

Dental LT Clear

Photoreactive Resin for Form 2

SAFETY DATA SHEET

Prepared: 09/28/2017

Revised: 09/28/2017

GHS/CLP Labelling
Hazard pictograms:



Signal word: Warning

1. Chemical Product and Company Identification

Product Identification: Photoreactive Resin

Product Class: Mixture of methacrylic acid esters and photoinitiator

Product Use: For use in 3D printing splints and retainers using the Form 2 3D printer.

Company: Formlabs, Inc.

35 Medford Street, Suite #201
Somerville, MA

Vertex-Dental B.V.

Centurionbaan 190
3769 AV Soesterberg, The Netherlands

Date of Preparation: 09/28/2017

For Emergencies: North America call +1 800 255 3924

Worldwide Intl. call +01 813 248 0585

Reference Contract Number MIS47075633

2. Hazards Identification

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

According to Regulation (EG) No. 1272/2008 [CLP].

Skin irrit. Cat. 2 H315

Skin sens. Cat. 1 H317

Eye irrit. Cat. 2 H319

Aquatic chronic. Cat. 2 H411

For full text of H phrases see section 16.

COLOR: CLEAR

PHYSICAL STATE: LIQUID

ODOR: ESTER LIKE

LABEL ELEMENTS

Hazard pictograms:



SIGNAL WORD: WARNING

HAZARD STATEMENTS

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H411: Toxic to aquatic life with long-lasting effects.

PRECAUTIONARY STATEMENT(S)

P280: Wear protective gloves/protective clothing/eye protection/face protection. P261 Avoid breathing dust/fumes/gas/mist/vapours/spray.

P264: Wash hands and exposed skin thoroughly after handling.

P272: Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment.

P302+P352 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.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

P501: Dispose of contents/container in accordance with local/regional/national/international regulation.

3. Composition/Information on Ingredient

SUBSTANCES

This product is a mixture.

MIXTURES

Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

According to Regulation (EG) Nr. 1272/2008 [CLP].

Hazardous Ingredients	% w/w	EG No.	Hazard Statement Code(s)	Hazard Class and Category	
A. Methacrylic oligomer	> 70	Proprietary	H315; H317; H319	Skin irrit. Skin Sens. Eye irrit.	Cat 2 Cat 1 Cat 2
B. Glycol Methacrylate	< 20	Proprietary	H317; H319	Skin Sens. Eye irrit.	Cat 1 Cat 2
C. Pentamethyl-piperidyl sebacate	< 5	255-437-1	H317; H400; H410	Skin irrit. Aquatic acute Aquatic chronic.	Cat 2 Cat 1 Cat 1
D. Phosphine oxide	< 2,5	278-355-8	H317; H361; H401; H411	Skin Sens. Repr. Aquatic acute Aquatic chronic.	Cat 1 Cat 2 Cat 1 Cat 1

4. First-Aid Measures

DESCRIPTION OF FIRST AID MEASURES

Inhalation: IF INHALED: Move into fresh air and keep at rest. Get medical attention if any discomfort continues.

Eye Contact: IF IN EYES: Continue to rinse for at least 15 minutes under running water with eyelids held open. Get medical attention.

Skin Contact: IF ON SKIN (or hair): Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention promptly if irritation or other symptoms occur after washing.

Ingestion: Do not induce vomiting. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions. Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable get medical attention.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11. Further important symptoms and effects are so far not known.

INDICATION OF THE IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Note to physician. Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

5. Fire-Fighting Measures

Extinguishing Media: Use carbon dioxide or dry chemical for small fires; aqueous foam or water spray for large fires. Unsuitable extinguishing media: water jet.

Special hazards arising from the substance or mixture: Hazards during fire-fighting include harmful vapours and evolution of fumes/fog.

High temperatures may cause spontaneous polymerizing reaction generating heat/pressure. Closed containers may rupture or explode during a runaway polymerization. Use a water spray or fog to reduce temperature of containers.

Special Firefighting Procedures: Firefighters should wear full protection clothing and self-contained breathing apparatus (SCBA). Thoroughly decontaminate firefighting equipment including all firefighting apparel after the incident.

6. Accidental Release Measures

Personal Precautions, protective equipment and emergency procedures: Use protective gloves, goggles and suitable protective clothing. In case of inadequate ventilation, use respiratory protection. Maximize ventilation after accidental release.

Environmental Precautions: Contain contaminated water / firefighting water. Do not discharge into drains/surface waters/ groundwater. Avoid release to the environment.

Methods and material for containment and cleaning Up: Remove sources of ignition. Absorb with sand or other inert absorbent. Spillage may be stored as chemical waste in approved area.

Waste Disposal Method: Do not dispose of in sewers, lakes, rivers or streams. Scoop all contaminated material into compatible bottles or drums for proper disposal. Dispose of in accordance with all applicable federal, state and local regulations. National or regional provisions may also be in force.

Reference to other sections: See section 8, 13.

7. Handling and Storage

Handling Precautions: Keep away from heat, sparks and open flame. Use mechanical ventilation in case of handling which causes formation of vapours. Handle and open container with care. Wear full protective clothing for prolonged exposure and/or high concentrations. Take precautionary measures against static discharges.

Storage Precautions: Protect from light, including direct sunrays. Container may be filled for only 90%. Keep containers tightly closed, separate from oxidizing agents. Store in original container in a dry, cool and well-ventilated place. Store at temperatures between 5°C and 30°C. Do not expose to temperatures above 50°C for more than 24 hours. High temperatures may cause spontaneous polymerization.

Specific end use(s): None.

Expiry date: Product expiry date can be found on container label. Product is only guaranteed for use prior to this date.

8. Exposure Controls & Personal Protection

CONTROL PARAMETERS

Substance	EG no.
Methacrylic oligomer (100%)	Proprietary

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1	1	1

PNEC (100% component)	
Aquatic Compartment	Not applicable
Terrestrial Compartment	Not applicable

1 Toxicity: DNEL not established.

Substance	EG No.	LTEL ppm (8 HR TWA)	LTEL mg/m3 (8 h TWA)
Glycol Methacrylate (100%)	Proprietary	0,05	0,24

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1	4,9 mg/m ³	1,3 mg/kg/d

PNEC (100% component)	
Aquatic Compartment	10 mg/l (Fresh water); 0,482 mg/l (Sea water); 3,79 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,476 mg/kg dry weight
1 Toxicity: DNEL not established.	

Substance	EG no.
Pentamethyl-piperidyl sebacate	255-437-1

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1	2,35 mg/m ³	2,5 mg/kg

PNEC (100% component)	
Aquatic Compartment	0,0022 mg/l (Fresh water); 0,00022 mg/l (Sea water); 1,05 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,21 mg/kg
1 Toxicity: DNEL not established.	

Substance	EG no.
Phosphine oxide (100%)	278-355-8

DNEL (100% component)	Oral	Inhalation	Dermal
Worker – Long Term – Systemic effects	1	3,5 mg/m ³	1,00 mg/kg

PNEC (100% component)	
Aquatic Compartment	0,00353 mg/l (Fresh water); 0,000353 mg/l (Sea water); 0,29 mg/kg dry weight (Sediment)
Terrestrial Compartment	0,0557 mg/kg
1 Toxicity: DNEL not established.	

EXPOSURE CONTROLS

Appropriate engineering controls: Do not eat, drink or smoke at the work place.

Ventilation Controls: Ensure adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded.

For operations where contact can occur a safety shower and eye-wash facility should be available.

Individual protection measures, such as personal protective equipment (PPE)

Respiratory Protection: Wear suitable respiratory protective equipment if engineering controls are insufficient, or not present, and exposure to levels above the DNEL is likely. A suitable mask with filter type A (EN141 or EN405) may be appropriate.

Eye and Face Protection: Wear eye/face protection. Wear approved chemical safety goggles where eye exposure may occur. High-efficiency particulate respirator with full face-piece recommended. Chemical splash goggles or a face shield is recommended during operations where splashing could occur.

Skin Protection: Avoid all skin contact. Wear suitable gloves. Butyl and nitrile rubber gloves offer short-term protection. Latex surgical gloves offer little protection. Gloves should be stored correctly and changed regularly, especially if excessive exposure has occurred. Depending on the conditions of use, cover as much of the exposed skin area as possible by wearing aprons, long pants, and long sleeved shirts.

Other Controls: Always use good personal hygiene and housekeeping practices. Keep working clothes separately. Take off contaminated clothing immediately. Wash soiled clothing before reuse. Keep away from food, drinks and animal feed. Wash hands thoroughly after handling.

9. Physical & Chemical Properties

Appearance: Clear, viscous liquid.

Odor: Ester like

	Value	Unit
Specific Gravity	1.12	g/cm ³
Boiling Point	> 200	°C
Melting Point	n/a	°C
Flash Point	>150	°C
Vapour Pressure	-	
Flammable limits (lower)	n/a	%v/v
Auto Ignition Temperature	380	°C
Explosive properties	n/a	
Oxidising properties	n/a	
Relative Density	1.1–1.3	(water=1)
Viscosity	1–2	Pa*s
pH	n/a	
Solubility (water)	Not soluble	
Solubility	Good solubility with most organic solvents	

10. Stability and Reactivity

Stability: Stable when stored in original container designed for use with light sensitive materials under 25 °C (77 °F) in dark, cool place.

Reactivity: See “Chemical stability”, below.

Chemical stability: Stable under normal temperature conditions. Stable if stored and handles as prescribed/indicated.

Conditions to Avoid: Avoid heat, flames and other sources of ignition. Avoid contact with free radical initiators. Avoid contact with isocyanates and oxidizing agents. Avoid contact with vinyl polymerization initiators. Avoid exposure to high temperatures, direct sunlight or ultra violet (UV) radiation.

Incompatible Materials to Avoid: Avoid contact with radical forming initiators, peroxides, strong alkalies or reactive metals to prevent exothermic polymerization.

Hazardous Decomposition Products: With regard to possible decomposition products refer to Section 5. Oxides of carbon.

Possibility of hazardous reactions / hazardous polymerization: Hazardous polymerization may occur. Uncontrolled polymerization may cause rapid evolution of heat and increase in pressure that could result in violent rupture of sealed storage vessels or containers.

11. Toxicological Information

INFORMATION ON TOXICOLOGICAL EFFECTS

Stable Acute toxicity:

Methacrylic oligomer (100%)	
Skin irritation	Irritating
Eye irritation	Irritating
Skin sensitisation	May cause sensitisation by skin contact.
Aspiration Hazard	No aspiration hazard expected.

Glycol methacrylate (100%)	
LD50 acute oral rat	> 5000 mg/kg
LD50 acute dermal rabbit	> 5000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	Non-irritant
Eye irritation (rabbit, Draize)	Irritating
Inhalation/skin sensitisation (guinea pig, GPMT)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity oral rat (OESO 422)	> 100 mg/kg
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.

Pentamethyl-piperidyl sebacate (100%)	
LD50 acute oral rat (conventional method)	3.230 mg/kg
Skin irritation (rabbit, OPP 81-5)	Non-irritant
Eye irritation (rabbit, Draize)	Non-irritant
Skin sensitisation guinea pig (OESO 406)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity (animal studies)	No known chronic effects.
Reproductive toxicity (animal studies)	No suspicion of a toxic effect on reproduction.
Experiences in humans	Sensitizing effect by skin contact.

Phosphine oxide (100%)	
LD50 acute dermal rat	> 2000 mg/kg
Skin irritation (rabbit, 24 h, Draize)	Non-irritant
Eye irritation (rabbit, Draize)	Non-irritant
Skin sensitisation mouse LLNA (OESO 429)	Sensitizing
Aspiration Hazard	No aspiration hazard expected.
Chronic toxicity (animal studies)	May cause damage after repeated ingestion of high doses.
Reproductive toxicity (animal studies)	Suggest a fertility impairing effect.

12. Ecological Information

TOXICITY

Glycol methacrylate (100%)		
Toxicity to fish (mg/l)	LC50 (96 h) (<i>Oryzias latipes</i>) (OESO 203)	> 100
Aquatic invertebrates (mg/l)	NOEC (21 d) (<i>Daphnia magna</i>) (OESO 202)	24,1
	EC50 (48 h) (<i>Daphnia magna</i>) (OESO 202)	380
Aquatic plants (mg/l)	EC50 (72 h) (<i>Selenastrum capricornutum</i>) (OESO 201)	836
	NOEC (72 h) (<i>Selenastrum capricornutum</i>) (OESO 201)	400
Micro-organisms (mg/l)	EC50 (16 h) (<i>Pseudomonas fluorescens</i>) (DEV L8)	> 3,000

Pentamethyl-piperidyl sebacate (100%)		
May cause long-term adverse effects in the aquatic environment. Very toxic (acute effect) to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.		
Toxicity to fish (mg/l)	LC50 (96 h) (<i>Lepomis macrochirus</i>) (OECD 203)	0,97
	LC50 (96 h) (<i>Oncorhynchus mykiss</i>) (OECD 203)	7,9
	LC50 (96 h) (<i>Brachydanio rerio</i>) (OECD 203)	0,9
Aquatic invertebrates (mg/l)	EC50 (24 h) (<i>Daphnia magna</i>) (OECD 202)	20
Aquatic plants (mg/l)	EC50 (72 h) (<i>Desmodesmus subspicatus</i>) (OECD 201)	1.68
Micro-organisms (mg/l)	EC50 (3 h) (OECD 209)	> 100

Phosphine oxide (100%)		
Acutely toxic for aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.		
Toxicity to fish (mg/l)	LC50 (48 h) (<i>Oryzias latipes</i>) (JIS K 0102-71)	6,53
Aquatic invertebrates (mg/l)	EC50 (48 h) (<i>Daphnia magna</i>) (OECD 202)	3.53
Aquatic plants (mg/l)	EC50 (72 h) (<i>Pseudokirchneriella subcapitata</i>) (OECD 201)	> 2,01
	EC10 (72 h) (<i>Pseudokirchneriella subcapitata</i>) (OECD 201)	1,56
Micro-organisms (mg/l)	EC20 (3 h) (OECD 209)	> 1,000

PERSISTENCE AND DEGRADABILITY

Methacrylic oligomer (100%)

No data available.

Glycol methacrylate (100%)

Easy biodegradable.

Elimination information:

84% DOC reduction (28 d) (OESO 301 D). Easy biodegradable.

Pentamethyl-piperidyl sebacate (100%)

Moderately/partially biodegradable. Not readily biodegradable (by OECD criteria). Elimination information: 38% DOC reduction (28 d) (OECD 301 F) (aerobic, aerobic Micro-organisms).

Phosphine oxide (100%)

Poorly biodegradable. Not readily biodegradable (by OECD criteria).

Elimination information:

< 20% BOD of the ThOD (28 d) (OECD 301 F) (activated sludge). Poorly biodegradable.

BIOACCUMULATIVE POTENTIAL**Methacrylic oligomer (100%)**

No data available.

Glycol methacrylate (100%)

Accumulation in organisms is not to be expected.

Pentamethyl-piperidyl sebacate (100%)

Accumulation in organisms is not to be expected.

Phosphine oxide (100%)

Does not significantly accumulate in organisms.

Bioconcentration factor: 23 – 55 (56 d), *Cyprinus carpio* (measured): does not significantly accumulate in organisms.

MOBILITY IN SOIL**Methacrylic oligomer (100%)**

No data available.

Glycol methacrylate (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is not expected.

Pentamethyl-piperidyl sebacate (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is expected.

Phosphine oxide (100%)

The substance will not evaporate into the atmosphere from the water surface. Adsorption to solid soil phase is not expected.

RESULTS OF PBT AND vPvB ASSESSMENT**Methacrylic oligomer (100%)**

PBT: no

vPvB: no

Glycol methacrylate (100%)

PBT: no vPvB: no

Pentamethyl-piperidyl sebacate (100%)

PBT: no vPvB: no

Phosphine oxide (100%)

PBT: no vPvB: no

OTHER ADVERSE EFFECTS**Methacrylic oligomer (100%)**

Not applicable.

Glycol methacrylate (100%)

Do not allow to enter soil, waterways or waste water channels.

Pentamethyl-piperidyl sebacate (100%)

Do not allow to enter soil, waterways or waste water channels. Inhibition of degradation activity in activated sludge is not to be anticipated during correct introduction of low concentrations.

Phosphine oxide (100%)

Not applicable.

13. Disposal Considerations

Do not discharge into drains/surface waters/groundwater. Dispose of in accordance with governmental regulations (community, national or regional). Incinerate under approved controlled conditions, using incinerators for the disposal for organic chemicals. Avoid release into the environment. Contact a licensed professional waste disposal service to dispose of this mixture.

Contaminated Packaging: Dispose of as unused product. Decontaminate empty drums before disposing, or expose the open emptied container to light, then dispose.

14. Transport Information

UN-Number: Not classified as a dangerous good under transport regulations

UN Proper Shipping Name: Not applicable.

Transport hazard class(es): Not applicable.

Packing group: Not applicable.

Environmental hazards: Toxic to aquatic life with long lasting effects.

Special precautions for user: N/A

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: N/A

Department of transportation classification: Not hazardous by D.O.T. regulations

D.O.T. proper shipping name: Not regulated

International Maritime Dangerous Goods Code (IMDG): Not regulated

International Air Transportation Association (IATA): Not regulated

ADR: Not regulated

Australian HazChem Code: N/A

Other requirements: N/A

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

If information other than the information in relation to safety, health and environmental regulations / legislation what is mentioned elsewhere in this Safety Data Sheet is required, please use the information listed in Section 1 to inquire whether that specific information is available. Related information about the separate components in the mixture can be accessed the same way.

Chemical Safety Assessment

A Chemical Safety Assessment has been carried out for the following individual components (100%): Glycol Methacrylate and Pentamethyl- piperidyl sebacate.

16. Other Information

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 453/2010.

To the best of our knowledge the information contained herein is accurate. However, Formlabs, Inc. makes no warranty, expressed or implied, regarding the accuracy of these results to be obtained from the use thereof. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. Formlabs, Inc. assumes no responsibility for injury from the use of the product described herein.

Legend

LTEL	Long Term Exposure Limit.
TWA	Time Weighted Average.
Repr.	Reproductive Toxicity.

Full text of H/P phrases	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long-lasting effects.
P261	Avoid breathing dust/fumes/gas/mist/vapours/spray.
P264	Wash hands and exposed skin thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/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.
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/container in accordance with local/regional/national/international regulation.

This is the end of the SDS for Formlabs Dental LT Clear.