



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**



The SCCP adopted this opinion at its 19th 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

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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.

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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.

Scientific Committee members

Claire Chambers, Gisela Degen, Ruta Dubakiene, Bozena Jazwiec-Kanyion, Vassilios Kapoulas, Jean Krutmann, Carola Lidén, Jean-Paul Marty, Thomas Platzek, Suresh Chandra Rastogi, Jean Revuz, Vera Rogiers, Tore Sanner, Günter Speit, Jacqueline Van Engelen, Ian White

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels
Sanco-Sc6-Secretariat@ec.europa.eu

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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

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Dr. C. Chambers (rapporteur)
Prof. G. Degen
Dr. B. Jazwicz-Kanyion
Prof. V. Kapoulas
Prof. J.-P. Marty
Prof. T. Platzek
Dr. S.C. Rastogi
Prof. J. Revuz
Prof. V. Rogiers
Prof. T. Sanner (chairman)
Dr. J. van Engelen
Dr. I.R. White

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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

1. BACKGROUND

In the opinion 0882/05 the SCCP concluded that *"the maximum permitted concentration of 0.15% (1500 F 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- 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.