

- The Cosmetic Products (Safety) Amendment) Regulations 2012 (implementing Directive 2011/84 EU which amends Directive 76/768/EEC) come into force on 31 October 2012. The General Dental Council (GDC) would like to remind its registrants:
- Products containing or releasing less than 0.1% of hydrogen peroxide, including mouth rinse, tooth paste and tooth whitening or bleaching products are **safe** and will continue to be freely available on the market.
- Tooth whitening products containing or releasing between 0.1% and 6% hydrogen peroxide can **ONLY** be sold to dental practitioners.
- Concentrations exceeding 6% of hydrogen peroxide present or released in oral products, including tooth whitening or bleaching products, remain prohibited unless wholly for the purpose of the treatment or prevention of disease.

# % Sodium Perborate in BlueM recipes

<i>Product</i>	<i>% Sodium Perborate</i>	<i>% Hydrogen Peroxide release</i>	<i>Category</i>
<i>Bluem toothpaste 15 ml/75 ml</i>	<i>0,16%</i>	<i>0,055%</i>	<i>Cosmetic</i>
<i>Bluem mouthwash 50 ml/500 ml</i>	<i>0,16%</i>	<i>0,055%</i>	<i>Cosmetic</i>
<i>Bluem mouth spray</i>	<i>0,16%</i>	<i>0,055%</i>	<i>Cosmetic</i>
<i>Bluem professional oxygen fluid 500 ml</i>	<i>0,69%</i>	<i>0,38%</i>	<i>Cosmetic: Professional use</i>
<i>Bluem professional implant care oral gel 15 ml/200 ml</i>	<i>1,72%</i>	<i>0,95%</i>	<i>Cosmetic: Professional use</i>

# Calculations

- 0,1% Hydrogen Peroxide = 1 g/kg = 29,40 mMol/kg (M=34,015)
- Maximum % Sodium Perborate = 29,40 mMol/kg = 2,934 g/kg = 0,29% (M=99,815)
- 6% Hydrogen Peroxide = 60 g/kg = 1763,927 mMol/kg (M=34,015)
- Maximum % Sodium Perborate for professional use = 1763,927 mMol/kg = 2,934 g/kg = 17,73 % (M=99,815)

# Attachments

- Position Statement on Tooth Whitening UD 29.05
- SCCS OPINION 027 OPINION ON BORON COMPOUNDS
- SCCS OPINION 031 ON SODIUM PERBORATE & PERBORIC ACID
- SCCS OPINION 146 ON THE SAFETY OF BORON COMPOUNDS IN COSMETIC PRODUCTS