

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 1/11

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

Trade name: **Combipress® N / LM, monomer**

Use of the preparation: Cold-curing dental resin component in conjunction with Combipress (powder) 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

Emergency call-centre (Poison)

Telephone: 0044-171-635 91 91(London SE 14 5ER)

2. COMPOSITION / INFORMATION ON INGREDIENTS

The preparation contains alkyl dimethacrylate and the following hazardous ingredients:

Methyl methacrylate

CAS number	80-62-6
EG (INDEX)	607-035-00-6
EINECS-(EG-, EWG-)number	201-297-1

Concentration	> 94%
GS	Xi ; F

Danger phrases:

R-Phrases	11-37/38-43
S-Phrases	(2)-24-37-46

3. HAZARDS IDENTIFICATION

Classification of the preparation

Highly flammable.

Irritating to respiratory system and skin.

May cause sensitization by skin contact.

Additional dangers to humans and the environment

See point 12.

4. FIRST- AID MEASURES

General information

Medical help is necessary in case of symptoms, which are obviously due to exposing the product to skin or eyes or the inhalation of its vapours.

After inhalation

Remove the casualty into fresh air and keep him calm. In case of breathing difficulty, allow him to inhale oxygen.

Refer for medical treatment.

After skin contact

In case of contact with skin wash off immediately with soap and water. Consult a doctor if skin irritation persists. Do not use alcohol, gasoline or other solvents under any circumstances. Remove contaminated soaked clothing immediately and dispose of safely.

4. FIRST- AID MEASURES (CONTINUATION)

After eye contact

In case of contact with eyes, rinse thoroughly with plenty of water for at least 10 minutes with eyes spread wide open and seek medical advice.

After swallowing

Administer medicinal carbon (3 table spoons mixed into a paste in 1 glass of water) and drink plenty of liquid (water). Induce vomiting. Do not administer edible oils, castor-oil plant, milk or alcohol under any circumstances. Summon a doctor immediately.

Notes for the doctor

Inhalation poisoning

Treatment of dry coughs with codeine. In severe cases, start with the prophylaxis of a toxic pulmonary oedema (inhalation and injection of glucocorticoids in the form of dexamethasone and prednisolone). Supply oxygen as required.

Cardiovascular effect – monitoring of cardiovascular function (ECG).

Skin contact

Flumetasone foam or ointment is recommended as a therapeutic agent.

Eye contact

Application of panthenol or prednisolone eye ointment.

Swallowing

After a longer period of exposure, abstain from vomiting and mechanical interferences and just use a combined dilution/laxative therapy.

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

Specific dangers arising from the substance or preparation itself, its combustion products or resulting gases

Noxious gases and monomer vapours from methyl methacrylate. CO₂ formation.

Protective equipment for fire-fighting

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

Further information

Vapours spread across the floor. Only use explosion-proof, spark-free and solvent-resistant equipment. Prevent intrusion of canalisation / surface water / ground water.

6. ACCIDENTAL RELEASE MEASURES

Person-related safety precautions

Provide sufficient ventilation.

Use personal protective clothing (respirator, protective glasses, protective boots and protective gloves)

Remove possible sources of ignition. - Evacuate endangered area. - Alert everyone in the affected area.

Use breathing protection when exposed to vapours / aerosol.

Measures for environmental protection

Do not allow to enter sewers / surface or ground water.

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 3/11

6. ACCIDENTAL RELEASE MEASURES (CONTINUATION)

Measures for cleaning / collecting

Larger quantities:

Take up mechanically (Pump off). Adhere to measures for explosion-protection!

Smaller quantities and / or surpluses:

Absorb with liquid-binding material (sand, sawdust, universal binders, diatomite, activated carbon) and dispose according to directions.

Afterwards, clean wetted surfaces with plenty of water. Apply wetting agent.

Then ventilate the area.

7. HANDLING AND STORAGE

Handling

Information for safe handling

Keep containers tightly sealed. Siphon and bottle, using solvent-resistant aids, under a suction unit or using a breathing protection mask with gas filter A (identification colour: brown) Avoid aerosol formation.

Wear personal protective equipment.

Ensure good ventilation.

In case of transport in fragile container, use a suitable outer-container.

To be used only by qualified personnel in accordance with the documentation.

Information about fire- and explosion protection

Keep away from sources of ignition. - Do not smoke.

Take precautionary measures against static discharges.

In case of fire, cool the endangered containers with water. Vapours can form an explosive mixture with air.

Only use explosion-proof equipment.

Storage

Requirements to be met by storerooms and receptacles

Keep only in original container in well ventilated areas, not at temperatures above 30°C. - Protect from light.

Only fill containers up to approx. 90%, as oxygen (air) is necessary for stabilisation.

Proceed with caution when dealing with emptied containers. In case of ignition, explosions are possible.

Prevent gases or vapours from reaching other areas where sources of ignition are present. Implement actions against electrostatic charges. Electric installations must comply with the Explosion Protection Directive.

Information about storage in one common storage facility

The preparation should not be stored with substances, with which dangerous chemical reactions are possible (polymer powder; oxidising agents; hydrocarbons containing chlorine).

Further information about storage conditions

None.

Specific usage

See attached documentation.

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 methyl methacrylate must be observed.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION (CONTINUATION)

Exposition limit values

methyl methacrylate

OES (long-term): 205 mg/m³ (50 ppm)

OES (short-term): 410 mg/m³ (100ppm)

Additional information

The lists valid during the making were used as basis.

Additional information about design of technical facilities

Laboratory vents, extraction hoods, variable point suction units and also ventilation units with activated carbon filters are recommended.

Limitation and monitoring of exposure

For exposure monitoring, the following may be used: direct-reading Photo Ionisation Detector Dosimeters (e.g. ToxiRAE made by Ansyco), short-term measuring tubes for methyl acrylate (e.g. made by Dräger) or pumps with adsorption tubes, and subsequent GC analysis by an accredited institute.

Measuring method:

- OSHA 94
- NIOSH 2537

Sources:

OSHA: *Analytical Methods Manual*. ACGIH, Cincinnati, 1991, with the method-number methods: <http://www.osha-slc.gov/dts/sltc/methods/toc.html>

NIOSH: *Manual of Analytical Methods*. 4th Ed., U.S. Department of Health and Human Services Cincinnati 1994, with the method-number methods: <http://www.cdc.gov/niosh/nmam/nmammenu.html>

Limitation and monitoring of exposure in the work place

Personal protective equipment

Protective and hygienic measures

Do not inhale vapours.
Avoid contact with eyes and skin.
Keep away from foodstuffs, beverages and feed.
Store work clothing separately.
Immediately remove all soiled and contaminated clothing.
Observe the usual working hygiene measures.

Respiratory protection

Breathing protection in case of high concentrations (exceeding air limit value)
Short-term filter machine, gas filter A (identification colour: brown).
Only use filter machines when the surrounding atmosphere contains at least 17% vol. oxygen.

Protection of hands

Protective gloves made from butyl rubber (impermeable up to 60 min with material thickness of > 0.5 mm; EN 374), nitrile (impermeable up to 10 min with material thickness of > 0.33 mm); natural latex (impermeable up to 10 min with material thickness of > 1 mm).

Since abnormal conditions often arise in practice, these details can only be an orientation guide when choosing suitable chemical protective gloves. In particular, these details do not replace any suitability tests carried out by the end-consumer.

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 5/11

8. EXPOSURE CONTROL AND PERSONAL PROTECTION (CONTINUATION)

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.

Skin-contact preventive skin protection (skin protection made from oil-in-water emulsion (O/W); skin cleanser with wash-active substances; skin care product subject to the skin condition of the user after the work)

Eye protection

Tightly sealed goggles with side protection.

Body protection

Wear safety working clothes (lab coat) and closed shoes.

Limitation and monitoring of environmental exposure

Do not allow to enter sewers / surface or ground water.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance

Form: liquid
Colour: colourless
Odour: pungent, ester-like

Important information for the protection of health and environment as well as for safety

Change in condition:

Boiling point / boiling range: approx. 100 °C (at 1013 hPa)
Flash point (method DIN 51755): 10 °C (methyl methacrylate)

Danger of explosion:
Ignition temperature (method DIN 51794): 430 °C (methyl methacrylate)
Lower explosion limit: 2.1% Vol or 87 g/m³ (methyl methacrylate)
Upper explosion limit: 12.5% Vol or 520 g/m³ (methyl methacrylate)
Max. explosion pressure: 7.7 bar

Oxidising characteristics:

Vapour pressure: 40 hPa (at 20 °C methyl methacrylate)
Relative density: approx. 1 g/cm³
Relative vapour density determined in air: 3.4 (at 20 °C for methyl methacrylate; air = 1)
Vapour saturation concentration: 193 g/m³ (at 20 °C for methyl methacrylate)

Solubility:

Solubility in water: 15.9 g/l (at 20 °C for methyl methacrylate)
Solubility in fat: not specified
Solubility in organic solvents: soluble in most organic solvents
Partition coefficient: (n-Octanol/Water): 1.4 log Pow (for methyl methacrylate Source: Literature)
pH-value: not applicable
Viscosity (dynamic) (Brookfield Method): 0.6 mPas (at 20 °C for methyl methacrylate)

Additional information:

Odour threshold: 0.8 – 85mg/m³

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 6/11

10. STABILITY AND REACTIVITY

Dangerous reactions

Conditions to be avoided

Heat (> 30 °C) or UV light should be avoided in order to prevent a spontaneous and explosive polymerisation and also to prevent the accompanying generation of heat.

Substances to be avoided

In the presence of radical formers (e.g. peroxides, persulfates), reducing or oxidising substances and/or heavy metal ions and other polymerisation initiators as well as polymethyl methacrylates (polymer powder), polymerisation takes place under heat generation. Forms an explosive mixture with air. With strong oxidants, e.g. peroxides - strong exothermic reactions, heat generation and risk of ignition or emergence of flammable gases or vapours.

Dangerous decomposition products

No dangerous decomposition products known if used according to specifications.

11. TOXICOLOGICAL INFORMATION

Toxicological tests

Specific effects in animal experiments

Acute oral toxicity (LD₅₀)

> 5000 mg/kg (species rat; method: OECD 401; Source: Literature)

Acute inhalational toxicity (LC₅₀)

29,8 mg/l (species rat; Source: Literature)

Acute dermal toxicity (LD₅₀)

> 5000 mg/kg (Species rabbit; Source: Literature)

Irritancy/caustic effect

- Irritant effect on eyes

non-irritant (species rabbit; method: Draize; Source: Literature)

- Irritant effect on skin

non-irritant (species rabbit; FDA 1959 Draize-Test; 24 h, occlusive; Source: Literature)

Sensitisation

In sensitisation tests on guinea pigs with and without adjuvant, both positive and negative results were recorded. (Source: Literature)

Effects after repeated or longer lasting exposure

Toxicity with repeated application

Rat, inhalant, 2a, 6h/d, 5d/w, 25 – 400ppm

NOAEL 25ppm

Finding: Mucous membrane damage in the nose at 400ppm

(Source: Literature)

Rat, in drinking water, 2a, 7d/w, 6 – 2000ppm

NOAEL 2000ppm

Finding: No toxic effects

(Source: Literature)

11. TOXICOLOGICAL INFORMATION (CONTINUATION)

Effects which are carcinogenic, mutagenic and toxic to reproduction

Mutagenicity

Both positive and negative results recorded in in-vitro mutagenicity/genotoxicity tests.

No experimental information on genotoxicity (in vivo) is available.

Overall assessment: Not mutagenic according to internationally recognised criteria.

(Source: Literature)

Cancerogenicity

Not carcinogenic in inhalation and feeding tests carried out on rats, mice and dogs. (Source: Literature)

Reproduction toxicity

In experiments on animals, no indications of effects which are toxic to reproduction were observed.

(Source: Literature)

Experiences made in practice

Experiences on humans

Cytogenetic investigations on those exposed to the substance revealed that under normal exposure conditions, the mutagenic risk for humans appears to be slight, whilst it cannot be completely ruled out when exposed to peak concentrations.

Allergic reactions with differing incidence were observed (symptoms: headache, eye irritation, skin trouble).
(Source: Literature)

Observations relevant to classification

None.

Acute toxicity

Irritating effects on skin and mucous membrane, sensitisation, malfunction of the central nervous system (CNS). Irritation symptoms: Contact eczema, inflammation or reddening of the skin. MMA vapours in concentrations of > 100-200 ppm have an irritant effect on the mucous membranes of the eye. Irritation, of different strengths, of the upper respiratory tracts as well as subjective complaints such as headache, sickness, loss of appetite.

Effects after repeated or longer lasting exposure

Chronic toxicity

Reversible irritation of the mucous membranes of the eyes and airways as well as CNS and circulatory disorders. Functional changes of the cardiovascular system as well as gastritis.

Other observations

Allergic reactions with differing incidence were observed in humans (symptoms: headache, eye irritation, skin trouble). (Source: Literature)

In different micro-biological and animal experiments, positive and negative results were recorded, which indicate that the formation of mutagenic metabolites cannot be ruled out.

Other information

Skin and eye contact with the product, as well as inhalation of product vapours, should be avoided.

The product is not tested as such. The preparation is classified in accordance with conventional methods (calculation procedure of EU Directive 1999/45/EC) and according to toxicological dangers. The data given above relates to the component methyl methacrylate.

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 8/11

12. ECOLOGICAL INFORMATION

Ecotoxicity

Aquatic toxicity

Fish toxicity

LC₅₀: > 79 mg/l

(Exposure duration: 96h; species Oncocrhynchus mykiss, rainbow trout; method: OECD 203; GLP;

(Source: Literature)

Daphnia toxicity

EC₅₀: 69 mg/l

(Exposure duration: 48h; species Daphnia magna; method: OECD 202; source: Literature)

NOEC: 37 mg/l

Exposure duration: 21d; species Daphnia magna; method: OECD 202-Part 2; flow; source: Literature)

Algae toxicity

EC₃: 37 mg/l

Exposure duration: 8d; species Scenedesmus quadricauda; method: DIN 38412-Part 9; source: Literature)

EC₅₀: 170 mg/l

Exposure duration: 96h; species: Selenastrum capricornutum; method: OECD 201; source: Literature)

Bacteria toxicity

EC₀: 100 mg/l

(species: Pseudomonas putida; source: Literature)

Mobility

Bio-accumulation, do not contaminate water courses.

Information concerning elimination (persistence and decomposition)

Biological decomposition

94 %

(Experiment duration: 14d; method: readily biodegradable; OECD 301 C; source: Literature)

Behaviour in environmental compartments

No data available

Bio-accumulation potential

LC₅₀/96h/minnow = 150 ppm,

LC₅₀/96h/American sunfish = 232 ppm

Other harmful effects

Evaluation number for acute toxicity

Mammals: 1

Further information

Do not allow to enter soil, waterways or waste water.

The preparation was evaluated on the basis of the conventional methods of the Preparation Directive (1999/45/EC) and was not classified as hazardous to the environment.

The data given above relates to the component methyl methacrylate.

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 9/11

13. DISPOSAL CONSIDERATIONS

Product

Recommendation

The waste is dangerous and is, therefore, particularly in need of monitoring. Disposal should be carried out in a suitable and licensed facility, after consultation between the competent local authority and the disposer and taking into consideration Paragraph 15 and the following regulations:

- 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.

Must not be disposed together with household garbage.

Small quantities can be cured together with other system components and can be disposed with household garbage.

Waste code

European Waste List

EWC Code: 18 01 06

EWC-Designation: Waste from natal care, diagnosis, treatment or prevention of disease in humans – chemicals, which consist of hazardous materials or which contain suchlike.

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 packaging

Recommendation

After appropriate professional cleaning, packing which has been completely emptied of all remnants can be passed through the dual waste management system. Uncleaned packing is to be professionally disposed in the same way as product waste and according to the recommendations made above.

14. TRANSPORT INFORMATION

Road & Rail – ADR, RID

UN No.: 1247

Class: 3

Packing group: II

Hazard label: 3

Danger No.: 339

Description: METHYL METHACRYLATE, MONOMER, STABILIZED

Notes:

Limited quantities (net): LQ 4 / compound packing: max. 3 l inner packages / max. 30 kg / parcel;
trays: 1l / 20 kg.

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 10/11

14. TRANSPORT INFORMATION (CONTINUATION)

Sea – IMDG-Code

UN No.: 1247
Class: 3
Packing group: II
Hazard label: 3
Danger No.: 339
Description: METHYL METHACRYLATE, MONOMER, STABILIZED
EMS: F-E S-D
Marine pollutant: No
Flashpoint: + 10 °C

Air – CAO, PAX

UN No.: 1247
Class: 3
Packing group: II
Hazard label: 3
Danger No.: 339
Description: METHYL METHACRYLATE, MONOMER, STABILIZED

Further information

Do not packing together with acrylate polymer powder!

15. REGULATORY INFORMATION

The product is subject to the regulations of the Medical Device Directive 93/42/EEC and the national Medical Device Act and is subject to compulsory marking in accordance with Art. 1, Para. 2. of the Preparation Directive 1999/45/EC.

Labelling according to EU guidelines

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials (67/548/EWG and 1999/45/EG)

Hazard symbols

Xi Irritant
F Highly flammable

Hazard-determining components of labelling

Contains methyl methacrylate

Risk-phrases

11 Highly flammable
37/38 Irritating to respiratory system and skin.
43 May cause sensitisation by skin contact.

Safety-phrases

9 Keep container in a well-ventilated place.
16 Keep away from sources of ignition --- No smoking.
24 Avoid contact with skin.
33 Take precautionary measures against static discharges.
37 Wear suitable gloves.
46 If swallowed, seek medical advice immediately and show this container or label.

VOC Directive (1999/13/EC)

Content: 100%

Material Safety Data Sheet

(according to 2001/58/EC)

Trade name: **Combipress® N / LM, monomer**

Version: 13.02.06

Merz Dental GmbH

Page 11/11

16. OTHER INFORMATION

The product is delivered stabilised.

However, if the date of expiry and/or storage temperature (max. 40°C) is significantly exceeded, then the product can polymerise under heat generation.

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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