

# THE MEDICAL COUNCIL

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## MALTA

Correspondence to be  
addressed to:  
'The Registrar'

SLH-OPD, Level 1,  
St. Luke's Square,  
G'Mangia, Malta  
WEBSITE: <https://health.gov.mt>

TEL: 21 255 540  
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E-MAIL: [medicalcouncil@gov.mt](mailto:medicalcouncil@gov.mt)

Dr Richard Zammit  
Superintendent of Public Health  
SLH\_OPD, Level 1,  
St. Luke's Square.  
Gwardamangia

5<sup>th</sup> November 2015

Re: **Tooth Whitening in Malta, October 2015**

"Tooth whitening" is any process that will make teeth appear whiter. Whitening products may be administered by dentists in the dental office, dispensed by dentists for home-use, or purchased over-the-counter (OTC). This can be achieved in two ways:

1. Peroxide containing bleaching products

- a) This involves both in-office bleaching and at home bleaching. In-office bleaching usually requires only one visit to the dental clinic. The dentist will apply either a protective gel to the gums or a rubber shield to protect the gums. Bleach is then applied to the teeth. A special light or laser might be used to enhance the action of the whitening agent.
- b) At-home bleaching Peroxide-containing whiteners, which actually bleach the tooth enamel. They typically contain less peroxide than the in-office bleach. They come in a gel and are placed in a tray that fits on the teeth. This is done under the prescription of a dentist

2. Non bleaching Whitening products

Whitening toothpastes (dentifrices): Unlike bleaches, these products do not change the colour of teeth because they can only remove stains on the surface.

Only peroxide containing products can bleach the tooth, which means that it actually changes the natural tooth colour. These help remove deep (intrinsic) and surface (extrinsic) stains. By contrast, non-bleaching whitening products contain agents that work by physical or chemical action to help remove surface stains only.

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In Malta, tooth whitening is a dental procedure taught in dental schools and documented in scientific literature and dental textbooks. Professional tooth whitening or bleaching, which is used to treat certain types of dental discoloration is, to date, offered to patients either as a clinic procedure carried by the dental surgeon or as a take-home kit custom-prepared in the clinic by the dental surgeon for each patient to be used under his/her supervision. Over the counter whitening toothpastes are also available in Malta.

Just like any other dental procedure, such as restorations and extractions, which are regulated within the practice of dentistry, this procedure should only be carried out by members of the dental profession and should be regulated accordingly.

Tooth whiteners may not correct all types of discoloration. In addition tooth whitening does have inherent risks since not everyone can have this procedure. It depends on the oral condition of the individual. Overuse of whiteners can also damage the tooth enamel or gums.

In recent times, non-members of the dental profession – namely beauticians have started offering tooth-whitening procedures using low concentrations bleaching products.

The idea of tooth whitening in Malta through using commercial products such as perboric acid or sodium perborate which release less than 0.1% hydrogen peroxide as laid down by directive 76/768 EEC (Scientific Committee on Consumer Products-SCCP) was based on the grounds that a maximum concentration of 0.1% of hydrogen peroxide or equivalent present in oral products, or released from other compounds or mixtures in those products, are considered to be safe for use directly by patients and non-dentists.

However, for the safety of patients, the local decision on tooth whitening must also take into consideration the presence of sodium perborate or perboric acid (which release hydrogen peroxide) as ingredients in the commercial products used for the purpose, which products have been banned in cosmetic products and no exception to the ban has been granted. These substances have been classified as carcinogenic, mutagenic, or toxic for reproduction (CMR), category 1B of Regulation (EC) 790/2009 amending Regulation 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP Regulation), as a result of being included in Part 3 of Annex VI of the CLP Regulation. This classification is applied since 1 December 2010.

Independently of its concentration, once a substance is classified as CMR 1B, its use in cosmetic products is prohibited (Article 15(2) of the Cosmetics Regulation 1223/2009). It is an automatic ban for which no implementing measures (such as amending Annexes to

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the Cosmetics Regulation) are needed. Exceptions may however be granted if the conditions laid down in Article 15(2) of the Cosmetics Regulation 1223/2009) are satisfied. As the conditions to authorize the use of these substances in cosmetic products were not met, the Commission did not grant an exception. Consequently, sodium perborate and perboric acid are considered banned in the EU as of 1 December 2010. (Vide attached declaration from the Council of European Dentists – CED – Doc\_2015\_033\_E 30 April 2015).

**As a general principle, the Medical Council, firmly believes that, in the interest of 100 % patient safety, and irrespective of chemical products used, the practice of tooth whitening should be restricted to the practice of dentistry. This is in line with the practice and policy of the General Dental Council, UK that limits the practice of tooth whitening only to the members of the dental profession.**

Moreover the American Dental Association recommends that if you choose to use a bleaching product, you should only do so after consultation with a dentist. This is especially important for patients with many fillings, crowns, and extremely dark stains. A thorough oral examination, performed by a licensed dentist, is essential to determine if bleaching is an appropriate course of treatment. The dentist and patient together can determine the most appropriate treatment. The dentist may then advise the patient and supervise the use of bleaching agents within the context of a comprehensive, appropriately sequenced treatment plan.

Since this is a very sensitive issue the Medical Council feels it should be brought to the attention of the Council of Health with a view to legislation, which will bring Malta in line with the practice as, is in the United Kingdom. Malta should be in the forefront of such legislation.

Attachments: Statement by Council of European Dentists  
Policy of the General Dental Council of UK

References:

### **EU rules for CMR substances**

Article 15 of the Cosmetics Regulation 1223/2009 contains provisions on the use of CMR in cosmetic products. As a general principle, substances classified as CMR substances of category 1A, 1B, or 2 under Part 3 of Annex IV to Regulation (EC) No 1272/2008 are

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banned for use in cosmetic products. Exceptions to this general rule are possible subject to the conditions laid down in Article 15 of the Cosmetics Regulation.

### **EU guidance for the overall exposure assessment of CMR substances in cosmetic products**

According to Regulation (EC) N° 1223/2009 on cosmetic products, the safety of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) should be assessed taking account of the exposure from all sources (cosmetics, chemicals, food, medicinal products) according to a comprehensive approach. The EU guidance for overall exposure assessment has been developed in consultation with the Scientific Committee on Consumer Safety (SCCS), the European Chemical Agency (ECHA), the European Medicine Agency (EMA) and the European Food Safety Authority (EFSA). It clarifies the respective roles of the industry, the Commission responsible Services, the SCCS and these European Agencies for collecting, providing and analyzing the exposure data.

Yours truly,

Svetlana Borg Cachia B.Com.(Hons.)(Melit.), M.A.(Public Policy)(Melit.)  
Registrar, Medical Council

cc Hons Mr Chris Fearne, Parliamentary Secretary for Health