capture</td><td>1: Disturbing room air currents</td></tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only</td><td>2: Contaminants of high toxicity</td></tr> <tr> <td>3: Intermittent, low production.</td><td>3: High production, heavy use</td></tr> <tr> <td>4: Large hood or large air mass in motion</td><td>4: Small hood - local control only</td></tr> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>	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
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										
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
-------------------	---------------

GI-MASK Automix New Formula

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/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

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	

GI-MASK Automix New Formula

	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/m3/4H ^[2]	Skin: no adverse effect observed (not irritating) ^[1]
	Oral (Rat) LD50: >4800 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]
dodecamethylcyclohexasiloxane		Skin: no adverse effect observed (not irritating) ^[1]
	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

	<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 decamethylcycllopentasiloxane (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

	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
dodecamethylcyclohexasiloxane	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
dodecamethylcyclohexasiloxane	HIGH	HIGH

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

Ingredient	Mobility
octamethylcyclotetrasiloxane	LOW (Log KOC = 17960)
decamethylcyclopentasiloxane	LOW (Log KOC = 145200)
dodecamethylcyclohexasiloxane	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 deformaties.

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

GI-MASK Automix New Formula

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

GI-MASK Automix New Formula

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

GI-MASK Automix New Formula

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 (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:	<p>Yes = All CAS declared ingredients are on the inventory</p> <p>No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.</p>

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

GI-MASK Automix New Formula

- 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