

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

1.1. Product identifier

Product form : Mixture
Product name : PROSEAL

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For RX only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave.
Itasca, IL 60143 USA
630-773-4009, during normal business hours
www.relianceorthodontics.com

EC Representative:

Emergo Europe, Prinsessgracht 20
2514 AP The Hague, The Netherlands

Australian Sponsor: Emergo Australia, 201 Sussex St.

Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia

1.4. Emergency telephone number

Emergency number : CHEMTREC - 24-Hour Hazmat Emergency Communications Center
Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

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 1 H318
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 2 H411
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. Toxic 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) : Danger

Hazardous ingredients : Hexafunctional Urethane Acrylate Oligomer; Polyethylene Glycol (600) Diacrylate; Trifunctional Acid Ester

Hazard statements (CLP) : H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage.

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Precautionary statements (CLP)	<p>H335 - May cause respiratory irritation H411 - Toxic to aquatic life with long lasting effects</p> <p>: P261 - Avoid breathing 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, eye protection, face protection P302+P352 - IF ON SKIN: Wash with plenty of soap and water P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a POISON CENTER, a doctor P312 - Call a POISON CENTER, a doctor if you feel unwell. P321 - Specific treatment (see First aid measures on this label) P332+P313 - If skin irritation occurs: Get medical advice/attention P333+P313 - If skin irritation or rash occurs: Get medical advice/attention P362+P364 - Take off contaminated clothing and wash it before reuse P391 - Collect spillage P403+P233 - Store in a well-ventilated place. Keep container tightly closed P405 - Store locked up P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste, a hazardous or special waste collection point.</p>
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2.3. Other hazards

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]
Ethoxylated 3 Bisphenol A Diacrylate	(CAS-No.) 64401-02-1	10 - 30	Aquatic Chronic 2, H411
Hexafunctional Urethane Acrylate Oligomer	(CAS-No.) Proprietary	10 - 30	Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 2, H411
Polyethylene Glycol (600) Diacrylate	(CAS-No.) 26570-48-9	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide	(CAS-No.) 75980-60-8 (EC-No.) 278-355-8	5 - 10	Aquatic Chronic 2, H411
Trifunctional Acid Ester	(CAS-No.) Proprietary	1 - 5	Eye Dam. 1, H318 Skin Sens. 1, H317

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Call a poison center or a doctor 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	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Serious damage to eyes.

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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 : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid breathing mist, vapours. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Use only outdoors or in a well-ventilated area. Avoid breathing mist, vapours. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place. Keep container tightly closed. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

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Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear, colorless liquid.
Colour	: Colorless
Odour	: Acrylic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
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)	: Not applicable
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

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

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

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Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
LD50 oral rat	N/A
LD50 dermal rat	N/A
LD50 dermal rabbit	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)	
LD50 oral rat	N/A
LD50 dermal rat	N/A
LD50 dermal rabbit	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Polyethylene Glycol (600) Diacrylate (26570-48-9)	
LD50 oral rat	> 5000 mg/kg (Rat)

Trifunctional Acid Ester (Proprietary)	
LD50 oral rat	N/A
LD50 dermal rat	N/A
LC50 inhalation rat (ppm)	N/A
LC50 inhalation rat (Dust/Mist - mg/l/4h)	N/A mg/l/4h
LC50 inhalation rat (Vapours - mg/l/4h)	N/A mg/l/4h

Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
LD50 oral rat	> 2000 mg/kg (Rat; Literature)

Skin corrosion/irritation : Causes skin irritation.
 Serious eye damage/irritation : Causes serious eye damage.
 Respiratory or skin sensitisation : May cause an allergic skin reaction.
 Germ cell mutagenicity : Not classified
 Carcinogenicity : Not classified
 Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
LOAEL (oral, rat)	N/A mg/kg bodyweight
LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)	
LOAEL (oral, rat)	N/A mg/kg bodyweight
LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

Trifunctional Acid Ester (Proprietary)	
LOAEL (oral, rat)	N/A mg/kg bodyweight
LOAEL (dermal, rat/rabbit)	N/A mg/kg bodyweight
LOAEC (inhalation, rat, gas)	N/A ppmv/4h
LOAEC (inhalation, rat, vapour)	N/A mg/l/4h
LOAEC (inhalation, rat, dust/mist/fume)	N/A mg/l/4h

STOT-repeated exposure : Not classified

Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day

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Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
LOAEC (inhalation, rat,dust/mist/fume, 90 days)	N/A mg/l/6h/day
Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)	
LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day
LOAEC (inhalation, rat,dust/mist/fume, 90 days)	N/A mg/l/6h/day
Trifunctional Acid Ester (Proprietary)	
LOAEL (oral, rat, 90 days)	N/A mg/kg bodyweight/day
LOAEL (dermal, rat/rabbit, 90 days)	N/A mg/kg bodyweight/day
LOAEC (inhalation, rat, gas, 90 days)	N/A ppmv/6h/day
LOAEC (inhalation, rat, vapour, 90 days)	N/A mg/l/6h/day
LOAEC (inhalation, rat,dust/mist/fume, 90 days)	N/A mg/l/6h/day

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

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

Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
LC50 fish 1	1 - 10 mg/l (LC50; OECD 203: Fish, Acute Toxicity Test; 48 h; Oryzias latipes)
EC50 Daphnia 1	10 - 100 mg/l (EC50; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna)
Threshold limit algae 1	> mg/l >10/100,EC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Algae

12.2. Persistence and degradability

Polyethylene Glycol (600) Diacrylate (26570-48-9)	
Persistence and degradability	Biodegradability in water: no data available.
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
Persistence and degradability	Not readily biodegradable in water. No (test)data on mobility of the substance available.

12.3. Bioaccumulative potential

Polyethylene Glycol (600) Diacrylate (26570-48-9)	
Bioaccumulative potential	No bioaccumulation data available.
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
BCF fish 1	< 40 (BCF; OECD 305: Bioconcentration: Flow-Through Fish Test; Cyprinidae sp.)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

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

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

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SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable
:



IMDG

Transport hazard class(es) (IMDG) : Not applicable
:



IATA

Transport hazard class(es) (IATA) : Not applicable
:



ADN

Transport hazard class(es) (ADN) : Not applicable
:



RID

Transport hazard class(es) (RID) : Not applicable
:



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14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment	: Yes
Marine pollutant	: Yes
Other information	: No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

No data available

- Rail transport

No data available

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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Full text of H- and EUH-statements:

Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
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
H411	Toxic to aquatic life with long lasting effects

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.