

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878 Revision date: 3/15/2024 Version: 1.1

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

#### 1.1. Product identifier

Product form : Mixture

Product name : Glass Lok Liquid

# 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

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# 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 1 H314
Skin sensitisation, Category 1 H317

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

### Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage. May cause an allergic skin reaction.

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#### 2.2. Label elements

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

Hazard pictograms (CLP)





GHS05

05 GHS07

Signal word (CLP)

Contains

Hazard statements (CLP)

Precautionary statements (CLP)

: Danger

2-Hydroxyethyl Methacrylate

: H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

: P260 - Do not breathe 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.

P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing.

Rinse skin with water or shower

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. P310 - Immediately call a POISON CENTER, a doctor.

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

P333+P313 - If skin irritation or rash occurs: 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.

# 2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

Component	
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]
2-Hydroxyethyl Methacrylate	CAS-No.: 868-77-9 EC-No.: 212-782-2 EC Index-No.: 607-124-00-X	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317

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Name	Product identifier		Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glycerol DMA	CAS-No.: 1830-78-0 EC-No.: 217-388-4	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
10-Methacryloyloxydecyl Dihydrogen Phosphate	CAS-No.: 85590-00-7	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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 : Get medical advice/attention 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 immediately with lots of water. Take off immediately all contaminated clothing and

wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse immediately with plenty of water. 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 out with water. If you feel unwell, seek medical advice.

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

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation.
Symptoms/effects after eye contact : May cause 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 chemical powder. Carbon dioxide. 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. Complete protective

clothing. Self-contained breathing apparatus.

# **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 fume, 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. Notify authorities if product enters sewers or public waters.

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#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Store away from other materials.

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, eyes and clothing. Avoid breathing fume, vapours. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when

leaving work.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash contaminated clothing before

reuse. Contaminated work clothing should not be allowed out of the workplace. 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. Keep container closed when not in use.

# 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.

# 8.2.2. Personal protection equipment

### Personal protective equipment:

Avoid all unnecessary exposure.

#### Personal protective equipment symbol(s):







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#### 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.

#### Other information:

Do not eat, drink or smoke during use.

# **SECTION 9: Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour Blue / Light yellow. Appearance Clear liquid. Odour : Acrylic. Odour threshold : Not available : Not applicable Melting point Freezing point : Not available Boiling point : Not available Flammability : Not applicable Lower explosion limit : Not available Upper explosion limit : Not available Flash point : Not available Auto-ignition temperature : Not available Decomposition temperature : Not available

pH : ≈ 1

: Not available Viscosity, kinematic 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 available Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

# 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

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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 of use.

#### 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

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 severe skin burns.

pH: ≈ 1

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

Serious eye damage/irritation : Assumed to cause serious eye damage  $pH: \approx 1$ 

2-Hydroxyethyl Methacrylate (8	260 77 01	

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
Reproductive toxicity : Not classified
STOT-single exposure : Not classified

# **Glycerol DMA (1830-78-0)**

STOT-single exposure May cause respiratory irritation.

# 10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)

STOT-single exposure May cause respiratory irritation.

STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

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2-Hydroxyethyl Methacrylate (868-77-9)	
Viscosity, kinematic	6.4 mm²/s (20 °C)

# 11.2. Information on other hazards

No additional information available

# SECTION 12: Ecological information

# 12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

: Not classified

Hazardous to the aquatic environment, short-term

(acute)

Hazardous to the aquatic environment, long-term : Not classified

(chronic)

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)
10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)	
NOEC chronic fish	48h 10 mg/l

# 12.2. Persistence and degradability

Glass Lok Liquid		
Persistence and degradability	Not established.	
2-Hydroxyethyl Methacrylate (868-77-9)		
Persistence and degradability	Biodegradability in soil: no data available. Readily biodegradable in water.	
Glycerol DMA (1830-78-0)		
Persistence and degradability	Biodegradability in water: no data available.	

# 12.3. Bioaccumulative potential

Glass Lok Liquid		
Bioaccumulative potential Not established.		
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.	
Glycerol DMA (1830-78-0)		
Bioaccumulative potential	No bioaccumulation data available.	

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# 12.4. Mobility in soil

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	
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.

Ecology - waste materials : Avoid release to the environment.

# **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 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

**ADN** 

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

RID

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

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# 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 Marine pollutant : No

Other information : No supplementary 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

### 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)

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# 15.1.2. National regulations

No additional information available

# 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# SECTION 16: Other information

Indication of changes				
Section	Changed item	Change	Comments	
	Revision date	Added		
	Supersedes version of	Added		
	Issue date	Removed		
1.3	Display additional SDS EU addresses	Added		
2.2	Precautionary statements (CLP)	Modified		
2.2	Hazard statements (CLP)	Modified		
4.1	First-aid measures after inhalation	Modified		
4.1	First-aid measures after skin contact	Modified		
4.1	First-aid measures after ingestion	Modified		
4.1	First-aid measures after eye contact	Modified		
4.2	Symptoms/effects after inhalation	Modified		
5.1	Suitable extinguishing media	Modified		
5.3	Protection during firefighting	Modified		
6.1	Emergency procedures	Modified		
6.2	Environmental precautions	Modified		
6.3	Methods for cleaning up	Modified		
7.1	Precautions for safe handling	Modified		
7.1	Hygiene measures	Modified		
7.2	Storage conditions	Modified		
8.2	Respiratory protection	Modified		
8.2	Hand protection	Modified		
8.2	Eye protection	Modified		
10.4	Conditions to avoid	Modified		

Full text of H- and EUH-statements:		
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2	
H314	Causes severe skin burns and eye damage.	
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	

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Full text of H- and EUH-statements:		
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.