

Safety Data Sheet

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

Date of issue: Version: 3

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

Product identifier

Product form : Mixture : Bond Aligner Product name

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

1.2.1. Relevant identified uses

Use of the substance/mixture : For RX only

1.2.2. Uses advised against

No additional information available

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

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

Classification of the substance or mixture

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

Acute toxicity (oral), Category 4 H302 Acute toxicity (dermal), Category 4 H312 Acute toxicity (inhalation:vapour) Category H331 Serious eye damage/eye irritation, Category H318

Skin sensitisation, Category 1 H317 Reproductive toxicity, Category 2 H361 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

Suspected of damaging fertility or the unborn child. Toxic if inhaled. Harmful in contact with skin. Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. Toxic to aquatic life with long lasting effects.

Label elements

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

Hazard pictograms (CLP)











GHS06

GHS07

Signal word (CLP)

Hazardous ingredients N,N-Dimethylacrylamide; Tricyclodecane Dimethanol Diacrylate; Pentaerythritol Tetrakis(3-

mercaptopropionate); Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide

Hazard statements (CLP) : H302+H312 - Harmful if swallowed or in contact with skin.

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H317 - May cause an allergic skin reaction.

H318 - Causes serious eye damage.

H331 - Toxic if inhaled.

H361 - Suspected of damaging fertility or the unborn child.

H411 - Toxic 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 mist, vapours.

P264 - Wash hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

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.

P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

P302+P352 - IF ON SKIN: Wash with plenty of 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.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P310 - Immediately call a POISON CENTER or doctor. P312 - Call a POISON CENTRE or doctor if you feel unwell.

P321 - Specific treatment (see First aid measures on this label).

P330 - Rinse mouth.

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/container to 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]
Tricyclodecane Dimethanol Diacrylate	(CAS-No.) 42594-17-2	50 - 75	Skin Sens. 1, H317 Repr. 2, H361 Aquatic Chronic 2, H411
N,N-Dimethylacrylamide	(CAS-No.) 2680-03-7 (EC-No.) 220-237-5	10 - 30	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Eye Dam. 1, H318
Pentaerythritol Tetrakis(3-mercaptopropionate)	(CAS-No.) 7575-23-7 (EC-No.) 231-472-8	5 - 10	Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317 Aquatic Chronic 1, H410
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide	(CAS-No.) 162881-26-7 (EC-No.) 423-340-5 (EC Index-No.) 015-189-00-5	< 1	Skin Sens. 1, H317 Aquatic Chronic 4, H413

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : IF exposed or concerned: Get medical advice/attention. 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 doctor.

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

: Rinse mouth. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : 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.

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

clothing.

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. Notify authorities if product enters sewers or public

waters

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

: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing mist, vapours. Do not get in eyes, on skin, or on clothing.

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

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Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

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 : Flowable paste
Colour : Yellow / Beige

Odour : Acrylic

Odour threshold : No data available : No data available Relative evaporation rate (butylacetate=1) No data available : Not applicable Melting point Freezing point : No data available Boiling point : No data available Flash point No data available : No data available Auto-ignition temperature Decomposition temperature : No data available Flammability (solid, gas) : Not applicable Vapour pressure No data available : No data available Relative vapour density at 20 °C Relative density : No data available Solubility : No data available Log Pow No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available : No data available Explosive properties Oxidising properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosive limits

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.

: No data available

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SECTION 11: Toxicological information	ation
11.1. Information on toxicological effect	ts control of the second of th
Acute toxicity (oral)	: Oral: Harmful if swallowed.
Acute toxicity (dermal)	: Dermal: Harmful in contact with skin.
Acute toxicity (inhalation)	: Inhalation:vapour: Toxic if inhaled.
ATE CLP (oral)	674.214 mg/kg bodyweight
ATE CLP (dermal)	1075.654 mg/kg bodyweight
ATE CLP (vapours)	2.402 mg/l/4h
N,N-Dimethylacrylamide (2680-03-7)	
LD50 oral rat	215 - 464 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Male/female, Experimental value)
LC50 inhalation rat (mg/l)	0.67 mg/l (4 h, Rat)
Phenyl Bis(2,4,6-trimethylbenzoyl)phosph	ine Oxide (162881-26-7)
LD50 oral rat	> 2000 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Male/female, Experimental value)
LD50 dermal rat	> 2000 mg/kg (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male/female, Experimental value)
Skin corrosion/irritation	: Not classified
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	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1	To	xicity	
12.	10	AIGILY	

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.

N,N-Dimethylacrylamide (2680-03-7)		
LC50 fish 1	> 120 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Static system, Fresh water, Experimental value)	
EC50 Daphnia 1	> 120 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)	
ErC50 (algae)	> 400 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value)	
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)		
LC50 fish 1	> 90 µg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Brachydanio rerio, Semi-static system, Experimental value)	
EC50 Daphnia 1	> 1175 μg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Experimental value)	

12.2. Persistence and degradability

N,N-Dimethylacrylamide (2680-03-7)		
Persistence and degradability	Not readily biodegradable in water.	
Pentaerythritol Tetrakis(3-mercaptopropionate) (7575-23-7)		
Persistence and degradability	Biodegradability in soil: no data available.	
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)		
Persistence and degradability	Not readily biodegradable in water.	

Bioaccumulative potential

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N,N-Dimethylacrylamide (2680-03-7)		
Log Pow	-0.3 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 23 °C)	
Bioaccumulative potential	Not bioaccumulative.	
Pentaerythritol Tetrakis(3-mercaptopropionate) (7575-23-7)		
Bioaccumulative potential	No bioaccumulation data available.	
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)		
BCF fish 1	< 5 (OECD 305: Bioconcentration: Flow-Through Fish Test, 28 day(s), Cyprinus carpio, Experimental value)	
Log Pow	5.8 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 22 °C)	
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).	

12.4. Mobility in soil

N,N-Dimethylacrylamide (2680-03-7)	
Log Koc	< 1.25 (log Koc, OECD 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), Experimental value, GLP)
Ecology - soil	Highly mobile in soil.
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)	

Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)	
Surface tension	70.7 - 71.4 mN/m (20 °C, 0.1 g/l)
Ecology - soil	Adsorption to soil is possible.

12.5. Results of PBT and vPvB assessment

Component	
N,N-Dimethylacrylamide (2680-03-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Phenyl Bis(2,4,6-trimethylbenzoyl)phosphine Oxide (162881-26-7)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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

W application

IMDG

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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



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

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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

Reference to AwSV : Water hazard class (WGK) 3, severe hazard to waters (Classification according to AwSV,

Annex 1)

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

SZW-lijst van mutagene stoffen

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Borstvoeding

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Ontwikkeling

: None of the components are listed

Danish National Regulations : 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

The requirements from the Danish Working Environment Authorities regarding work with

carcinogens must be followed during use and disposal

Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Revision date:

Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), 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 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Repr. 2	Reproductive toxicity, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H361	Suspected of damaging fertility or the unborn child.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
SDS ELL (REACH Anney 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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