
Zobozdravstvo - Smernice za ravnanje z materiali na osnovi metakrilata v zobozdravstvenem laboratoriju

Dentistry - Guidelines for handling methacrylate-based materials in the dental laboratory

Zahnheilkunde - Leitlinien zur Handhabung von methacrylatbasierenden Materialien im zahntechnischen Labor

Médecine bucco-dentaire - Lignes directrices relatives à la manipulation des matériaux à base de méthacrylate en laboratoire dentaire

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**Dentistry - Guidelines for handling methacrylate-based materials
in the dental laboratory**

Médecine bucco-dentaire - Lignes directrices relatives à la
manipulation des matériaux à base de méthacrylate en
laboratoire dentaire

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methacrylatbasierenden Materialien im zahntechnischen
Labor

This Technical Report was approved by CEN on 10 June 2012. It has been drawn up by the Technical Committee CEN/TC 55.

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Foreword

This document (CEN/TR 16386:2013) has been prepared by Technical Committee CEN/TC 055 "Dentistry", the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared by Working Group 8 *Occupational risk assessments* of CEN/TC 55 *Dentistry*.

Introduction

In 2008 CEN/TC 55 established a new working group WG 8 *Occupational risk assessments*. The rationale for the group was concern about occupational health issues for personnel working with methacrylate-based products in dentistry. These materials (e.g. removable denture and orthodontic base materials, tray materials, dental repair materials etc.) may pose a risk because of the presence of methacrylate monomers. The objective of WG 8 was to review the present status regarding the prevalence and awareness of the risk of methacrylate based materials among dental personnel. In addition the occupational health and safety regulations in different countries were considered. Based on the results of the survey carried out by the group, this Technical Report has been produced as a guideline for handling methacrylate based materials in dental laboratories to maintain the safety of the occupational environment.

Aspects of this report may be applicable to dental practises.

After reviewing the scientific literature and making an investigation among European dental technicians, adverse effects on the skin seem to be the main occupational risk for dental technicians. Uncured methyl methacrylate is a risk factor for skin disease and it has been defined by The European Chemicals Bureau as a risk substance [1]. The report concluded that there is a risk for toxic, neurotoxic as well as sensitising reactions to personnel in dental laboratories and there is need for limiting the risks.

Other risk factors for occupational related skin reactions as eczema are wet work, handling of different chemicals and plaster.

Dust from grinding polymer-based materials and vapour of monomers may also be a risk to the airways.

CEN/TR 16386:2013 (E)

1 Scope

This Technical Report gives guidance for handling all methacrylate-based materials for dental purposes used in dental laboratories. The intention is to lower the risk of adverse effects on skin and airways when working with such materials.

Aspects of this document may be applicable for other areas in Dentistry.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 374-1, *Protective gloves against chemicals and micro-organisms — Part 1: Terminology and performance requirements*

EN ISO 1942, *Dentistry — Vocabulary (ISO 1942)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 1942, EN 374-1 and the following apply.

3.1 methacrylate

ester of methacrylic acid

3.2 local exhaust ventilation

engineering control system to reduce exposures to airborne contaminants such as dust, mist, fume, vapour or gas in a work place

4 Risk management

4.1 Risk assessment

Risk assessments for each material and procedure shall be compiled and documented by a responsible person in the dental laboratory.

This shall be in accordance with European regulation [2], national regulation/legislation and/or EN ISO 14971 as appropriate.

Information from instructions for use or other sources (e.g. material safety data sheets) shall be incorporated in the risk assessment.

4.2 Health surveillance

Regular health surveillance shall be carried out according to the risk assessment

4.3 Medical advice

Medical advice is required:

- a) when a person has a pre-existing condition and enhanced risk of adverse effects from methacrylate-based materials;
- b) if there is evidence of disease after handling these materials.

4.4 Reduction of risks

4.4.1 General

Uncured methacrylate-based materials constitute a risk to skin and airways. All personnel handling uncured materials shall be provided with suitable information about risks. Handling instructions and appropriate training shall be provided. Appropriate warning signs and a summary of safety precautions shall be displayed at each workstation [3].

4.4.2 Skin

Avoid direct skin contact wherever possible.

When handling uncured methacrylate-based materials, use gloves and change them after each procedure. Do not reuse the gloves.

If skin contact has occurred, immediately wash the affected area carefully with soap and water and dry thoroughly.

Avoid the use of alcoholic solutions for disinfection.

Use skin protection and care procedures (e.g. barrier creams).

NOTE Important information about gloves is given in Annex A.

4.4.3 Airways

Local exhaust ventilation capable of reducing the concentration of dust particles and methacrylate vapour to below the European[4]/national recommended safety levels shall be installed and used according to the manufacturers instructions.

4.4.4 Eye protection

When handling uncured or cured methacrylates, use eye protection such as safety glasses, visors or goggles.

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Annex A

(informative)

Use of gloves

A.1 General

When working with uncured methacrylates, the use of ordinary protective gloves can be insufficient due to their permeability to monomers. The time taken to penetrate the glove material will depend upon its composition, the type of chemicals and the length of exposure [5]. Users should be aware of symptoms associated with glove use and latex including the possibility of type 1 allergy caused by latex.

For risk assessment on permeability of methacrylate monomers penetrating gloves, appropriate information shall be collected from the manufacturer

NOTE: Current information [6,7] suggests that most gloves useful in dental laboratories, are ineffective after 2 minutes of exposure to methacrylates.

A.2 Recommendations

The following recommendations are given:

- a) Use gloves when handling methacrylates.
- b) Do not to use gloves for a longer period of time as recommended by the manufacturer. Change gloves at this point.
- c) The use of two gloves on each hand may increase the usage period by a factor of two.
- d) Change gloves immediately if contamination by monomers has occurred.
- e) Do not reuse gloves.
- f) Do not clean gloves with alcohol-based detergents, solvents containing alcohol and/or acetone, which can increase the permeability of gloves