

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

1.1. Product identifier

Product form : Mixture
Product name : First and Final

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 : Professional Dental Polishing Paste

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

FDA Registration:

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

Adverse physicochemical, human health and environmental effects

Will cause eye irritation.
May cause skin irritation.
Prolong exposure may cause respiratory system irritation.
Ingestion of large amounts may cause nausea, vomiting, headaches, or dizziness.

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2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
Contains : Glycerol
Hazard statements (CLP) : H315, H319
Precautionary statements (CLP) : P404, P403+ 235

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]
Glycerol	CAS Number 56-81-5 EINECS # 200-289-5	20-30	Danger Symbol – GHS07 Hazard Statement – H315, H319 Precautionary Statement – P404, P403+ 235

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 : No additional information available
First-aid measures after inhalation : Move to fresh air. If having breathing difficulty, give oxygen. Seek medical attention if discomfort persists.
First-aid measures after skin contact : Wash thoroughly with soap and water. Remove contaminated clothing. Get medical help if discomfort persists.
First-aid measures after eye contact : Flush with water for 15 minutes, including under eyelids. Get medical help if discomfort persists.
First-aid measures after ingestion : If greater than normal dose is swallowed, do not induce vomiting. Drink large quantity of water or milk. Seek medical attention.

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

Symptoms/effects after skin contact : Repeated/prolonged contact may cause mild irritation of the skin. Symptoms include redness, burning, or itching.
Symptoms/effects after eye contact : Vapors are irritating to the eyes. Splashes may cause redness of the eye.
Symptoms/effects after ingestion : Swallowing small amounts during normal handling is not likely to cause harmful effects; swallowing large amounts may be harmful. Symptoms include irritation of the throat, nausea, dizziness, and upset stomach.
Symptoms/effects after inhalation : If fine small particles are inhaled, irritation of the throat with a feeling of tightness in the chest may occur.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Suitable extinguishing media for the surrounding fire should be used.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : No additional information available.

5.3. Advice for firefighters

Protection during firefighting : During a fire, irritating or highly toxic gases may be generated by thermal decomposition. If potential for exposure, wear complete personal protective equipment including self contained breathing apparatus, with full face operated in pressure demand. Fight fire from a safe distance/protected location.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Minor spills – Clean up immediately, avoid contact with skin and eyes. Mop area and clean with soapy water.
Major spills – Clear area of personnel. Restrict access to area. Avoid contact with skin and eyes, and mop / squeegee area with soapy water. Collect contaminated water and dispose of properly.

6.1.2. For emergency responders

Protective equipment : No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Minor spills – Clean up immediately, avoid contact with skin and eyes. Mop area and clean with soapy water.
Major spills – Clear area of personnel. Restrict access to area. Avoid contact with skin and eyes, and mop / squeegee area with soapy water. Collect contaminated water and dispose of properly.

Other information : No additional information available

6.4. Reference to other sections

See Section 8 and Section 12

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Limit all unnecessary personal contact. Avoid breathing dust / vapors. Wear appropriate PPE.

Hygiene measures : No additional information available

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a cool, well ventilated area away from heat, sparks and flame. Keep containers closed when not in use. Keep in original container provided by manufacturer.

7.3. Specific end use(s)

No additional information available

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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:

General exhaust is adequate under normal operating conditions.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):

To identify additional Personal Protective Equipment (PPE) requirements, it is recommended that a hazard assessment in accordance with the OSHA PPE Standard (29CFR1910.132), or European Standard EN166 be conducted before using this product.

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses / goggles or splash shields are required when handling. Ensure eye bath is on hand.

8.2.2.2. Skin protection

Skin and body protection:

No special equipment for minor exposure (i.e. when handling small quantities), but is recommended to use impermeable clothing to prevent ANY contact with this product, such as gloves, apron, boots, or whole body suit.

Hand protection:

No additional information available

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:

No additional information available

Other information:

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Paste
Colour	: No additional information available
Appearance	: Colored Paste
Odour	: Odor of Stated Flavor

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Odour threshold	: N/A
Melting point	: N/A
Freezing point	: N/A
Boiling point	: N/A
Flammability	: N/A
Lower explosion limit	: N/A
Upper explosion limit	: N/A
Flash point	: N/A
Auto-ignition temperature	: N/A
Decomposition temperature	: N/A
pH	: 6-8
pH solution	: N/A
Viscosity, kinematic	: N/A
Solubility	: N/A
Partition coefficient n-octanol/water (Log Kow)	: N/A
Vapour pressure	: N/A
Vapour pressure at 50°C	: N/A
Density	: N/A
Relative density	: N/A
Relative vapour density at 20°C	: N/A
Particle size	: N/A

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

No additional information available

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will not occur

10.4. Conditions to avoid

Heat and incompatible materials

10.5. Incompatible materials

Strong Acids

10.6. Hazardous decomposition products

Toxic Fumes (HF)

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: N/DA
Acute toxicity (dermal)	: N/DA
Acute toxicity (inhalation)	: N/DA
Respiratory or skin sensitisation	: N/DA

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Germ cell mutagenicity : N/DA

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No additional information available
Hazardous to the aquatic environment, short-term (acute) : N/DA
Hazardous to the aquatic environment, long-term (chronic) : N/DA

12.2. Persistence and degradability

First and Final

Persistence and degradability	Biodegradable. This material is not expected to significantly bioaccumulate.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Biodegradable. This material is not expected to significantly bioaccumulate.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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

Product/Packaging disposal recommendations : Dispose of in compliance with governmental regulation (state and federal). Dispose of container and unused contents in accordance with federal, state and local requirements. For EU Member States, please refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.
Ecology - waste materials : No additional information available.

SECTION 14: Transport information

Not regulated for transport

14.1. UN number or ID number

Not regulated for transport

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14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not regulated

IMDG

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

IATA

Transport hazard class(es) (IATA) : Not regulated

AND

Transport hazard class(es) (ADN) : Not regulated

RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

Packing group (ADR)	: Not regulated
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not regulated
Packing group (RID)	: Not regulated

14.5. Environmental hazards

Dangerous for the environment	: No additional information available
Marine pollutant	: No additional information available
Other information	: No additional information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

CDSL: Canadian Inventory (on Canadian Transitional List)	Glycerol – CAS # 56-81-5
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15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

No additional information available

REACH Annex XIV (Authorisation List)

No additional information available

REACH Candidate List (SVHC)

No additional information available

PIC Regulation (Prior Informed Consent)

No additional information available

POP Regulation (Persistent Organic Pollutants)

No additional information available

Ozone Regulation (1005/2009)

No additional information available

Explosives Precursors Regulation (2019/1148)

No additional information available

Drug Precursors Regulation (273/2004)

No additional information available

15.1.2. National regulations

Clean Air Act: HAP/ODS	This product contains the following HAP's or ODS: <ul style="list-style-type: none">None
Clean Water Act: Priority Pollutant	This product contains the following chemicals listed under the U. S. Clean Water Act Priority Pollutant and Hazardous Substance List: <ul style="list-style-type: none">None
FDA: Food Packaging Status	This product has not been cleared by the FDA for use in food packaging and / or other applications as an indirect food-packaging additive.
Occupational Safety and Health Act	This product is considered to be hazardous under the OSHA Hazard Communication Standard. It's hazards are: <ul style="list-style-type: none">None
RCRA	This product contains the following chemicals considered to be hazardous waste under RCRA (40 CFR 261). <ul style="list-style-type: none">None
SARA Title III: Section 302 (RQ)	This product contains no chemicals regulated under Section 302 as extremely hazardous substances.
SARA Title III: Section 302 (TPQ)	This product is not considered hazardous under the OSHA Hazard Communication Standard and is regulated under Section 311-312 (40 CFR370).
SARA Title III: Section 311-312:	This product contains chemicals regulated under Section 304 as extremely hazardous chemicals for emergency release notification (CERCLA List). <ul style="list-style-type: none">None
SARA Title III: Section 313:	This product contains the following chemicals which are subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372: <ul style="list-style-type: none">None
TSCA Section 8(b): Inventory: TSCA Significant New Use Rule:	This product does contain chemicals listed on the TSCA inventory or otherwise complies with TSCA pre-manufacture notification requirements. None of the chemicals in this material have a SNUR under TSCA.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

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SECTION 16: Other information

Indication of changes

Section	Changed item	Change	Comments
-	Initial release, Reliance generated	Initial release	-

Full text of H- and EUH-statements:

H315	Causes skin irritation.
H319	Causes serious eye irritation.
GHS07	Warning / Irritants.
P404	Store in a closed container.
P403+235	Store in a well ventiated place. Keep cool.

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.