



Brussels, 31 August 2012

## Fact sheet

### Tooth Whitening or Bleaching Products – Council Directive 2011/84/EU

1. The use of tooth whitening and bleaching products is regulated under [Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products](#), as amended by [Council Directive 2011/84/EU of 20 September 2011 \(hereinafter “the Directive”\)](#) as well as partially regulated by [Regulation \(EC\) n° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products](#) (which will enter into complete force on 11 July 2013). They are classified as cosmetic products and not as medical devices.
2. The substances affected concern **hydrogen peroxide** and other compounds or mixtures that release hydrogen peroxide in tooth whitening or bleaching products, including **carbamide peroxide** (where 16.62% of carbamide peroxide corresponds to 6% of hydrogen peroxide), **zinc peroxide** and **sodium perborate and perboric acid** (as they are considered to be hydrogen peroxide releasing substances, pursuant to the opinion of the Scientific Committee on Consumer Safety (SCCS) on sodium perborate and perboric acid, published on 22 June 2010).
3. The Directive prohibits the marketing of products containing over 6 % of hydrogen peroxide and establishes new conditions for using products between 0.1% and 6% of hydrogen peroxide, regardless the place where their use occurs – in the dental office or at home.
4. According to the Directive, products between 0.1% and 6% of hydrogen peroxide:
  - 4.1. can only be sold to dental practitioners<sup>1</sup>. Distributors need to ensure that these products cannot be supplied directly to retail;
  - 4.2. must have their first use within the dental office i.e., by dental practitioners (or under their direct supervision if an equivalent level of safety is ensured), in order to ensure that a clinical examination takes place and the exposure to these products is limited;
  - 4.3. cannot be used on a person under 18 years of age;
  - 4.4. for the rest of cycle of use, can be performed by consumers themselves as long as the access to the product is provided by dental practitioners, or by other qualified dental professionals who are under the dental practitioner’s direct supervision and responsibility.
5. The conditions of use and warnings which must be printed on the label of tooth whitening and bleaching products containing more than 0.1% and up to 6% of hydrogen peroxide, present or released are specified on entry 12 of the first part of Annex III of the Directive.
6. The Directive aims at implementing the opinion of the [Scientific Committee on Consumer Products \(SCCP\) of 18 December 2007 on hydrogen peroxide, in its free form or when released, in oral hygiene products and tooth whitening products \(SCCP/1129/07\)](#). It intends to adapt to technical progress Directive 76/768/EEC while ensuring the protection of public health. SCCP was replaced by the new Scientific Committee on Consumer Safety (hereinafter “SCCS”).

For further information please consult the CED website [www.eudental.eu](http://www.eudental.eu) or contact CED Brussels Office by telephone +32 2 736 34 29 or by email [ced@eudental.eu](mailto:ced@eudental.eu).

<sup>1</sup> Dental practitioner (i.e. dentist) is the term used by [Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications](#) (see Articles 34-37).