



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

#### 1.1. Product identifier

Product form : Mixture  
Product name : Phase II Paste A (with and without Fluoride)

#### 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](http://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 :

Proprietary; BisGMA

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 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]
BisGMA	(CAS-No.) 1565-94-2	9.75 - 10.25	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	<= 1.207	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2, H319
Proprietary	(CAS-No.) Proprietary (EC-No.) Proprietary	1.1345918688 - 1.1469045441	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	0.0041979899 1456 - 0.0042435468 1317	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 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.

### 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.

## 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 <sup>3</sup> )	2.5 mg/m <sup>3</sup> (Fluorides, inorganic; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value)
Belgium	Limit value (mg/m <sup>3</sup> )	2.5 mg/m <sup>3</sup> (Fluoride (en F); Belgium; Time-weighted average exposure limit 8 h)
France	VME (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup> (Sodium (Fluoride), en F; France; Time-weighted average exposure limit 8 h )
Netherlands	Grenswaarde TGG 15MIN (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup> (Fluoride (als F); Netherlands; Short time value; Public occupational exposure limit value; als F)
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	2.5 mg/m <sup>3</sup> Fluorides (inorganic as F); United Kingdom; Time-weighted average exposure limit 8 h; Workplace exposure limit (EH40/2005)
USA - ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	2.5 mg/m <sup>3</sup> (Fluorides, as F; USA; Time-weighted average exposure limit 8 h; TLV - Adopted Value)
Acetic Acid (64-19-7)		
EU	IOELV TWA (mg/m <sup>3</sup> )	25 mg/m <sup>3</sup> (Acetic acid; EU; Time-weighted average exposure limit 8 h; Indicative occupational exposure limit value)
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 <sup>3</sup> )	25 mg/m <sup>3</sup> (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 <sup>3</sup> )	38 mg/m <sup>3</sup> (Acetic Acid; Belgium; Short time value)
Belgium	Short time value (ppm)	15 ppm (Acetic Acid; Belgium; Short time value)

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Acetic Acid (64-19-7)		
France	VLE (mg/m <sup>3</sup> )	25 mg/m <sup>3</sup> (Acetic Acid; France; Short time value;)
France	VLE (ppm)	10 ppm (Acetic Acid; France; Short time value;)
Netherlands	Grenswaarde TGG 8H (mg/m <sup>3</sup> )	25 mg/m <sup>3</sup> (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	: Tooth.
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
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

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### 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

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

Proprietary (Proprietary)	
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

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)

Proprietary (Proprietary)	
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)

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<b>Proprietary (Proprietary)</b>	
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

<b>Sodium Fluoride (7681-49-4)</b>	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable

<b>Proprietary (Proprietary)</b>	
Persistence and degradability	Readily biodegradable in water.

<b>Acetic Acid (64-19-7)</b>	
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 <sub>2</sub> /g substance
Chemical oxygen demand (COD)	1.03 g O <sub>2</sub> /g substance
ThOD	1.07 g O <sub>2</sub> /g substance

### 12.3. Bioaccumulative potential

<b>Sodium Fluoride (7681-49-4)</b>	
BCF fish 1	2.3 (BCF)
Bioaccumulative potential	Not bioaccumulative.

<b>Proprietary (Proprietary)</b>	
Log Pow	0.75 (Calculated)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).

<b>Acetic Acid (64-19-7)</b>	
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

<b>Sodium Fluoride (7681-49-4)</b>	
Ecology - soil	Toxic to flora.

<b>Acetic Acid (64-19-7)</b>	
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

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### 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
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#### IMDG

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

Transport hazard class(es) (IATA)	: Not applicable
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#### ADN

Transport hazard class(es) (ADN)	: Not applicable
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#### 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	: 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

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### 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. 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
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
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*