Vertex Self-Curing - Holland Dental Self-Curing Slow Set

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 10/7/2021 Revision date: 6/10/2025 Supersedes version of: 10/7/2021 Version: 2.0

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

1.1. Product identifier

Product form : Mixture
Product name : Vertex Self-Curing - Holland Dental Self-Curing Slow Set
Product group : Trade product

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

Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Manufacturing of dental applications.
Use of the substance/mixture : Dentistry

Title	Life cycle stage	Use descriptors
Vertex Self-Curing - Holland Dental Self-Curing Slow Set	Professional	SU20

Full text of use descriptors: see section 16

1.3. Details of the supplier of the safety data sheet

Manufacturer
Vertex-Dental
Centurionbaan 190
3769 AV Soesterberg
The Netherlands
T +31 886160400
info@vertex-dental.com, www.vertex-dental.com

1.4. Emergency telephone number

Emergency number : (Only for the purpose of informing medical personnel in cases of accidental intoxications. The emergency phone number is 24 hours/day available.)

Country/Area	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Endocrine disruptor for human health, Category 1 EUH380
Organic peroxide Not classified
Hazardous to the aquatic environment – Chronic Hazard, Category 2 H411
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS09

Signal word (CLP) : Danger

Contains : dicyclohexyl phthalate

Hazard statements (CLP) : EUH380 - May cause endocrine disruption in humans.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.
P391 - Collect spillage.
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P263 - Avoid contact during pregnancy and while nursing.
P280 - Wear protective gloves, protective clothing, eye protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

EUH-statements : EUH208 - Contains dibenzoyl peroxide; benzoyl peroxide, methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate, dicyclohexyl phthalate. May produce an allergic reaction.

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	dicyclohexyl phthalate (84-61-7)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	dicyclohexyl phthalate (84-61-7)

The mixture contains substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

Component	
Substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605	dicyclohexyl phthalate (84-61-7)

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Product name	Product identifier	% w/w (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit (Note D)	CAS-No.: 80-62-6 EC-No.: 201-297-1 EC Index-No.: 607-035-00-6 REACH-no: 01-2119452498-28	0.1 – 1	Flam. Liq. 2, H225 STOT SE 3, H335 Skin Irrit. 2, H315 Skin Sens. 1, H317
dibenzoyl peroxide; benzoyl peroxide substance with national workplace exposure limit(s) (GB)	CAS-No.: 94-36-0 EC-No.: 202-327-6 EC Index-No.: 617-008-00-0 REACH-no: 01-2119511472-50	0.1 – 1	Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)
dicyclohexyl phthalate substance listed on REACH Candidate List substance with national workplace exposure limit(s) (GB); substance identified as having endocrine disrupting properties	CAS-No.: 84-61-7 EC-No.: 201-545-9 REACH-no: 01-2119978223-34	< 0,3	ED ENV 2, EUH431 ED HH 1, EUH380 Skin Sens. 1, H317 Repr. 1B, H360D Aquatic Chronic 1, H410 (M=1)
titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] substance with national workplace exposure limit(s) (GB)	CAS-No.: 13463-67-7 EC-No.: 236-675-5 EC Index-No.: 022-006-00-2 REACH-no: 01-2119489379-17	0.1 – 1	Carc. 2, H351

Note D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In case of doubt or persistent symptoms, consult always a physician.

First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Seek medical attention if ill effect develops.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Dry chemical, CO2, or water spray or regular foam. Making extinguishing agents environment-friendly.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Reactivity in case of fire : Combustion produces irritating gases.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Wear personal protective equipment.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal. Avoid dust production. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. Wear personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool well ventilated place. Keep container tightly closed.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No supplementary information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

National occupational exposure and biological limit values

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Dibenzoyl peroxide
WEL TWA (OEL TWA)	5 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
United Kingdom - Occupational Exposure Limits	
Local name	Titanium dioxide
WEL TWA (OEL TWA)	10 mg/m³ (total inhalable) 4 mg/m³ (respirable)
WEL STEL (OEL STEL)	30 mg/m³ (calculated-total inhalable) 12 mg/m³ (calculated-respirable)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Methyl methacrylate
IOEL TWA	50 ppm
IOEL STEL	100 ppm
Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU
United Kingdom - Occupational Exposure Limits	
Local name	Methyl methacrylate
WEL TWA (OEL TWA)	208 mg/m³
	50 ppm
WEL STEL (OEL STEL)	416 mg/m³
	100 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

dicyclohexyl phthalate (84-61-7)	
United Kingdom - Occupational Exposure Limits	
Local name	Dicyclohexyl phthalate
WEL TWA (OEL TWA)	5 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

DNEL and PNEC

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	6.6 mg/kg bodyweight/day
Long-term - local effects, dermal	0.034 mg/m³

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
Long-term - systemic effects, inhalation	11.75 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	1.65 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	2.9 mg/m³
Long-term - systemic effects, dermal	3.3 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.602 µg/l
PNEC aqua (marine water)	0.0602 µg/l
PNEC aqua (intermittent, freshwater)	0.602 µg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.338 mg/kg dwt
PNEC sediment (marine water)	0.0338 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.0758 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	6.67 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	0.35 mg/l

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	10 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	700 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.184 mg/l
PNEC aqua (marine water)	0.0184 mg/l
PNEC aqua (intermittent, freshwater)	0.193 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1000 mg/kg dwt
PNEC sediment (marine water)	100 mg/kg dwt
PNEC (Soil)	
PNEC soil	100 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	100 mg/l

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
DNEL/DMEL (Workers)	
Acute - local effects, dermal	1.5 mg/cm²
Acute - local effects, inhalation	416 mg/m³

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
Long-term - systemic effects, dermal	13.67 mg/kg bw/day
Long-term - local effects, dermal	1.5 mg/cm²
Long-term - systemic effects, inhalation	348.4 mg/m³
Long-term - local effects, inhalation	208 mg/m³
DNEL/DMEL (General population)	
Acute - local effects, dermal	1.5 mg/cm²
Acute - local effects, inhalation	208 mg/m³
Long-term - systemic effects,oral	8.2 mg/kg bw/day
Long-term - systemic effects, inhalation	74.3 mg/m³
Long-term - systemic effects, dermal	8.2 mg/kg bw/day
Long-term - local effects, dermal	1.5 mg/cm²
Long-term - local effects, inhalation	104 mg/m³
PNEC (Water)	
PNEC aqua (freshwater)	0.94 mg/l
PNEC aqua (marine water)	0.094 mg/l
PNEC aqua (intermittent, freshwater)	0.69 mg/l
PNEC aqua (intermittent, marine water)	0.94 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	10.2 mg/kg dwt
PNEC sediment (marine water)	1.02 mg/kg dwt
PNEC (Soil)	
PNEC soil	1.48 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	10 mg/l

dicyclohexyl phthalate (84-61-7)	
DNEL/DMEL (Workers)	
Acute - systemic effects, dermal	0.5 mg/kg bodyweight/day
Acute - systemic effects, inhalation	35.2 mg/m³
Long-term - systemic effects, dermal	0.5 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	35.2 mg/m³
DNEL/DMEL (General population)	
Acute - systemic effects, dermal	0.25 mg/kg bodyweight/day
Acute - systemic effects, inhalation	0.87 mg/m³
Acute - systemic effects, oral	0.25 mg/kg bodyweight/day
Long-term - systemic effects,oral	0.25 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	0.87 mg/m³
Long-term - systemic effects, dermal	0.25 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.00362 mg/l

dicyclohexyl phthalate (84-61-7)	
PNEC aqua (marine water)	0.000362 mg/l
PNEC aqua (intermittent, freshwater)	0.0362 mg/l
PNEC aqua (intermittent, marine water)	0.02 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	1.06 mg/kg dwt
PNEC sediment (marine water)	0.106 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.21 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	133 g/kg food
PNEC (STP)	
PNEC sewage treatment plant	10 mg/l

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:
Provide adequate ventilation.

Personal protection equipment

Personal protective equipment:
Gloves. Protective clothing. Safety glasses.
Personal protective equipment symbol(s):

Eye and face protection

Eye protection:
Wear eye glasses with side protection according to EN 166.

Skin protection

Skin and body protection:
Wear suitable protective clothing. Standard. EN 13034

Hand protection:
Recommendation: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): e.g. nitrile rubber (>=0.4 mm), butyl rubber (>=0.7 mm) and others. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Respiratory protection

Respiratory protection:
Dust production: dust mask with filter type P2. Standard. EN 149

Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.
Other information:
If on skin, take off contaminated clothing. Keep away from food, drink and animal feedingstuffs. Avoid contact with skin and eyes. Wash hands before breaks and after work.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	coloured.
Appearance	:	Fine grains.
Odour	:	typical. Methyl methacrylate.
Odour threshold	:	Not available
Melting point	:	150 – 230 °C
Freezing point	:	Not available
Boiling point	:	Not available
Flammability	:	Not available
Explosive properties	:	Weakly to moderately explosive.
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	≈ 465 °C
Decomposition temperature	:	No data available
pH	:	Not applicable
pH solution	:	Not available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Solubility	:	Water: Negligible
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Partition coefficient n-octanol/water (Log Pow)	:	Not applicable
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	1.1 – 1.18 g/cm3
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

9.2. Other information

Other safety characteristics

VOC content	:	0 %
Bulk density	:	0.6 – 0.7 g/ml

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. No dangerous reactions known.

10.4. Conditions to avoid

ignition sources. Direct sunlight.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
LD50 oral rat	> 5000 mg/kg bodyweight Animal: rat, Animal sex: male

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
LD50 oral rat	> 2000 mg/kg (Source: ECHA)
LD50 oral	5000 mg/kg
LC50 Inhalation - Rat	3.43 – 6.82 mg/l/4h

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
LD50 oral rat	≈ 7900 mg/kg bodyweight
LD50 oral	9400 mg/kg bodyweight rat
LD50 dermal rabbit	> 5000 mg/kg bodyweight 24h. Strain: New Zealand White. male. OECD 402
LC50 Inhalation - Rat	29.8 mg/l/4h
LC50 Inhalation - Rat (Vapours)	29.8 mg/l/4h Strain: Sprague-Dawley. male/female.
ATE oral	7900 mg/kg bodyweight
ATE vapours	29.8 mg/l/4h
ATE dust/mist	29.8 mg/l/4h

dicyclohexyl phthalate (84-61-7)	
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method), Guideline: EU Method B.1 tris (Acute Oral Toxicity - Acute Toxic Class Method)
LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal))

Skin corrosion/irritation : Not classified
pH: Not applicable

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
pH	7

Serious eye damage/irritation : Not classified
pH: Not applicable

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
pH	7

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
IARC group	2B - Possibly carcinogenic to humans

Reproductive toxicity : Not classified

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
NOAEL (animal/male, F0/P)	500 mg/kg bodyweight Animal: rat, Animal sex: male, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEL (animal/female, F0/P)	≥ 1000 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

STOT-single exposure : Not classified

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
NOAEL (oral, rat, 90 days)	190 – 1000
NOAEL (dermal, rat/rabbit, 90 days)	833 mg/kg bodyweight/day

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
LOAEC (inhalation, rat, vapour, 90 days)	416 mg/m³ air
NOAEL (oral, rat, 90 days)	124.1 – 164 mg/kg bodyweight/day
NOAEC (inhalation, rat, dust/mist/fume, 90 days)	500 – 1000 ppm

dicyclohexyl phthalate (84-61-7)	
NOAEL (oral, rat, 90 days)	50 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Aspiration hazard : Not classified

Vertex Self-Curing - Holland Dental Self-Curing Slow Set	
Viscosity, kinematic	No data available

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
Viscosity, kinematic	0.564 mm²/s 20 °C

11.2. Information on other hazards

Endocrine disrupting properties

Component	
dicyclohexyl phthalate (84-61-7)	The substance is identified for having endocrine disrupting properties but there is no additional data available (see section 2.3)

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Avoid release to the environment.

Hazardous to the aquatic environment, short–term (acute) : Not classified

Hazardous to the aquatic environment, long–term (chronic) : Toxic to aquatic life with long lasting effects.

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
LC50 - Fish [1]	0.0602 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	0.11 mg/l Test organisms (species): Daphnia magna

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
EC50 72h - Algae [1]	0.071 mg/l

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
LC50 - Fish [1]	155 mg/l Test organisms (species): other:Japanese Medaka
EC50 - Crustacea [1]	19.3 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	27.8 mg/l Test organisms (species): Daphnia magna
EC50 - Other aquatic organisms [1]	> 100 mg/l Test organisms (species):
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
LOEC (chronic)	5 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	≥ 2.92 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
LC50 - Fish [1]	> 79 mg/l 96 h. Oncorhynchus mykiss. EPA OTS 797.1400.
LC50 - Fish [2]	33.7 mg/l 35 d. Danio rerio. OECD 210.
EC50 - Crustacea [1]	69 mg/l 48h. Daphnia magna. EPA OTS 797.1300
EC50 72h - Algae [1]	> 110 mg/l Raphidocelis subcapitata. OECD 201.
LOEC (chronic)	68 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (acute)	40 mg/l (4 d)
NOEC (chronic)	37 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	9.4 mg/l 35 d. Danio rerio. OECD 210.
NOEC chronic crustacea	37 mg/l 21 d. Daphnia magna. OECD 211.

dicyclohexyl phthalate (84-61-7)	
LC50 - Fish [1]	> 2 mg/l Test organisms (species): Oryzias latipes
EC50 72h - Algae [1]	> 2 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
LOEC (chronic)	0.572 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	0.181 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

Vertex Self-Curing - Holland Dental Self-Curing Slow Set	
Persistence and degradability	Rapidly degradable

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
Persistence and degradability	Rapidly degradable

titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm] (13463-67-7)	
Persistence and degradability	Rapidly degradable
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
Persistence and degradability	Rapidly degradable
Biodegradation	94 % 14 d. OECD 301C

dicyclohexyl phthalate (84-61-7)	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative potential

Vertex Self-Curing - Holland Dental Self-Curing Slow Set	
Partition coefficient n-octanol/water (Log Pow)	Not applicable

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
Partition coefficient n-octanol/water (Log Pow)	3.2

methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate (80-62-6)	
Partition coefficient n-octanol/water (Log Pow)	≈ 1.38 20 °C. pH ca. 7. OECD 107

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Component	
Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII	dicyclohexyl phthalate (84-61-7)
Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII	dicyclohexyl phthalate (84-61-7)

12.6. Endocrine disrupting properties

Component	
dicyclohexyl phthalate (84-61-7)	The substance is identified for having endocrine disrupting properties but there is no additional data available (see section 2.3)

12.7. Other adverse effects

Vertex Self-Curing - Holland Dental Self-Curing Slow Set	
Other information	Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation : Disposal must be done according to official regulations.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Ecological waste information : Avoid release to the environment.
European List of Waste (LoW, EC 2000/532) : 18 00 00 - WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
HP Code : HP14 - “Ecotoxic:” waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
Special provision(s) applied : 375	Special provision(s) applied : 969	Special provision(s) applied : A197	Special provision(s) applied : 375	Special provision(s) applied : 375
These substances when carried in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less for liquids or having a net mass per single or inner packaging of 5 kg or less for solids, are not subject to any other provisions of the transport regulations provided the packagings meet the general provisions.				
14.1. UN number or ID number				
UN 3077	UN 3077	UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate)	Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate)
Transport document description				
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide ; dicyclohexyl phthalate), 9, III
14.3. Transport hazard class(es)				
9	9	9	9	9
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes
No supplementary information available.				

14.6. Special precautions for user

Overland transport

Classification code (ADR)	:	M7
Special provisions (ADR)	:	274, 335, 375, 601
Limited quantities (ADR)	:	5kg
Excepted quantities (ADR)	:	E1
Packing instructions (ADR)	:	P002, IBC08, LP02, R001
Special packing provisions (ADR)	:	PP12, B3

Mixed packing provisions (ADR)	:	MP10
Portable tank and bulk container instructions (ADR)	:	T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	:	TP33
Tank code (ADR)	:	SGAV, LGBV
Vehicle for tank carriage	:	AT
Transport category (ADR)	:	3
Special provisions for carriage - Packages (ADR)	:	V13
Special provisions for carriage - Bulk (ADR)	:	VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	:	CV13
Hazard identification number (Kemler No.)	:	90
Orange plates	:	
Tunnel restriction code (ADR)	:	-
EAC code	:	2Z

Transport by sea

Special provisions (IMDG)	:	274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	:	5 kg
Excepted quantities (IMDG)	:	E1
Packing instructions (IMDG)	:	LP02, P002
Special packing provisions (IMDG)	:	PP12
IBC packing instructions (IMDG)	:	IBC08
IBC special provisions (IMDG)	:	B3
Tank instructions (IMDG)	:	BK1, BK2, BK3, T1
Tank special provisions (IMDG)	:	TP33
Stowage category (IMDG)	:	A
Stowage and handling (IMDG)	:	SW23

Air transport

PCA Excepted quantities (IATA)	:	E1
PCA Limited quantities (IATA)	:	Y956
PCA limited quantity max net quantity (IATA)	:	30kgG
PCA packing instructions (IATA)	:	956
PCA max net quantity (IATA)	:	400kg
CAO packing instructions (IATA)	:	956
CAO max net quantity (IATA)	:	400kg
Special provisions (IATA)	:	A97, A158, A179, A197, A215
ERG code (IATA)	:	9L

Inland waterway transport

Classification code (ADN)	:	M7
Special provisions (ADN)	:	274, 335, 375, 601
Limited quantities (ADN)	:	5 kg
Excepted quantities (ADN)	:	E1
Carriage permitted (ADN)	:	T* B**
Equipment required (ADN)	:	PP, A***
Number of blue cones/lights (ADN)	:	0
Additional requirements/Remarks (ADN)	:	* Only in the molten state. ** For carriage in bulk see also 7.1.4.1. *** Only in the case of transport in bulk.

Rail transport

Classification code (RID)	:	M7
Special provisions (RID)	:	274, 335, 375, 601
Limited quantities (RID)	:	5kg
Excepted quantities (RID)	:	E1
Packing instructions (RID)	:	P002, IBC08, LP02, R001
Special packing provisions (RID)	:	PP12, B3
Mixed packing provisions (RID)	:	MP10

Portable tank and bulk container instructions (RID)	:	T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (RID)	:	TP33
Tank codes for RID tanks (RID)	:	SGAV, LGBV
Transport category (RID)	:	3
Special provisions for carriage – Packages (RID)	:	W13
Special provisions for carriage – Bulk (RID)	:	VC1, VC2
Special provisions for carriage - Loading, unloading and handling (RID)	:	CW13, CW31
Colis express (express parcels) (RID)	:	CE11
Hazard identification number (RID)	:	90

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

EU-Regulations

REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)		
Reference code	**Applicable on**	**Entry title or description**
3(a)	methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F
3(b)	methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains substance(s) listed on the REACH Candidate List in concentrations ≥ 0.1 % or SCL: Dicyclohexyl phthalate (EC 201-545-9, CAS 84-61-7)

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

VOC Directive (2004/42)

VOC content : 0 %

Seveso Directive (Disaster Risk Reduction)

Seveso III Part I (Categories of dangerous substances)	Qualifying quantity (tonnes)	
	Lower-tier	**Upper-tier**
E2 Hazardous to the Aquatic Environment in Category Chronic 2	200	500

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	Supersedes	**Added**
	Revision date	**Added**
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	**Modified**
2.1	Adverse physicochemical, human health and environmental effects	**Removed**
2.2	Signal word (CLP)	**Modified**
2.2	Hazard statements (CLP)	**Modified**
2.2	Precautionary statements (CLP)	**Modified**
2.2	Extra phrases	**Removed**
2.2	Hazard pictograms (CLP)	**Modified**
3	Composition/information on ingredients	**Modified**
4.1	First-aid measures after ingestion	**Modified**
4.1	First-aid measures after skin contact	**Modified**
4.1	First-aid measures general	**Added**
4.1	First-aid measures after inhalation	**Added**
4.1	First-aid measures after eye contact	**Added**
5.1	Unsuitable extinguishing media	**Added**
5.1	Suitable extinguishing media	**Added**
5.2	Reactivity in case of fire	**Added**
5.3	Firefighting instructions	**Added**
5.3	Protection during firefighting	**Added**
5.3	EAC code	**Added**
6.1	General measures	**Added**
6.1	Emergency procedures	**Added**
6.3	Methods for cleaning up	**Added**
6.3	For containment	**Added**
7.1	Precautions for safe handling	**Added**
7.2	Incompatible products	**Added**
7.2	Incompatible materials	**Added**

Indication of changes		
Section	**Changed item**	**Comments**
7.2	Storage conditions	**Modified**
7.3	Specific end uses	**Added**
8.2	Hand protection	**Modified**
8.2	Skin and body protection	**Modified**
8.2	Eye protection	**Modified**
8.2	Other information	**Added**
8.2	Environmental exposure controls	**Added**
8.2	Appropriate engineering controls	**Added**
9	Density	**Removed**
9	Odour	**Modified**
9	Solubility in organic solvents	**Removed**
9	Relative density	**Modified**
10.1	Reactivity	**Added**
10.3	Possibility of hazardous reactions	**Modified**
10.5	Incompatible materials	**Added**
13.1	Product/Packaging disposal recommendations	**Added**
13.1	Ecology - waste materials	**Added**
13.1	European List of Waste (LoW, EC 2000/532)	**Added**
14.1	UN-No. (ADN)	**Added**
14.1	UN-No. (IATA)	**Added**
14.1	UN-No. (IMDG)	**Added**
14.1	UN-No.	**Added**
14.2	Proper Shipping Name (ADN)	**Added**
14.2	Proper Shipping Name	**Added**
14.3	Danger labels (RID)	**Added**
14.3	Class (RID)	**Added**
14.3	Class (IMDG)	**Added**
14.3	Class (ADR)	**Added**
14.3	Danger labels (UN)	**Added**
14.3	Class (UN)	**Added**
14.4	Packing group (ADN)	**Added**
14.4	Packing group (IATA)	**Added**
14.4	Packing group (IMDG)	**Added**
14.4	Packing group (UN)	**Added**
14.6	Additional requirements/Remarks (ADN)	**Added**
14.6	Special provisions (ADN)	**Added**
14.6	Special packing provisions (IMDG)	**Added**

Indication of changes		
Section	**Changed item**	**Comments**
14.6	Packing instructions (IMDG)	**Added**
14.6	Transport category (ADR)	**Added**
14.6	Special provisions (ADR)	**Added**
14.6	Excepted quantities (ADR)	**Added**
14.6	Limited quantities (ADR)	**Added**
14.6	Tunnel restriction code	**Added**
14.6	Hazard identification number (Kemler No.)	**Added**
14.6	Classification code (UN)	**Added**
15.1	REACH Annex XVII	**Modified**
16	Abbreviations and acronyms	**Added**
16	Other information	**Modified**

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EINECS	European Inventory of Existing Commercial Chemical Substances
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
N.O.S.	Not Otherwise Specified
NOAEL	No-Observed Adverse Effect Level
OEL	Occupational Exposure Limit
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Abbreviations and acronyms:	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
UFI	Unique Formula Identifier
SDS	Safety Data Sheet
WGK	Water Hazard Class
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic

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Full text of H- and EUH-statements:	
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Carc. 2	Carcinogenicity, Category 2
ED ENV 2	Endocrine disruptor for the environment, Category 2
ED HH 1	Endocrine disruptor for human health, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Org. Perox. B	Organic Peroxides, Type B
Repr. 1B	Reproductive toxicity, Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
EUH380	May cause endocrine disruption in humans.
EUH431	Suspected of causing endocrine disruption in the environment.
H225	Highly flammable liquid and vapour.
H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

Full text of H- and EUH-statements:	
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H360D	May damage the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
EUH208	Contains dibenzoyl peroxide; benzoyl peroxide, methyl methacrylate; methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate, dicyclohexyl phthalate. May produce an allergic reaction.

Full text of use descriptors	
SU20	Health services

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
ED HH 1	EUH380	Calculation method
Org. Perox. Not classified		Expert judgement
Aquatic Chronic 2	H411	Calculation method

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.