

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form : Mixture
Trade name : Mucohard
Product code : S484, S486

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 : Hard denture relines

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

Causes skin irritation. Causes serious 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

Hazardous ingredients :

Dibenzoyl peroxide; 2-Propenoic acid, 2-methyl-, 1,12-dodecanediyl ester; 2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl ester

Hazard statements (CLP) :

H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Precautionary statements (CLP)	: H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H412 - Harmful to aquatic life with long lasting effects. P261 - Avoid breathing mist, spray, vapours. P264 - Wash hands thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. 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]
1,12-dodecanediyl bismethacrylate	(CAS-No.) 72829-09-5 (EC-No.) 276-900-4	20 - 40	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
2-Propenoic acid, 2-methyl-, 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl ester	(CAS-No.) 72869-86-4 (EC-No.) 276-957-5	15 - 25	Skin Sens. 1, H317
Poly(oxy-1,2-ethanediy), .alpha.,.alpha.'-[(1-methylethylidene)di-4,1-phenylene]bis[.omega.-[(2-methyl-1-oxo-2-propenyl)oxy]-	(CAS-No.) 41637-38-1	10 - 20	Aquatic Chronic 4, H413
Dibenzoyl peroxide	(CAS-No.) 94-36-0 (EC-No.) 202-327-6 (EC Index-No.) 617-008-00-0	< 3	Org. Perox. B, H241 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	< 3	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
Benzenamine, N,N,4-trimethyl-	(CAS-No.) 99-97-8 (EC-No.) 202-805-4 (EC Index-No.) 612-056-00-9	< 3	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 STOT RE 2, H373 Aquatic Chronic 3, H412
2,6-Di-tert-butyl-4-methylphenol	(CAS-No.) 128-37-0 (EC-No.) 204-881-4 (REACH-no) Not available	< 1	Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
First-aid measures after skin contact	: Rinse immediately with plenty of water for 15 minutes. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.
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. If eye irritation persists: Get medical advice/attention.
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.
Symptoms/effects after ingestion	: May cause irritation to the digestive tract.

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.
------------------------------	-------------------------------------------------------------

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Unsuitable extinguishing media : None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not classified as flammable but will burn. Hazardous decomposition products. Carbon oxides.
Explosion hazard : Product is not explosive.
Reactivity in case of fire : Stable under normal conditions.

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

General measures : Avoid contact with skin, eyes and clothing. Do not breathe mist, spray, vapours.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel. Wearing protective equipment as required

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection. Refer to Section 8 for PPE requirements.
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. Avoid contact with eyes, skin and clothing. Dispose of contents/container to comply with applicable local, national and international regulation.

6.4. Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide good ventilation in process area. Avoid breathing mist, spray, vapours. Use only outdoors or in a well-ventilated area.
Hygiene measures : Wash hands thoroughly after handling. 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 tightly closed. Keep out of reach of children.
Incompatible materials : Oxidizing agent. Reducing agents. 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/m ³)	10 mg/m ³
Belgium	Limit value (mg/m ³)	10 mg/m ³
Bulgaria	OEL TWA (mg/m ³)	10 mg/m ³
Bulgaria	OEL STEL (mg/m ³)	50 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	10 mg/m ³
Denmark	Grænseværdie (langvarig) (mg/m ³)	10 mg/m ³
Finland	HTP-arvo (8h) (mg/m ³)	10 mg/m ³
Finland	HTP-arvo (15 min)	20 mg/m ³
France	Local name	2,6-Di-tert-butyl-p-crésol
France	VME (mg/m ³)	10 mg/m ³
France	Note (FR)	Valeurs recommandées/admises
Greece	OEL TWA (mg/m ³)	10 mg/m ³
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

2,6-Di-tert-butyl-4-methylphenol (128-37-0)		
Netherlands	Grenswaarde TGG 8H (mg/m ³)	10 mg/m ³
Portugal	OEL TWA (mg/m ³)	2 mg/m ³ (inhalable fraction, aerosol and vapor)
Slovenia	OEL TWA (mg/m ³)	10 mg/m ³ (inhalable fraction)
United Kingdom	Local name	2,6-Di-tert-butyl-p-cresol
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	30 mg/m ³ (calculated)
Switzerland	MAK (mg/m ³)	10 mg/m ³ (inhalable dust)
Dibenzoyl peroxide (94-36-0)		
Austria	MAK (mg/m ³)	5 mg/m ³ (inhalable fraction)
Austria	MAK Short time value (mg/m ³)	10 mg/m ³ (inhalable fraction)
Belgium	Limit value (mg/m ³)	5 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	5 mg/m ³
Czech Republic	Expoziční limity (PEL) (mg/m ³)	5 mg/m ³
Denmark	Grænseværdie (langvarig) (mg/m ³)	5 mg/m ³
Estonia	OEL TWA (mg/m ³)	5 mg/m ³
Finland	HTP-arvo (8h) (mg/m ³)	5 mg/m ³
Finland	HTP-arvo (15 min)	10 mg/m ³
France	VME (mg/m ³)	5 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	5 mg/m ³ (inhalable fraction)
Greece	OEL TWA (mg/m ³)	5 mg/m ³
Hungary	AK-érték	5 mg/m ³
Hungary	CK-érték	5 mg/m ³
Ireland	OEL (8 hours ref) (mg/m ³)	5 mg/m ³
Ireland	OEL (15 min ref) (mg/m ³)	15 mg/m ³ (calculated)
Poland	NDS (mg/m ³)	5 mg/m ³
Poland	NDSch (mg/m ³)	10 mg/m ³
Portugal	OEL TWA (mg/m ³)	5 mg/m ³
Slovakia	NPHV (priemerná) (mg/m ³)	5 mg/m ³
Slovakia	NPHV (Hraničná) (mg/m ³)	5 mg/m ³
Slovenia	OEL TWA (mg/m ³)	5 mg/m ³ (inhalable fraction)
Slovenia	OEL STEL (mg/m ³)	5 mg/m ³ (inhalable fraction)
Spain	VLA-ED (mg/m ³)	5 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	5 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	15 mg/m ³ (calculated)
Norway	Grenseverdier (AN) (mg/m ³)	5 mg/m ³
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	10 mg/m ³ (value calculated)
Switzerland	MAK (mg/m ³)	5 mg/m ³ (inhalable dust)
Switzerland	KZGW (mg/m ³)	5 mg/m ³ (inhalable dust)
Australia	TWA (mg/m ³)	5 mg/m ³
Benzenamine, N,N,4-trimethyl- (99-97-8)		
Czech Republic	Expoziční limity (PEL) (mg/m ³)	5 mg/m ³

8.2. Exposure controls

Appropriate engineering controls:

Provide adequate ventilation. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Hand protection:

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

Eye protection:

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

Skin and body protection:

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Wear suitable protective clothing

Respiratory protection:

Wear appropriate mask

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	: Pink
Odour	: Mild fruity odour
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

Extremely high or low temperatures. Keep out of reach of children. Protect from sunlight. Incompatible materials.

10.5. Incompatible materials

Oxidising agents. Reducing agents. Peroxides. Free radical initiators.

10.6. Hazardous decomposition products

On combustion forms : Carbon oxides.

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)

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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
Benzenamine, N,N,4-trimethyl- (99-97-8)	
LD50 oral rat	1650 mg/kg
LD50 dermal rabbit	> 2000 mg/kg
LC50 inhalation rat (mg/l)	1400 mg/m ³ (Exposure time: 4 h)
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)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: May cause respiratory irritation.
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

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)
Benzenamine, N,N,4-trimethyl- (99-97-8)	
LC50 fish 1	42 - 50.5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])

12.2. Persistence and degradability

Mucohard	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Mucohard	
Bioaccumulative potential	Not established.

2,6-Di-tert-butyl-4-methylphenol (128-37-0)	
BCF fish 1	230 - 2500
Log Pow	0.62

Benzenamine, N,N,4-trimethyl- (99-97-8)	
Log Pow	2.81

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.

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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 : None of the components are 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 : None of the components are 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

Mucohard

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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. Supplier's Safety Data Sheet.

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
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
Org. Perox. B	Organic Peroxides, Type B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H241	Heating may cause a fire or explosion.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
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.

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

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