

Material Safety Data Sheet

(according to 1907/2006 (EC))

Trade name: **Combipress® N, polymer, pink**

Version: 07.06.2007

Merz Dental GmbH

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1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Trade name: **Combipress® N, polymer, pink**

Use of the preparation: Cold-curing dental resin component in conjunction with Combipress (liquid) for the production of prostheses in complete and partial denture prosthetics and also in casting technology, for the relining and repair of prostheses according to the documentation.

Manufacturer / Supplier

Merz Dental GmbH

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Emergency-Info

National Poison Inform. Centre

Medical Toxicology Unit

Avalonley Road, London SE14 5ER

Telephone: 0044 (171) 635 91 91

2. HAZARDS IDENTIFICATION

Classification of the preparation

Can cause allergic reactions.

Additional dangers to humans and the environment

See point 12.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Preparation based on

> 98 % methacrylate copolymerisates

< 0,1 % azo condensation pigment and inorganic dyes

Dangerous ingredients

<u>CAS No.</u>	<u>EINECS/ELINCS</u>	<u>Designation</u>	<u>(%)</u>	<u>Classification</u>
72846-00-5	276-940-2	1-Benzyl-5-Phenylbarbituric acid	< 1	Xi ; R 36/38

4. FIRST - AID MEASURES

General information

Discard soiled clothing.

After inhalation

In case of trouble, seek medical advice.

After eye contact

In case of mechanical eye irritation, rinse thoroughly with large amounts of water. Consult a doctor if irritation persists.

After skin contact

In case of contact with skin wash off with soap and water. Consult a doctor if skin irritation persists.

After swallowing

In case of swallowing, seek medical advice.

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5. FIRE-FIGHTING MEASURES

Suitable extinguishing agents

Water spray jet, foam, dry powder, carbon dioxide

For safety reasons unsuitable extinguishing agents

Water with full jet.

Protective equipment for fire-fighting

Use self-contained respirator (breathing apparatus). -Wear full protection suit.

6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions

Avoid build up of dust. Use breathing protection (Fine dust mask FFP) when exposed to dust. Use personal protective equipment (overalls, protective glasses and protective gloves).

Cleaning / Absorption procedures

Gather substance mechanically. Dispose of substance according to directions.

7. HANDLING AND STORAGE

Handling

Information for safe handling

Avoid build up and deposition of dust.

Information about fire- and explosion protection

No special measures are required.

Storage

Requirements to be met by storerooms and receptacles

Storage: dry.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Components or decomposition products according to Point 10 with work-place related exposure limit values have to be controlled.

In each case, the currently valid national exposure limit values for dust, methyl methacrylate, methyl acrylate and dibenzoyl peroxide must be observed.

Exposure limit values

dust, particulates

WEL (long-term) 2005 (inhalable dust) 10 mg/m³

WEL (long-term) 2005 (respirable dust) 4 mg/m³

methyl methacrylate (80-62-6)

WEL (long-term) 2005 208 mg/m³ 50 ppm

WEL (short-term) 2005 416 mg/m³ 100 ppm

methyl acrylate (96-33-3)

WEL (long-term) (36) mg/m³ (10) ppm

The UK Advisory Committee on Toxic Substances has expressed concern that, for the OELs shown in parentheses, health may not be adequately protected because of doubts that the limit was not soundly-based. These OELs were included in the published UK 2002 list and its 2003 supplement, but are omitted from the published 2005 list.

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8. EXPOSURE CONTROL AND PERSONAL PROTECTION (CONTINUATION)

dibenzoyl peroxide (94-36-0)

WEL (long-term) 2005

5 mg/m³

Personal protective equipment

General protective measures

Do not inhale dust.

Hygienic measures

Observe the usual working hygiene measures. Preventive skin protection using barrier lotion.

Respiratory protection

Breathing protection in case of build up of dust (exceeding air limit values)

Fine dust mask (FFP) or short-term filter machine with P2 particle filter.

Protection of hands

Protective gloves against mechanical risks according to EN 388.

General information

Protective gloves should be changed regularly, particularly after intensive contact with the product. A suitable type of glove must be selected for each work place.

Eye protection

Tightly sealed goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form: powder

Colour: pink

Odour: weak inherent smell

Safety-relevant data

Change in condition

Softening temperature approx. 110 °C

Boiling point not applicable

Flash point > 250 °C (ASTM D 1929-68)

Ignition temperature > 400 °C (ASTM D 1929-68)

Autoflammability not specified

Lower explosion limit not specified

Upper explosion limit not specified

Vapour pressure not specified

Density 1,16 g/cm³ at 20°C

Bulk density 680 – 730 kg/m³ at 20°C

Solubility in water not soluble

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9. PHYSICAL AND CHEMICAL PROPERTIES (CONTINUATION)

Solubility (qualitative)	e.g. in esters, ketones and chlorinated hydrocarbons: easily soluble
pH-value	not applicable
Viscosity (dynamic)	not applicable
Additional information	the possibility of dust explosions can generally be anticipated with dust-making organic products.

10. STABILITY AND REACTIVITY

Thermal decomposition

> 250 °C

Dangerous reactions

No dangerous reactions known.

Dangerous decomposition products

When thermal decomposition occurs, flammable vapours, which are irritating to the eyes and respiratory organs, develop. These mainly consist of: methyl methacrylate, methyl acrylate.

11. TOXICOLOGICAL INFORMATION

Sensitisation

Allergic reactions were reported in humans. The product contains small quantities of sensitising substances (see Chapter 9). Intensive skin contact, especially with the dissolved product, can trigger an allergic reaction in persons previously sensitised.

Further information

No toxicological data is available for the product. The data given above (see Chapter 9) refers to the small concentration of dibenzoyl peroxide and methyl methacrylate which is contained in the product. The fines contained in the product can lead to mechanical irritations of the skin, eyes, and mucous membranes. Skin and eye contact with the product should be avoided. The inhalation of product dusts/aerosol should be avoided.

12. ECOLOGICAL INFORMATION

Information concerning elimination (persistence and decomposition)

Ecotoxic Effect

No ecotoxicological data is available for the product.

Further ecological information

Due to the consistency as well as the small water solubility of the product a bio-availability is not probable. Investigations at products of similar composition confirm this acceptance. Do not allow to enter sewers / surface or ground water.

13. DISPOSAL CONSIDERATIONS

Product

Recommendation

The waste is not dangerous. Small quantities can be cured together with other system components and can be disposed with household garbage. Larger quantities are to be disposed in a suitable and licensed facility, taking into consideration the regulations after consultation between the competent local authority and the disposer.

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13. DISPOSAL CONSIDERATIONS (CONTINUATION)

- Directive 91/689/EEC on hazardous wastes 2000/532/EC
- EC Waste List
- EC Catalogue of dangerous wastes
- EC Waste Catalogue (EAK/EWC)
- EAK Regulation
- national and/or regional regulations for the disposal of dangerous wastes.

Waste code

European Waste List

EWC Code: 18 01 07

EWC Designation: Waste from natal care, diagnosis, treatment or prevention of disease in humans – chemicals with the exception of those which fall under 18 01 06.

According to EAK regulation, the allocation of waste code numbers is to be carried out specific to the industry and the process.

The waste code mentioned is a recommendation on the basis of the probable use of this product according to paragraph 1.

Owing to the user's specific conditions for use and disposal, other waste codes may also be allocated in certain circumstances. These are to be verified by the user.

Uncleaned packages

Contaminated packing is to be completely emptied. After appropriate professional cleaning is carried out, the packing can then be recycled. Packing which cannot be cleaned is to be professionally disposed. Uncontaminated packing can be recycled.

14. TRANSPORT INFORMATION

Non-dangerous material according to Transport Regulations.

15. REGULATORY INFORMATION

The product is subject to the regulations of the Medical Device Directive 93/42/EEC, as well as to the national Medical Device Act and the Chemicals Act.

Marking according to Dangerous Substances Regulation including EC Directive (67/548/EEC as well as 1999/45/EC)

The preparation must be marked according to Appendix V Paragraph 9 of the Preparation Directive 1999/45/EC:

“Contains methyl methacrylate, dibenzoyl peroxide. Can cause allergic reactions.”

On the basis of the calculation procedure in the latest version of the “EC General Classification Directive for Preparations”, compulsory marking is not applicable.

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16. OTHER INFORMATION

The lines marked with † have been changed since the last version.

The data given in items 4 to 8 and 10 to 12 are in part not based on the use and correct application of the product (see usage and product information), but rather on the release of large quantities during accidents or irregularities.

The information contained herein refers solely to the explicitly specified product and the hazard-determining components which it contains. The data corresponds to our present knowledge and satisfies national as well as EC legislation. However, Merz Dental GmbH makes no express or implied warranty or guarantee as to the correctness, reliability or completeness of the information. Persons who receive this information are strongly urged by Merz Dental GmbH not to use the product for any other purpose, other than specified in Paragraph 1, without written authorisation. The user is responsible for adherence to all necessary legal regulations. The data in this safety sheet describes the safety requirements of our product and does not constitute a warranty of product attributes. (n.a. – not applicable, n.s. – not specified)

Department issuing MSDS

Quality Assurance Department

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