



Health & Consumer Protection  
Directorate-General

Scientific Committee on Consumer Products

SCCP

**Clarification on the Opinions  
SCCNFP/0653/03 and SCCP/0882/05**

on

**the Safety of Fluorine Compounds in Oral Hygiene Products  
for Children under the Age of 6 Years**



Scientific Committees

- on consumer products
- on emerging and newly identified health risks
- on health and environmental risk

The SCCP adopted this opinion at its 19<sup>th</sup> plenary on 21 January 2009

**Clarification on the opinions SCCNFP/0653/03 and SCCP/0882/05 on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years**

**About the Scientific Committees**

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

**SCCP**

Questions concerning the safety of consumer products (non-food products intended for the consumer).

In particular, the Committee addresses questions related to the safety and allergenic properties of cosmetic products and ingredients with respect to their impact on consumer health, toys, textiles, clothing, personal care products, domestic products such as detergents and consumer services such as tattooing.

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**ACKNOWLEDGMENTS**

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## **1. BACKGROUND**

In the opinion 0882/05 the SCCP concluded that "*the maximum permitted concentration of 0.15% (1500 F<sup>-</sup> ppm) fluoride does not pose a safety concern when used by children under the age of 6 years, based on the available scientific evidence.*" The Cosmetics Directive regulates in Annex III, part 1 **fluorine compounds** and the scientific opinion given by the SCCP was based on the assessment of fluorine compounds.

## **2. TERMS OF REFERENCE**

*Did the SCCP mean in the conclusion of its opinion the concentration of 0.15% fluorine instead of fluoride?*

## **3. CLARIFICATION**

Confusion may have been generated since the terms 'fluorine' and 'fluoride' are often used interchangeably in the literature as generic terms. However, in the opinion SCCP/0882/05 the term 'fluoride' was used deliberately, as only safety data on sodium fluoride in toothpaste was made available for evaluation. In addition, SCCP opinion SCCP/0882/05, stated that 'If the sole source of fluoride exposure is toothpaste containing fluoride between 1000-1500 F<sup>-</sup> ppm, used as recommended, there is a minimal concern that children under the age of 6 will develop fluorosis since the amount absorbed would be less than half the accepted adequate intake of 0.7 mg/day fluoride intake for children between the ages of 1 and 3, that maximally reduces dental caries without causing unwanted side effects'.

In both opinion SCCNFP/0653/03 and SCCP/0882/05, it is pointed out that extrapolation to other fluorine containing compounds listed in Annex III, part 1 can only be made with respect to fluorosis.

However, for the purpose of the reference to fluorine containing compounds in Annex III, part 1, made in Directive 2007/53/EC, the SCCP considers that the terms "fluorine" and "fluoride" are equivalent and interchangeable.