TPO in dental medical devices

Manufacturers regard continued use of TPO under the requirements of the European Medical Device Regulation (MDR) to be justified

Diphenyl (2,4,6-trimethylbenzoyl) phosphine oxide (TPO) is an organophosphorus substance widely used in the dental industry as a photoinitiator for manufacturing various products.

Currently, TPO still has a CMR classification Repr. 2, H 361f. However, it can be assumed that a reclassification to Repr. 1B and subsequent labeling as a "substance of very high concern" (SVHC) will take place.
This means that the further use of this substance in medical devices in a concentration greater than 0.1 % weight by weight (w/w) has to be justified by the individual manufacturers according to Annex 1 No. 10.4.1 and 10.4.2 of the MDR.

Against this background, in a joint initiative various VDDI member companies analysed in accordance with Annex I No. 10.4.2 of the MDR, the potential exposure of TPO to patients for two products on the market, compared TPO with alternative substances and conducted a benefit-risk assessment.

In their more than 40-page detailed statement, the companies conclude that the TPO-containing products under consideration are safe in practice when used in accordance with the instructions for use.

Comparison of TPO with alternatives

Many materials and substances used in dental therapy are comparable and show the same or similar properties.

TPO-containing therapies, whether direct or indirect (inlays, onlays, veneer) fillings, are mostly characterized by higher aesthetics, lower environmental impact, less complex processing and lower therapy costs compared to TPO-free therapies (amalgam, gold leaf, cements, composites, ceramics, glass-ceramics, metals, etc.).

When other essential properties are considered objectively, in particular stability and lifetime - this applies above all to composites and ceramics - no differences can be detected between TPO-containing and TPO-free forms of therapy.
Therefore, the treating dentists have an essential role. They decide on a case-by-case basis, which form of therapy is appropriate and necessary for a particular patient. With regard to the variety of therapies, it should also be possible in the future to select the most suitable one for the patient from various forms of therapy. In the context of this selection, TPO-containing materials show advantages e.g. in tooth-preserving therapy, possible allergic reactions and aesthetics.

Exposure scenarios for dental medical devices containing TPO

In order to be able to make statements about the effects of TPO-containing products on patients, the manufacturers chemically analysed products with short-term patient contact (drilling template) and with medium- to long-term contact (temporary crowns and bridges). For the evaluation, patient groups were differentiated taking into account the respective average body weight (children, women, men) and the material was analysed in the cured and uncured state.

As a result, the extensive calculations show that the exposures for products in the cured state differ substantially from those in the uncured state. In the uncured state, the limit value is exceeded, with the consequence that adverse effects for the patient cannot be ruled out. For cured products, the toxicological limit of TPO is not reached even under "worst-case" considerations. The curing of the product leads to a strong reduction of the TPO content in the medical device and to a binding of the remaining rest. Therefore, these products can be considered safe. There is a high probability of no adverse health effects in the patient.

Measures for the safe use of products containing TPO

By taking suitable measures, manufacturers of dental medical devices can minimize or almost eliminate the risks associated with the use of TPO in these products. This is based on corresponding specifications by the manufacturer on the requirements for appropriate curing of the material, which must be described in the respective instructions for use of the product. In a next step, the user (dentist/dental technician) is required to implement the specified measures and to ensure a proper handling of the products during patient treatment. By applying these specifications on the curing of the material by the user, the patient receives a safe medical device.

Concluding remark

The data used in the position paper can be an important basis for all manufacturers concerned for their own justification and further use of TPO. Nevertheless, the authors of this position paper explicitly point out that the data obtained were always collected for one product only. Therefore, it is not sufficient to generalise the results and to use them for other products without further examination. Each company must therefore carry out its own additional testing as well as its own benefit-risk assessment of its own products containing TPO.

The following companies have developed the statement:

BEGO Bremer Goldschlägerei Wilh. Herbst GmbH & Co. KG
Coltène/Whaledent AG
DMG – Dental Material Gesellschaft mbH
Kulzer GmbH
Institut Straumann AG

The detailed statement on "TPO in dental medical devices" jointly written by the above-mentioned companies will be gladly made available by the companies or the VDDI office upon request.

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