

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

1.1. Product identifier

Product form : Mixture
Product name : Band Lok (with and without Fluoride) 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/Importer/Representative/User/Distributor:

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

Australian Sponsor:

Emergo Australia, 201 Sussex St.
Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia
T +61 2 9006 1662

Switzerland Representative:

MedEnvoy Global BV
Leidschendam-Voorburg, Zug Branch Office
Gotthardstrasse 28, 6302 Zug, Switzerland
T +41 41 462 01 42

U.S. Federal Register:

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012
/ Rules and Regulations
FDA Registration: 1420089

EC Representative:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
T +31 70 345 8570

U.K. Person Responsible:

Emergo Consulting (UK) Limited
c/o Cr360 - UL International Compass House, Vision Park Histon
Cambridge CB24 9BZ
England, United Kingdom
T +44(0) 1223 772 671

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
Specific target organ toxicity - Single exposure, Category 3,	H335
Respiratory tract irritation	

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

2-Hydroxyethyl Methacrylate; BisGMA; Glass Filler

Hazard statements (CLP) :

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P261 - Avoid breathing dust, fume, vapours.

P264 - Wash hands thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, eye 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.

P312 - Call a POISON CENTER, doctor if you feel unwell.

P321 - Specific treatment (see supplemental first aid instruction on this label).

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.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

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.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Sodium Fluoride (7681-49-4)	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
2-Hydroxyethyl Methacrylate (868-77-9)	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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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]
Glass Filler	CAS-No.: N/A	50 - 70	Eye Irrit. 2, H319 STOT SE 3, H335

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
BisGMA	CAS-No.: 1565-94-2 EC-No.: 216-367-7	15 - 25	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335
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 substance with a Community workplace exposure limit	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

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, seek medical advice.
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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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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 dust, fume, vapours.
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Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing dust, fume, 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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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
Colour	: Light brown / Blue.
Appearance	: Paste.
Odour	: Acrylic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not applicable
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Sodium Fluoride (7681-49-4)	
LD50 oral rat	223 mg/kg bodyweight (EPA OPPTS 870.1100: Acute Oral Toxicity, Rat, Male, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg Source: ECHA

2-Hydroxyethyl Methacrylate (868-77-9)	
LD50 oral rat	5564 mg/kg bodyweight (Rat, Experimental value, Oral)
LD50 dermal rabbit	> 5000 mg/kg (24 h, Rabbit, Male, Experimental value, Dermal)

Skin corrosion/irritation : Causes skin irritation.

Sodium Fluoride (7681-49-4)	
pH	7.4

2-Hydroxyethyl Methacrylate (868-77-9)	
pH	No data available in the literature

Serious eye damage/irritation : Causes serious eye irritation.

Sodium Fluoride (7681-49-4)	
pH	7.4

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

2-Hydroxyethyl Methacrylate (868-77-9)	
pH	No data available in the literature
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Sodium Fluoride (7681-49-4)	
IARC group	3 - Not classifiable
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
BisGMA (1565-94-2)	
STOT-single exposure	May cause respiratory irritation.
Glass Filler (N/A)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Sodium Fluoride (7681-49-4)	
LOAEL (oral, rat, 90 days)	≈ 4 mg/kg bodyweight Animal: rat, Guideline: other:
NOAEL (oral, rat, 90 days)	≈ 25 mg/kg bodyweight Animal: rat, Guideline: other:
Aspiration hazard	: Not classified
Band Lok (with and without Fluoride) Part A	
Viscosity, kinematic	Not applicable
Sodium Fluoride (7681-49-4)	
Viscosity, kinematic	0.38 mm ² /s
2-Hydroxyethyl Methacrylate (868-77-9)	
Viscosity, kinematic	6.4 mm ² /s (20 °C)

11.2. Information on other hazards

No additional information available

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.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

Sodium Fluoride (7681-49-4)	
LC50 - Fish [1]	38 - 68 mg/l Source: NCIS; Toxic Substances Information Report
LC50 - Fish [2]	165 mg/l Test organisms (species): other:
EC50 - Crustacea [1]	97 mg/l (48 h, Daphnia magna, Static system, Fresh water, Experimental value, Fluorine ion)
EC50 72h - Algae [1]	850 mg/l Source: NCIS; Toxic Substances Information Report
EC50 96h - Algae [1]	43 mg/l (Scenedesmus sp., Static system, Experimental value, Fluorine ion)

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Sodium Fluoride (7681-49-4)	
NOEC (chronic)	14.1 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC chronic fish	4 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri) Duration: '21 d'
2-Hydroxyethyl Methacrylate (868-77-9)	
LC50 - Fish [1]	> 100 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oryzias latipes, Semi-static system, Fresh water, Experimental value, GLP)
EC50 - Crustacea [1]	380 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)
ErC50 algae	836 mg/l (OECD 201: Alga, Growth Inhibition Test, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP)
BisGMA (1565-94-2)	
LC50 - Fish [1]	0.537 mg/l Source: ECOSAR
12.2. Persistence and degradability	
Sodium Fluoride (7681-49-4)	
Persistence and degradability	Biodegradability: not applicable.
Chemical oxygen demand (COD)	Not applicable (inorganic)
ThOD	Not applicable (inorganic)
2-Hydroxyethyl Methacrylate (868-77-9)	
Persistence and degradability	Biodegradability in soil: no data available. Readily biodegradable in water.
BisGMA (1565-94-2)	
Persistence and degradability	Biodegradability in water: no data available.
12.3. Bioaccumulative potential	
Sodium Fluoride (7681-49-4)	
BCF - Fish [1]	53 - 58 (Pisces, Fresh water, Literature study, Fresh weight)
Partition coefficient n-octanol/water (Log Pow)	-0.77 Source: EPISUITE
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).
2-Hydroxyethyl Methacrylate (868-77-9)	
Partition coefficient n-octanol/water (Log Pow)	0.42 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 25 °C)
Bioaccumulative potential	Not bioaccumulative.
BisGMA (1565-94-2)	
Partition coefficient n-octanol/water (Log Pow)	4.94 (Estimated value)
Bioaccumulative potential	No bioaccumulation data available.
12.4. Mobility in soil	
Sodium Fluoride (7681-49-4)	
Ecology - soil	Adsorbs into the soil. Toxic to flora.

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

2-Hydroxyethyl Methacrylate (868-77-9)	
Surface tension	No data available in the literature
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	0.164 - 0.708 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Adsorbs into the soil.

12.5. Results of PBT and vPvB assessment

Component	
Sodium Fluoride (7681-49-4)	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
2-Hydroxyethyl Methacrylate (868-77-9)	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. Endocrine disrupting properties

No additional information available

12.7. 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 / IMDG / IATA / ADN / RID

14.1. UN number or ID number

Not regulated for transport

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

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

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. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

Band Lok (with and without Fluoride) Part A

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Issue date	Removed	
	Revision date	Added	
	Supersedes version of	Added	
1.3	Display additional SDS EU addresses	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures general	Modified	
6.1	Emergency procedures	Modified	
7.1	Precautions for safe handling	Modified	

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
H301	Toxic if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
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

Safety Data Sheet (SDS), EU

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.