

Safety Data Sheet (SDS)

according to Regulation (EC) No 1907/2006, article 31*



1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **Plurafill**

Product type: Light-curing resin-based dental restorative material

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

Use of the substance or mixture: High-quality, light-curing nano-hybrid composite for the standard of care in the anterior and incisor region.

Uses advised against: Restricted to professional users.

1.3* Details of the supplier of the safety data sheet

Company name: Pluradent AG & Co KG

Street/Mailbox: Kaiserleistr. 3

Place: D-63067 Offenbach a.M.

Contact for technical information: Pluradent Vertrieb

Phone / Telefax / E-Mail:
+49 (0) 69-82983-0 / +49 (0) 69-82983-271 / regulatory.affairs@pluradent.de

1.4* Emergency telephone number

Germany: Giftnotruf Mainz - 24 Hour Service - Tel.: +49 (0) 6131/19240

2. Hazards identification

2.1 Classification of the substance or mixture

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



Skin Irrit. 2 - H315 Causes irritation.
Eye Irrit. 2 - H319 Causes serious eye irritation.
Skin Sens. 1 - H317 May cause an allergic skin reaction.

Classification according to Directive 67/548/EEC or 1999/45/EC:



X_i; Irritant, Sensibilized

R36/37/38 - Irritating to eyes, respiratory system and skin.
R43 - May cause sensitisation by skin contact.

2.2 Label elements

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

The product is classified and labelled according to the CLP regulation.

Hazard-determining components of labelling:

- Bis-GMA
- urethane dimethacrylate
- triethylene glycol dimethacrylate

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Hazard pictograms:



GHS07

Signal word : Warning

Hazard statements

H315 Causes severe skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P363 Wash contaminated clothing before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.
vPvB: Not applicable.

3. Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Dangerous components:

Chemical Name	Index-No. CAS-No. EC-No. Registr. No.	Classification according (67/548/EEC)	Classification according to Regulation EC No. 1272/2008)	Concen- tration (%)
ytterbium trifluoride	CAS: 13760-80-0 EINECS: 237-354-2	X _i – R36/37/38	Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; STOT SE 3 - H335;	10-<25 %
Bis-GMA	CAS-Nr.: 1565-94-2	X _i – R43	Skin Irrit. 2 – H315; Eye Irrit. 2 – H319; Skin Sens. 1 – H317;	3-<10 %
urethane dimethacrylate	CAS: 72869-86-4 EINECS: 276-957-5	X _i – R43	Eye Irrit. 2 - H319; Skin Sens. 1 - H317; Aquatic Chronic 3 - H412;	3-<10 %

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Chemical Name	Index-No. CAS-No. EC-No. Registr. No.	Classification according (67/548/EEC)	Classification according to Regulation EC No. 1272/2008)	Concentration (%)
triethylene glycol dimethacrylate	CAS: 109-16-0	X _i – R36/37/38	Skin Irrit. 2 - H315; Eye Irrit. 2 - H319; Skin Sens. 1 - H317; STOT SE 3 - H335;	3-<10 %

Additional information: For the wording of the listed risk phrases refer to section 16.

4. First aid measures



4.1 Description of first aid measures

General information

If you feel unwell, seek medical advice and demonstrate this material safety data sheet.

After inhalation

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

After skin contact

Rinse with water.

If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. Then consult a doctor.

After swallowing

Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

Unsuitable extinguishing media: -

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

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6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Not required.

6.2 Environmental precautions

Do not allow product to reach ground water, water course or sewage system.

6.3 Methods and material for containment and cleaning up

Pick up mechanically.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

Information about fire- and explosion-protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: -

Requirements for storage rooms and vessels: Store only in the original receptacle.

Advice on storage compatibility: Not required.

Further information about storage conditions:

Protect from exposure to the light.

Keep container tightly sealed.

7.3 Specific end use(s)

No further relevant information available.

8. Exposure controls/personal protection

8.1 Control parameters

8.1.1 Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the making were used as basis.

8.1.2. DNEL/PNEC-values

No further relevant information available.

8.1.3. Control-Banding

No further relevant information available.

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8.2 Exposure controls

8.2.1 Appropriate engineering controls

No further relevant information available.

8.2.2 Individual protection measures - Personal protective equipment

General protective and hygienic measures:

Usual hygienic measures for dental practice.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.

Respiratory protection: Not Required

Protection of hands



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.

Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Eye protection



Safety glasses

8.2.3 Environmental exposure controls:

General notes:

Do not allow product to reach ground water, water course or sewage system.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: - Form : - Colour : Odour : Odour threshold :	Pasty According to product specification characteristic Not determined
pH-value at 20 °C :	Not applicable
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	undetermined undetermined
Flash point : Flammability (solid, gaseous) : Evaporation rate : Auto-ignition temperature : Danger of explosion :	Not applicable Not applicable Not applicable Product is not self igniting. Product does not present an explosion hazard.

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Explosion limits	
- lower :	Not determined
- upper :	Not determined
Vapour pressure at 20°C :	Not determined
Vapour density :	Not determined
Density at 20 °C :	Not determined
Relative density :	Not determined
Solubility in / Miscibility with water :	Nearly insoluble.
Partition coefficient (n-octanol/water) :	Not determined
Viscosity	
dynamic :	Not determined
cinematic :	Not determined

9.2 Other information

No further relevant information available.

10. Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

Photoreactive (Danger of polymerization).
Stable under normal handling and storage conditions.

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Protect from exposure to the light.
Keep away from heat and direct sunlight.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

None under normal conditions of storage and use.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Primary irritant effect:

On the skin: Irritant to skin and mucous membranes.

On the eye: Irritating effect.

Sensitization: Sensitization possible through skin contact.

Germ cell mutagenicity

No further relevant information available.

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Carcinogenicity

No further relevant information available.

Reproductive toxicity

No further relevant information available.

Specific target organ toxicity - single exposure

No further relevant information available.

Specific target organ toxicity - repeated exposure

No further relevant information available.

Severe effects after repeated or prolonged exposure

No further relevant information available.

Aspiration hazard

No further relevant information available.

Additional toxicological information

No further relevant information available.

12. Ecological information

12.1 Toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects

No further relevant information available.

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13. Disposal considerations

13.1 Waste treatment methods

Recommendation:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Contaminated packaging:

Recommendation:

Disposal must be made according to official regulations.

Waste codes / waste designations according to EWC / AVV:

No further relevant information available.

Packaging:

Disposal must be made according to official regulations.

14. Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA

No hazardous material as defined by the transport regulations.

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA

No hazardous material as defined by the transport regulations.

14.3 Transport hazard class(es)

No hazardous material as defined by the transport regulations.

14.4 Packing group

ADR/RID, ADN, IMDG, IATA

No hazardous material as defined by the transport regulations.

14.5 Transport/Additional information:

No hazardous material as defined by the transport regulations.

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

Not applicable.

14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

14.9 UN "Model Regulation"

Not applicable.

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15. Regulatory information

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

EU regulations:

The product is a medical device and classified and labelled according to the CLP regulation. See Chapter 2.

National regulations:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The receiver of our product is solely responsible for adhering to existing laws and regulations.

Changes compared to the previous version

* Data changed compared to the previous version are marked with *.

Abbreviations and acronyms:

ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR	Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical Instructions by the "International Civil Aviation Organization" (ICAO)
IMDG	International Maritime Code for Dangerous Goods
IATA	International Air Transport Association
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
CAS	Chemical Abstracts Service (division of the American Chemical Society)
GefStoffV	Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC ₅₀	Lethal concentration, 50 percent
LD ₅₀	Lethal dose, 50 percent
EC ₅₀	half maximal effective concentration
NOEC	No Observed Effect Concentration

Skin Irrit.	Skin corrosion/irritation
Skin Sens.	Skin corrosion/irritation
Aquatic Chronic	Chronical aquatic toxicity
Eye Dam.	Serious eye damage/eye irritation
Eye Irrit.	Serious eye damage/eye irritation
STOT SE	Specific target organ toxicity - single exposure

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Relevant phrases

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

R36/37/38	Irritating to eyes, respiratory system and skin.
R43	May cause sensitization by skin contact.

Further information

Department issuing MSDS: Regulatory Affairs

The information contained in this security data sheet is based on our best knowledge and conscience on topically available information about the correct use of the product under normal conditions. The user is solely responsible for any other usage of this product in connection with other processes / procedures which is not described in this data sheet. This document does not show any explicit or implicit guarantee with regard to product quality or suitability for a certain purpose.