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

1.1. Product identifier

Product form : Mixture
Trade name : Hyperfil
Product code : S323, S326, S231, S233

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Dual-Cure Resin Composite Restorative

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

Authorized Representative in Europe (Regulatory affairs only)
Directa AB
P.O. Box 723, Finvids väg 8
SE-194 27 Upplands Väsby
Sweden

1.4. Emergency telephone number

Emergency number : INFOTRAC 1-352-323-3500 (International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1	H317
Reproductive toxicity, Category 2	H361
Hazardous to the aquatic environment - Chronic Hazard, Category 3	H412

Full text of H 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) :

GHS07 GHS08

Signal word (CLP) : Warning

Hazardous ingredients : Dibenzoyl peroxide; Triethylene glycol dimethacrylate; Trimethylolpropane triacrylate; 11,14-Dioxa-2,9-diazaheptadec-16-enoic acid, 4,6,6,16-tetramethyl-10,15-dioxo-, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester; Bicyclo[2.2.1]heptane-2,3-dione, 1,7,7-trimethyl-, (.+-.)-; Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide; 2-Hydroxyethyl methacrylate

Hazard statements (CLP) : H317 - May cause an allergic skin reaction
H361 - Suspected of damaging fertility or the unborn child
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing vapours

P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves, protective clothing, eye protection

2.3. Other hazards not contributing to the classification

No additional information available

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]
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	11 - 19,5	Aquatic Chronic 4, H413
Triethylene glycol dimethacrylate	(CAS-No.) 109-16-0 (EC-No.) 203-652-6 (REACH-no) not available	5,5 - 12,5	Skin Sens. 1B, H317
Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide	(CAS-No.) 75980-60-8 (EC-No.) 278-355-8 (EC Index-No.) 015-203-00-X	3,5 - 7	Skin Sens. 1B, H317 Repr. 2, H361f Aquatic Chronic 2, H411
11,14-Dioxa-2,9-diazaheptadec-16-enoic acid, 4,6,6,16-tetramethyl-10,15-dioxo-, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester	(CAS-No.) 74389-53-0	3,5 - 6,5	Skin Sens. 1, H317
Trimethylolpropane triacrylate	(CAS-No.) 15625-89-5 (EC-No.) 239-701-3 (EC Index-No.) 607-111-00-9	1,5 - 3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
Ethanol, 2,2'-[(4-methylphenyl)imino]bis-	(CAS-No.) 3077-12-1 (EC-No.) 221-359-1	0,25 - 2	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
2-Hydroxyethyl methacrylate	(CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X	0,35 - 1	Skin Irrit. 2, H315 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 (REACH-no) Not available	0,005 - 0,5	Aquatic Chronic 1, H410
Dibenzoyl peroxide	(CAS-No.) 94-36-0 (EC-No.) 202-327-6 (EC Index-No.) 617-008-00-0	0,05 - 0,5	Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317
Bicyclo[2.2.1]heptane-2,3-dione, 1,7,7-trimethyl-, (.+-.)-	(CAS-No.) 10373-78-1 (EC-No.) 233-814-1	0,005 - 0,15	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335

Full text of H-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.

First-aid measures after inhalation : Allow victim to breathe fresh air.

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. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

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 : Suspected of damaging fertility or the unborn child.

Symptoms/effects after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

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

Symptoms/effects after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

Symptoms/effects after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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 : Minimal fire hazard. On combustion, forms: carbon oxides (CO and CO2).

Explosion hazard : Product is not explosive.

Reactivity in case of fire : None known.

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.

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

6.1.1. For non-emergency personnel

Emergency procedures : Do not breathe vapour.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Mechanically recover the product.

6.4. Reference to other sections

See Heading 8. Exposure controls and 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 : Provide good ventilation. Avoid breathing vapours. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Incompatible materials. Keep container closed when not in use.

Incompatible materials : Reducing agents. Oxidizing agent. Peroxides. Free radical initiators.

7.3. Specific end use(s)

Refer to Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Austria	MAK (mg/m³)	10 mg/m³
Belgium	Limit value (mg/m³)	10 mg/m³
Bulgaria	OEL TWA (mg/m³)	10 mg/m³
Bulgaria	OEL STEL (mg/m³)	50 mg/m³
Croatia	GVI (granična vrijednost izloženosti) (mg/m³)	10 mg/m³
Denmark	Grænseværdie (langvarig) (mg/m³)	10 mg/m³
Finland	HTP-arvo (8h) (mg/m³)	10 mg/m³

2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Finland	HTP-arvo (15 min)	20 mg/m³
France	Local name	2,6-Di-tert-butyl-p-crésol
France	VME (mg/m³)	10 mg/m³
France	Note (FR)	Valeurs recommandées/admises
Greece	OEL TWA (mg/m³)	10 mg/m³
Ireland	OEL (8 hours ref) (mg/m³)	10 mg/m³
Netherlands	Grenswaarde TGG 8H (mg/m³)	10 mg/m³
Portugal	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction, aerosol and vapor)
Slovenia	OEL TWA (mg/m³)	10 mg/m³ (inhalable fraction)
United Kingdom	Local name	2,6-Di-tert-butyl-p-cresol
United Kingdom	WEL TWA (mg/m³)	10 mg/m³
United Kingdom	WEL STEL (mg/m³)	30 mg/m³ (calculated)
Switzerland	MAK (mg/m³)	10 mg/m³ (inhalable dust)
Dibenzoyl peroxide (94-36-0)		
Austria	MAK (mg/m³)	5 mg/m³ (inhalable fraction)
Austria	MAK Short time value (mg/m³)	10 mg/m³ (inhalable fraction)
Belgium	Limit value (mg/m³)	5 mg/m³
Croatia	GVI (granična vrijednost izloženosti) (mg/m³)	5 mg/m³
Czech Republic	Expoziční limity (PEL) (mg/m³)	5 mg/m³
Denmark	Grænseværdie (langvarig) (mg/m³)	5 mg/m³
Estonia	OEL TWA (mg/m³)	5 mg/m³
Finland	HTP-arvo (8h) (mg/m³)	5 mg/m³
Finland	HTP-arvo (15 min)	10 mg/m³
France	VME (mg/m³)	5 mg/m³
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	5 mg/m³ (inhalable fraction)
Greece	OEL TWA (mg/m³)	5 mg/m³
Hungary	AK-érték	5 mg/m³
Hungary	CK-érték	5 mg/m³
Ireland	OEL (8 hours ref) (mg/m³)	5 mg/m³
Ireland	OEL (15 min ref) (mg/m3)	15 mg/m³ (calculated)
Poland	NDS (mg/m³)	5 mg/m³
Poland	NDSCh (mg/m³)	10 mg/m³
Portugal	OEL TWA (mg/m³)	5 mg/m³
Slovakia	NPHV (priemerná) (mg/m³)	5 mg/m³
Slovakia	NPHV (Hraničná) (mg/m³)	5 mg/m³
Slovenia	OEL TWA (mg/m³)	5 mg/m³ (inhalable fraction)
Slovenia	OEL STEL (mg/m³)	5 mg/m³ (inhalable fraction)
Spain	VLA-ED (mg/m³)	5 mg/m³
United Kingdom	WEL TWA (mg/m³)	5 mg/m³
United Kingdom	WEL STEL (mg/m³)	15 mg/m³ (calculated)
Norway	Grenseverdier (AN) (mg/m³)	5 mg/m³
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	10 mg/m³ (value calculated)
Switzerland	MAK (mg/m³)	5 mg/m³ (inhalable dust)
Switzerland	KZGW (mg/m³)	5 mg/m³ (inhalable dust)
Australia	TWA (mg/m³)	5 mg/m³
2-Hydroxyethyl methacrylate (868-77-9)		
Lithuania	IPRV (mg/m³)	20 mg/m³
Norway	Grenseverdier (AN) (mg/m³)	11 mg/m³
Norway	Grenseverdier (AN) (ppm)	2 ppm
Norway	Grenseverdier (Korttidsverdi) (mg/m3)	16,5 mg/m³ (value calculated)
Norway	Grenseverdier (Korttidsverdi) (ppm)	4 ppm (value calculated)

8.2. Exposure controls

Appropriate engineering controls:

Provide adequate ventilation.

Hand protection:

Impermeable protective gloves. (to European standard EN 374 or equivalent)

Eye protection:

Chemical goggles or safety glasses. (to European standard EN 166 or equivalent)

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended.

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	:	Solid
Appearance	:	Paste
Colour	:	Off-white, tooth shade
Odour	:	Odourless.
Odour threshold	:	No data available
pH	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
Freezing point	:	No data available
Boiling point	:	No data available
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Flammability (solid, gas)	:	Non flammable.
Vapour pressure	:	No data available
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Log Pow	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	No data available
Oxidising properties	:	No data available
Explosive limits	:	No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Incompatible materials. Keep away from heat.

10.5. Incompatible materials

Reducing agents. Oxidizing agent. Peroxides. Free radical initiators.

10.6. Hazardous decomposition products

On combustion, forms: carbon oxides (CO and CO2).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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)

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
LD50 oral	650 mg/kg (mouse)
LD50 dermal rat	> 2000 mg/kg

Dibenzoyl peroxide (94-36-0)	
LD50 oral rat	7710 mg/kg

Triethylene glycol dimethacrylate (109-16-0)	
LD50 oral rat	10837 mg/kg

Trimethylolpropane triacrylate (15625-89-5)	
LD50 oral	4200 mg/kg
LD50 dermal rabbit	5000 mg/kg
LD50 dermal	4280 mg/kg

2-Hydroxyethyl methacrylate (868-77-9)	
LD50 oral rat	5050 mg/kg
LD50 dermal rabbit	> 3000 mg/kg

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
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)
Reproductive toxicity : Suspected of damaging fertility or the unborn child.
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : Harmful to aquatic life with long lasting effects.
Acute aquatic toxicity : Not classified
Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
EC50 72h algae (1)	6 mg/l (Species: Pseudokirchneriella subcapitata)
EC50 72h algae (2)	> 0,42 mg/l (Species: Desmodesmus subspicatus)

2-Hydroxyethyl methacrylate (868-77-9)	
LC50 fish 1	213 - 242 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
LC50 fish 2	227 mg/l (Exposure time: 96 h - Species: Pimephales promelas)

12.2. Persistence and degradability

Hyperfil	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Hyperfil	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container to comply with applicable local, national and international regulation.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN 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
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. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide is listed

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

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	:	None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	:	Diphenyl-2,4,6-trimethylbenzoyl phosphine oxide is listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	:	None of the components are listed

Denmark

Recommendations Danish Regulation	:	Young people below the age of 18 years are not allowed to use the product Pregnant/breastfeeding women working with the product must not be in direct contact with the product The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Sources of Key Data: According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
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 Irrit. 2	Serious eye damage/eye irritation, Category 2
Org. Perox. B	Organic Peroxides, Type B
Repr. 2	Reproductive toxicity, Category 2
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
H241	Heating may cause a fire or explosion
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child
H361f	Suspected of damaging fertility
H410	Very toxic to aquatic life with long lasting effects
H411	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

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Sens. 1	H317	Calculation method
Repr. 2	H361	Calculation method
Aquatic Chronic 3	H412	Calculation method

SDS EU (REACH Annex II)

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