



## Commentary

## Opinion of the Scientific Committee on Consumer safety (SCCS) – Final opinion on water-soluble zinc salts used in oral hygiene products

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## ABSTRACT

The SCCS has estimated that exposure to water-soluble zinc salts via toothpaste and mouthwash at the concentrations of 1 and 0.1%, respectively, may lead to a daily intake level of 3.54 mg for adults and children aged 6–17 years. This exposure constitutes between 14 and 35% of the Upper Limit (UL) for these age groups. Therefore, the SCCS considers that the use of zinc in toothpaste and mouthwash per se is safe for adults and children aged 6–17 years.

The SCCS has estimated that exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% may lead to a daily intake level of 1.0–2.00 mg for children aged 0.5–5 years. This exposure constitutes between 10 and 29% of the UL for this age group. Therefore, the SCCS considers that the use of zinc in toothpaste per se is safe for children aged 0.5–5 years.

Exposure to zinc may also occur from sources other than oral hygiene products. An important source of zinc in the population is the diet. This assessment has not taken into account the daily dietary intake of zinc.

The dietary zinc intake (estimated by EFSA in 2014) ranges from 6.8 to 14.5 mg/day in adolescents aged 10 to < 18 years, from 5.5 to 9.3 mg/day in children aged 3 to < 10 years and from 4.6 to 6.2 mg/day in children aged 1 to < 3 years. Therefore, exposure to zinc via the diet may already exceed or be close to exceeding the upper limits of 18, 13, 10 and 7 mg/day for the age groups 11–14, 7–10, 3–7 and 1–3 years, respectively. Any additional source of exposure, including cosmetics, may lead to exceeding the upper limits for children.

The SCCS cannot advise which portion of the upper limit should be allocated to exposure from cosmetic products. When assessing exposure to chemicals, allocation factors that reflect a reasonable level of exposure while still being protective may be applied. For exposure via toys or drinking water, for example, allocation factors of 10% or 20% of the reference value may be considered as safe. In the case of zinc, the use of 1% in toothpaste and 0.1% in mouthwash constitutes between 10 and 35% of the upper limit depending on the age group. The SCCS is aware that upper limits may be exceeded in some cases because the default values used in this Opinion are based on conservative estimates.

Water-soluble Zinc salts, including amongst other Zinc Acetate and Zinc Chloride with the exception of Zinc 4-hydroxybenzenesulphonate and Zinc Pyrithione, are regulated in entry 24 of the Annex III of the Regulation (EC) 1223/2009. They are currently allowed for use in cosmetic products in concentrations of up to 1% as Zinc with a wide range of functions ranging from antioxidant to antimicrobial and skin protecting.

Tolerable total uptake level (UL) for Zinc up to 25 mg was established by the Scientific Committee on Food in 2003. Cosmetic products might account for maximum 10% of the UL.

In July 2014, the German authority, Federal Institute for Risk Assessment (BfR), has submitted a dossier expressing potential safety

concerns related to the use of Zinc salts in oral products such as toothpastes and mouthwashes. According to BfR, cosmetic products might account for maximum 10% of the UL. While confirming the safety for adults of toothpastes containing zinc (maximum Zinc content: 1%), BfR concluded that: "The use of mouthwashes with a Zinc content of up to 1%, however, can lead to the 10% share of UL which should be accounted for by cosmetic products being significantly exceeded. The BfR categorises these products as potentially dangerous for the consumer if used regularly and over an extended period."

In addition, BfR has shown concerns for the particular age group of children and adolescents (1–17 years old) due to their lower body weight as the use of toothpastes with a maximum content up to 1% of

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Zinc might lead to a significant excess of the maximum 10% share of UL contribution of the cosmetic products, particularly in the age group 1–10 years old.

To minimize the potential risks, BfR has proposed to lower the maximum Zinc concentration to 0.1% in oral hygiene products for adults while free Zinc should not be present in these products for children and young people aged under 18.

In February 2016, Cosmetics Europe has transmitted an aggregate exposure assessment for children and adults to demonstrate that the combined exposure from food as well as oral care products, at the current allowed concentration of up to 1% as Zinc in toothpastes is safe across all age groups. On the other hand, for mouthwashes they support the maximum use level at concentration of up to 0.1% as Zinc for all age groups. The SCCS has estimated that exposure to water-soluble zinc salts via toothpaste and mouthwash at the concentrations of 1 and 0.1%, respectively, may lead to a daily intake level of 3.54 mg for adults and children aged 6–17 years. This exposure constitutes between 14 and 35% of the Upper Limit (UL) for these age groups. Therefore, the SCCS considers that the use of zinc in toothpaste and mouthwash per se is safe for adults and children aged 6–17 years. The SCCS has estimated that exposure to water-soluble zinc salts via toothpaste at the concentrations of 1% may lead to a daily intake level of 1.0–2.00 mg for children aged 0.5–5 years. This exposure constitutes between 10 and 29% of the UL for this age group. Therefore, the SCCS considers that the use of zinc in toothpaste per se is safe for children aged 0.5–5 years.

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#### Reference

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