



## General provisions for the Toothfriendly certification of children's toothpastes (February, 2021)

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### 1. General aspects

- 1.1 The present provisions are mandatory for Toothfriendly International and its affiliated national organizations in relation to the Toothfriendly certification of children's toothpastes. Certified toothpastes may be promoted with the Toothfriendly device mark and the associated word marks on the product label and in the associated commercial communications under a license agreement with the manufacturer or distributor of the product.
- 1.2 Generally, products that are not in compliance with the applicable national regulations may not be certified.

For certification, products must comply with the present provisions that have been laid down and have been accepted by a panel of independent, qualified experts convened and consulted by Toothfriendly International between March to May 2015.

- 1.3 Modification of a provision (Articles 2 - 4) may be requested by a national Toothfriendly organization for its territory only if the existing provision conflicts substantially with the recommendations of the respective national medical dental association because of specific national conditions (e.g., drinking water fluoridation). However, such modification may be made only if (a) it does not foreseeably diminish the caries preventive benefit or the safety of the children's toothpaste, and (b) Toothfriendly International, after having consulted its Expert Panel, accepts the requested modification.



## 2. Provisions on the fluoride content and the conditions of use

- 2.1 For the purpose of this document, the "fluoride content" of a toothpaste is its content of bioavailable fluoride calculated from measurements of fluoride in the aqueous suspension of the toothpaste with a fluoride-sensitive electrode or, if appropriate, in the toothpaste/saliva mixture recovered quantitatively after toothbrushing. This method allows to detect (a) interactions between sources of fluoride and other components of the toothpaste that could impair its caries-preventive efficacy and (b) changes of the bioavailable fluoride content due to inappropriate storage conditions and storage time of the toothpaste.
- 2.2 On request, other equivalent methods for the determination of bioavailable fluoride may be accepted. However, such request must be based on (a) publicly available and generally recognized scientific data and (b) a written consensus statement of independent experts who are qualified on basis of their education and experience in the subject matter.
- 2.3 The fluoride content and the recommended conditions of use are as follows:

### From eruption of the first tooth to the second birthday:

Fluoride content: 500 – 1000 ppm

Recommended use:

at 500 ppm: pea-size amount (about 250 mg), once per day

at >500 ppm: grain of rice or smear (about 100 mg), twice per day.

### From the second to the sixth birthday:

Fluoride content: 500 – 1000 ppm\*

Recommended use:

at 500 ppm: up to full length of brush (250 mg – 500 mg), twice per day

at 1000 ppm: pea-size amount (about 250 mg), twice per day.

\*For children 2–6 years, 1000+ fluoride concentrations may be considered based on the individual caries risk



Six years and older:

Fluoride content: 1400 – 1500 ppm

Recommended use: up to full length of brush (about 500 mg – 1000 mg), twice per day.

- 2.4 In countries in which additional fluoridation programs are implemented at population level (fluoridated drinking water, fluoridated table salt) or at individual level (fluoride tablets), care must be taken that the total fluoride ingestion from all source does not exceed 0.05 – 0.07 mg/kg bodyweight/day.
- 2.5 Note in this regard that the use of fluoridated tablets is explicitly not recommended by the Swiss and German Toothfriendly associations ("Aktion Zahnfreundlich", Switzerland and "Aktion Zahnfreundlich e.V.", Germany).

3. Provisions on labelling

- 3.1 The instructions of use shall be clearly legible (type size, color, contrast) and be shown in a conspicuous place of the toothpaste tube.
- 3.2 The instructions of use of toothpastes destined for children before the sixth birthday must be supplemented by a statement according to which the application of the toothpaste and the toothbrushing must be supervised.
- 3.3 The terms "pea-size" and "smear" [cf. Article 2(3)] should be illustrated on the toothpaste tube, its cardboard box or an inserted leaflet. If none of this is feasible or acceptable, a link (QR-Code, Web address) to the company's or the national Toothfriendly association's respective information site must be applied conspicuously on the toothpaste tube or its cap, its cardboard box or an inserted leaflet.



#### 4. Additional provisions

4.1 Excluded from the use of the Toothfriendly certification is children's toothpaste with

- a taste that makes it appear as a food,
- bactericidal or bacteriostatic ingredients except permitted preservatives, fluorides as well as extracts and essential oils of plant origin.

4.2 Tensides and preservatives are to be used in technologically needed concentrations only ("quantum satis").

#### 5. Review of certifications

Certifications may be reviewed by the competent national Toothfriendly association or Toothfriendly International under the conditions specified in the License Agreement under which the right for the use of the Toothfriendly device and word marks is granted to the manufacturer or distributor of the children's toothpaste.