according to Regulation (EC) No. 1907/2006 (REACH)

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Pluracryl Press / Xpress Pulver

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

1.1. Product identifier

Trade name/designation:

Pluracryl Press / Xpress Pulver

Article No.:

236000; 236001; 236003; 236004; 236006; 236007; 247224; 247225; 235984; 235985; 235987; 235988; 235990; 235991; 247230; 247231

Additional information:

Manufacturing of dental products.

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

Use of the substance/mixture:

The product is intended for professional use.

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

Pluradent AG & Co.KG

Kaiserleistrasse 3 63067 Offenbach a.M.

Germany

Telephone: +49 69 82983-0 **Telefax:** +49 69 82938-271

E-mail: regulatory.affairs@pluradent.de

Website: www.pluradent.de

1.4. Emergency telephone number

Poisoning Information Centre of Health Austria, 24h: +43 1 406 43 43

poison emergency call Mainz, 24h: +49 (0) 6131/19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Hazard statements: -

Supplemental hazard information: -

Precautionary Statements: -

2.3. Other hazards

Adverse human health effects and symptoms:

Contains Methyl methacrylate, Dibenzoyl peroxide. May produce an allergic reaction.

Other adverse effects:

This mixture contains no substances that are persistent, bioaccumulating and toxic (PBT).





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SECTION 3: Composition / information on ingredients

3.2. Mixtures

Description:

Mixture based on methyl methacrylate.

Hazardous ingredients / Hazardous impurities / Stabilisers:

product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concen- tration
CAS No.: 9011-14-7	Acrylic polymer The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	95 - ≤ 100 Wt %
CAS No.: 94-36-0 EC No.: 202-327-6 INDEX No.: 617-008-00-0	dibenzoyl peroxide Eye Irrit. 2, Org. Perox. B, Skin Sens. 1 Danger H241-H317-H319	0 - < 1 Wt %

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. If unconscious place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air.

In case of skin contact:

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

After ingestion:

Rinse mouth. Let water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

Self-protection of the first aider:

Self-protection of the first aider

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

alcohol resistant foam, Dry extinguishing powder, Carbon dioxide (CO2), Water spray jet

Unsuitable extinguishing media:

Full water jet

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

5.4. Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.







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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Avoid breathing dust/fume/gas/mist/vapours/spray. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2. For emergency responders

No data available

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For containment:

Take up mechanically.

Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

No special measures are necessary.

Fire prevent measures:

No special fire protection measures are necessary.

Advices on general occupational hygiene

When using do not eat, drink or smoke.

Avoid contact with eyes and skin.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

No special measures are necessary.

Storage class: 11 - Combustible solids that cannot be assigned to any of the above storage classes

7.3. Specific end use(s)

Recommendation:

Manufacturing of dental products.





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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	 long-term occupational exposure limit value short-term occupational exposure limit value Instantaneous value Monitoring and observation processes Remark
MAK (AT)	dibenzoyl peroxide CAS No.: 94-36-0	 2 10 mg/m³ 5 (einatembare Fraktion max. 8x5 min./Schicht, Momentanw ert)
TRGS 900 (DE)	dibenzoyl peroxide CAS No.: 94-36-0	① 5 mg/m³ ② 5 mg/m³ ⑤ (einatembare Fraktion)
MAK (AT)	dibenzoyl peroxide CAS No.: 94-36-0	① 5 mg/m³ ⑤ (einatembare Fraktion)



No data available

8.1.3. DNEL-/PNEC-values

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

No data available

8.2.2. Personal protection equipment

Eye/face protection:

Wear eye protection/face protection.

Skin protection:

Tested protective gloves must be worn EN ISO 374

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

Respiratory protection:

In case of inadequate ventilation wear respiratory protection.

Other protection measures:

Take off contaminated clothing and wash it before reuse.

Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Powder Colour: various

Odour: characteristic





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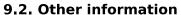
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Safety relevant basis data

parameter		at °C	Method	Remark
рН	not determined			
Melting point	110 °C			
Freezing point	not determined			
Initial boiling point and boiling range	not determined			
Decomposition temperature	not determined			
Flash point	> 250 °C			
Evaporation rate	not determined			
Auto-ignition temperature	> 400 °C			
Upper/lower flammability or explosive limits	not determined			
Vapour pressure	not determined			
Vapour density	not determined			
Density	1.16 g/cm³	20 °C		
Bulk density	700 - 750 kg/m ³	20 °C		
Water solubility	The study does not need to be conducted because the substance is known to be insoluble in water.			
Partition coefficient: n-octanol/ water	not determined			
Dynamic viscosity	not determined			
Kinematic viscosity	not determined			
Solid content (%)	100 %			



No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

Exothermic decomposition with formation of: methyl methacrylate

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity:

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

Acute dermal toxicity:

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

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Acute inhalation toxicity:

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

Skin corrosion/irritation:

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

Serious eye damage/irritation:

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

Respiratory or skin sensitisation:

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.

STOT-single exposure:

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

STOT-repeated exposure:

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

Aspiration hazard:

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

Additional information:

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

Additional ecotoxicological information:

The product is not: Ecotoxic

12.2. Persistence and degradability

Additional information:

The product has not been tested.

12.3. Bioaccumulative potential

Accumulation / Evaluation:

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

Appropriate disposal / Package:

Wash with plenty of water. Completely emptied packages can be recycled.

SECTION 14: Transport information

No dangerous good in sense of these transport regulations.





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Land transport (ADR/ RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO- TI / IATA-DGR)
14.1. UN-No.			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2. UN proper sh	ipping name		
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3. Transport has	zard class(es)		
not relevant			
14.4. Packing grou	р		
not relevant	-		
14.5. Environmenta	al hazards		
not relevant		1	
14.6. Special preca	utions for user	,	_
not relevant			

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code not applicable

SECTION 15: Regulatory information

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

15.1.1. EU legislation

Other regulations (EU):

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances [Seveso-III-Directive]: This product is not assigned to a hazard category.

15.1.2. National regulations

[DE] National regulations

Störfallverordnung

for substances contained in the product:

This product is not assigned to a hazard category.

Water hazard class (WGK)

WGK:

1 - schwach wassergefährdend

Berufsgenossenschaftliche Vorschriften (BGV)

Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Other regulations, restrictions and prohibition regulations

To follow:

- 850/2004/EC
- 79/117/EEC
- 689/2008/EC

15.2. Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

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SECTION 16: Other information

16.1. Indication of changes

No data available

16.2. Abbreviations and acronyms

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG - International Maritime Dangerous Goods

IATA - International Air Transport Association

IATA-DGR - Dangerous Goods Regulations for the Transport of Dangerous Goods by IATA.

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

LC50 - Lethal concentration, 50 %

LD50 - Lethal Dose, 50 %

16.3. Key literature references and sources for data

No data available

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

16.6. Training advice

No data available

16.7. Additional information

The information is based on the current state of our knowledge, but they do not constitute an assurance of product properties and do not establish a contractual relationship.

The information contained in this safety 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.



