Revision: 20.07.2023



Safety data sheet according to 1907/2006/EC, Article 31

Printing date 20.07.2023

Version number 3 (replaces version 2)

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

- · 1.1 Product identifier
- · Trade name: ACRY POL HI POLVERE
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Life cycle stages PW Widespread use by professional workers
- · Application of the substance / the mixture Material for dental use
- · Uses advised against Any use other than those identified is not recommended.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Dental Manufacturing S.p.a. Via Cà Mignola Nuova, 1699 45021 - Badia Polesine (RO) - Italy Tel. +39 0425 51628 - Fax +39 0425 590156

- · Further information obtainable from: info @ruthinium.it
- · 1.4 Emergency telephone number:

Dental Manufacturing S.p.a. - Tel. +39 0425 51628 (Office Hours)

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

The product is not classified, according to the CLP regulation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Additional information:

EUH208 Contains methyl methacrylate, dibenzoyl peroxide. May produce an allergic reaction.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
- · Description: Mixture based on polymethyl methacrylate

| · Dangerous components: | | |
|---|---|---------|
| CAS: 80-62-6 EINECS: 201-297-1 Index number: 607-035-00-6 Reg.nr.: 01-2119452498-28- xxxx | methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335 | 0.1-<1% |
| CAS: 94-36-0 EINECS: 202-327-6 Index number: 617-008-00-0 | dibenzoyl peroxide Self-react. B, H241; Org. Perox. B, H241; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10); Skin Sens. 1B, H317, EUH208 | 0.1-<1% |

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

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · IF INHALATED: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Do not induce vomiting; call for medical help immediately.
- 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.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- · For safety reasons unsuitable extinguishing agents: None in particular
- · 5.2 Special hazards arising from the substance or mixture

No further relevant information available.

- · 5.3 Advice for firefighters
- · Protective equipment:

Wear personal protective clothing.

See Section 8 for information on personal protection equipment.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

See Section 8 for information on personal protection equipment.

- · 6.2 Environmental precautions: No special measures required.
- · 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.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

You should follow the usual precautions for handling chemical products

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Store only in the original receptacle.

Store in a dry place

- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

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SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

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

CAS: 80-62-6 methyl methacrylate (0.1-<1%)

OEL Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens

CAS: 94-36-0 dibenzoyl peroxide (0.1-<1%)

OEL Long-term value: 5 mg/m³ Sens

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection:

Suitable respiratory protective device recommended.

Short term filter device:

Filter P2

· Hand protection

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

PVA gloves

Natural rubber, NR

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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Breakthrough time:> = 480 min - Material thickness:> = 0.7 mm Breakthrough time:> = 60 min - Material thickness:> = 0.5 mm Breakthrough time:> = 30 min - Material thickness:> = 0.2 mm

· Eye/face protection Not required.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Colour: Various colours
Odour: Characteristic
Odour threshold: Not determined.

• Melting point/freezing point: 110 °C

· Boiling point or initial boiling point and

boiling range Undetermined.
Flammability Not determined.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.

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· **pH** Not applicable.

· Viscosity:

Kinematic viscosityDynamic:Not applicable.Not applicable.

· Solubility

· water: Soluble.

· Partition coefficient n-octanol/water (log

value) Not determined.Vapour pressure: Not applicable.

Density and/or relative density

Density at 20 °C:
Relative density at 20 °C

Relative density at 20 °C

700 - 750 Kg/m3

Not determined.

Vapour density

Not applicable.

· Particle characteristics

See section 3.

· 9.2 Other information

· Appearance:

· Form: Powder

· Important information on protection of health

and environment, and on safety.

· **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

Change in condition

· Evaporation rate Not applicable.

Information with regard to physical hazard

classes · Explosives Void · Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void Void · Pyrophoric solids Self-heating substances and mixtures Void

Substances and mixtures, which emit flammable gases in contact with water
 Oxidising liquids
 Oxidising solids
 Organic peroxides
 Corrosive to metals
 Desensitised explosives

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- · 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.

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· 10.6 Hazardous decomposition products:

When heated or in case of fire can release gases and vapors which are dangerous to health. Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute 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.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability Easily biodegradable
- 12.3 Bioaccumulative potential Non significant accumulation in organisms
- 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to Article 57(f) of REACH or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or more;

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes: Not hazardous for water.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Do not discard the product or its packaging. Do not empty into drains. Recycle the product. When recycling is not possible, dispose through an authorized company in compliance with the local or national regulations. The assignment of the waste code is the user's responsibility, after determining the properties of the waste and the process generating it and after discussing it with the authorities responsible for disposal.

- · Uncleaned packaging:
- · Recommendation:

Empty the containers before disposal. Do not reuse the emptied containers. Send the empty containers to recycling or to an authorized company in compliance with local and national regulations.

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· Recommended cleansing agents: Water.

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| SECTION 14: Transport informat | tion |
|--|--|
| 14.1 UN number or ID number ADR, ADN, IMDG, IATA | Void |
| 14.2 UN proper shipping name ADR, ADN, IMDG, IATA | Void |
| 14.3 Transport hazard class(es) | |
| ADR, ADN, IMDG, IATA Class | Void |
| 14.4 Packing group ADR, IMDG, IATA | Void |
| 14.5 Environmental hazards: | Not applicable. |
| 14.6 Special precautions for user | Not applicable. |
| 14.7 Maritime transport in bulk accordi IMO instruments | ng to Not applicable. |
| Transport/Additional information: | Not dangerous according to the above specifications. |
| UN "Model Regulation": | Void |

SECTION 15: Regulatory information

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

Safety data sheet prepared in accordance with Regulation 1907/2006/EC Article 31, Regulation (EU) No 878/2020 as subsequent amendments.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
- · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H241 Heating may cause a fire or explosion.

H315 Causes skin irritation.

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H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH208 Contains . May produce an allergic reaction.

Classification according to Regulation (EC) No 1272/2008

As required by Regulation 1272/2008/CE art. 9, the classification of this compound is based on the calculation method taken from the data of the single substances therein and from the experimental data of this compound where available (viewable in sections 9, 11 and 12 in this document).

Procedure used for the classification of the mixture

Version number of previous version: 2

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Lig. 2: Flammable liquids - Category 2

Self-react. B: Self-reactive substances and mixtures - Type B

Org. Perox. B: Organic peroxides - Type B

Skin Irrit. 2: Skin corrosion/irritation - Category 2

Eye Irrit. 2: Serious eye damage/eye irritation -

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1B: Skin sensitisation - Category 1B

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1