

SAFETY DATA SHEET

DentaMODEL

SECTION 1: IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product Identifier: **DentaMODEL**
- 1.2. Relevant identified uses of the mixture and uses advised against:
For use in Asiga DLP Printer. For use in 3D printer. For professional and consumer use.
- 1.3. Details of the supplier of the safety data sheet:
Manufacturer:
ASIGA
Unit 2, 19-21 Bourke Road,
Alexandria, NSW 2015
Tel.: +61 2 9690 2737
- Importer:**
Ivoclar Vivadent Ltd
12 Omega St, Rosedale,
Auckland, New Zealand,
Tel: +64 9 914 9999 Fax: +64 9 914 9990
- 1.3.1. Responsible person E-mail: info@asiga.com www.ivoclarvivadent.co.nz
- 1.4. Emergency Telephone Number: Poison Center Worldwide Intl. call +01 813 248 0585 or
National Poison Centre: 0800 764 766

SECTION 2: HAZARDS IDENTIFICATION

- 2.1. Classification of the mixture:

Classification according to Regulation 1272/2008/EC (CLP):
Skin corrosion/irritation, Hazard Category 2 – H315
Sensitisation - Skin, hazard category 1 – H317
Serious eye damage/eye irritation, Hazard Category 2 – H319
Specific target organ toxicity – Single exposure, Hazard Category 3, Respiratory tract irritation – H335
Reproductive toxicity, Hazard Category 2 - H361f
Hazardous to the aquatic environment – Chronic Hazard, Category 3 – H412

Warning H statements:

H315 – Causes skin irritation.
H317 – May cause an allergic skin reaction.
H319 – Causes serious eye irritation.
H335 – May cause respiratory irritation.
H361f – Suspected of damaging fertility (causing atrophy of the testes).
H412 – Harmful to aquatic life with long lasting effects.

- 2.2. Label elements:

Components which define the hazards: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane- 1,16-diyl bismethacrylate; Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide; Tetrahydrofurfuryl methacrylate



Warning H statements:

H315 – Causes skin irritation.
H317 – May cause an allergic skin reaction.
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H335 – May cause respiratory irritation.
H361f – Suspected of damaging fertility (causing atrophy of the testes).
H412 – Harmful to aquatic life with long lasting effects.

Precautionary P statements:

- P201** – Obtain special instructions before use.
P202 – Do not handle until all safety precautions have been read and understood.
P261 – Avoid breathing dust/ fume/gas/mist/vapours/spray.
P273 – Avoid release to the environment.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.
P308 + P313 – IF exposed or concerned: Get medical advice/attention.
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.
P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P501 – Dispose of contents/container in accordance with local regulations.

2.3. Other hazards:

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions.
 Results of PBT and vPvB assessment: no data available.

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Substance : Not applicable.

3.2. Mixture:

| Description | CAS number | EU number/ ECHA list number | REACH reg. nr. | Conc. (%) | Classification: 1272/2008/EC (CLP) | | |
|--|------------|-----------------------------------|-------------------|--------------|------------------------------------|--|--|
| | | | | | Hazard pict. | Hazard cat. | H phrase |
| 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate* | 72869-86-4 | 276-957-5 | - | 10 – 25 | GHS07 GHS09 Warning | Skin Sens. 1 Aquatic Chronic 2 | H317 H411 |
| Tetrahydrofurfuryl methacrylate* | 2455-24-5 | 219-529-5 | - | 10 – 20 | GHS07 Warning | Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 | H315 H319 H335 |
| Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide Index: 015-203-00-X | 75980-60-8 | 278-355-8 | - | 10 – 20 | GHS08 Warning | Repr. 2 | H361f (causing atrophy of the testes) |

*: Substance classified by the manufacturer or substance which has no obligatory classification according to the EU regulations.

For the full text of H phrases: see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures:

IN CASE OF INGESTION:

Measures:

- Do NOT induce vomiting.
- Drink plenty of water and seek medical treatment.

IN CASE OF INHALATION:

Measures:

- Move affected person to fresh air.
- If respiratory irritation occurs, if breathing becomes difficult seek medical attention immediately.

IN CASE OF SKIN CONTACT:

Measures:

- In case of contact with skin, wash off with soap and water.
- Immediately remove any contaminated clothing, shoes or stockings.
- Consult a doctor if skin irritation persists.

IN CASE OF EYE CONTACT:

Measures:

- In case of contact with eyes, rinse with plenty of water carefully.
 - In the event of persistent symptoms seek medical treatment.
- 4.2. **Most important symptoms and effects, both acute and delayed:** See section 11.
- 4.3. **Indication of any immediate medical attention and special treatment needed:** No special treatment needed, treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

- 5.1. **Extinguishing media:**
- 5.1.1. Suitable extinguishing media: Foam, dry powder or carbon dioxide.
- 5.1.2. Unsuitable extinguishing media: Full water jet.
- 5.2. **Special hazards arising from the substance or mixture:**
In case of fire, smoke and other combustion products may be formed, the inhalation of such combustion products can have serious adverse effects on health.
- 5.3. **Advise for firefighters:**
Use breathing apparatus with independent air supply.
Fire residues and contaminated firefighting water must be disposed of in accordance with local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- 6.1. **Personal precautions, protective equipment and emergency procedures:**
- 6.1.1. For non-emergency personnel: Keep unprotected people away, allow only well-trained experts wearing suitable protective clothing to abide in the field of accident.
- 6.1.2. For emergency responders: Use personal protective clothing. Keep away sources of ignition.
- 6.2. **Environmental precautions:** Do not discharge into the drains/surface waters/ground waters.
- 6.3. **Methods and material for containment and cleaning up:** Take up with absorbent material (e.g. diatomaceous earth).
- 6.4. **Reference to other sections:** For further and detailed information see section 8 and 13.

SECTION 7: HANDLING AND STORAGE

- 7.1. **Precautions for safe handling:**
Observe conventional hygiene precautions.
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Technical measures:
No special precautions.
Precautions against fire and explosion:
Keep away sources of ignition.
- 7.2. **Conditions for safe storage, including any incompatibilities:**
Technical measures and storage condition:
Keep container tightly closed.
Store at 5 to 40 °C (= 41 to 104 °F).
Incompatible materials: see section 10.5.
Packaging material: no special prescriptions.
- 7.3. **Specific end use(s):** No specific instructions available.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters:

Occupational exposure limit values:

The components of the mixture are not regulated with exposure limit value.

| DNEL | | <u>Routes of exposure</u> | <u>Exposure frequency:</u> | <u>Remarks:</u> |
|-------------------|-------------------|---------------------------|--|-------------------|
| Worker | Consumer | | | |
| no data available | no data available | Dermal | Short term (acute) Long term (repeated) | no data available |
| no data available | no data available | Inhalative | Short term (acute) Long term (repeated) | no data available |
| no data available | no data available | Oral | Short term (acute) Long term (repeated) | no data available |

| PNEC | | | <u>Exposure frequency:</u> | <u>Remarks:</u> |
|-------------------|-------------------|-------------------|---|-------------------|
| <u>Water</u> | <u>Soil</u> | <u>Air</u> | | |
| no data available | no data available | no data available | Short term (single use) Long term (continuous) | no data available |
| no data available | no data available | no data available | Short term (single use) Long term (continuous) | no data available |
| no data available | no data available | no data available | Short term (single use) Long term (continuous) | no data available |

8.2. Exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls:

In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.

Ensure adequate ventilation.

8.2.2. Individual protection measures, such as personal protective equipment:

Avoid contact with eyes and skin.

1. Eye/face protection: use appropriate safety goggles with side protection. (EN 166).
2. Skin protection:
 - a. Hand protection: use appropriate synthetic rubber gloves. (EN 374).
 - b. Other: no special precautions.
3. Respiratory protection: Respirators are generally not needed under normal conditions of use. If this product is handled at elevated temperature, under mist forming conditions or in case of accidental release of large quantities of product use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
4. Thermal hazards: none known.

8.2.3. Environmental exposure controls:

No specific prescription.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|------|--|--------------|----------|
| 9.1. | <u>Information on basic physical and chemical properties:</u> | Test method: | Remarks: |
| | Parameter | | |
| | 1. Appearance: | | |
| | 2. Odour: | | |
| | 3. Odour threshold: | | |
| | 4. pH value: | | |
| | 5. Melting point/ freezing point: | | |
| | 6. Initial boiling point and boiling range: | | |
| | 7. Flash point: | | |
| | 8. Evaporation rate: | | |
| | 9. Flammability (solid, gas): | | |
| | 10. Upper/lower flammability or explosive limits: | | |
| | 11. Vapour pressure: | | |
| | 12. Vapour density: | | |
| | 13. Relative density: | | |
| | 14. Solubility(ies): | | |
| | 15. Partition coefficient: n-octanol/water: | | |
| | 16. Auto-ignition temperature: | | |
| | 17. Decomposition temperature: | | |
| | 18. Viscosity: | dynamic | |
| | 19. Explosive properties: | | |
| | 20. Oxidizing properties: | | |
| 9.2. | <u>Other information:</u> No data available. *: The manufacturer did not carry out any tests on this parameter for the product or the results of the tests are not available at the time of publication of the data sheet. | | |

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity: See sections 10.3 – 10.5.
- 10.2. Chemical stability: See sections 10.3 – 10.5.
- 10.3. Possibility of hazardous reactions:
Reactions with light – risk of polymerization.
Reactions with peroxides and other radical components.
Additional information:
If unstable product polymerization is possible.
- 10.4. Conditions to avoid: Light.
- 10.5. Incompatible materials: Peroxides and other radical components.
- 10.6. Hazardous decomposition products: No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on toxicological effects:
Acute toxicity: Based on available data, the classification criteria are not met.
Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/eye irritation: Causes serious eye irritation.
Respiratory or skin sensitisation: May cause an allergic skin reaction.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Suspected of damaging fertility (causing atrophy of the testes).
STOT-single exposure: May cause respiratory irritation.
STOT-repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.
- 11.1.1. For substances subject to registration, brief summaries of the information derived from the test conducted:
No data available.
- 11.1.2. Relevant toxicological properties of the hazardous substances:
Acute toxicity: LD50 (oral): > 2000 mg/kg (rat OECD 401) (information concerns the main component)
Irritability/skin: Non-irritant (rabbit, OECD 404).
Irritability/eye: Non-irritant (rabbit eye, OECD 405).
- 11.1.3. Information on likely routes of exposure: Ingestion, inhalation, skin contact, eye contact.
- 11.1.4. Symptoms related to the physical, chemical and toxicological characteristics: No data available.

- 11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
May cause respiratory irritation.
Suspected of damaging fertility (causing atrophy of the testes).
- 11.1.6. Interactive effects: No data available.
- 11.1.7. Absence of specific data: Product has not been tested. The statement is derived from the properties of the components.
- 11.1.8. Other information: The classification of this mixture was performed based on the calculation method detailed in "General Classification guideline for mixtures of the EU" in the latest valid version.

SECTION 12: ECOLOGICAL INFORMATION

- 12.1. Toxicity:
Harmful to aquatic life with long lasting effects.
Do not allow uncontrolled leakage of product into the environment. Product is not allowed to be discharged into the ground water or aquatic environment.
- 12.2. Persistence and degradability: Not readily degradable.
- 12.3. Bioaccumulation potential: No data available.
- 12.4. Mobility in soil: No data available.
- 12.5. Results of PBT and vPvB assessment: No data available.
- 12.6. Other adverse effects:
Obtain approval of the relevant authorities before discharging into sewage treatment plants.
Water contaminating class (D): 1 - slightly water contaminating

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods:
Disposal according to the local regulations.
- 13.1.1. Information regarding the disposal of the product:
Do not allow to enter into surface water or drains.
Dispose of waste according to applicable legislation.
European Waste Code:
Waste code of waste from residues/unused products:
07 02 08* WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues
Waste code of used product:
07 02 08* WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues
*: hazardous waste.
- 13.1.2. Information regarding the disposal of the packaging:
This material and its container must be disposed of as hazardous waste.
Handle contaminated packages in the same way as the product itself.
European Waste Code:
Waste code of contaminated packaging:
07 02 08* WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; other still bottoms and reaction residues
*: hazardous waste.
- 13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified: None known.
- 13.1.4. Sewage disposal: None known.
- 13.1.5. Special precautions for any recommended waste treatment: No data available.

SECTION 14: TRANSPORT INFORMATION

ADR/RID; ADN; IMDG; IATA: Not dangerous good in sense of the transport regulations.

- 14.1. UN Number: None.
- 14.2. UN proper shipping name: None.
- 14.3. Transport hazard class(es): None.
- 14.4. Packaging group: None.
- 14.5. Environmental hazards: No relevant information available.
- 14.6. Special precautions for user: No relevant information available.
- 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code: Not applicable.

SECTION 15: REGULATORY INFORMATION

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

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria of the classifying hazardous substances [NOHSC: 1008] 3rd edition. Standard for the Uniform Scheduling of Medicines and Poisons.
Carcinogen classification under WHS Regulation 2011, Schedule 10.
Notification status in accordance with section 3 and current national legislation.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Information regarding the revision of the safety data sheet: none.

Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction. PBT: Persistent, bioaccumulative and toxic. vPvB: Very Persistent, Very Bioaccumulative. n.d.: not defined. n.a.: not applicable. ADR: European agreement concerning the carriage of dangerous goods by road. RID: Regulation concerning the international transport of dangerous goods by train. ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways. IMDG: International maritime code for dangerous goods. IATA DGR: International air transport association dangerous goods regulation.

Data sources:

safety data sheet (dated 03.11.2020., version 1.4) issued by the manufacturer.

Methods used for the classification according to Regulation 1272/2008/EC:

| | |
|--|-----------------------------|
| Skin corrosion/irritation, Hazard Category 2 – H315 | Based on calculation method |
| Sensitisation - Skin, hazard category 1 – H317 | Based on calculation method |
| Serious eye damage/eye irritation, Hazard Category 2 – H319 | Based on calculation method |
| Specific target organ toxicity – Single exposure, Hazard Category 3, Respiratory tract irritation – H335 | Based on calculation method |
| Reproductive toxicity, Hazard Category 2 – H361f | Based on calculation method |
| Hazardous to the aquatic environment – Chronic Hazard, Category 3 – H412 | Based on calculation method |

Relevant H-Phrases (number and full text) of Section 2 and 3:

- H315** – Causes skin irritation.
- H317** – May cause an allergic skin reaction.
- H319** – Causes serious eye irritation.
- H335** – May cause respiratory irritation.
- H361f** – Suspected of damaging fertility.
- H411** – Toxic to aquatic life with long lasting effects.
- H412** – Harmful to aquatic life with long lasting effects.

Training advice: no data available.

Disclaimer: -

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