

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 4 November 2022 Version: 1.0

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

1.1. Product identifier

Product form : Mixture

: Absolute Dentin® (all shades) - Base Trade name

Product code : SKU S300, Various

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : Trained Dental Clinicians

Use of the substance/mixture : Dual-cure composite resin for core fabrication.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Parkell Inc.

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Authorized Representative in Europe (Regulatory affairs only)

Directa AB Finvids väg 8

SE-194 27 Upplands Väsby

Sweden

1.4. Emergency telephone number

: INFOTRAC 1-352-323-3500 (International);INFOTRAC 1-800-535-5053 (North America) **Emergency number**

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2 H315 H319 Serious eye damage/eye irritation, Category 2 Skin sensitisation, Category 1 H317 Specific target organ toxicity - Single exposure, Category 3, Respiratory H335 tract irritation

Hazardous to the aquatic environment - Chronic Hazard, Category 3 H412

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

Adverse physicochemical, human health and environmental effects

Causes skin and eye irritation. May cause an allergic skin reaction. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)

GHS07

Signal word (CLP) Warning

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Contains : Triethylene glycol dimethacrylate, Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-

methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]-, Ethanol,

2,2'-[(4-methylphenyl)imino]bis-

Hazard statements (CLP) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing vapours.

P273 - Avoid release to the environment.

P280 - Wear eye protection, protective gloves, protective clothing.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. P312 - Call a POISON CENTRE or doctor if you feel unwell.

2.3. Other hazards

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triethylene glycol dimethacrylate	CAS-No.: 109-16-0 EC-No.: 203-652-6	< 25	Skin Sens. 1B, H317
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega[(2-methyl-1-oxo-2-propenyl)oxy]-	CAS-No.: 41637-38-1 EC-No.: 609-946-4	< 25	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Chronic 4, H413
2,6-Di-tert-butyl-4-methylphenol	CAS-No.: 128-37-0 EC-No.: 204-881-4	< 1	Aquatic Chronic 1, H410 (M=1)
Ethanol, 2,2'-[(4-methylphenyl)imino]bis-	CAS-No.: 3077-12-1 EC-No.: 221-359-1	< 1	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 3, H412

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).

First-aid measures after inhalation : If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing.

Obtain medical attention if breathing difficulty persists.

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First-aid measures after ingestion

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First-aid measures after skin contact : Rinse immediately with plenty of water for 15 minutes. Take off contaminated clothing and

wash it before reuse. Seek medical attention if ill effect or irritation develops.

First-aid measures after eye contact : Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present

and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops.

: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Presents no particular fire or explosion hazard.

Explosion hazard : No hazard identified.

Hazardous decomposition products in case of fire : Thermal decomposition may produce : Carbon oxides (CO, CO2). Sulphur oxides. Barium

oxides (BaOx). Nitrogen oxides.

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering

the environment.

Protective equipment for firefighters : 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 : In case of large spillages: Evacuate unnecessary personnel. Avoid all unnecessary

exposure.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. For further information refer to section

8: "Exposure controls/personal protection".

Emergency procedures : Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid breathing

vapours.

6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment. For further information refer to section

8: "Exposure controls/personal protection".

Emergency procedures : In case of large spillages: Ventilate spillage area. Stop leak if safe to do so. Notify

authorities if liquid enters sewers or public waters.

6.2. Environmental precautions

Avoid release to the environment. In case of large spillages: 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. Take up liquid spill into inert absorbent material.

Methods for cleaning up : Absorb spillage to prevent material damage. Wipe up with absorbent material (for example

cloth). Store away from other materials.

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Other information : Dispose in a safe manner in accordance with local/national regulations.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Read instructions/label before use. Observe the label precautions. Ensure adequate

ventilation. Avoid breathing vapours. Avoid contact with skin, eyes and clothing.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Wash contaminated clothing before reuse. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and

safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep container closed when

not in use.

Incompatible materials : Strong bases. Strong oxidizing agents. chemically active metals. Amines.

7.3. Specific end use(s)

For further information see section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Austria - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-kresol (Butylhydroxytoluol)	
MAK (OEL TWA)	10 mg/m³	
Regulatory reference	BGBI. II Nr. 156/2021	
Belgium - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-crésol (vapeur et aérosol) # Di-tert-butyl-4-methylfenol (damp en aërosol)	
OEL TWA	2 mg/m³	
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021	
Bulgaria - Occupational Exposure Limits		
Local name	Дибутилпаракрезол	
OEL TWA	10 mg/m³	
OEL STEL	50 mg/m³	
Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр. 47 от 2021 г., в сила от 04.06.2021 г.)	
Croatia - Occupational Exposure Limits		
Local name	2,6-Di-tert-butil-p-krezol	
GVI (OEL TWA) [1]	10 mg/m³	

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)			
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)		
Denmark - Occupational Exposure Limits			
Local name	2,6-Di-tert-butyl-p-cresol (Butylhydroxytoluen)		
OEL TWA [1]	10 mg/m³		
Regulatory reference	BEK nr 1054 af 28/06/2022		
Finland - Occupational Exposure Limits			
Local name	2,6-Di-tert-butyyli-p-kresoli		
HTP (OEL TWA) [1]	10 mg/m³		
HTP (OEL STEL)	20 mg/m³		
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveysministeriö)		
France - Occupational Exposure Limits			
Local name	2,6-Di-tert-butyl-p-crésol		
VME (OEL TWA)	10 mg/m³		
Remark	Valeurs recommandées/admises		
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)		
Germany - Occupational Exposure Limits (TRGS 90	00)		
Local name	2,6-Di-tert-butyl-p-kresol		
AGW (OEL TWA) [1]	10 mg/m³ (E)		
Peak exposure limitation factor	4(II)		
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission); Y - Ein Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes (BGW) nicht befürchtet zu werden; 11 - Summe aus Dampf und Aerosolen		
Regulatory reference	TRGS900		
Greece - Occupational Exposure Limits			
Local name	Βουτυλο-υσροξυ-τολουόλιο		
OEL TWA	10 mg/m³		
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους		
Ireland - Occupational Exposure Limits			
Local name	2,6-Ditertiary-butyl-para-cresol [Butylated hydroxytoluene (BHT)]		
OEL TWA [1]	2 mg/m³		
Regulatory reference	Chemical Agents Code of Practice 2021		
Netherlands - Occupational Exposure Limits			
TGG-8u (OEL TWA)	10 mg/m³		
Portugal - Occupational Exposure Limits			
Local name	Hidroxitoluenobutilado (2,6-Di-terc-butil-p-cresol) (BHT)		
OEL TWA	2 mg/m³ FIV (Fração inalável e vapor)		
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen		
Remark	A4 (Agente não classificável como carcinogénico no Homem)		

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Regulatory reference	Norma Portuguesa NP 1796:2014	
Slovenia - Occupational Exposure Limits		
Local name	2,6-di-terc-butil-p-krezol	
OEL TWA	10 mg/m³	
OEL STEL	40 mg/m³	
Remark	Y (Snovi, pri katerih ni nevarnosti za zarodek ob upoštevanju mejnih vrednosti in bat vrednosti)	
Regulatory reference	Uradni list RS, št. 72/2021 z dne 11.5.2021	
Spain - Occupational Exposure Limits		
Local name	2,6-Diterc-butil-p-cresol	
VLA-ED (OEL TWA) [1]	10 mg/m³	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT	
USA - ACGIH - Occupational Exposure Limits		
Local name	Butylated hydroxytoluene	
ACGIH OEL TWA	2 mg/m³ (IFV - Inhalable fraction and vapor)	
Remark (ACGIH)	TLV [®] Basis: URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)	
ACGIH chemical category	Not Classifiable as a Human Carcinogen	
Regulatory reference	ACGIH 2022	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses. EN 166

8.2.2.2. Skin protection

Hand protection:

Impermeable protective gloves. EN 374. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer

Other skin protection

Materials for protective clothing:

Long sleeved protective clothing

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8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection. An approved organic vapour respirator/supplied air or self-contained breathing apparatus must be used when vapour concentration exceeds applicable exposure limits

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Colour Light blue Paste. Appearance Odour Odourless Odour threshold : Not available Melting point : Not available Freezing point : Not available Boiling point : Not available Flammability : Non flammable. **Explosive limits** : Not available Lower explosion limit : Not available Upper explosion limit : Not available Flash point : Not available Auto-ignition temperature : Not available Decomposition temperature : Not available рΗ : Not available : Not available Viscosity, kinematic : Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) Vapour pressure Not available Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not available

9.2. Other information

Particle characteristics

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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

The product is stable at normal handling and storage conditions.

: Not applicable

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10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong bases. Strong oxidizing agents. chemically active metals. Amines.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce: Carbon oxides (CO, CO2). Sulphur oxides. Barium oxides (BaOx). Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Re	gulation (EC) No 1272/2008
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Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Triethylene glycol dimethacrylate (109-16-0)		
LD50 oral rat	10837 mg/kg	
2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
LD50 oral rat	> 2930 mg/kg	
LD50 oral	650 mg/kg (mouse)	
LD50 dermal rat	> 2000 mg/kg	
LC50 Inhalation - Rat (Dust/Mist)	> 2 mg/l Source: OSHRI GLP toxicity test	
Ethanol 2.2 [//_mothylphonyl]iminolhis_ (3077-12-1)		

Ethanol, 2,2'-[(4-methylphenyl)imino]bis- (3077-12-1)

 LD50 dermal rat
 > 2000 mg/kg

 Skin corrosion/irritation
 : Causes skin irritation.

 Serious eye damage/irritation
 : Causes serious eye irritation.

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

2,6-Di-tert-butyl-4-methylphenol (128-37-0)

IARC group 3 - Not classifiable

2,6-Di-tert-butyl-4-methylphenol (128-37-0)

NOAEL (chronic, oral, animal/male, 2 years) 25 mg/kg bodyweight Animal: rat, Animal sex: male, Remarks on results: other:

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : May cause respiratory irritation.

Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)

STOT-single exposure May cause respiratory irritation.

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

Triethylene glycol dimethacrylate (109-16-0)

LOAEC (inhalation, rat, gas, 90 days)

350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:

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Triethylene glycol dimethacrylate (109-16-0)	
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEC (inhalation, rat, gas, 90 days)	100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:
Aspiration hazard :	Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine

: None known

disrupting properties

11.2.2. Other information

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.

Ecology - water : Harmful to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term

cute)

: Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term : Harmful to aquatic life with long lasting effects.

(chronic)

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Triethylene glycol dimethacrylate (109-16-0)	
LC50 - Fish [1]	16.4 mg/l (Exposure time: 96 h - Species: Danio rerio [semi-static])
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
EC50 72h - Algae [2]	72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
LOEC (chronic)	100 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	32 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
LC50 - Fish [1]	> 0.57 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	0.48 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	6 mg/l (Species: Pseudokirchneriella subcapitata)
EC50 72h - Algae [2]	> 0.42 mg/l (Species: Desmodesmus subspicatus)
LOEC (chronic)	1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	0.023 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	0.053 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Triethylene glycol dimethacrylate (109-16-0)	
Partition coefficient n-octanol/water (Log Pow)	1.88 Source: ChemIDplus

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Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)		
Partition coefficient n-octanol/water (Log Pow)	3.43 – 5.62 (at pH 6.44)	
2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
BCF - Fish [1]	230 – 2500	
Partition coefficient n-octanol/water (Log Pow) 5.1		
Ethanol, 2,2'-[(4-methylphenyl)imino]bis- (3077-12-1)		
Partition coefficient n-octanol/water (Log Pow)	2 (at 35 °C (at pH 7)	

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations

: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials

: Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID n	14.1. UN number or ID number			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shippin	14.2. UN proper shipping name			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

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14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

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

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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 (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (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 (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)

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

WGK remark : Most stringent classification due to insufficient data.

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed SZW-lijst van mutagene stoffen : None of the components are listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

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SZW-lijst van reprotoxische stoffen – : None of the components are listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people under 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other information : None.

Full text of H- and EUH-statements:		
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3	
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4	
Eye Dam. 1	Serious eye damage/eye irritation, Category 1	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H302	Harmful if swallowed.	
H315	Causes skin irritation.	
H317	May cause an allergic skin reaction.	
H318	Causes serious eye damage.	
H319	Causes serious eye irritation.	
H335	May cause respiratory irritation.	
H410	Very toxic to aquatic life with long lasting effects.	
H412	Harmful to aquatic life with long lasting effects.	
H413	May cause long lasting harmful effects to aquatic life.	
Skin Irrit. 2	Skin corrosion/irritation, Category 2	
Skin Sens. 1	Skin sensitisation, Category 1	
Skin Sens. 1B	Skin sensitisation, category 1B	
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method
STOT SE 3	H335	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 4 August 2017 Revision date: 4 November 2022 Supersedes version of: 4 August 2017 Version: 2.0

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

1.1. Product identifier

Product form : Mixture

: Absolute Dentin® (all shades) - Catalyst Trade name

Product code : S300, various

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

1.2.1. Relevant identified uses

Industrial/Professional use spec

Trained Dental Clinicians

Use of the substance/mixture : Dual-cure composite resin for core fabrication.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Parkell Inc.

300 Executive Drive Edgewood, NY 11717 T (631) 249-1134 Info@parkell.com

Authorized Representative in Europe (Regulatory affairs only)

Directa AB Finvids väg 8 SE-194 27 Upplands Väsby

Sweden

1.4. Emergency telephone number

Emergency number : INFOTRAC 1-352-323-3500 (International);INFOTRAC 1-800-535-5053 (North America)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2 H315 Serious eye damage/eye irritation, Category 2 H319 H317 Skin sensitisation, Category 1 Specific target organ toxicity - Single exposure, Category 3, Respiratory H335 tract irritation

Hazardous to the aquatic environment - Chronic Hazard, Category 3 H412

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

Adverse physicochemical, human health and environmental effects

Causes skin and eye irritation. May cause an allergic skin reaction. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP) : Warning

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Contains : Dibenzoyl peroxide, Triethylene glycol dimethacrylate, Poly(oxy-1,2-ethanediyl),

.alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-

propenyl)oxy]-

Hazard statements (CLP) : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing vapours.

P273 - Avoid release to the environment.

P280 - Wear eye protection, protective gloves, protective clothing.

P302+P352 - If on skin: Wash with plenty of water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing. P312 - Call a POISON CENTRE or doctor if you feel unwell.

2.3. Other hazards

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not 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 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triethylene glycol dimethacrylate	CAS-No.: 109-16-0 EC-No.: 203-652-6	< 25	Skin Sens. 1B, H317
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega[(2-methyl-1-oxo-2-propenyl)oxy]-	CAS-No.: 41637-38-1 EC-No.: 609-946-4	< 25	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 Aquatic Chronic 4, H413
Dibenzoyl peroxide	CAS-No.: 94-36-0 EC-No.: 202-327-6 EC Index-No.: 617-008-00-0	< 1	Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317
2,6-Di-tert-butyl-4-methylphenol	CAS-No.: 128-37-0 EC-No.: 204-881-4	< 1	Aquatic Chronic 1, H410 (M=1)

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).

First-aid measures after inhalation : If inhaled, remove to fresh air and keep at rest in a position comfortable for breathing.

Obtain medical attention if breathing difficulty persists.

First-aid measures after skin contact : Rinse immediately with plenty of water for 15 minutes. Take off contaminated clothing and

wash it before reuse. Seek medical attention if ill effect or irritation develops.

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First-aid measures after eye contact : Rinse immediately with plenty of water for 15 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 : Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Presents no particular fire or explosion hazard.

Explosion hazard : No hazard identified.

Hazardous decomposition products in case of fire : Thermal decomposition may produce : Carbon oxides (CO, CO2).

5.3. Advice for firefighters

Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering

the environment.

Protective equipment for firefighters : 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 : In case of large spillages: Evacuate unnecessary personnel. Avoid all unnecessary

exposure.

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment. For further information refer to section

8: "Exposure controls/personal protection".

Emergency procedures : Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid breathing

vapours.

6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment. For further information refer to section

8: "Exposure controls/personal protection".

Emergency procedures : In case of large spillages: Ventilate spillage area. Stop leak if safe to do so. Notify

authorities if liquid enters sewers or public waters.

6.2. Environmental precautions

Avoid release to the environment. In case of large spillages: 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. Take up liquid spill into inert absorbent material.

Methods for cleaning up : Absorb spillage to prevent material damage. Wipe up with absorbent material (for example

cloth). Store away from other materials.

Other information : Dispose in a safe manner in accordance with local/national regulations.

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6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Read instructions/label before use. Observe the label precautions. Ensure adequate

ventilation. Avoid breathing vapours. Avoid contact with skin, eyes and clothing.

Hygiene measures

: Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Wash contaminated clothing before reuse. Always wash hands after handling the product. Handle in accordance with good industrial hygiene and

safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed in a cool, well-ventilated place. Keep container closed when

not in use.

Incompatible materials : Strong bases. Strong oxidizing agents, chemically active metals. Amines.

7.3. Specific end use(s)

For further information see section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Dibenzoyl peroxide (94-36-0)		
Austria - Occupational Exposure Limits		
Local name	Dibenzoylperoxid (Benzoylperoxid)	
MAK (OEL TWA)	5 mg/m³ (inhalable fraction)	
MAK (OEL STEL)	10 mg/m³ (inhalable fraction)	
Remark	Sh	
OEL chemical category	Skin sensitizer	
Regulatory reference	BGBI. II Nr. 156/2021	
Belgium - Occupational Exposure Limits		
Local name	Peroxyde de dibenzoyle # Dibenzoylperoxide	
OEL TWA	5 mg/m³	
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021	
Croatia - Occupational Exposure Limits		
Local name	Dibenzoil peroksid; benzoil peroksid	
GVI (OEL TWA) [1]	5 mg/m³	
Remark	Alergen koža (tvar koja može izazvati alergijsku reakciju na koži (H317))	
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)	
Czech Republic - Occupational Exposure Limits		
Local name	Benzoylperoxid (Dibenzoylperoxid)	

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Dibenzoyl peroxide (94-36-0)			
PEL (OEL TWA)	5 mg/m³		
NPK-P (OEL C)	10 mg/m³		
Remark	I - dráždí sliznice (oči, dýchací cesty), respektive kůži, S - látka má senzibilizující účinek (s větou H317, H334).		
OEL chemical category	Sensitizer		
Regulatory reference	Nařízení vlády č. 361/2007 Sb. (Předpis 195/2021 Sb.)		
Denmark - Occupational Exposure Limits			
Local name	Benzoylperoxid (Dibenzoylperoxid)		
OEL TWA [1]	5 mg/m³		
Regulatory reference	BEK nr 1054 af 28/06/2022		
Estonia - Occupational Exposure Limits			
Local name	Bensoüülperoksiid		
OEL TWA	5 mg/m³		
Regulatory reference	Vabariigi Valitsuse 20. märtsi 2001. a määruse nr 105 (RT I, 15.05.2021, 1)		
Finland - Occupational Exposure Limits			
Local name	Bentsoyyliperoksidi		
HTP (OEL TWA) [1]	5 mg/m³		
HTP (OEL STEL)	10 mg/m³		
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveysministeriö)		
France - Occupational Exposure Limits			
Local name	Peroxyde de dibenzoyle		
VME (OEL TWA)	5 mg/m³		
Remark	Valeurs recommandées/admises		
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)		
Germany - Occupational Exposure Limits (TRGS 90	Germany - Occupational Exposure Limits (TRGS 900)		
Local name	Dibenzoylperoxid		
AGW (OEL TWA) [1]	5 mg/m³ (inhalable fraction)		
Peak exposure limitation factor	1(I)		
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission)		
Regulatory reference	TRGS900		
Greece - Occupational Exposure Limits			
Local name	Υπεροξείδιο του βενζοϋλίου		
OEL TWA	5 mg/m³		
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους		
Hungary - Occupational Exposure Limits			
Local name	DIBENZOIL-PEROXID		
AK (OEL TWA)	5 mg/m³		
CK (OEL STEL)	5 mg/m³		

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Dibenzoyl peroxide (94-36-0)	
Remark	b (Bőrön át is felszívódik), i (ingerlő anyag, amely izgatja a bőrt, nyálkahártyát, szemet vagy mindhármat), sz (Túlérzékenységet okozó (szenzibilizáló) tulajdonságú anyag. Az anyagra érzékeny egyéneken "túlérzékenységen" alapuló bőr-, légzőrendszeri, esetleg más szervet/szervrendszert károsító megbetegedést okozhat); N (Irritáló anyagok, egyszerű fojtógázok, csekély egészségkárosító hatással bíró anyagok)
OEL chemical category	Sensitizer, Potential for cutaneous absorption
Regulatory reference	5/2020. (II. 6.) ITM rendelet - A kémiai kóroki tényezők hatásának kitett munkavállalók egészségének és biztonságának védelméről
Ireland - Occupational Exposure Limits	
Local name	Dibenzoyl peroxide [Benzoyl peroxide]
OEL TWA [1]	5 mg/m³
OEL STEL	15 mg/m³ (calculated)
Remark	Sens. (In the workplace respiratory or dermal exposures to sensitising agents may occur. Sensitizers may evoke respiratory or dermal reactions, e.g. asthma, rhinitis and allergic contact dermatitis. The notation does not distinguish between respiratory or dermal sensitisation. Chemical agents that are sensitizers present special problems in the workplace. Should an employee become sensitised, subsequent exposure may cause intense responses, even at low exposure concentrations well below the OELV. Exposure should be eliminated or significantly reduced through control measures such as engineering and process controls and use of personal protective equipment (PPE))
OEL chemical category	Sensitizer
Regulatory reference	Chemical Agents Code of Practice 2021
Poland - Occupational Exposure Limits	
Local name	Nadtlenek dibenzoilowy (benzoilu nadtlenek)
NDS (OEL TWA)	5 mg/m³
NDSCh (OEL STEL)	10 mg/m³
Regulatory reference	Dz. U. 2018 poz. 1286
Portugal - Occupational Exposure Limits	
Local name	Peróxido de benzoílo
OEL TWA	5 mg/m³
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen
Remark	A4 (Agente não classificável como carcinogénico no Homem)
Regulatory reference	Norma Portuguesa NP 1796:2014
Slovakia - Occupational Exposure Limits	
Local name	Dibenzoyldioxidán (dibenzoylperoxid)
NPHV (OEL TWA) [1]	5 mg/m³
Regulatory reference	Nariadenie vlády č. 355/2006 Z. z. (236/2020 Z. z.)
Slovenia - Occupational Exposure Limits	·
Local name	dibenzoilperoksid (benzoilperoksid)
OEL TWA	5 mg/m³ (inhalable fraction)
OEL STEL	5 mg/m³ (inhalable fraction)
Regulatory reference	Uradni list RS, št. 72/2021 z dne 11.5.2021

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Dibenzoyl peroxide (94-36-0)			
Spain - Occupational Exposure Limits			
Local name	Peróxido de benzoilo		
VLA-ED (OEL TWA) [1]	5 mg/m³		
Remark	Sen (Sensibilizante).		
OEL chemical category	Sensitizer		
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT		
Norway - Occupational Exposure Limits			
Local name	Benzoylperoksid (Dibenzoylperoksid)		
Grenseverdi (OEL TWA) [1]	5 mg/m³		
Korttidsverdi (OEL STEL)	10 mg/m³ (value calculated)		
Remark	A: Kjemikalier som skal betraktes som at de fremkaller allergi eller annen overfølsomhet i øynene eller luftveier, eller som skal betraktes som at de fremkaller allergi ved hudkontakt.		
OEL chemical category	Allergenic substance		
Regulatory reference	FOR-2021-06-28-2248		
USA - ACGIH - Occupational Exposure Limits			
Local name	Benzoyl peroxide		
ACGIH OEL TWA	5 mg/m³		
Remark (ACGIH)	TLV [®] Basis: URT & skin irr. Notations: A4 (Not classifiable as a Human Carcinogen)		
ACGIH chemical category	Not Classifiable as a Human Carcinogen		
Regulatory reference	ACGIH 2022		
2,6-Di-tert-butyl-4-methylphenol (128-37-0)	2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Austria - Occupational Exposure Limits			
Local name	2,6-Di-tert-butyl-p-kresol (Butylhydroxytoluol)		
MAK (OEL TWA)	10 mg/m³		
Regulatory reference	BGBI. II Nr. 156/2021		
Belgium - Occupational Exposure Limits			
Local name	2,6-Di-tert-butyl-p-crésol (vapeur et aérosol) # Di-tert-butyl-4-methylfenol (damp en aërosol)		
OEL TWA	2 mg/m³		
Regulatory reference	Koninklijk besluit/Arrêté royal 11/05/2021		
Bulgaria - Occupational Exposure Limits			
Local name	Дибутилпаракрезол		
OEL TWA	10 mg/m³		
OEL STEL	50 mg/m³		
Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа (изм. и доп. ДВ. бр. 47 от 2021 г., в сила от 04.06.2021 г.)		
Croatia - Occupational Exposure Limits			
Local name	2,6-Di-tert-butil-p-krezol		
GVI (OEL TWA) [1]	10 mg/m³		

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Regulatory reference	Pravilnik o zaštiti radnika od izloženosti opasnim kemikalijama na radu, graničnim vrijednostima izloženosti i biološkim graničnim vrijednostima (NN 1/2021)	
Denmark - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-cresol (Butylhydroxytoluen)	
OEL TWA [1]	10 mg/m³	
Regulatory reference	BEK nr 1054 af 28/06/2022	
Finland - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyyli-p-kresoli	
HTP (OEL TWA) [1]	10 mg/m³	
HTP (OEL STEL)	20 mg/m³	
Regulatory reference	HTP-ARVOT 2020 (Sosiaali- ja terveysministeriö)	
France - Occupational Exposure Limits		
Local name	2,6-Di-tert-butyl-p-crésol	
VME (OEL TWA)	10 mg/m³	
Remark	Valeurs recommandées/admises	
Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)	
Germany - Occupational Exposure Limits (TRGS 90	00)	
Local name	2,6-Di-tert-butyl-p-kresol	
AGW (OEL TWA) [1]	10 mg/m³ (E)	
Peak exposure limitation factor	4(II)	
Remark	DFG - Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission); Y - Ein Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes (BGW) nicht befürchtet zu werden; 11 - Summe aus Dampf und Aerosolen	
Regulatory reference	TRGS900	
Greece - Occupational Exposure Limits		
Local name	Βουτυλο-υσροξυ-τολουόλιο	
OEL TWA	10 mg/m³	
Regulatory reference	Π.Δ. 90/1999 - Προστασία της υγείας των εργαζομένων που εκτίθενται σε ορισμένους χημικούς παράγοντες κατά τη διάρκεια της εργασίας τους	
Ireland - Occupational Exposure Limits		
Local name	2,6-Ditertiary-butyl-para-cresol [Butylated hydroxytoluene (BHT)]	
OEL TWA [1]	2 mg/m³	
Regulatory reference	Chemical Agents Code of Practice 2021	
Netherlands - Occupational Exposure Limits		
TGG-8u (OEL TWA)	10 mg/m³	
Portugal - Occupational Exposure Limits		
Local name	Hidroxitoluenobutilado (2,6-Di-terc-butil-p-cresol) (BHT)	
OEL TWA	2 mg/m³ FIV (Fração inalável e vapor)	
OEL chemical category	A4 - Not Classifiable as a Human Carcinogen	
Remark	A4 (Agente não classificável como carcinogénico no Homem)	

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2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Regulatory reference	Norma Portuguesa NP 1796:2014	
Slovenia - Occupational Exposure Limits		
Local name	2,6-di-terc-butil-p-krezol	
OEL TWA	10 mg/m³	
OEL STEL	40 mg/m³	
Remark	Y (Snovi, pri katerih ni nevarnosti za zarodek ob upoštevanju mejnih vrednosti in bat vrednosti)	
Regulatory reference	Uradni list RS, št. 72/2021 z dne 11.5.2021	
Spain - Occupational Exposure Limits		
Local name	2,6-Diterc-butil-p-cresol	
VLA-ED (OEL TWA) [1]	10 mg/m³	
Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2022. INSHT	
USA - ACGIH - Occupational Exposure Limits		
Local name	Butylated hydroxytoluene	
ACGIH OEL TWA	2 mg/m³ (IFV - Inhalable fraction and vapor)	
Remark (ACGIH)	TLV [®] Basis: URT irr. Notations: A4 (Not classifiable as a Human Carcinogen)	
ACGIH chemical category	Not Classifiable as a Human Carcinogen	
Regulatory reference	ACGIH 2022	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure adequate ventilation. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses. EN 166

8.2.2.2. Skin protection

Hand protection:

Impermeable protective gloves. EN 374. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer

Other skin protection

Materials for protective clothing:

Long sleeved protective clothing

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8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection. An approved organic vapour respirator/supplied air or self-contained breathing apparatus must be used when vapour concentration exceeds applicable exposure limits

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Off-white. Colour Appearance Paste. Odour · Odourless Odour threshold Not available Melting point : Not available Freezing point : Not available Boiling point : Not available Flammability : Non flammable. **Explosive limits** : Not available Lower explosion limit : Not available Upper explosion limit : Not available Flash point : Not available Auto-ignition temperature : Not available Decomposition temperature : Not available рΗ : Not available : Not available Viscosity, kinematic : Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) Vapour pressure Not available Vapour pressure at 50°C : Not available Density : Not available Relative density : Not available Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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

The product is stable at normal handling and storage conditions.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong bases. Strong oxidizing agents. chemically active metals. Amines.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition may produce : Carbon oxides (CO, CO2).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in R	egulation (EC) No 1272/2008
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Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

7710 mg/kg

LD50 oral rat
Triethylene glycol dimethacrylate (109-16-0)

Dibenzoyl peroxide (94-36-0)

LD50 oral rat 10837 mg/kg

2.6-Di-tert-butyl-4-methylphenol (128-37-0)

2,6-Di-tert-butyi-4-methylphenoi (126-37-0)	
LD50 oral rat	> 2930 mg/kg
LD50 oral	650 mg/kg (mouse)
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 2 mg/l Source: OSHRI GLP toxicity test

 Skin corrosion/irritation
 : Causes skin irritation.

 Serious eye damage/irritation
 : Causes serious eye irritation.

 Respiratory or skin sensitisation
 : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)

Dibenzoyl peroxide (94-36-0)

STOT-single exposure

IARC group 3 - Not classifiable

2,6-Di-tert-butyl-4-methylphenol (128-37-0)

IARC group 3 - Not classifiable

2,6-Di-tert-butyl-4-methylphenol (128-37-0)

NOAEL (chronic, oral, animal/male, 2 years) 25 mg/kg bodyweight Animal: rat, Animal sex: male, Remarks on results: other:

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure : May cause respiratory irritation.

Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)

STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

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May cause respiratory irritation.

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Triethylene glycol dimethacrylate (109-16	i-0)
LOAEC (inhalation, rat, gas, 90 days)	350 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:
NOAEL (oral, rat, 90 days)	1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEC (inhalation, rat, gas, 90 days)	100 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Remarks on results: other:

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine

disrupting properties

: None known

11.2.2. Other information

Other information : Likely routes of exposure: ingestion, inhalation, skin and eye

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects. Ecology - water Harmful to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term

Hazardous to the aquatic environment, long-term

: Harmful to aquatic life with long lasting effects.

: Not classified (Based on available data, the classification criteria are not met)

(chronic)

Dibenzoyl peroxide (94-36-0) LC50 - Fish [1] 0.0602 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [semi-static]) Triethylene glycol dimethacrylate (109-16-0) LC50 - Fish [1] 16.4 mg/l (Exposure time: 96 h - Species: Danio rerio [semi-static]) EC50 72h - Algae [1] > 100 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) EC50 72h - Algae [2] 72.8 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) LOEC (chronic) 100 mg/l Test organisms (species): Daphnia magna Duration: '21 d' NOEC (chronic) 32 mg/l Test organisms (species): Daphnia magna Duration: '21 d' 2,6-Di-tert-butyl-4-methylphenol (128-37-0) LC50 - Fish [1] > 0.57 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio) EC50 - Crustacea [1] 0.48 mg/l Test organisms (species): Daphnia magna 6 mg/l (Species: Pseudokirchneriella subcapitata) EC50 72h - Algae [1] EC50 72h - Algae [2] > 0.42 mg/l (Species: Desmodesmus subspicatus) LOEC (chronic) 1 mg/l Test organisms (species): Daphnia magna Duration: '21 d' NOEC (chronic) 0.023 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

No additional information available

NOEC chronic fish

0.053 mg/l

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12.3. Bioaccumulative potential

Dibenzoyl peroxide (94-36-0)		
Partition coefficient n-octanol/water (Log Pow)	3.2 (at 22 °C (at pH 7.02)	
Triethylene glycol dimethacrylate (109-16-0)		
Partition coefficient n-octanol/water (Log Pow)	1.88 Source: ChemIDplus	
Poly(oxy-1,2-ethanediyl), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega[(2-methyl-1-oxo-2-propenyl)oxy]- (41637-38-1)		
Partition coefficient n-octanol/water (Log Pow)	3.43 – 5.62 (at pH 6.44)	
2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
BCF - Fish [1]	230 – 2500	

5.1

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Partition coefficient n-octanol/water (Log Pow)

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations

: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials

: Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

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ADR	IMDG	MDG IATA ADN		RID
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

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

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

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 (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (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 (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)

15.1.2. National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).

WGK remark : Most stringent classification due to insufficient data.

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

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Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people under 18 years are not allowed to use the product

: None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
1.2	Relevant identified uses	Modified	
2	Hazard identification	Modified	
3	Composition/information on ingredients	Modified	
4	First aid measures	Modified	
5	Firefighting measures	Modified	
6	Accidental release measures	Modified	
7	Handling and storage	Modified	
8	Exposure controls / Personal protection equipment	Modified	
9	Physical and chemical properties	Modified	
10	Stability and reactivity	Modified	
11	Toxicological information	Modified	
12.	Ecological information	Modified	
13	Disposal considerations	Modified	
15	Regulatory information	Modified	

Other information : None.

Full text of H- and EUH-statements:	
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H241	Heating may cause a fire or explosion.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.