VANNINI DENTAL INDUSTRY

Safety Data Sheet
PROTESIL CATALYST GEL

Revision nr. 3
Dated 11/12/2023

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

1.1. Product identifier

Mixture identification:

Product Name: PROTESIL CATALYST GEL

Code: 056021 - 056022 - 056116 - 056217 - 056306

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

Vannini Dental Industry S.r.l.

Via di Campigliano 55/a

50012 Grassina (FI)

Italy

tel. +39 055-644698

Competent person responsible for the safety data sheet:

info@vanninidental.com

1.4. Emergency telephone number

UK Emergency number: 999 (24 hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

Skin Irrit. 2, H315 Causes skin irritation.

STOT RE 2, H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed.

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.

Hazard pictograms:



Warning

Hazard statements:

H315 Causes skin irritation.

H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed.

Precautionary statements:

P233 Keep container tightly closed.

P262 Do not get in eyes, on skin, or on clothing.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/clothing.

P314 Get medical advice/attention if you feel unwell.

Special Provisions:

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

Contains

Tetrakis(2-butoxyethyl)orthosilicate

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

None

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration >= 0.1%

Other Hazards:

No other hazards

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. Number	Classification
>= 20% - < 25%	Tetrakis(2-butoxyethyl) orthosilicate	CAS: 18765-38-3 EC: 242-560-0 REACH No.: 01-21207615 33-55-XXXX	STOT RE 2 H373 May cause damage to organs (blood) through prolonged or repeated exposure if swallowed. Skin Irrit. 2 H315 Causes skin irritation.
>= 5% - < 8%	Dioctyltin oxide	CAS: 870-08-6 EC: 212-791-1 REACH No.: 01-21199712 68-27-XXXX	STOT SE 2 H371 May cause damage to organs (immune system) if swallowed.
>= 0,3% - < 0,5%	carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one	Index number: 606-148-00-8 CAS: 99-49-0 EC: 202-759-5	Skin Sens. 1 H317 May cause an allergic skin reaction. Acute Tox. 4 H302 Harmful if swallowed. Acute Toxicity Estimate: ATE - Oral 1640 mg/kg bw
<0,1%	methanol	Index number: 603-001-00-X CAS: 67-56-1 EC: 200-659-6 REACH No.: 01-21194333 07-44-XXXX	STOT SE 1 H370 Causes damage to organs. Flam. Liq. 2 H225 Highly flammable liquid and vapour. Acute Tox. 3 H301 Toxic if swallowed. Acute Tox. 3 H311 Toxic in contact with skin. Acute Tox. 3 H331 Toxic if inhaled. Specific Concentration Limits: C >= 10%: STOT SE 1 H370 3% <= C < 10%: STOT SE 2 H371 Acute Toxicity Estimate: ATE - Oral 100 mg/kg bw ATE - Dermal 300 mg/kg bw ATE - Inhalation (Vapours) 3 mg/l

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Immediately take off all contaminated clothing.
Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.
Wash thoroughly the body (shower or bath).
Remove contaminated clothing immediatley and dispose off safely.
After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an opthalmologist immediately.
Protect uninjured eye.
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

None

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
Treatment:
None

SECTION 5: Firefighting measures

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.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
See also section 8 for recommended protective equipment.
Advice on general occupational hygiene:
Contamined clothing should be changed before entering eating areas.
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

PROTESIL CATALYST GEL
Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

Dioctyltin oxide - CAS: 870-08-6

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
AGW	0.01 mg/m3	0.002 ppm	8h	0.02 mg/m3	0.004 ppm	15min	Inhalable fraction and vapour	GERMANY

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

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

methanol - CAS: 67-56-1

OEL Type	TWA		Duratio	STEL		Duratio	Notes	Country

			n			n		
AGW	270 mg/m3	200 ppm	8h	1080 mg/m3	800 ppm	15min	Skin	GERMANY
MAK	130 mg/m3	100 ppm	8h	260 mg/m3	200 ppm	15min	Skin	GERMANY
MAK	260 mg/m3	200 ppm	8h	1040 mg/m3	800 ppm	15min	Skin	SWITZERLAND
VME/VLE	260 mg/m3	200 ppm	8h	1040 mg/m3	800 ppm	15min	Skin	SWITZERLAND
MV	260 mg/m3	200 ppm	8h	1040 mg/m3	800 ppm	15min	Skin	SLOVENIA
AK	260 mg/m3		8h				Skin	HUNGARY
GVI/KGVI	260 mg/m3	200 ppm	8h				Skin	CROATIA
HTP	270 mg/m3	200 ppm	8h	330 mg/m3	250 ppm	15min	Skin	FINLAND
MAK	260 mg/m3	200 ppm	8h	1040 mg/m3	800 ppm	15min	Skin	AUSTRIA
NDS/NDSCh	100 mg/m3		8h	300 mg/m3		15min	Skin	POLAND
NGV/KGV	250 mg/m3	200 ppm	8h	Ceiling 350 mg/m3	Ceiling 250 ppm	15min	Skin	SWEDEN
NPEL	260 mg/m3	200 ppm	8h				Skin	SLOVAKIA (Slovak Republic)
EU	260 mg/m3	200 ppm	8h				Skin	
OELV	260 mg/m3	200 ppm	8h				Skin	IRELAND
RD	260 mg/m3	200 ppm	8h				Skin	LITHUANIA
RV	260 mg/m3	200 ppm	8h				Skin	LATVIA
TGG	133 mg/m3		8h				Skin	NETHERLANDS
TLV	260 mg/m3	200 ppm	8h	325 mg/m3	250 ppm	15min		GREECE
TLV	260 mg/m3	200 ppm	8h				Skin	ESTONIA
TLV	260 mg/m3	200 ppm	8h				Skin	MALTA
TLV	130 mg/m3	100 ppm	8h				Skin	NORWAY
TLV	260 mg/m3	200 ppm	8h				Skin	ROMANIA
TLV	250 mg/m3	188.5 ppm	8h	1000 mg/m3	754 ppm	15min	Skin	CZECH REPUBLIC
TLV	260 mg/m3	200 ppm	8h				Skin	DENMARK
TLV	260 mg/m3	200 ppm	8h				Skin	CYPRUS
TLV	260	200	8h				Skin	BULGARIA

	mg/m3	ppm						
TLV-ACGIH		200 ppm	8h		250 ppm	15min	Skin	
VL	260 mg/m3	200 ppm	8h				Skin	LUXEMBOURG
VLE	260 mg/m3	200 ppm	8h				Skin	PORTUGAL
VLEP	260 mg/m3	200 ppm	8h	1300 mg/m3	1000 ppm	15min	Skin	FRANCE
VLEP	260 mg/m3	200 ppm	8h				Skin	ITALY
VLEP	266 mg/m3	200 ppm	8h	333 mg/m3	250 ppm	15min	Skin	BELGIUM
WEL	266 mg/m3	200 ppm	8h	333 mg/m3	250 ppm	15min	Skin	UNITED KINGDOM
VLA	266 mg/m3	200 ppm	8h				Skin	SPAIN
ACGIH		200 ppm	8h		250 ppm		Skin, BEI - Headache, eye dam, dizziness, nausea	

DNEL Exposure Limit Values

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Consumer: 12.5 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Consumer: 10.9 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Worker Professional: 44 mg/m3 - Exposure: Human Inhalation - Frequency: Long Term, systemic effects

Consumer: 12.5 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Worker Professional: 25 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Dioctyltin oxide - CAS: 870-08-6

Consumer: 0.0005 mg/kg bw/d - Exposure: Human Oral - Frequency: Long Term, systemic effects

Consumer: 0.025 mg/kg bw/d - Exposure: Human Dermal - Frequency: Long Term, systemic effects

Consumer: 0.0009 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

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Target: Fresh Water - Value: 10 mg/l

Target: Marine water - Value: 1 mg/l

Target: Freshwater sediments - Value: 63.6 mg/kg
Target: Marine water sediments - Value: 6.4 mg/kg
Target: Microorganisms in sewage treatments - Value: 463 mg/l
Target: Soil (agricultural) - Value: 0.57 mg/kg

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 (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Permeation resistant gloves A H J in PVA or fluorinated rubber (EN 374).
The following should be considered when choosing work glove material (EN 374): 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 AB 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

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
Physical state:	Liquid	--	--
Colour:	Red	--	--
Odour:	mint	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	107 ° C	EN ISO	--

		3679	
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not Relevant	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	0.92 g/cm3 (@23°C)	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

9.2. Other information

No other relevant information

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.

10.5. Incompatible materials

Water
Avoid contact with strong oxidizing materials.
Alkalis
Acids

10.6. Hazardous decomposition products

May develop: 2-Butoxyethanol.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological information of the product:

PROTESIL CATALYST GEL

a) acute toxicity

Not classified

b) skin corrosion/irritation

The product is classified: Skin Irrit. 2 H315

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
The product is classified: STOT RE 2 H373
j) aspiration hazard
Not classified

Toxicological information of the main substances found in the product:
Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3
a) acute toxicity:
Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (OECD TG 402, MSDS supplier).
Test: LD50 - Route: Oral - Species: Rat > 2000 mg/kg - Source: (OECD TG 401, MSDS supplier).
b) skin corrosion/irritation:
Species: Rabbit - Skin Irritant - 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: Rat - Based on available data, the classification criteria are not met - Source: (OECD 406, Buehler test, MSDS supplier).
e) germ cell mutagenicity:
Test: In vitro - Negative - Source: (OECD 471, 490, OECD 473, MSDS supplier).
g) reproductive toxicity:
Route: Oral - Species: Rat - Based on available data, the classification criteria are not met - Source: (OECD 422, MSDS supplier).
i) STOT-repeated exposure:
Test: NOAEL - Route: Oral - Species: Rat 25 mg/kg - Notes: Target organ: blood. - Positive - Source: (OECD 422, MSDS supplier).
Dioctyltin oxide - CAS: 870-08-6
a) acute toxicity:
Test: LD50 - Route: Oral - Species: Rat > 2500 mg/kg - Source: (MSDS supplier)
carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one - CAS: 99-49-0
a) acute toxicity
ATE - Oral 1640 mg/kg bw
Test: LD50 - Route: Oral - Species: Rat 1640 mg/l - Source: (MSDS supplier).
methanol - CAS: 67-56-1
a) acute toxicity
ATE - Oral 100 mg/kg bw
ATE - Dermal 300 mg/kg bw
ATE - Inhalation (Vapours) 3 mg/l
Test: LD50 - Route: Oral - Species: Rat 100 mg/kg - Source: MSDS SUPPLIER
Test: LD50 - Route: Skin - Species: Rat 300 mg/kg - Source: MSDS SUPPLIER
Test: LC50 - Route: Inhalation Vapour - Species: Rat 3 mg/l - Duration: 4h - Source: MSDS SUPPLIER

b) skin corrosion/irritation:
Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
c) serious eye damage/irritation:
Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
d) respiratory or skin sensitisation:
Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
e) germ cell mutagenicity:
Test: In vitro - Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
Test: In vivo - Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
f) carcinogenicity:
Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER
g) reproductive toxicity:
Based on available data, the classification criteria are not met - Source: MSDS SUPPLIER

11.2. Information on other hazards

Endocrine disrupting properties:
No endocrine disruptor substances present in concentration >= 0.1%

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.
PROTESIL CATALYST GEL
Not classified for environmental hazards
Based on available data, the classification criteria are not met
Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3
a) Aquatic acute toxicity:
Endpoint: LC50 - Species: Fish > 201 mg/l - Duration h: 96h (Danio rerio, MSDS supplier).
Endpoint: EC50 - Species: Daphnia > 90 mg/l - Duration h: 48h (Daphnia magna, MSDS supplier).
b) Aquatic chronic toxicity:
Endpoint: NOEC - Species: Fish > 100 mg/l - Duration h: 21d (Danio rerio, MSDS supplier).
Endpoint: NOEC - Species: Daphnia 100 mg/l - Duration h: 21d (Daphnia magna, MSDS supplier).
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: EC50 - Species: .Bacteria > 1000 mg/l - Duration h: 3h (Activated Sludge, Respiration Inhibition Test), MSDS supplier
methanol - CAS: 67-56-1
a) Aquatic acute toxicity:
Endpoint: LC50 - Species: lepomis 15.400 mg/l - Duration h: 96h MSDS SUPPLIER
Endpoint: EC50 - Species: Daphnia 18.260 mg/l - Duration h: 96h MSDS SUPPLIER
Endpoint: EC50 - Species: Algae 22.000 mg/l - Duration h: 96h MSDS SUPPLIER

Endpoint: EC50 - Species: Microorganisms > 1.000 mg/l - Duration h: 3h MSDS SUPPLIER

b) Aquatic chronic toxicity:

Endpoint: EC50 - Species: Microorganisms > 1.000 mg/l - Duration h: 3h MSDS SUPPLIER

12.2. Persistence and degradability

Tetrakis(2-butoxyethyl)orthosilicate - CAS: 18765-38-3

Biodegradability: Readily biodegradable

Dioctyltin oxide - CAS: 870-08-6

Biodegradability: Non-readily biodegradable

methanol - CAS: 67-56-1

Biodegradability: readily biodegrada - Notes: MSDS SUPPLIER

12.3. Bioaccumulative potential

methanol - CAS: 67-56-1

Not bioaccumulative - Test: BCF - Bioconcentrantion factor 10 - Notes: MSDS SUPPLIER

Test: Kow - Partition coefficient -0.77 - Notes: MSDS SUPPLIER

12.4. Mobility in soil

methanol - CAS: 67-56-1

Not mobile - Test: Koc 1 - Notes: MSDS SUPPLIER

12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

12.7. Other adverse effects

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number or ID number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

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. Maritime transport in bulk according to IMO instruments

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) n. 2020/878
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)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 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

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:

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:

Dioctyltin oxide

SECTION 16: Other information

Full text of phrases referred to in Section 3:

H370 Causes damage to organs.
H371 May cause damage to organs.

Hazard class and	Code	Description

hazard category		
Flam. Liq. 2	2.6/2	Flammable liquid, Category 2
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/Oral	Acute toxicity (oral), Category 4
Skin Irrit. 2	3.2/2	Skin 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 RE 2	3.9/2	Specific target organ toxicity - repeated exposure, Category 2

This safety data sheet has been completely updated in compliance to Regulation 2020/878.
Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Skin Irrit. 2, H315	Calculation method
STOT RE 2, H373	Calculation method

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.