

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: **Gips- und Alginatlöser PluLine**

Product type: Plaster and Alginate Remover

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

Use of the substance or mixture: Plaster and Alginate Remover, ready for use.

Uses advised against: No information available.

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:



GHS07

Skin Irrit. 2 – H315 → Causes skin irritation.

Eye Irrit. 2 – H319 → Causes serious eye irritation.

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



Xi - Irritant

R38 Irritating to skin.

R36 Irritating to eyes.

Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

2.2 Label elements

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

Labelling for contents according to Regulation (EC) No 648/2004:

- >= 30 % EDTA and salts thereof

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Hazard pictograms:



GHS07

Signal word : Attention

Hazard statements

H319 Causes serious eye irritation.
H315 Causes skin irritation.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

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.

Chemical Characterization: complexing agent

Dangerous components:

Chemical Name	CAS-No. EC-No. REACH-No.	Classification according to Regulation EC No. 1272/2008	Concentration (%)
Disodium dihydrogen ethylene diamine tetra acetate	CAS-Nr.: 139-33-3 EINECS : 205-358-3 01-2119486775-20	Acute Tox. 4 – H332 STOT RE2 – H373	20 - 35 %
potassium carbonate	CAS-Nr.: 584-08-7 EINECS: 209-529-3 01-2119532646-36	Skin Irrit. 2 - H315 Eye Irrit. 2A - H319 STOT SE 3 - H335	2,5 – 9,5 %

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

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4. * First aid measures



4.1 Description of first aid measures

General information

Remove contaminated clothing and wash before reuse.

After inhalation

Provide fresh air. In all cases of doubt or when symptoms persist, seek medical advice.

After skin contact

Immediately wash with water and soap and rinse thoroughly. In case of skin irritation, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water. Remove contact lenses, if present and easy to do. Continue rinsing. In case of eye irritation, consult an ophthalmologist.

After swallowing

Rinse mouth immediately and drink plenty of water. Medical treatment necessary.

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

Treat symptomatically.

5. * Firefighting measures

5.1 Extinguishing media

The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

5.2 Special hazards arising from the substance or mixture

Thermal decomposition can lead to the escape of irritating gases and vapours.

5.3 Advice for firefighters

No special protective measures required.

6. * Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment.

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

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.

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7. * Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes.
When using do not eat, drink or smoke.

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

Further information on handling: Use personal protection equipment.

7.2 Conditions for safe storage, including any incompatibilities

Storage: -

Requirements for storage rooms and vessels: No special requirements.

Advice on storage compatibility: Not required.

Further information about storage conditions: Do not store at temperatures below 0 °C

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.

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.
Avoid contact with the eyes, skin and clothes.
Wash hands before breaks and at the end of work.
Keep away from food, drink and animal feedingstuffs.

Respiratory protection:

Usually no personal respirative protection necessary.
Use only in well-ventilated areas.

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Protection of hands



Protective gloves

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

Tested protective gloves must be worn

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material: 0,4 mm

Breakthrough time: > 480 min

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

Eye protection



Eye / face protection

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 :	Liquid Colourless Odourless Not determined
pH-value at 20 °C :	8
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	undetermined 100°C
Flash point : Flammability (solid, gaseous) : Evaporation rate : Auto-ignition temperature : Danger of explosion : Explosion limits - lower : - upper :	Not applicable Not determined Not determined Product is not self igniting. Product does not present an explosion hazard. Not determined Not determined
Vapour pressure at 20°C : Vapour density :	23 hPa Not determined
Density at 20 °C :	1,10-1,30 g/cm ³
Relative density :	Not determined
Solubility in / Miscibility with water :	Completely miscible
Partition coefficient (n-octanol/water) :	Not determined
Viscosity dynamic : cinematic :	Not determined Not determined
Solvent content :	

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Organic solvents :	Not determined
Water :	Not determined
VOC (EC) :	Not determined
Solids content :	> 30 %

9.2 Other information

No further relevant information available.

10. Stability and reactivity

10.1 Reactivity

No special measures are necessary.

10.2 Chemical Stability

The mixture is chemically stable under recommended conditions of storage, use and temperature.

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

No special measures are necessary.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

carbon dioxide (CO₂)

11. * Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

CAS-No.	Chemical name				
	Exposure routes	Method	Dose	Species	Source
139-33-3	Disodium dihydrogen ethylene diamine tetra acetate				
	oral	LD ₅₀	2800 mg/kg	Rate	OECD 401
	Inhalation vapor	ATE	11 mg/l		
	Inhalation Aerosol	ATE	1,5 mg/l		
584-08-7	Potassium carbonate				
	oral	LD ₅₀	1870 mg/kg	Rate	

Primary irritant effect:

On the skin: Causes skin irritation.

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On the eye:	Causes serious eye irritation.
Sensitization:	Based on available data, the classification criteria are not met.
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	Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Severe effects after repeated or prolonged exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.
Additional toxicological information	The product has not been tested. The statement is derived from the properties of the single components.

12. Ecological information

12.1 Toxicity

No further relevant information available.

12.2 Persistence and degradability

Easily biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulation potential.

12.4 Mobility in soil

No further relevant information available.

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

The product has not been tested. The statement is derived from the properties of the single components.

Do not allow uncontrolled discharge of product into the environment.

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

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13. Disposal considerations

13.1 Waste treatment methods

Recommendation:

Disposal must be made according to official regulations.

Contaminated packaging:

Recommendation:

Handle contaminated packages in the same way as the substance itself.

Waste codes / waste designations according to EWC / AVV:

European waste catalogue

07 07 01 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fine chemicals and chemical products not otherwise specified; aqueous washing liquids and mother liquors Classified as hazardous waste.

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 these transport regulations.

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA

No dangerous good in sense of these transport regulations.

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Transport/Additional information:

No further relevant information available.

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

No further relevant information available.

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:

2004/42/EC (VOC): not applicable

Additional information

Labelling for contents according to regulation (EC) No. 648/2004:
15 - 30 % EDTA and salts thereof
perfume

National regulations:

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

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
EC ₅₀	half maximal effective concentration
NOEC	No Observed Effect Concentration

Skin Corr.	Skin corrosion/irritation
Skin Sens.	Skin sensitisation
Eye Dam.	Serious eye damage/eye irritation
Eye Irrit.	Serious eye damage/eye irritation
Repr.	Reproductive toxicity
STOT SE	Specific target organ toxicity - single exposure

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Relevant phrases

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.

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.
