

ICS 11.060.10

English Version

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

Zahnheilkunde - Leitlinien zur Handhabung von
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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....	3
Introduction	3
1 Scope.....	4
2 Normative references.....	4
3 Terms and definitions	4
4 Risk management.....	4
4.1 Risk assessment.....	4
4.2 Health surveillance.....	4
4.3 Medical advice.....	4
4.4 Reduction of risks.....	5
4.4.1 General	5
4.4.2 Skin.....	5
4.4.3 Airways.....	5
4.4.4 Eye protection.....	5
Annex A (informative) Use of gloves.....	6
A.1 General	6
A.2 Recommendations	6
Bibliography.....	7

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.

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: