

#### Revision nr. 6 Dated 02/10/2020

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

#### 1.1. Product identifier

Mixture identification:

Product Name: INDURENT GEL Code: C100700

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

For professional use only. Catalyst for condensation silicone for dental impression.

Avoid use: in article for supply to, or use by, the general public.

#### 1.3. Details of the supplier of the safety data sheet

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

#### 1.4. Emergency telephone number

+39 0425 597611 (office hours)

#### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

#### 2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

EUH208 Contains carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one. May produce an allergic reaction.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

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#### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not Applicable

#### 3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Numb	er	Classification
>= 5% - < 10%	Trimethoxypropylsilane	CAS: EC: REACH No.:	1067-25-0 213-926-7 01-21199723	2.6/3 Flam. Liq. 3 H226 3.2/2 Skin Irrit. 2 H315
>= 5% - < 10%	Dioctyltin oxide	CAS: EC: REACH No.:	14-37-XXXX 870-08-6 212-791-1 01-21199712 68-27-XXXX	<b>♦</b> 3.8/2 STOT SE 2 H371
>= 3% - < 5%	tetraethyl silicate; ethyl silicate	Index number: CAS: EC: REACH No.:	014-005-00-0 78-10-4 201-083-8 01-21194961 95-28-XXXX	3.8/3 STOT SE 3 H335 2.6/3 Flam. Liq. 3 H226 3.1/4/Inhal Acute Tox. 4 H332 3.3/2 Eye Irrit. 2 H319
>= 0,3% - < 0,5%	carvone (ISO); 2-methyl-5-(prop-1-en- 2-yl)cyclohex-2-en-1-o ne	Index number: CAS: EC:	606-148-00-8 99-49-0 202-759-5	3.4.2/1 Skin Sens. 1 H317 3.1/4/Oral Acute Tox. 4 H302
< 0.1%	methanol	Index number: CAS: EC:	603-001-00-X 67-56-1 200-659-6 01-21194333 07-44-XXXX	<ul> <li>♣ 3.8/1 STOT SE 1 H370</li> <li>♠ 2.6/2 Flam. Liq. 2 H225</li> <li>♠ 3.1/3/Oral Acute Tox. 3 H301</li> <li>♠ 3.1/3/Dermal Acute Tox. 3 H311</li> <li>♠ 3.1/3/Inhal Acute Tox. 3 H331</li> </ul>

#### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

#### 4.2. Most important symptoms and effects, both acute and delayed

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

Treatment:

None

#### SECTION 5: Firefighting measures

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#### 5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

#### 5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

#### 5.3. Advice for firefighters

Use suitable breathing apparatus.

Collect contaminated fire extinguishing water separately. This must not be discharged into drains

Move undamaged containers from immediate hazard area if it can be done safely.

#### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

#### 6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

#### 6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

#### 6.4. Reference to other sections

See also section 8 and 13

#### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

#### 7.3. Specific end use(s)

See section 1.2.

#### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

INDURENT GEL

Trimethoxypropylsilane - CAS: 1067-25-0

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country



		n		n	
No data available					

Dioctyltin oxide - CAS: 870-08-6

OEL Type	TWA		Duratio	STEL		Duratio	Notes	Country
			n			n		
AGW	0.01	0.002	8h	0.02	0.004	15min		GERMANY
	mg/m3	ppm		mg/m3	ppm			

tetraethyl silicate; ethyl silicate - CAS: 78-10-4

OEL Type	TWA		Duratio	STEL		Duratio	Notes	Country
			n			n		
VME/VLE	85	10 ppm	8h	85	10 ppm	15min		SWITZERLA
	mg/m3	''		mg/m3	''			ND
AK	44		8h					HUNGARY
	mg/m3							
GVI/KGVI	44	5 ppm	8h					CROATIA
	mg/m3	''						
HTP	43	5 ppm	8h	86	10 ppm	15min		FINLAND
	mg/m3	''		mg/m3	'''			
MAK	44	5 ppm	8h	88	10 ppm	15min		AUSTRIA
	mg/m3	''		mg/m3	'''			
NDS/NDSCh	44		8h					POLAND
	mg/m3							
NPEL	44	5 ppm	8h					SLOVAKIA
	mg/m3	''						(Slovak
								Republic)
EU	44	5 ppm	8h					
	mg/m3	''						
OELV	44	5 ppm	8h					IRELAND
	mg/m3	''						
RD	44	5 ppm	8h					LITHUANIA
	mg/m3	''						
RV	44	5 ppm	8h					LATVIA
	mg/m3	''						
TGG	44		8h					NETHERLAN
	mg/m3							DS
TLV	44	5 ppm	8h					MALTA
	mg/m3	''						
TLV	44	5 ppm	8h					NORWAY
	mg/m3	''						
TLV	44	5 ppm	8h					ROMANIA
	mg/m3	''						
TLV	50	5.85	8h	200	23.4	15min		CZECH
	mg/m3	ppm		mg/m3	ppm			REPUBLIC
TLV	85	10 ppm	8h		1			DENMARK
	mg/m3	''						
TLV	44	5 ppm	8h					CYPRUS
	mg/m3	''						
TLV	44	5 ppm	8h					BULGARIA
	mg/m3	''						
TLV	44	5 ppm	8h					GREECE



	mg/m3							
TLV-ACGIH	85 mg/m3	10 ppm	8h					
VL	44 mg/m3	5 ppm	8h					LUXEMBOUR G
VLE	44 mg/m3	5 ppm	8h					PORTUGAL
VLEP	85 mg/m3	10 ppm	8h					FRANCE
VLEP	44 mg/m3	5 ppm	8h	0 mg/m3	0 ppm			ITALY
VLEP	44 mg/m3	5 ppm	8h					BELGIUM
WEL	44 mg/m3	5 ppm	8h					UNITED KINGDOM
MAK	86 mg/m3	10 ppm	8h	86 mg/m3	10 ppm	15min		GERMANY
AGW	12 mg/m3	1.4 ppm	8h	12 mg/m3	1.4 ppm	15min		GERMANY
MV	170 mg/m3	20 ppm	8h	170 mg/m3	20 ppm	15min		SLOVENIA
MAK	85 mg/m3	10 ppm	8h	85 mg/m3	10 ppm	15min		SWITZERLA ND
ACGIH		10 ppm	8h				URT and eye irr, kidney dam	
TLV-ACGIH		10 ppm	8h				URT & eye irr, kidney dam	

carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one - CAS: 99-49-0

OEL Type	TWA	Duratio	STEL	Duratio	Notes	Country
		n		n		
No data available						

methanol - CAS: 67-56-1

OEL Type	TWA		Duratio	STEL		Duratio	Notes	Country
			n			n		
AGW	270	200	8h	1080	800	15min	Skin	GERMANY
	mg/m3	ppm		mg/m3	ppm			
MAK	130	100	8h	260	200	15min	Skin	GERMANY
	mg/m3	ppm		mg/m3	ppm			
MAK	260	200	8h	1040	800	15min	Skin	SWITZERLA
	mg/m3	ppm		mg/m3	ppm			ND
VME/VLE	260	200	8h	1040	800	15min	Skin	SWITZERLA
	mg/m3	ppm		mg/m3	ppm			ND
MV	260	200	8h	1040	800	15min	Skin	SLOVENIA
	mg/m3	ppm		mg/m3	ppm			
AK	260		8h				Skin	HUNGARY
	mg/m3							
GVI/KGVI	260	200	8h				Skin	CROATIA



	mg/m3	nnm	1		1	1	1	
UTD		ppm	05	220	250	15	Clein	FINIL AND
HTP	270 mg/m3	200 ppm	8h	330 mg/m3	250 ppm	15min	Skin	FINLAND
MAK	260	200	8h	1040	800	15min	Skin	AUSTRIA
1717 11 3	mg/m3	ppm		mg/m3	ppm	10111111		, COTTAIA
NDS/NDSCh	100	1 - 1 - 1 - 1	8h	300	1512	15min	Skin	POLAND
. 15 5,145 5 511	mg/m3		"	mg/m3		.5		
NGV/KGV	250	200	8h	Ceiling	Ceiling	15min	Skin	SWEDEN
140 7/10 7	mg/m3	ppm	011	350	250	10111111	Ottiri	OWEDEN
	Inginio	PPIII		mg/m3	ppm			
NPEL	260	200	8h	Inginio	PP		Skin	SLOVAKIA
	mg/m3	ppm	• • • • • • • • • • • • • • • • • • •					(Slovak
								Republic)
EU	260	200	8h				Skin	
	mg/m3	ppm						
OELV	260	200	8h		1		Skin	IRELAND
	mg/m3	ppm						
RD	260	200	8h		1		Skin	LITHUANIA
	mg/m3	ppm						
RV	260	200	8h		1		Skin	LATVIA
	mg/m3	ppm						
TGG	133	1	8h				Skin	NETHERLAN
	mg/m3							DS
TLV	260	200	8h	325	250	15min	1	GREECE
	mg/m3	ppm		mg/m3	ppm			
TLV	260	200	8h	1	1		Skin	ESTONIA
	mg/m3	ppm						
TLV	260	200	8h				Skin	MALTA
	mg/m3	ppm						
TLV	130	100	8h				Skin	NORWAY
	mg/m3	ppm						
TLV	260	200	8h				Skin	ROMANIA
	mg/m3	ppm						
TLV	250	188.5	8h	1000	754	15min	Skin	CZECH
	mg/m3	ppm		mg/m3	ppm			REPUBLIC
TLV	260	200	8h				Skin	DENMARK
	mg/m3	ppm						
TLV	260	200	8h				Skin	CYPRUS
	mg/m3	ppm			<u>                                     </u>			
TLV	260	200	8h				Skin	BULGARIA
	mg/m3	ppm						
TLV-ACGIH		200	8h		250	15min	Skin	
		ppm			ppm			
VL	260	200	8h				Skin	LUXEMBOUR
	mg/m3	ppm	<u></u>		<u>L</u>			G
VLE	260	200	8h				Skin	PORTUGAL
	mg/m3	ppm					<u> </u>	
VLEP	260	200	8h	1300	1000	15min	Skin	FRANCE
	mg/m3	ppm		mg/m3	ppm			
VLEP	260	200	8h				Skin	ITALY
	mg/m3	ppm						



VLEP	266	200	8h	333	250	15min	Skin	BELGIUM
	mg/m3	ppm		mg/m3	ppm			
WEL	266	200	8h	333	250	15min	Skin	UNITED
	mg/m3	ppm		mg/m3	ppm			KINGDOM
VLA	266	200	8h				Skin	SPAIN
	mg/m3	ppm						
ACGIH		200	8h		250		Skin, BEI -	
		ppm			ppm		Headache,	
							eye dam,	
							dizziness,	
							nausea	

**DNEL Exposure Limit Values** 

Trimethoxypropylsilane - CAS: 1067-25-0

Consumer: 154.17 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term,

systemic effects

Consumer: 8.77 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term,

systemic effects

Consumer: 30.25 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term,

systemic effects

Consumer: 1.26 mg/kg/d - Exposure: Human Oral - Frequency: Long Term, systemic

effects

Worker Professional: 17.86 mg/kg/d - Exposure: Human Dermal - Frequency: Long

Term, systemic effects

Worker Professional: 123.82 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, systemic effects

Dioctyltin oxide - CAS: 870-08-6

Worker Professional: 0.03 mg/m3 - Exposure: Human Inhalation - Frequency: Short

Term, local effects

Consumer: 0.001 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term,

systemic effects

Worker Professional: 0.03 mg/m3 - Exposure: Human Inhalation - Frequency: Short

Term, systemic effects

tetraethyl silicate; ethyl silicate - CAS: 78-10-4

Consumer: 14 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term, local

effects

Consumer: 14 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, local

effects

Worker Professional: 85 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, local effects

Consumer: 3 mg/kg/d - Exposure: Human Dermal - Frequency: Short Term, systemic

effects

Consumer: 14 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term,

systemic effects

Consumer: 3 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term, systemic

effects

Consumer: 14 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic

effects

Worker Professional: 56 mg/kg/d - Exposure: Human Dermal - Frequency: Short Term,

systemic effects

Worker Professional: 56 mg/kg/d - Exposure: Human Dermal - Frequency: Long Term,

systemic effects

Worker Professional: 85 mg/m3 - Exposure: Human Inhalation - Frequency: Long

Term, systemic effects

methanol - CAS: 67-56-1



Consumer: 8 mg/kg - Exposure: Human Dermal - Frequency: Short Term, systemic effects

Consumer: 50 mg/kg - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

Worker Professional: 40 mg/kg - Exposure: Human Dermal - Frequency: Short Term, systemic effects

Worker Professional: 260 mg/m3 - Exposure: Human Inhalation - Frequency: Short Term, systemic effects

PNEC Exposure Limit Values

Trimethoxypropylsilane - CAS: 1067-25-0

Target: Soil (agricultural) - Value: 0.25 mg/kg

Target: Fresh Water - Value: 1.49 mg/l

Target: intermittent release - Value: 14.9 mg/l

Target: Marine water - Value: 0.149 mg/l

Target: Freshwater sediments - Value: 5.6 mg/kg Target: Marine water sediments - Value: 0.56 mg/kg

Target: Microorganisms in sewage treatments - Value: 10 mg/l

tetraethyl silicate; ethyl silicate - CAS: 78-10-4

Target: Soil (agricultural) - Value: 0.05 mg/kg

Target: Fresh Water - Value: 0.19 mg/l

Target: intermittent release - Value: 10 mg/l

Target: Marine water - Value: 0.019 mg/l

Target: Freshwater sediments - Value: 0.83 mg/kg Target: Marine water sediments - Value: 0.083 mg/kg

Target: Microorganisms in sewage treatments - Value: 4000 mg/l

methanol - CAS: 67-56-1

Target: Fresh Water - Value: 154 mg/l Target: Marine water - Value: 15.4 mg/l

Target: Freshwater sediments - Value: 570.4 mg/l

Target: Microorganisms in sewage treatments - Value: 100 mg/l

Biological Exposure Index

methanol - CAS: 67-56-1

Value: 15 mg/L - Biological Indicator: Methyl alcohol in urine - Sampling Period: End of

turn

#### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles.

Protection for skin:

Wear professional overalls and safety footwear.

Protection for hands:

Permeation resistant gloves A H J in PVA or fluorinated rubber.

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Mask with a type AX filter

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

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Environmental exposure controls:

None

Appropriate engineering controls:

None

#### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes
Appearance and colour:	Gel,red		
Odour:	mint		
Odour threshold:	Not available		
pH:	Not Relevant		
Melting point / freezing point:	Not available		
Initial boiling point and boiling range:	Not available		
Flash point:	63.9°C ° C	EN ISO 3679	
Evaporation rate:	Not available		
Solid/gas flammability:	Not Relevant		
Upper/lower flammability or explosive limits:	Not available		
Vapour pressure:	Not available		
Vapour density:	Not available		
Relative density:	0.94 g/cm3		
Solubility in water:	Insoluble		
Solubility in oil:	Not available		
Partition coefficient (n-octanol/water):	Not available		
Auto-ignition temperature:	Not available		
Decomposition	Not available		
temperature:			
Viscosity:	25 kPa*s (@23°C)		
Explosive properties:	Not available		
Oxidizing properties:	Not available		

#### 9.2. Other information

Properties	Value	Method:	Notes
Miscibility:	Not available		
Fat Solubility:	Not available		
Conductivity:	Not available		
Substance Groups relevant properties	Not available		

#### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions

#### 10.2. Chemical stability

Stable under normal conditions

#### 10.3. Possibility of hazardous reactions

The vapours may also form explosive mixtures with the air.

#### 10.4. Conditions to avoid

Avoid moisture and high temperature.

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Avoid bunching of electrostatic charges.

Avoid all sources of ignition.

#### 10.5. Incompatible materials

Water

Avoid contact with strong oxidizing materials.

Acids

Alkalis

#### 10.6. Hazardous decomposition products

None.

#### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Toxicological information of the product:

**INDURENT GEL** 

a) acute toxicity

Not classified

- b) skin corrosion/irritation Not classified
- c) serious eye damage/irritation Not classified
- d) respiratory or skin sensitisation Not classified
- e) germ cell mutagenicity Not classified
- f) carcinogenicity Not classified
- g) reproductive toxicity Not classified
- h) STOT-single exposure Not classified
- i) STOT-repeated exposure Not classified
- j) aspiration hazard Not classified

Toxicological information of the main substances found in the product:

Trimethoxypropylsilane - CAS: 1067-25-0

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 22.2 mg/l - Duration: 4h - Source: (OECD 403, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat > 5170 mg/kg - Source: (OECD 401, ECHA dossier).

b) skin corrosion/irritation:

Species: Rabbit - Skin Irritant - Source: (OECD 404, ECHA dossier).

c) serious eye damage/irritation:

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Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 405, ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Guinea pig - Based on available data, the classification criteria are not met - Source: (OECD 406, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Species: Salmonella Typhimurium - Negative - Source: (OECD 471, ECHA dossier).

Test: In vivo - Species: Mouse - Negative - Source: (OECD 474, ECHA dossier). Dioctyltin oxide - CAS: 870-08-6

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat > 2500 mg/kg - Source: (MSDS supplier)
Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (OECD 402, ECHA dossier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Based on available data, the classification criteria are not met - Source: (LLNA, ECHA dossier).

e) germ cell mutagenicity:

Test: In vitro - Species: Salmonella Typhimurium - Negative - Source: (ECHA dossier). Test: In vivo - Species: Mouse - Negative - Source: (OECD 474, ECHA dossier).

i) STOT-repeated exposure:

Route: Oral - Species: Rat - Notes: Target organ: Immune system - Positive - Source: (ECHA dossier).

tetraethyl silicate; ethyl silicate - CAS: 78-10-4

a) acute toxicity:

Test: LC50 - Route: Inhalation - Species: Rat 16 mg/l - Duration: 4h - Source: (OECD 403, MSDS supplier).

Test: LD50 - Route: Oral - Species: Rat > 2500 mg/kg - Source: (OECD 423, MSDS supplier).

b) skin corrosion/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 404, MSDS supplier).

c) serious eye damage/irritation:

Species: Rabbit - Based on available data, the classification criteria are not met - Source: (OECD 405, MSDS supplier).

d) respiratory or skin sensitisation:

Test: Skin Sensitization - Species: Guinea pig - Based on available data, the classification criteria are not met - Source: (OECD 406, MSDS supplier).

i) STOT-repeated exposure:

Test: NOAEL - Route: Oral - Species: Rat 10 mg/kg - Based on available data, the classification criteria are not met - Source: (OECD 422, MSDS supplier).

Test: LOAEL - Route: Inhalation - Species: Mouse 0.43 mg/l - Based on available data, the classification criteria are not met - Source: (OECD 412, MSDS supplier).

carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one - CAS: 99-49-0 a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat 1640 mg/l - Source: (MSDS supplier).

#### SECTION 12: Ecological information

#### 12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment. INDURENT GEL

Not classified for environmental hazards

Based on available data, the classification criteria are not met

Trimethoxypropylsilane - CAS: 1067-25-0

a) Aquatic acute toxicity:

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Endpoint: EC50 - Species: Daphnia > 816 mg/l - Duration h: 48h (EU Method C.2,

Daphnia magna, ECHA dossier).

Endpoint: EC50 - Species: Algae > 913 mg/l - Duration h: 72h (EU Method C.3,

Scenedesmus subspicatus, ECHA dossier).

Endpoint: LC50 - Species: Fish > 746 mg/l - Duration h: 96h (read across, Brachydanio rerio, ECHA dossier).

Dioctyltin oxide - CAS: 870-08-6

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 0.21 mg/l - Duration h: 48h (Daphnia magna, Immobilisation Test, MSDS supplier).

Endpoint: LC50 - Species: Fish > 0.09 mg/l - Duration h: 96h (Brachydanio rerio, MSDS supplier).

Endpoint: NOEC - Species: Algae 0.0097 mg/l (OECD 201, ECHA dossier).

tetraethyl silicate; ethyl silicate - CAS: 78-10-4

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia > 75 mg/l - Duration h: 48h (OECD 202, Daphnia magna, MSDS supplier).

Endpoint: EC50 - Species: Algae > 100 mg/l - Duration h: 72h (OECD 201,

Pseudokirchnerella subcapitata, MSDS supplier).

Endpoint: LC50 - Species: Fish > 245 mg/l - Duration h: 96h (OECD 203, Brachydanio rerio, MSDS supplier).

Endpoint: NOEC - Species: Algae > 100 mg/l (OECD 201, Pseudokirchnerella subcapitata, MSDS supplier).

Endpoint: NOEC - Species: Daphnia > 75 mg/l (OECD 202, Daphnia magna, MSDS supplier).

Endpoint: NOEC - Species: Fish > 245 mg/l (OECD 203, Brachydanio rerio, MSDS supplier).

#### 12.2. Persistence and degradability

Trimethoxypropylsilane - CAS: 1067-25-0

Biodegradability: Non-readily biodegradable

Dioctyltin oxide - CAS: 870-08-6

Biodegradability: Non-readily biodegradable tetraethyl silicate; ethyl silicate - CAS: 78-10-4
Biodegradability: Readily biodegradable

#### 12.3. Bioaccumulative potential

tetraethyl silicate; ethyl silicate - CAS: 78-10-4
Test: BCF - Bioconcentrantion factor 3.16
Test: Kow - Partition coefficient 3.18

#### 12.4. Mobility in soil

Not available

#### 12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

#### 12.6. Other adverse effects

None

#### **SECTION** 13: Disposal considerations

#### 13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

#### SECTION 14: Transport information

#### 14.1. UN number

Not classified as dangerous in the meaning of transport regulations.

#### 14.2. UN proper shipping name

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Not available

#### 14.3. Transport hazard class(es)

Not available

#### 14.4. Packing group

Not available

#### 14.5. Environmental hazards

ADR-Enviromental Pollutant: No IMDG-Marine pollutant: No

#### 14.6. Special precautions for user

Not available

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not Applicable

#### SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) 2015/830

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP) Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

Restriction 3

Restrictions related to the substances contained:

Restriction 20

Restriction 69

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

WGK2 - Hazardous for water

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

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Dioctyltin oxide.

California Proposition 65

Substance(s) listed under California Proposition 65:

methanol - Listed as reproductive toxicant.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

Trimethoxypropylsilane

Dioctyltin oxide

tetraethyl silicate; ethyl silicate

#### SECTION 16: Other information

Full text of phrases referred to in Section 3:

H226 Flammable liquid and vapour.

H315 Causes skin irritation.

H371 May cause damage to organs (immune system) if swallowed.

H335 May cause respiratory irritation.

H332 Harmful if inhaled.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H302 Harmful if swallowed.

Hazard class and hazard category	Code	Description
Flam. Liq. 2	2.6/2	Flammable liquid, Category 2
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Acute Tox. 3	3.1/3/Dermal	Acute toxicity (dermal), Category 3
Acute Tox. 3	3.1/3/Inhal	Acute toxicity (inhalation), Category 3
Acute Tox. 3	3.1/3/Oral	Acute toxicity (oral), Category 3
Acute Tox. 4	3.1/4/Inhal	Acute toxicity (inhalation), Category 4
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Skin Irrit. 2	3.2/2	Skin irritation, Category 2
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
Skin Sens. 1	3.4.2/1	Skin Sensitisation, Category 1
STOT SE 1	3.8/1	Specific target organ toxicity - single exposure, Category 1
STOT SE 2	3.8/2	Specific target organ toxicity - single exposure, Category 2
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3

This document was prepared by a competent person who has received appropriate training. Main bibliographic sources:

ECHA - European Chemical Agency

GESTIS - Information system on hazardous substances of the German Social Accident Insurance

IARC - International Agency for Research on Cancer

IPCS INCHEM - International Programme on Chemical Safety

ISS - Istituto Superiore di Sanità

PubChem - open chemistry database at the National Institutes of Health (NIH)



A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of

Dangerous Goods by Road.

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

CAS: Chemical Abstracts Service (division of the American Chemical

Society).

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

EINECS: European Inventory of Existing Commercial Chemical Substances.

GefStoffVO: Ordinance on Hazardous Substances, Germany.

GHS: Globally Harmonized System of Classification and Labeling of

Chemicals.

IATA: International Air Transport Association.

IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

Association" (IATA).

ICAO: International Civil Aviation Organization.

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

(ICAO).

IMDG: International Maritime Code for Dangerous Goods. INCI: International Nomenclature of Cosmetic Ingredients.

KSt: Explosion coefficient.

LC50: Lethal concentration, for 50 percent of test population.

LD50: Lethal dose, for 50 percent of test population.

PNEC: Predicted No Effect Concentration.

RID: Regulation Concerning the International Transport of Dangerous Goods

by Rail.

STEL: Short Term Exposure limit.
STOT: Specific Target Organ Toxicity.
TLV: Threshold Limiting Value.
TWA: Time-weighted average
WGK: German Water Hazard Class.