

## CED feedback to the consultation by the European Chemicals Agency (ECHA) on Sodium Fluoride

Following the proposal by the French ANSES (French Agency for Food, Environmental and Occupational Health & Safety) to classify sodium fluoride as an endocrine disruptor and reproductive toxicant.

The use of sodium fluoride in toothpaste and other low-concentration topical dental products is a cornerstone of contemporary preventive dentistry, supported by decades of robust clinical evidence. As also emphasized in the [CED White Paper on Prevention](#), daily toothbrushing with fluoridated toothpaste represents a fundamental, population-wide intervention that significantly reduces the incidence and progression of dental caries across all age groups. On the other hand, fluoridated dental care products should not be ingested, with only marginal effects resulting from ingesting small quantities of fluoride.

Sodium fluoride in toothpaste acts predominantly through topical mechanisms at the tooth surface. Repeated exposure of the tooth surface to low concentrations of fluoride fortifies the enamel, inhibits demineralization under acidic conditions, enhances remineralization of early carious lesions and reduces the metabolic activity of cariogenic bacteria.

Studies consistently show that brushing twice daily with fluoride toothpaste provides greater protection than once-daily brushing, and that caries reduction increases with fluoride concentration within commonly recommended ranges. Concentrations around 1,000–1,450 ppm fluoride have been shown to provide an effective balance between preventive benefit and safety for general use, while higher concentrations may be reserved for individuals with elevated caries risk under professional guidance. The CED therefore welcomes the EFSA's latest [Updated consumer risk assessment of fluoride](#), with updated opinions on the maximum levels of fluoride intake for preventing neurodevelopment risks, as well as thyroid, and bone issues and risks of fluorosis in children. The levels indicated above therefore fall under the scope recommended by EFSA, with safeguards needed to minimize the ingestion of fluoridated dental products.

Considerations related to dental fluorosis must be interpreted in light of exposure patterns and actual conditions of use. Dental fluorosis is associated with excessive systemic fluoride intake during enamel development, most commonly due to ingestion of fluoride-containing products rather than their intended topical action. Preventive guidelines therefore focus on appropriate toothpaste quantities, age-adapted fluoride concentrations, and parental supervision of brushing in young children. When used in

accordance with established guidelines, the risk of clinically significant dental fluorosis is extremely low.

From a public health perspective, sodium fluoride toothpaste plays a particularly crucial role in protecting vulnerable populations, including children, individuals with high caries activity, orthodontic patients, older adults, and persons with reduced salivary flow. In these groups, topical fluoride exposure contributes to disease control, reduces the need for invasive treatments, and supports oral health equity.

The European Region was identified in 2019 as the region with the highest prevalence of dental caries on permanent teeth across all WHO regions. This is coupled with the highest economic costs associated with caries treatment in Europe in comparison to other diseases; according to the European Observatory on Health Systems and Policies (2022) the treatment cost for oral diseases is ranked the third highest after the treatment of diabetes and cardiovascular diseases.

Untreated dental caries impose substantial indirect social and economic burdens, including reduced productivity, impaired school attendance and academic performance in children, increased pediatric hospitalizations, and a diminished quality of life. It may also lead to irreversible consequences on general and overall health as a future adult and widened existing oral health inequalities across Europe.

It is therefore essential to maintain safely proven and cost-effective preventative measures across the European Union. The CED urges caution when evaluating the proposal to revise the classification of sodium fluoride by ECHA, including the need to differentiate topical from internal use of fluoride (and specifically cases of the swallowing of fluoride). The CED emphasizes the critical need to assess the risk versus benefit factor.

**In conclusion, the use of sodium fluoride in toothpaste ensures a favorable risk-benefit balance, with preventive benefits far outweighing any potential adverse effects in all ages.** The evidence, as well as multiple years of clinical knowledge, highlight continued reliance on fluoride toothpaste as a cornerstone of caries prevention. Benefits of fluoride in preventative oral health treatments as well as for oral and general health promotion, from childhood all the way to older age outweigh the risks. Nevertheless, further-in depth assessments must be carried out for evaluating the safety of topical uses of dental care products.