

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: **Pren blau PluLine**

Product type: precision impression material

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

Use of the substance or mixture: Low viscosity, thixotropic, elastomeric precision impression material based on polysiloxane. Base paste. For dental use.

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:

This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008.

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

This mixture is not classified as hazardous according to Directive 1999/45/EC.

2.2 Label elements

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

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

Hazard pictograms: none

Hazard statements: none

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.

vPvB: Not applicable.

No risks worthy of mention.

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3. Composition/information on ingredients

3.2 Mixtures

Description: Preparation of silicone polymers and fillers.

4. First aid measures



4.1 Description of first aid measures

After inhalation

Not applicable

After skin contact

In general the product is not skin irritative.

After eye contact

Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing

Seek medical attention if problems persist.

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 media: Water fog. Foam. Carbon dioxide (CO₂).

5.2 Special hazards arising from the substance or mixture

No release of hazardous substances.

5.3 Advice for firefighters

Extinguishing materials should be selected according to the surrounding area.

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

Collect mechanically.

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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

No special precautionary measures are necessary.

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: No special requirements are necessary.

Advice on storage compatibility: Not required.

Further information about storage conditions: No special requirements are necessary.

7.3 Specific end use(s)

For use by trained specialist staff.

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.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Not applicable.

8.2.2 Individual protection measures - Personal protective equipment

General protective and hygienic measures:

The usual precautions when handling chemicals have to be obtained.

Avoid contact with skin, eye and clothing.

Respiratory protection:

With correct and proper use, and under normal conditions, breathing protection is not required.

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Protection of hands



Protective gloves

Single-use gloves.

Suitable material: PE (polyethylene).

Unsuitable materials: NR (Natural rubber (Caoutchouc), Natural latex).

In the cases of special applications, it is recommended to check the chemical resistance with the manufacturer of the gloves.

Eye protection



Not required.

8.2.3 Environmental exposure controls:

Not required.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: - Form : - Colour : Odour : Odour threshold :	Paste product specific Odourless Not applicable
pH-value at 20 °C :	Neutral
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	Not applicable Not applicable
Flash point : Flammability (solid, gaseous) : Evaporation rate : Ignition temperature : Auto-ignition temperature : - Solid : - Gas : Decomposition temperature : Oxidizing properties Danger of explosion : Explosion limits - lower : - upper :	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable Product does not present an explosion hazard. Not applicable Not applicable
Vapour pressure at 20°C : Vapour density :	Not applicable Not applicable
Density at 20 °C :	Ca. 1,3 g/cm ³
Relative density :	Not applicable
Solubility in / Miscibility with water :	insoluble
Partition coefficient (n-octanol/water) :	Not applicable
Viscosity Dynamic at 23°C : cinematic :	Not applicable Not applicable

9.2 Other information

No further relevant information available.

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10. Stability and reactivity

10.1 Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2 Chemical Stability

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

None by intended use.

10.5 Incompatible materials

None by intended use.

10.6 Hazardous decomposition products

None by intended use.

Further information

Please pay attention to the Directions for Use.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

For the product itself a LD₅₀ (orally, species rat) of > 2000 mg/kg has been found.

Primary irritant effect:

On the skin: Not an irritant.

On the eye: Not an irritant.

Sensitization: No danger of sensitization.

Germ cell mutagenicity

No further relevant information available.

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.

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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

The product has not been tested.

12.2 Persistence and degradability

The product has not been tested.

12.3 Bioaccumulative potential

The product has not been tested.

12.4 Mobility in soil

The product has not been tested.

General notes:

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.

13. Disposal considerations

13.1 Waste treatment methods

Advise on disposal:

Do not allow product to reach ground water, water course or sewage system.
Disposal must be made according to official regulations.

Contaminated packaging:

Completely emptied packaging can be re-cycled.

Waste codes / waste designations according to EWC / AVV:

07 02 17 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, Synthetic rubber and man-made fibres; wastes containing silicones other than those mentioned in 07 02 16

20 03 99 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal wastes not otherwise specified

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Packaging:

Disposal must be made according to official regulations.

14. Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA

No dangerous good in sense of this transport regulation.

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA

No dangerous good in sense of this transport regulation.

14.3 Transport hazard class(es)

No dangerous good in sense of this transport regulation.

14.4 Packing group

ADR/RID, ADN, IMDG, IATA

No dangerous good in sense of this transport regulation.

14.5 Transport/Additional information:

No dangerous good in sense of this transport regulation.

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

14.9 UN "Model Regulation"

No dangerous good in sense of this transport regulation.

15. Regulatory information

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

EU regulations:

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

National regulations:

Water hazard class : 1 - slightly water contaminating
(German Regulation) (Self-assessment)

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15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

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
ErC ₅₀	EC ₅₀ in terms of reduction of growth rate.
EC ₅₀	The effective concentration of a substance that causes 50% of the maximum response.
NOEC	No Observed Effect Concentration

Relevant phrases

Not applicable.

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.