



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

1.1. Product identifier

Product form : Mixture
Product name : Bonding Resin Part B

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 2 H319
Skin sensitisation, Category 1 H317

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 irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazardous ingredients :

BisGMA; Dibenzoyl Peroxide

Hazard statements (CLP) :

H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P261 - Avoid breathing vapours.
P264 - Wash hands thoroughly after handling.
P272 - Contaminated work clothing should not be allowed out of the workplace.
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.

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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.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
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.

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] |
|--------------------|--|---------|---|
| BisGMA | (CAS-No.) 1565-94-2 | 50 - 75 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 |
| Dibenzoyl Peroxide | (CAS-No.) 94-36-0 (EC-No.) 202-327-6 (EC Index-No.) 617-008-00-0 | 1 - 5 | Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=10) |

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. If eye irritation persists: Get medical advice/attention.
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 : Eye irritation.

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

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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

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

| Dibenzoyl Peroxide (94-36-0) | | |
|------------------------------|----------------------------------|---|
| Belgium | Limit value (mg/m ³) | 5 mg/m ³ (Dibenzoyl Peroxide; Belgium; Time-weighted average exposure limit 8 h) |
| France | VME (mg/m ³) | 5 mg/m ³ (Dibenzoyl Peroxide; France; Time-weighted average exposure limit 8 h) |
| United Kingdom | WEL TWA (mg/m ³) | 5 mg/m ³ |
| USA - ACGIH | ACGIH TWA (mg/m ³) | 5 mg/m ³ (Dibenzoyl Peroxide; France; Time-weighted average exposure limit 8 h); 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:

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 : Liquid
Appearance : Viscous liquid.
Colour : Pale yellow.
Odour : Acrylic.

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| | |
|--|---------------------|
| 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 |

Dibenzoyl Peroxide (94-36-0)

| | |
|-----------------------------------|--|
| LD50 oral rat | > 5000 mg/kg (Rat) |
| 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 |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

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SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Acute aquatic toxicity | : Not classified |
| Chronic aquatic toxicity | : Not classified |

Dibenzoyl Peroxide (94-36-0)

| | |
|----------------|---|
| LC50 fish 1 | 0.0602 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value) |
| EC50 Daphnia 1 | 0.11 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value) |

12.2. Persistence and degradability

Dibenzoyl Peroxide (94-36-0)

| | |
|-------------------------------|---------------------------------|
| Persistence and degradability | Readily biodegradable in water. |
|-------------------------------|---------------------------------|

12.3. Bioaccumulative potential

Dibenzoyl Peroxide (94-36-0)

| | |
|---------------------------|---|
| Log Pow | 3.2 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 22 °C) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

12.4. Mobility in soil

Dibenzoyl Peroxide (94-36-0)

| | |
|----------------|--|
| Log Koc | 3.8 (log Koc, OECD 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), Experimental value) |
| Ecology - soil | Adsorbs into the soil. |

12.5. Results of PBT and vPvB assessment

Component

| | |
|------------------------------|---|
| Dibenzoyl Peroxide (94-36-0) | 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

IMDG

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

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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 : No

Marine pollutant : No

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

Reference to AwSV : Water hazard class (WGK) 1, low 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. 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

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NIET-limitatieve lijst van voor de voortplanting : None of the components are listed
giftige stoffen – Ontwikkeling

Denmark

Danish National Regulations : 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

SECTION 16: Other information

Full text of H- and EUH-statements:

| | |
|-----------------|---|
| Aquatic Acute 1 | Hazardous to the aquatic environment — Acute Hazard, 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 |
| H241 | Heating may cause a fire or explosion. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H400 | Very toxic to aquatic life. |

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