

Dental Model

SAFETY DATA SHEET

Prepared: 15/03/2017 Version: 1



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

1.1 Product identifier

Product name : Dental Model **Product code** : Not available.

Mixture of acrylic and methacrylic acid esters, photoinitiators, proprietary pigment **Product description**

and additive package.

Product type : Liquid.

: Not available. Other means of

identification

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

Identified uses : Photoreactive Resin for Form 1+, Form 2.

1.3 Details of the supplier of the safety data sheet

Supplier's details : Formlabs, Inc. Formlabs GmbH

> 35 Medford Street, Suite #201 Greifswalder Strasse 212

Somerville, MA 10405 Berlin USA Germany

+1 617 932 5227 +49 30 308 06718

E-mail address of : sds@formlabs.com

person responsible for

this SDS

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : North America call +1 800 255 3924

Worldwide Intl. call +01 813 248 0585

Reference MIS4707563

Hours of operation : 24/7

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture.

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

Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT SE 3, H335

Aquatic Chronic 3, H412

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms



Signal word : Warning

Hazard statements : H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction. H335 - May cause respiratory irritation.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention : P280 - Wear protective gloves.

P273 - Avoid release to the environment.

P261 - Avoid breathing vapour.

P304 + P340 + P312 - IF INHALED: Remove person to fresh air and keep

comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.

Storage : P405 - Store locked up.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

Hazardous ingredients : Methacrylated monomers

Methacrylated oligomers

Photoinitiators

Supplemental label

elements

Response

: Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant

fastenings

: Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification

: None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

| CI | ass | itic | at | ion |
|----|-----|------|----|-----|
| | | | | |

| Product/ingredient name | Identifiers | % | Regulation (EC) n. 1272/2008 [CLP] | Туре |
|-------------------------|-----------------------------|-------------|--|------|
| Methacrylated monomers | Proprietary or not assigned | Proprietary | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Aquatic Chronic 3, H412 | [1] |
| Methacrylated oligomers | Proprietary or not assigned | Proprietary | Eye Irrit. 2, H319 STOT SE3, H335 | [1] |
| Photoinitiators | Proprietary or not assigned | Proprietary | Skin Sens. 1, H317 Aquatic Chronic 2, H411 | [1] |
| | | | See Section 16 for the full text of the H statements declared above. | |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

| 4.1 Description of first | aid measures |
|--------------------------|---|
| Eye contact | : Immediately flush 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 20 minutes. Get medical attention. |
| Inhalation | : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison centre or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. |
| Skin contact | : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse. |

Ingestion

: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first-aiders

: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : May cause respiratory irritation.

Skin contact: Causes skin irritation. May cause an allergic skin reaction.

Ingestion: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:

pain or irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact : Adverse symptoms may include the following:

irritation redness

Ingestion : No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing

media

: None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture

: This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being

discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products

: No specific data.

5.3 Advice for firefighters

Special protective actions for fire-fighters

: No special measures are required.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders

: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.

6.3 Methods and material for containment and cleaning up

Small spill

: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill

Stop leak if without risk. Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

6.4 Reference to other sections

See Section 1 for emergency contact information.

See Section 8 for information on appropriate personal protective equipment.

See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures

Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapour or mist. Avoid release to the environment. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific : Not available.

solutions

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures

: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNEL/DMEL

No DNELs/DMELs available.

PNEC

No PNEC available.

8.2 Exposure controls

Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below and recommended or statutory limits.

Individual protection measures Hygiene measures

Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: 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 specialist before handling this product.

Other skin protection

Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid.
Colour : Beige

Odour : Light/Characteristic/Acrylate.

Odour threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

Initial boiling point and boiling range

>100°C

Flash point : Closed cup: >100°C [Pensky-Martens.]

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Upper/lower flammability : Not available.

or explosive limits

Vapour pressure : Not available.
Vapour density : Not available.
Relative density : 1.08 to 1.09
Solubility(ies) : Not available
Partition coefficient: : Not available.

n-octanol/water

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Kinematic (room temperature): 8.5 to 9 cm²/s

Explosive properties : Not available. **Oxidising properties** : Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : Stable when stored in original container designed for use with light sensitive materials

under 35°C (95°F) in dark, cool place.

10.3 Possibility of Hazardous polymerization may occur. Uncontrolled polymerization may cause rapid hazardous reactions evolution of heat and increase in pressure that could result in violent rupture of sealed

storage vessels or containers.

10.4 Conditions to avoid Storage >100°F, exposure to light, loss of dissolved air, and contamination with

incompatible materials.

10.5 Incompatible materials Polymerization initiators, including peroxides, strong oxidizing agents, alcohols, copper,

copper alloys, carbon steel, iron, rust, and strong bases.

Hazardous decomposition products may include oxides of carbon, nitrogen and 10.6 Hazardous decomposition products

various hydrocarbon fragments.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitisation

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Product/ingredient name

Methacrylated oligomers

Specific target organ toxicity (single exposure)

Route of exposure

Not applicable

Specific target organ toxicity (repeated exposure)

Category

Category 3

There is no data available.

Target organs

Respiratory tract irritation

Aspiration hazard

There is no data available.

Information on likely routes of exposure

: Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : May cause respiratory irritation.

Skin contact: Causes skin irritation. May cause an allergic skin reaction.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Adverse symptoms may include the following:

pain or irritation watering redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to

very low levels.

Carcinogenicity
 No known significant effects or critical hazards.
 Mutagenicity
 No known significant effects or critical hazards.
 Teratogenicity
 No known significant effects or critical hazards.
 Developmental effects
 No known significant effects or critical hazards.
 Fertility effects
 No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

There is no data available.

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

There is no data available.

12.4 Mobility in soil

Soil/water partition

: Not available.

coefficient (KOC)

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal

: The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste

: The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal

: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions

This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

| | ADR/RID | ADN | IMDG | IATA |
|---------------------------------|----------------|----------------|----------------|----------------|
| 14.1 UN number | Not regulated. | Not regulated. | Not regulated. | Not regulated. |
| 14.2 UN proper shipping name | - | - | - | - |
| 14.3 Transport hazard class(es) | - | - | - | - |
| 14.4 Packing group | - | - | - | - |
| 14.5 Environmental hazards | No. | No. | No. | No. |
| Additional information | - | - | - | - |

14.6 Special precautions

for user

: Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable. on the manufacture, placing on the market

dangerous substances, mixtures and articles

Other EU regulations

and use of certain

Europe inventory : Not determined.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

D.Lqs. 152/06 : Not classified.

15.2 Chemical safety

assessment

: This product contains substances for which Chemical Safety Assessments

are still required.

SECTION 16: Other information

 ATE = Acute Toxicity Estimate Abbreviations and acronyms

CLP = Classification, Labelling and Packaging Regulation (Regulation (EC) No.

DMEL = Derived Minimal Effect Level DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement PBT = Persistent, Bioaccumulative and Toxic PNEC = Predicted No Effect Concentration RRN = REACH Registration Number

vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification

Justification Skin Irrit. 2, H315 Calculation method Skin Sens. 1, H317 Calculation method **STOT SE 3, H335** Calculation method Aquatic Chronic 3, H412 Calculation method

Full text of abbreviated

H statements

Causes skin irritation. : H315 May cause an allergic skin reaction. H317 Causes serious eye irritation. H319 May cause respiratory irritation. H335

Toxic to aquatic life with long lasting effects. H411 Harmful to aquatic life with long lasting effects. H412

Full text of classifications

[CLP/GHS]

: Aquatic Chronic 2, H411

Aquatic Chronic 3, H412

Eye Irrit. 2, H319 Skin Irrit. 2, H315 LONG-TERM AQUATIC HAZARD - Category 2 LONG-TERM AQUATIC HAZARD - Category 3

SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 SKIN CORROSION/IRRITATION - Category 2

SKIN SENSITISATION - Category 1 Skin Sens. 1, H317

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE STOT SE 3, H335

(Respiratory tract irritation) - Category 3

History

: 15/03/2017 Date of issue (dd/mm/yyyy)

Version

Prepared by : KMK Regulatory Services Inc.

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.