

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

1.1 Product identifier

Trade name: **Pluralgin Adhäsiv**

Product type: Adhesive Liquid

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

Use of the substance or mixture: Adhesive Liquid for alginate impression material
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:



GHS02 – flame

Flam. Liq. 2 - H225 Highly flammable liquid and vapour.

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:

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

Hazard-determining components of labelling: -

Hazard pictograms:



GHS02

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Trade name: **Pluralgin Adhäsiv**

Signal word : Danger

Hazard statements

H225 Highly flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P233 Keep container tightly closed.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P501 Dispose of contents/container in accordance with local / regional / national / international regulations.

Additional information:

Contains 2-(2-aminoethylamino)ethanol. May produce an allergic reaction.

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 to Regulation EC No. 1272/2008)	Concentration (%)
ethanol	CAS-Nr.: 64-17-5 EINECS: 200-578-6	Flam.Liq. 2 – H225	50 - 100 %
2-(2-aminoethylamino) ethanol	CAS-Nr.: 111-41-1 EINECS: 203-867-5	Repr. 1B – H360Fd Skin Corr. 1B – H314 Skin Sens. 1 – H317	≤ 0,5%

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

After inhalation

Supply fresh air; consult doctor in case of complaints.

After skin contact

Generally the product does not irritate the skin.

After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing

Rinse out mouth and then drink plenty of water.

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.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Dilute with plenty of water.
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 (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.

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

Keep receptacles tightly sealed.

Information about fire- and explosion-protection:

Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.

7.2 Conditions for safe storage, including any incompatibilities

Storage: -

Requirements for storage rooms and vessels: Store in a cool location.

Advice on storage compatibility: Not required.

Further information about storage conditions:

Keep container tightly sealed.
Store in upright position.
Store in cool, dry conditions in well sealed receptacles.

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:

64-17-5 ethanol	
AGW (Germany)	Long-term value: 960 mg/m ³ , 500 ml/m ³ [2(II); DFG; Y]
MAK (Austria)	Short-term value: 3800 mg/m ³ , 2000 ml/m ³ Long-term value: 1900 mg/m ³ , 1000 ml/m ³
MAK (Switzerland)	Short-term value: 1920 mg/m ³ , 1000 ml/m ³ Long-term value: 960 mg/m ³ , 500 ml/m ³ ; SSc;
WEL (Denmark)	Long-term value: 1920 mg/m ³ , 1000 ppm

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.
 Keep away from foodstuffs, beverages and feed.
 Wash hands before breaks and at the end of work.

Respiratory protection:

Not required.

Protection of hands



Protective gloves

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
 Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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.

As protection from splashes gloves made of the following materials are suitable:

Natural rubber, NR
 Nitrile rubber, NBR
 Butyl rubber, BR

Eye protection



Tightly sealed goggles

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 :	Fluid Red Alcohol-like Not determined
pH-value at 20 °C :	Not applicable
Change in condition Melting point/ freezing point : Boiling point/Boiling range :	Not determined 78 °C
Flash point : Ignition temperature : Evaporation rate : Self-igniting :	13 °C 425 °C Not applicable Product is not self igniting.

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Danger of explosion :	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
Explosion limits - lower : - upper :	3,5 Vol % 15,0 Vol %
Vapour pressure at 20°C :	59 hPa.
Vapour density :	Not determined
Density at 20 °C :	0,89 g/cm ³
Relative density :	Not determined
Solubility in / Miscibility with water :	Partly miscible.
Partition coefficient (n-octanol/water) :	Not determined
Viscosity dynamic : cinematic :	Not determined Not determined
Solvent content: Organic solvents : VOC (EC)	58 % 58 %

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

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

No further relevant information available.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

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Trade name: **Pluralgin Adhäsiv**

11. * Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD/LC ₅₀ values relevant for classification:		
64-17-5 - ethanol		
oral	LD ₅₀	7.060 mg/kg (rat)
inhalative	LC ₅₀ / 4h	20.000 mg/l (rat)
111-41-1 - 2-(2-aminoethylamino)ethanol		
oral	LD ₅₀	3.000 mg/kg (rat)
dermal	LD ₅₀	2.250 mg/kg (rat)

Primary irritant effect:

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

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

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
No further relevant information available.

12. Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability

Easily biodegradable.

12.3 Bioaccumulative potential

Does not accumulate in organisms.

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Trade name: **Pluralgin Adhäsiv**

12.4 Mobility in soil

No further relevant information available.

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it 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

Recommendation:

Must not be disposed together with household garbage. Do not allow product to reach sewage system..

Contaminated packaging:

Recommendation:

Disposal must be made according to official regulations.

Recommended cleansing agents:

Water, if necessary together with cleansing agents.

European waste catalogue

08 00 00	WASTES FROM THE MANUFACTURE, FORMULATION, SUPPLY AND USE (MFSU) OF COATINGS (PAINTS, VARNISHES AND VITREOUS ENAMELS), ADHESIVES, SEALANTS AND PRINTING INKS
08 04 00	wastes from MFSU of adhesives and sealants (including waterproofing products)
08 04 09*	waste adhesives and sealants containing organic solvents or other dangerous substances

Packaging:

Disposal must be made according to official regulations.

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14. * Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA UN1133

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA 1133 ADHESIVES
ADHESIVES

14.3 Transport hazard class(es)

ADR, IMDG, IATA



· Class 3 Flammable liquids.
· Label 3

14.4 Packing group

ADR/RID, ADN, IMDG, IATA II

14.5 Transport/Additional information:

ADR

· Excepted quantities (EQ): E2
· Limited quantities (LQ): 5L
· Excepted quantities (EQ): Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· Transport category: 2
· Tunnel restriction code: D/E

· IMDG

· Limited quantities (LQ): 5L
· Excepted quantities (EQ): Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

Warning: Flammable liquids.
· Danger code (Kemler): 33
· EMS Number: F-E,S-D

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

Not applicable.

14.9 UN "Model Regulation"

UN1133, ADHESIVES, 3, II

Trade name: **Pluralgin Adhäsiv**

15. * Regulatory information

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

EU regulations:

Regulation (EC) No 1272/2008:

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

Directive 2012/18/EU

- | | |
|---|----------|
| · Qualifying quantity (tonnes) for the application of lower-tier requirements | 5.000 t |
| · Qualifying quantity (tonnes) for the application of upper-tier requirements | 50.000 t |

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 30

National regulations:

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

Other regulations, limitations and prohibitive regulations

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

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

Flam. Liq.	Flammable liquids
Skin Corr.	Skin corrosion/irritation
Skin Sens.	Skin corrosion/irritation
Aquatic Chronic	Chronical aquatic toxicity

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Eye Dam.	Serious eye damage/eye irritation
Eye Irit.	Serious eye damage/eye irritation
Repr.	Reproductive toxicity
STOT SE	Specific target organ toxicity - single exposure

Relevant phrases

H225	Highly flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H360Fd	May damage fertility. Suspected of damaging the unborn child.

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.
