



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

1.1. Product identifier

Product form : Mixture
Product name : Band Lok Part A

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]

Acute toxicity (oral), Category 4 H302
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

Harmful if swallowed. 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 : Sodium Fluoride; 2-Hydroxyethyl Methacrylate; 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid; BisGMA
Hazard statements (CLP) : H302 - Harmful if swallowed
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
P270 - Do not eat, drink or smoke when using this product

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P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves, eye protection, face protection
P301+P312 - IF SWALLOWED: Call a POISON CENTER, a doctor if you feel unwell.
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
P321 - Specific treatment (see First aid measures on this label)
P330 - Rinse mouth
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 | 15 - 25 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 |
| 2-Hydroxyethyl Methacrylate | (CAS-No.) 868-77-9 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X | 1 - 10 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 |
| Sodium Fluoride | (CAS-No.) 7681-49-4 (EC-No.) 231-667-8 (EC Index-No.) 009-004-00-7 | 1 - 5 | Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319 |
| 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid | (CAS-No.) 2530-85-0 (EC-No.) 219-785-8 | 1 - 5 | Skin Sens. 1B, H317 |
| Acetic Acid substance with a Community workplace exposure limit | (CAS-No.) 64-19-7 (EC-No.) 200-580-7 (EC Index-No.) 607-002-00-6 | < 0.01 | Flam. Liq. 3, H226 Skin Corr. 1A, H314 |

Specific concentration limits:

| Name | Product identifier | Specific concentration limits |
|-------------|--|---|
| Acetic Acid | (CAS-No.) 64-19-7 (EC-No.) 200-580-7 (EC Index-No.) 607-002-00-6 | (10 =<C < 25) Eye Irrit. 2, H319 (10 =<C < 25) Skin Irrit. 2, H315 (25 =<C < 90) Skin Corr. 1B, H314 (C >= 90) Skin Corr. 1A, H314 |

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.
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 : Rinse mouth. 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.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

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.

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 : Mechanically recover the product.

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

| Sodium Fluoride (7681-49-4) | | |
|-----------------------------|--|--|
| EU | IOELV TWA (mg/m ³) | 2.5 mg/m ³ (Fluorides, inorganic; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value) |
| Belgium | Limit value (mg/m ³) | 2.5 mg/m ³ (Fluoride (en F); Belgium; Time-weighted average exposure limit 8 h) |
| France | VME (mg/m ³) | 2 mg/m ³ (Sodium (Fluoride), en F; France; Time-weighted average exposure limit 8 h) |
| Netherlands | Grenswaarde TGG 15MIN (mg/m ³) | 2 mg/m ³ (Fluoride (als F); Netherlands; Short time value; Public occupational exposure limit value; als F) |
| United Kingdom | WEL TWA (mg/m ³) | 2.5 mg/m ³ Fluorides (inorganic as F); United Kingdom; Time-weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005) |
| USA - ACGIH | ACGIH TWA (mg/m ³) | 2.5 mg/m ³ (Fluorides, as F; USA; Time-weighted average exposure limit 8 h; TLV - Adopted Value) |
| Acetic Acid (64-19-7) | | |
| EU | IOELV TWA (mg/m ³) | 25 mg/m ³ (Acetic acid; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value) |

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| Acetic Acid (64-19-7) | | |
|-----------------------|---|---|
| EU | IOELV TWA (ppm) | 10 ppm (Acetic acid; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value) |
| Belgium | Limit value (mg/m ³) | 25 mg/m ³ (Acetic Acid; Belgium; Time-weighted average exposure limit 8 h) |
| Belgium | Limit value (ppm) | 10 ppm (Acetic Acid; Belgium; Time-weighted average exposure limit 8 h) |
| Belgium | Short time value (mg/m ³) | 38 mg/m ³ (Acetic Acid; Belgium; Short time value) |
| Belgium | Short time value (ppm) | 15 ppm (Acetic Acid; Belgium; Short time value) |
| France | VLE (mg/m ³) | 25 mg/m ³ (Acetic Acid; France; Short time value;) |
| France | VLE (ppm) | 10 ppm (Acetic Acid; France; Short time value;) |
| Netherlands | Grenswaarde TGG 8H (mg/m ³) | 25 mg/m ³ (Acetic Acid; Netherlands; Time-weighted average exposure limit 8 h; Public occupational exposure limit value) |
| USA - ACGIH | ACGIH TWA (ppm) | 10 ppm (Acetic acid; USA; Time-weighted average exposure limit 8 h; TLV - Adopted Value) |
| USA - ACGIH | ACGIH STEL (ppm) | 15 ppm (Acetic acid; USA; Short time value; TLV - Adopted Value) |

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Eye protection:

Protective goggles

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 | : Solid |
| Appearance | : Paste. |
| Colour | : Light brown / Blue. |
| 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 | : Not applicable |
| Boiling point | : No data available |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| 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 | : Not applicable |
| Solubility | : No data available |
| Log Pow | : No data available |

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| | |
|----------------------|---------------------|
| Viscosity, kinematic | : Not applicable |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : Not applicable |

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) | : Oral: Harmful if swallowed. |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

| | |
|----------------|----------------------------------|
| ATE CLP (oral) | 1857.1428571429 mg/kg bodyweight |
|----------------|----------------------------------|

| | |
|------------------------------------|----------------|
| Sodium Fluoride (7681-49-4) | |
| LD50 oral rat | 52 mg/kg (Rat) |

| | |
|---|--|
| 2-Hydroxyethyl Methacrylate (868-77-9) | |
| LD50 oral rat | 5564 mg/kg bodyweight (Rat; Experimental value) |
| LD50 dermal rabbit | > 5000 mg/kg bodyweight (Rabbit; Experimental value) |

| | |
|--|---|
| 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid (2530-85-0) | |
| LD50 oral rat | > 2000 mg/kg bodyweight (Rat; Literature study) |
| LD50 dermal rat | > 2000 mg/kg bodyweight (Rat; Literature study) |

| | |
|------------------------------|---|
| Acetic Acid (64-19-7) | |
| LD50 oral rat | 3310 mg/kg bodyweight (Rat; Other; Read-across) |

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

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 |

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Chronic aquatic toxicity : Not classified

| Sodium Fluoride (7681-49-4) | |
|--|---|
| LC50 fish 1 | > 530 mg/l (LC50; 96 h) |
| EC50 Daphnia 1 | 98 mg/l (EC50; 48 h) |
| 2-Hydroxyethyl Methacrylate (868-77-9) | |
| LC50 fish 1 | 227 mg/l (LC50; 96 h) |
| EC50 Daphnia 1 | 171 mg/l (NOEC; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value) |
| EC50 Daphnia 2 | 380 mg/l (EC50; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value) |
| Threshold limit algae 1 | 836 mg/l (ErC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value) |
| Threshold limit algae 2 | 345 mg/l (EbC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value) |
| 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid (2530-85-0) | |
| LC50 fish 1 | 175 mg/l (LC50; 96 h) |
| LC50 fish 2 | > 100 mg/l (LC50; EU Method C.1; 96 h; Brachydanio rerio; Semi-static system; Fresh water; Experimental value) |
| EC50 Daphnia 1 | > 100 mg/l (EC50; EU Method C.2; 48 h; Daphnia magna; Static system; Fresh water; Experimental value) |
| EC50 Daphnia 2 | >= 100 mg/l (NOEC; EU Method C.2; 48 h; Daphnia magna; Static system; Fresh water; Experimental value) |
| Threshold limit algae 1 | > 100 mg/l (EC50; EU Method C.3; 72 h; Scenedesmus subspicatus; Static system; Fresh water; Experimental value) |
| Threshold limit algae 2 | > 100 mg/l (EC50; EU Method C.3; 72 h; Scenedesmus subspicatus; Static system; Fresh water; Experimental value) |

12.2. Persistence and degradability

| Sodium Fluoride (7681-49-4) | |
|--|---|
| Persistence and degradability | Biodegradability: not applicable. |
| Biochemical oxygen demand (BOD) | Not applicable |
| Chemical oxygen demand (COD) | Not applicable |
| ThOD | Not applicable |
| 2-Hydroxyethyl Methacrylate (868-77-9) | |
| Persistence and degradability | Readily biodegradable in water. Biodegradability in soil: no data available. Adsorbs into the soil. |
| 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid (2530-85-0) | |
| Persistence and degradability | Readily biodegradable in water. |
| Acetic Acid (64-19-7) | |
| Persistence and degradability | Readily biodegradable in water. Biodegradable in the soil. Highly mobile in soil. |
| Biochemical oxygen demand (BOD) | 0.6 - 0.74 g O ₂ /g substance |
| Chemical oxygen demand (COD) | 1.03 g O ₂ /g substance |
| ThOD | 1.07 g O ₂ /g substance |

12.3. Bioaccumulative potential

| Sodium Fluoride (7681-49-4) | |
|--|---|
| BCF fish 1 | 2.3 (BCF) |
| Bioaccumulative potential | Not bioaccumulative. |
| 2-Hydroxyethyl Methacrylate (868-77-9) | |
| BCF fish 1 | 1.3 - 1.5 (BCF) |
| Log Pow | -0.55 - 0.49 (0.42; Experimental value; OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method; 25 °C) |
| Bioaccumulative potential | Low potential for bioaccumulation (BCF < 500). |
| 3-(Trimethoxysilyl)propyl-2-Methyl-2-Propenoic Acid (2530-85-0) | |
| Log Pow | 0.75 (Calculated) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

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| Acetic Acid (64-19-7) | |
|---------------------------|--|
| BCF fish 1 | 3.16 (BCF; Pisces) |
| Log Pow | -0.17 (Experimental value; 25 °C) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

12.4. Mobility in soil

| Sodium Fluoride (7681-49-4) | |
|-----------------------------|-----------------|
| Ecology - soil | Toxic to flora. |

| Acetic Acid (64-19-7) | |
|-----------------------|---|
| Surface tension | 0.028 N/m (20 °C) |
| Log Koc | log Koc,0.06; QSAR |
| Ecology - soil | May be harmful to plant growth, blooming and fruit formation. |

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

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

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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

VwVwS Annex reference : Water hazard class (WGK) 2, significant 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

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. 3 (Oral) | Acute toxicity (oral), Category 3 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Flam. Liq. 3 | Flammable liquids, Category 3 |
| Skin Corr. 1A | Skin corrosion/irritation, Category 1A |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| Skin Sens. 1B | Skin sensitisation, category 1B |
| H226 | Flammable liquid and vapour |
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |

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| | |
|------|-------------------------------|
| H319 | Causes serious eye irritation |
|------|-------------------------------|

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