

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 2/6/2024 Revision date: 2/6/2024 Supersedes version of: 7/7/2022 Version: 2.1

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

1.1. Product identifier

Product form : Mixture

Trade name : LUX 3D MODEL 4K
Product code : 0100-CR11

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only

Dental laboratories

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FAMADENT S.L.U.

Garrotxa, 6 Polígono Empordà Internacional

ES 17469 Vilamalla

España

T +34 972 526 169

protechno@protechno.com, www.protechno.com

E-mail address of competent person responsible for the SDS : SDS@protechno.com

1.4. Emergency telephone number

Emergency number : +34 972 526 169

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317 Hazardous to the aquatic environment – Chronic Hazard, H412

Category 3

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

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H317 - May cause an allergic skin reaction.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P261 - Avoid breathing vapours.

P280 - Wear eye protection, protective gloves.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P501 - Dispose of contents and container to an approved waste disposal plant.

P273 - Avoid release to the environment.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3. Other hazards

Other hazards which do not result in classification : Product polymerizes slowly by contact with sunlight or other light.

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---------|---|
| Urethane methacrylate | CAS-No.: 72869-86-4 EC-No.: 276-957-5 | 10 – 50 | Skin Sens. 1B, H317 |
| Bisphenol A polyethylene glycol diether dimethacrylate | CAS-No.: 41637-38-1 EC-No.: 609-946-4 | 10 – 50 | Aquatic Chronic 4, H413 |
| (octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate | CAS-No.: 43048-08-4 EC-No.: 256-062-6 | 1 – 10 | Skin Sens. 1B, H317 Aquatic Chronic 2, H411 |
| Photoinitiator | CAS-No.: PROPIETARY | 1 – 10 | Aquatic Chronic 2, H411 |
| Photoinitiator | CAS-No.: PROPIETARY | 0.1 – 1 | Skin Sens. 1, H317 |
| BAPO Bisacylphosphane oxide | CAS-No.: 162881-26-7 EC-No.: 423-340-5 EC Index-No.: 015-189-00-5 | 0.1 – 1 | Skin Sens. 1A, H317 Aquatic Chronic 4, H413 |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a

doctor if you feel unwell.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water,

followed by warm water rinse. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : Immediately rinse with water for a prolonged period while holding the eyelids wide open.

Remove contact lenses, if present and easy to do. Continue rinsing. Consult an eye

specialist.

First-aid measures after ingestion : Do NOT induce vomiting. Get medical advice/attention. Never give anything by mouth to an

unconscious person.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

2/6/2024 (Revision date) EN (English) 2/9

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing measures appropriate to the source of the fire. Water spray. dry chemical

powder, alcohol-resistant foam, carbon dioxide (CO2).

Unsuitable extinguishing media : Strong water jet.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing. Use water stream to cool containers.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin and eyes.

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Do not allow to enter drains or water courses.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Collect in closed containers for disposal.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Use only by appropriate trained persons. Ensure good ventilation of the work station. Wear

personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the

product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool. Keep in original containers closed. Protect from

heat and direct sunlight. Keep away from food, drink and animal feeding stuffs.

Storage temperature : \leq 40 °C

7.3. Specific end use(s)

No additional information available

2/6/2024 (Revision date) EN (English) 3/9

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Common hygienic measures in a dental laboratory. Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Eye protection (goggles)

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Wear protective gloves. Nitrile-rubber protective gloves. Gloves must be replaced after each use and whenever signs of wear or perforation appear

8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : (Dependent on composition).

Odour : Characteristic.

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Odour threshold : Not available Melting point : Not applicable Freezing point : Not available : Not available Boiling point Flammability : Not applicable Lower explosion limit Not available Upper explosion limit Not available Flash point : > 100 °C Auto-ignition temperature : Not available Decomposition temperature : Not available : Not available рΗ Viscosity, kinematic Not available

Solubility : immiscible and insoluble.

Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure : Not available Vapour pressure at 50°C : Not available Density : Not available Relative density : 1.13 – 1.15 Relative vapour density at 20°C : Not available Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. May polymerise.

10.4. Conditions to avoid

Protect from sunlight. Keep away from heat, sparks and flame.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified
Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

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

(acute)

Hazardous to the aquatic environment, long-term : Harmful to aquatic life with long lasting effects.

(chronic)

12.2. Persistence and degradability

| Persistence and degradability | Rapidly degradable | |
|--|--------------------|--|
| Bisphenol A polyethylene glycol diether dimethacrylate (41637-38-1) | | |
| Persistence and degradability | Rapidly degradable | |
| (octahydro-4,7-methano-1H-indenediyl)bis(methylene) bismethacrylate (43048-08-4) | | |
| Persistence and degradability | Rapidly degradable | |
| Photoinitiator (PROPIETARY) | | |
| Persistence and degradability | Rapidly degradable | |
| Photoinitiator (PROPIETARY) | | |
| Persistence and degradability | Rapidly degradable | |
| Urethane methacrylate (72869-86-4) | | |
| Persistence and degradability Rapidly degradable | | |
| BAPO Bisacylphosphane oxide (162881-26-7) | | |
| Persistence and degradability | Rapidly degradable | |

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Product/Packaging disposal recommendations : Dispose of contents/container to an approved waste disposal plant. European List of Waste (LoW, EC 2000/532) : 16 03 05* - organic wastes containing dangerous substances

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

| ADR | IMDG | IATA | RID |
|--|---------------|---------------|---------------|
| 14.1. UN number or ID number | | | |
| Not regulated for transport | | | |
| 14.2. UN proper shipping name | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | | |
| Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available | | | |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

SDS EU format according to COMMISSION REGULATION (EU) 2020/878.

| Abbreviations and acronyms: | | |
|-----------------------------|---|--|
| | Spain - BLV | |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road | |
| ATE | Acute Toxicity Estimate | |
| BCF | Bioconcentration factor | |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 | |
| DMEL | Derived Minimal Effect level | |
| DNEL | Derived-No Effect Level | |
| DPD | Dangerous Preparations Directive 1999/45/EC | |
| EC50 | Median effective concentration | |
| DSD | Dangerous Substances Directive 67/548/EEC | |
| SDS | Safety Data Sheet | |
| IATA | International Air Transport Association | |
| IMDG | International Maritime Dangerous Goods | |
| LC50 | Median lethal concentration | |
| LD50 | Median lethal dose | |

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

| Abbreviations and acronyms: | | |
|-----------------------------|---|--|
| LOAEL | Lowest Observed Adverse Effect Level | |
| vPvB | Very Persistent and Very Bioaccumulative | |
| NOAEC | No-Observed Adverse Effect Concentration | |
| NOAEL | No-Observed Adverse Effect Level | |
| NOEC | No-Observed Effect Concentration | |
| PBT | Persistent Bioaccumulative Toxic | |
| PNEC | Predicted No-Effect Concentration | |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 | |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail | |
| TLM | Median Tolerance Limit | |

Data sources

: Classification according to Classification, Labelling and Packaging of Substances and Mixtures (SEA) Regulation published in the Official Journal numbered 28848 on December 11, 2013. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Training advice

: Normal use of this product shall imply use in accordance with the instructions on the packaging.

| Full text of H- and EUH-statements: | | |
|-------------------------------------|---|--|
| Aquatic Chronic 2 | Hazardous to the aquatic environment – Chronic Hazard, Category 2 | |
| Aquatic Chronic 4 | Hazardous to the aquatic environment – Chronic Hazard, Category 4 | |
| H317 | May cause an allergic skin reaction. | |
| H411 | Toxic to aquatic life with long lasting effects. | |
| H412 | Harmful to aquatic life with long lasting effects. | |
| H413 | May cause long lasting harmful effects to aquatic life. | |
| Skin Sens. 1 | Skin sensitisation, Category 1 | |
| Skin Sens. 1A | Skin sensitisation, category 1A | |
| Skin Sens. 1B | Skin sensitisation, category 1B | |

| Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: | | |
|---|------|--------------------|
| Skin Sens. 1 | H317 | Calculation method |
| Aquatic Chronic 3 | H412 | Calculation method |

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.