

## Safety Data Sheet

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

2015/830

Date of issue: 1/17/2018 Version: 2

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

## 1.1. Product identifier

Product form : Mixture
Product name : LED 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 <a href="https://www.relianceorthodontics.com">www.relianceorthodontics.com</a>

#### **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 H318
1

Skin sensitisation, Category 1 H317
Hazardous to the aquatic environment — H411

Chronic Hazard, Category 2

Full text of H statements : see section 16

# Adverse physicochemical, human health and environmental effects

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) :







GHS05 GHS07

GHS09

Signal word (CLP) : Danger

Hazardous ingredients : Hexafunctional Urethane Acrylate Oligomer; Ethoxylated (9 EO) Trimethylolpropane

Triacrylate; Hydroquinone

Hazard statements (CLP) : H315 - Causes skin irritation

H317 - May cause an allergic skin reaction H318 - Causes serious eye damage.

H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP) : P261 - Avoid breathing vapours

P264 - Wash hands thoroughly after handling

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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

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

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

P501 - Dispose of contents and container to a hazardous or special waste collection point, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste, hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 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]
Hexafunctional Urethane Acrylate Oligomer	(CAS-No.) Proprietary	30 - 50	Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 2, H411
Ethoxylated (9 EO) Trimethylolpropane Triacrylate	(CAS-No.) 28961-43-5	30 - 50	Eye Irrit. 2, H319 Skin Sens. 1, H317
Ethoxylated 3 Bisphenol A Diacrylate	(CAS-No.) 64401-02-1	10 - 30	Aquatic Chronic 2, H411
Camphorquinone	(CAS-No.) 10373-78-1 (EC-No.) 233-814-1	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Hydroquinone	(CAS-No.) 123-31-9 (EC-No.) 204-617-8 (EC Index-No.) 604-005-00-4	<1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Skin Sens. 1, H317 Muta. 2, H341 Carc. 2, H351 Aquatic Acute 1, H400

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.

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 skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Serious damage to eyes.

## 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.

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#### 5.2. Special hazards arising from the substance or mixture

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

fire

#### 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 contact with skin and eyes. Avoid breathing mist, vapours.

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 : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal

protective equipment. Avoid breathing mist, vapours.

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 in a well-ventilated place. Keep cool.

# 7.3. Specific end use(s)

No additional information available

# **SECTION 8: Exposure controls/personal protection**

# 8.1. Control parameters

Hydroquinone (123-31-9)		
Belgium	Limit value (mg/m³)	1 mg/m³ (Hydroquinone; Belgium; Time-weighted average exposure limit 8 h)
France	VME (mg/m³)	2 mg/m³ (Hydroquinone; France; Time-weighted average exposure limit 8 h; VL: Valeur non réglementaire indicative)
United Kingdom	WEL TWA (mg/m³)	0.5 mg/m³ Hydroquinone; United Kingdom; Time- weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005); Hydroquinone; 0.5 mg/m³; United Kingdom; Time-weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005)
USA - ACGIH	ACGIH TWA (mg/m³)	1 mg/m³ (Hydroquinone; USA; Time-weighted average exposure limit 8 h; TLV - Adopted Value)

## 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Eye protection:

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Safety glasses

#### Skin and body protection:

Wear suitable protective clothing

## 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: LiquidAppearance: Yellow liquid.Colour: Yellow.Odour: Acrylic.

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 : > °C

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 : > 1
Relative density of saturated gas/air mixture : >

Solubility : Insoluble in water.

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.

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# **SECTION 11: Toxicological information**

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

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

Ethoxylated (9 EO) Trimethylolpropane Triacrylate (28961-43-5)	
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

# Hydroquinone (123-31-9)

LD50 dermal rabbit > 2000 mg/kg bodyweight (Rabbit; Experimental value; OECD 402: Acute Dermal Toxicity)

 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 : Not classified

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
Ethanolated 2 Pinchand A Pinchand (24404 00 4)	

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

Ethoxylated (9 EO) Trimethylolpropane Triacrylate (28961-43-5)	
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

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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	
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	
Ethoxylated (9 EO) Trimethylolpropane Triacrylate (28961-43-5)		
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.

Hydroquinone (123-31-9)	
LC50 fish 2	0.17 mg/l (LC50; 96 h; Brachydanio rerio)
EC50 Daphnia 1	0.09 - 0.29 mg/l (EC50; 48 h)

# 12.2. Persistence and degradability

Camphorquinone (10373-78-1)		
Persistence and degradability	Biodegradability in water: no data available.	
ThOD	2.41 g O₂/g substance	
Hydroquinone (123-31-9)		
Persistence and degradability	Readily biodegradable in water. Photolysis in water. Readily biodegradable in the soil. Highly mobile in soil. Low potential for adsorption in soil. Photolysis in the air.	
Biochemical oxygen demand (BOD)	0.48 - 1.1 g O₂/g substance	
Chemical oxygen demand (COD)	1.83 g O₂/g substance	
ThOD	1.89 g O₂/g substance	
BOD (% of ThOD)	0.25 - 0.53	

# 12.3. Bioaccumulative potential

Camphorquinone (10373-78-1)		
Bioaccumulative potential	No bioaccumulation data available.	
Hydroquinone (123-31-9)		
BCF fish 1	40 (BCF; 72 h; Leuciscus idus)	
BCF other aquatic organisms 1	40 - 65 (BCF; 48 h)	
BCF other aquatic organisms 2	35 (BCF)	
Log Pow	0.59 (Experimental value; Other; 20 - 25 °C)	
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).	

# 12.4. Mobility in soil

Hydroquinone (123-31-9)	
Log Koc	Koc,SRC PCKOCWIN v2.0; 38.47; Experimental value; log Koc; SRC PCKOCWIN v2.0; 1.585; Experimental value

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## 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.

## 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. BlmSchV (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

: None of the components are listed

giftige stoffen – Vruchtbaarheid NIET-limitatieve lijst van voor de voortplanting

: None of the components are listed

giftige stoffen – Ontwikkeling

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Recommendations Danish Regulation

: Young people below the age of 18 years are not allowed to use 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**

## Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Carc. 2	Carcinogenicity, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Muta. 2	Germ cell mutagenicity, 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
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
H341	Suspected of causing genetic defects
H351	Suspected of causing cancer
H400	Very toxic to aquatic life
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.

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