

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 1 of 17

Surgical Guide Resin

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

1.1 Product identifier

Product Name: Surgical Guide Resin

Product code: FLSGAM01

UFI: E300-P0FU-700C-GKYT

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: s: For use in Formlabs SLA printers

Uses advised against: Not determined or not applicable.

Reasons why uses advised against: Not determined or not applicable.

1.3 Details of the manufacturer/supplier of the safety data sheet

Manufacturer:

United States

Formlabs, Inc
35 Medford St
Suite 201 Somerville, MA 02143
+1 617 855 0762
sds@formlabs.com

Supplier:

Germany

Formlabs GmbH
Nalepastr. 18
Berlin, . 12459
+49 30 700 146 501

1.4 Emergency telephone number:

European Union

CHEMTREC (EMEA)

+44 20 3885 0382 (24/7)

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture:

Classification according to Regulation (EC) No. 1272/2008 (CLP):

Skin irritation, category 2

Eye Irritation, category 2

Skin sensitization, category 1

Chronic aquatic hazard, category 2

Hazard-determining components of labeling:

2-hydroxyethyl methacrylate

Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

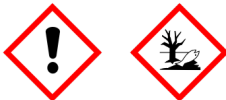
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate

Additional Information: None

2.2 Label elements

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

Hazard pictograms:



Signal Word: Warning

Hazard statements:

H315 Causes skin irritation

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 2 of 17

Surgical Guide Resin

H319 Causes serious eye irritation
H317 May cause an allergic skin reaction
H411 Toxic to aquatic life with long lasting effects

Precautionary statements:

P264 Wash skin thoroughly after handling.
P280 Wear protective gloves, protective clothing and eye protection.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray
P272 Contaminated work clothing should not be allowed out of the workplace
P273 Avoid release to the environment
P302+P352 IF ON SKIN: Wash with plenty of soap and water
P332+P313 If skin irritation occurs: Get medical advice/attention
P362 Take off contaminated clothing
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 If eye irritation persists: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention
P363 Wash contaminated clothing before reuse
P391 Collect spillage
P501 Dispose of contents and container in accordance with local, regional, national, and international regulations.

2.3 Other hazards: None known

SECTION 3: Composition/information on ingredients

3.1 Substance: Not applicable.

3.2 Mixture:

Identification	EU REACH Registration No.	Name	Classification according to Regulation (EC) No. 1272/2008 (CLP)	Weight %
CAS number: 72869-86-4 EC number: 276-957-5	-	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Skin Sens. 1; H317 Aquatic Chronic 2; H411	55-75
CAS number: 868-77-9 EC number: 212-782-2	-	2-hydroxyethyl methacrylate	Skin Irrit. 2; H315 Skin Sens. 1; H317 Eye Irrit. 2; H319	25-45
CAS number: 162881-26-7 EC number: 423-340-5	-	Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Aquatic Chronic 4; H413 Skin Sens. 1A; H317	1-2

Additional information: None

Full Text of H and EUH statements: See section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

Following inhalation:

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 3 of 17

Surgical Guide Resin

If inhaled, remove person to fresh air and place in a position comfortable for breathing. If respiratory symptoms develop or persist, seek medical advice/attention.

Following skin contact:

Wash affected area with plenty of soap and water. Remove contaminated clothing and launder before reuse. If skin irritation develops or persists, seek medical advice/attention.

Following eye contact:

Immediately rinse eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 15 minutes. If eye irritation develops or persists, seek medical advice/attention.

Following ingestion:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Self-Protection of the first aider:

Not determined or not available.

4.2 Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

Skin contact may result in redness, pain, burning and inflammation.

Eye contact may result in irritation, redness, pain, inflammation, itching, burning and tearing.

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

4.3 Indication of any immediate medical attention and special treatment needed

Specific treatment:

Not determined or not available.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

5.2 Special hazards arising from the substance or mixture:

Thermal decomposition may produce irritating/toxic fumes/gases.

5.3 Advice for firefighters

Personal protection equipment:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA).

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts.

Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers.

Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 4 of 17

Surgical Guide Resin

6.1 Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

6.2 Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

6.4 Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

7.2 Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

7.3 Specific end use(s):

Refer to Section 1 (Recommended Use).

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Only those substances with limit values have been included below.

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
Lithuania	2-hydroxyethyl methacrylate	868-77-9	8-Hour TWA: 20 mg/m ³

Biological limit values:

No biological exposure limits noted for the ingredient(s).

Derived No Effect Level (DNEL):

Ingredient Name: 2-hydroxyethyl methacrylate

CAS #: 868-77-9

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 5 of 17

Surgical Guide Resin

Workers - Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	4.9 mg/m ³
	Chronic - Dermal	1.3 mg/kg bw/day
Workers - Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	0.83 mg/kg bw/day
	Chronic - Inhalation	2.9 mg/m ³
	Chronic - Dermal	0.83 mg/kg bw/day
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No hazard identified
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No hazard identified
	Chronic - Dermal	No hazard identified

Ingredient Name: Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

CAS #: 162881-26-7

Workers - Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	Not determined or not applicable.
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	21 mg/m ³
	Chronic - Dermal	3 mg/kg bw/day
Workers - Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	Not determined or not applicable.
	Acute - Dermal	Hazard identified but no DNEL available
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	Not determined or not applicable.
	Chronic - Dermal	Hazard identified but no DNEL available

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 6 of 17

Surgical Guide Resin

General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	Not determined or not applicable.
	Acute - Dermal	No hazard identified
	Chronic - Oral	1.5 mg/kg bw/day
	Chronic - Inhalation	5.2 mg/m ³
	Chronic - Dermal	1.5 mg/kg bw/day
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	Not determined or not applicable.
	Acute - Dermal	Hazard identified but no DNEL available
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	Not determined or not applicable.
	Chronic - Dermal	Hazard identified but no DNEL available

Ingredient Name: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

CAS #: 72869-86-4

Workers - Systemic Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No exposure expected
	Acute - Dermal	No hazard identified
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	3.3 mg/m ³
	Chronic - Dermal	1.3 mg/kg bw/day
Workers - Local Effects	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No exposure expected
	Acute - Dermal	Hazard identified but no DNEL available
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No exposure expected
	Chronic - Dermal	Hazard identified but no DNEL available
General Population - Systemic Effects	Acute - Oral	No hazard identified
	Acute - Inhalation	No exposure expected
	Acute - Dermal	No hazard identified
	Chronic - Oral	0.3 mg/kg bw/day
	Chronic - Inhalation	0.6 mg/m ³
	Chronic - Dermal	0.7 mg/kg bw/day
General Population - Local Effect	Acute - Oral	Not determined or not applicable.
	Acute - Inhalation	No exposure expected
	Acute - Dermal	No exposure expected
	Chronic - Oral	Not determined or not applicable.
	Chronic - Inhalation	No exposure expected
	Chronic - Dermal	Hazard identified but no DNEL available

Predicted No Effect Concentration (PNEC):

Ingredient Name: 2-hydroxyethyl methacrylate

CAS #: 868-77-9

Environmental Protection Target	PNEC
Fresh water	0.482 mg/L

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 7 of 17

Surgical Guide Resin

Freshwater sediments	3.79 mg/kg
Marine water	0.482 mg/L
Marine sediments	3.79 mg/kg
Microorganisms in sewage treatment	10 mg/L
Soil (agricultural)	0.476 mg/kg
Air	No hazard identified

Ingredient Name: Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

CAS #: 162881-26-7

Environmental Protection Target	PNEC
Fresh water	0.8 µg/L
Freshwater sediments	0.712 mg/kg
Marine water	0.8 µg/L
Marine sediments	0.712 mg/kg
Microorganisms in sewage treatment	Not determined or not available.
Soil (agricultural)	0.012 mg/kg soil dw
Air	No hazard identified
Oral (Secondary Poisoning)	No exposure expected

Ingredient Name: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

CAS #: 72869-86-4

Environmental Protection Target	PNEC
Fresh water	0.01 mg/L
Freshwater sediments	4.56 mg/kg sediment dw
Marine water	0.001 mg/L
Marine sediments	0.46 mg/kg sediment dw
Microorganisms in sewage treatment	3.61 mg/L
Soil (agricultural)	0.91 mg/kg soil dw
Air	No hazard identified
Oral (Secondary Poisoning)	No exposure expected

Information on monitoring procedures:

Not determined or not applicable.

8.2 Exposure controls

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 8 of 17

Surgical Guide Resin

specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

Environmental exposure controls:

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Product (substance / mixture) related measures to prevent exposure:	Not determined or not applicable.
Instruction measures to prevent exposure:	Not determined or not applicable.
Organisational measures to prevent exposure:	Not determined or not applicable.
Technical measures to prevent exposure:	Not determined or not applicable.

Risk management measures to control exposure:

Not determined or not applicable.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical State	Transparent Liquid
Color	Yellow
Odor/Odor threshold	Characteristic acrylate
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	>100°C (>212°F)
Flash point (closed cup)	>93.5°C (>199.4°F)
Flammability	Not flammable
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Relative vapor density	Not determined or not available.
Density	1.09 g/cm ³
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.

9.2 Other information

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 9 of 17

Surgical Guide Resin

9.2.1 Information with regard to physical hazard classes

Explosives	No data available
Flammable gases	No data available
Aerosols	No data available
Oxidizing gases	No data available
Gases under pressure	No data available
Flammable liquids	No data available
Flammable solids	No data available
Self-reactive substances and mixtures	No data available
Pyrophoric liquids	No data available
Pyrophoric solids	No data available
Self-heating substances and mixtures	No data available
Substances and mixtures, which emit flammable gases in contact with water	No data available
Oxidizing liquids	No data available
Oxidizing solids	No data available
Organic peroxides	No data available
Corrosive to metals	No data available
Desensitized explosives	No data available

9.2.2 Other safety characteristics

None.

SECTION 10: Stability and reactivity

10.1 Reactivity:

Not reactive under recommended handling and storage conditions.

10.2 Chemical stability:

Stable under recommended handling and storage conditions.

Store the containers at 10 - 25 °C (50 - 77 °F).

10.3 Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Stable under recommended handling and storage conditions.

10.4 Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Do not exceed 25 °C (77 °F) when in storage

10.5 Incompatible materials:

Polymerization initiators, including peroxides, strong oxidizing agents, alcohols, copper, copper alloys, carbon steel, iron, rust, and strong bases.

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

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 10 of 17

Surgical Guide Resin

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
2-hydroxyethyl methacrylate	oral	LD50 Rat: 5564 mg/kg
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	oral	LD50 Rat: >2000 mg/kg
	dermal	LD50 Rat: >2000 mg/kg
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rat: >2000 mg/kg

Skin corrosion/irritation

Assessment:

Causes skin irritation.

Product data:

No data available.

Substance data:

Name	Result
2-hydroxyethyl methacrylate	Causes skin irritation.

Serious eye damage/irritation

Assessment:

Causes serious eye irritation.

Product data:

No data available.

Substance data:

Name	Result
2-hydroxyethyl methacrylate	Causes serious eye irritation.

Respiratory or skin sensitization

Assessment:

May cause an allergic skin reaction.

Product data:

No data available.

Substance data:

Name	Result
2-hydroxyethyl methacrylate	May cause an allergic skin reaction.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	May cause an allergic skin reaction.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	May cause an allergic skin reaction.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 11 of 17

Surgical Guide Resin

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC):

Name	Classification
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Not Applicable
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Not Applicable

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

Reproductive Toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (single exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Information on likely routes of exposure:

No data available.

Symptoms related to the physical, chemical and toxicological characteristics:

No data available.

11.2 Information on other hazards

Endocrine disrupting properties:

Substance data: No data available.

Other information:

No data available.

SECTION 12: Ecological information

12.1 Toxicity

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 12 of 17

Surgical Guide Resin

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Aquatic Plants EC50 Green algae: >0.26 mg/L (72 hr [growth rate])
	Fish LC50 Freshwater fish: >0.09 mg/L (96 hr)
	Aquatic Invertebrates EC50 Not specified: >1.175 mg/L (48 hr [mobility])
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Fish LC50 Danio rerio: 10.1 mg/L (96 hr)
	Aquatic Invertebrates EC50 Daphnia magna: > 1.2 mg/L (48 hr)

Chronic (long-term) toxicity

Assessment:

Toxic to aquatic life with long lasting effects.

Product data: No data available.

Substance data:

Name	Result
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	Aquatic Plants NOEC Desmodium subspicatus: 0.21 mg/L (72 hr)

12.2 Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
2-hydroxyethyl methacrylate	This substance is considered readily biodegradable.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	This substance is not readily biodegradable. No degradation was observed during 28 day test period.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	The substance is not readily biodegradable (22% degradation in 28 days).

12.3 Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
2-hydroxyethyl methacrylate	This substance has low potential to bioaccumulate.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Bioaccumulation is not expected. BCF (aquatic species): 5 dimensionless

12.4 Mobility in soil

Product data: No data available.

Substance data:

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 13 of 17

Surgical Guide Resin

Name	Result
2-hydroxyethyl methacrylate	This substance has low potential to be adsorbed by the soil.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Based upon the log Koc of 3.85 an adsorption to the soil is expected.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	The substance has moderate potential to adsorb to organic soil and sediment particles (log Koc: 3.66 dimensionless).

12.5 Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

2-hydroxyethyl methacrylate	This substance is not PBT.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	This substance is not PBT.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	This substance is not PBT.

vPvB assessment:

2-hydroxyethyl methacrylate	This substance is not vPvB.
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	This substance is not vPvB.
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	This substance is not vPvB.

12.6 Endocrine disrupting properties

Substance data: No data available.

12.7 Other adverse effects: No data available.

12.8 Hazard to the ozone layer

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

13.1.1 Product / Packaging disposal:

Dispose contaminated packages in a safe manner in accordance with local and national regulations. Do not allow the product to be released into the environment.

Waste codes / waste designations according to LoW: Not determined or not available.

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 14 of 17

Surgical Guide Resin

13.1.2 Waste treatment-relevant information: Not determined or not available.


13.1.3 Sewage disposal-relevant information: Not determined or not available.

13.1.4 Other disposal recommendations:

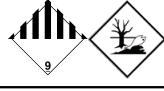
Do not discharge into public wastewater or surface waters. It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities.

SECTION 14: Transport information

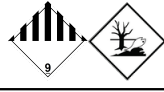
International Carriage of Dangerous Goods by Road/Rail (ADR/RID)

UN number or ID number	UN 3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. Urethane dimethacrylate
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant
Special precautions for user	None
Additional Information	This product is not regulated as a dangerous good when a single unit is transported in container sizes of ≤5 L provided the packaging meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

International Carriage of Dangerous Goods by Inland Waterways (ADN)

UN number or ID number	UN 3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. Urethane dimethacrylate
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant
Special precautions for user	None
Additional Information	This product is not regulated as a dangerous good when a single unit is transported in container sizes of ≤5 L provided the packaging meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

International Maritime Dangerous Goods (IMDG)

UN number or ID number	UN 3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. Urethane dimethacrylate
UN transport hazard class(es)	9 
Packing group	III
Environmental hazards	Marine Pollutant
Special precautions for user	None

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 15 of 17

Surgical Guide Resin

Additional Information	This product is not regulated as a dangerous good when a single unit is transported in container sizes of ≤ 5 L provided the packaging meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.
-------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number or ID number	UN 3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. Urethane dimethacrylate
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	Marine Pollutant
Special precautions for user	None
Additional Information	This product is not regulated as a dangerous good when a single unit is transported in container sizes of ≤ 5 L provided the packaging meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

Maritime Transport in Bulk according to IMO Instruments

Bulk Name	None
Ship type	None
Pollution category	None
IMO hazard class	None
Environmental hazards	None
Material hazardous only in bulk	None
Cargo Group	None

SECTION 15: Regulatory information

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

European regulations

Inventory listing (EINECS):

868-77-9	2-hydroxyethyl methacrylate	Listed
162881-26-7	Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Not Listed
162881-26-7	Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	Not Listed
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	Listed

REACH SVHC candidate list: None of the ingredients are listed.

REACH SVHC Authorizations: None of the ingredients are listed.

REACH Restriction: None of the ingredients are listed.

Water hazard class (WGK) (Product): Not determined.

Water hazard class (WGK) (Substance):

Ingredient Name	CAS	Class
2-hydroxyethyl methacrylate	868-77-9	Water hazard class 1: slightly hazardous to water

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 16 of 17

Surgical Guide Resin

Ingredient Name	CAS	Class
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	Water hazard class 1: slightly hazardous to water
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	Water hazard class 1: slightly hazardous to water

Other regulations

Germany TA Luft: None of the ingredients are listed.

Additional information: Not determined.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: Other information

Abbreviations and Acronyms: None

Classification procedure:

Classification according to Regulation (EC) No. 1272/2008 (CLP)	Method Used
Skin irritation, category 2	Calculation method
Eye Irritation, category 2	Calculation method
Skin sensitization, category 1	Calculation method
Chronic aquatic hazard, category 2	Calculation method

Summary of classification(s) in section 3:

Skin Sens. 1	Skin sensitization, category 1
Aquatic Chronic 2	Chronic aquatic hazard, category 2
Skin Irrit. 2	Skin irritation, category 2
Eye Irrit. 2	Eye Irritation, category 2
Aquatic Chronic 4	Chronic aquatic hazard, category 4
Skin Sens. 1A	Skin sensitization, category 1A

Summary of hazard statements in section 3:

H317	May cause an allergic skin reaction
H411	Toxic to aquatic life with long lasting effects
H315	Causes skin irritation
H319	Causes serious eye irritation
H413	May cause long lasting harmful effects to aquatic life

Disclaimer:

This product has been classified in accordance with EC No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and EC No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation, and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

Initial preparation date: 12.29.2022

Safety Data Sheet

According to Regulation (EC) No. 1272/2008 (CLP), as amended by Commission Regulation (EU) 2019/521 and Commission Delegated Regulation (EU) 2020/217, and (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878.

Initial preparation date: 12.29.2022

Page 17 of 17

Surgical Guide Resin

End of Safety Data Sheet