AKTION ZAHNFREUNDLICH

Criteria for Oral Care Products (Implementing Regulations)

(V27.02.21/22.11.21)

1. Toothpastes for juniors and adults

The Toothfriendly logo can be awarded if the toothpaste fulfils the following criteria concerning:

1) Caries prophylaxis
2) Abrasiveness
3) Cleaning efficacy

The Toothfriendly logo cannot be awarded if the toothpaste contains triclosan.

Assessment criteria for fluoride toothpastes:

1) Caries prophylaxis

According to the current state of knowledge, a toothpaste first and foremost has a caries prophylactic efficacy due to fluoride. This efficacy is influenced by the fluoride concentration, the type of fluoride compound and the question as to whether the fluoride is present in a compatible formulation that makes it bioavailable and thus effective. The total fluoride content may vary from the following recommendations and must meet the respective national guidelines.

a) Fluoride content

The following classification is applied for **junior and adult toothpastes** (as of age six):

0 to 700 ppm	= insufficient fluoride concentration
>700 to 900 ppm	= sufficient fluoride concentration
>900 to 1,000 ppm	= satisfactory fluoride concentration
>1,000 to 1,250 ppm	= high fluoride concentration
>1,250 ppm	= very high fluoride concentration

The assessment is modified by the type of fluoride compound.

b) Type of fluoride compound

This is rated with the following rank order:

I. Sodium fluoride (NaF); amine fluoride (AmF), stannous fluoride (SnF2) and a combination of these compounds.
II. Monofluorophosphate (MFP)
The sole use of MFP leads to a devaluation of 10% compared to the other fluoride compounds (NaF, AmF, SnF2).

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A toothpaste containing ionically bound fluoride and soluble calcium compounds, e.g., calcium carbonate, cannot be awarded the Toothfriendly logo because the formulation is incompatible.

Using these criteria, an assessment is made on the basis of the fluoride concentration.

The following rating scale is applied:

- very good caries prophylaxis (very high fluoride concentration)
- good caries prophylaxis (high fluoride concentration)
- satisfactory caries prophylaxis (satisfactory fluoride concentration)
- low caries prophylaxis (sufficient fluoride concentration)
- no caries prophylaxis (insufficient fluoride concentration)

The other factors mentioned have a modifying effect. For example, a toothpaste with a fluoride concentration of 1,300 ppm is rated as "very good caries prophylaxis" (due to its very high fluoride concentration). If it contains NaMFP as a fluoride source, however, its rating drops by 10%. It would thus end up with a fluoride equivalent of 1,170 ppm and would then only have "good caries prophylaxis" (a high fluoride concentration).

Only toothpastes with "very good" caries prophylaxis can be awarded the Toothfriendly logo.

c) Abrasives
A toothpaste must be formulated in such a way that the abrasives used do not lead to inactivation of the fluoride that the toothpaste contains. Calcium carbonate can partially inactivate this in the tube already by reacting with the fluoride to form low-solubility calcium fluoride (CaF2). (See above)

2) Abrasiveness
The dentin abrasivity (RDA) and enamel abrasivity (REA) are key factors. The toothpaste should not exceed an RDA value of 150 and a REA value of 15, determined by the radiotracer method of HEFFERREN et al. (1984). The same limits also apply for the RDA – PE and REA-PE method.

Only toothpastes with RDA/RDA-PE ≤ 150 and REA/REA-PE ≤ 15 can be awarded the Toothfriendly logo.

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3) Cleaning efficacy
The Pellicle Cleaning Ratio indicates the extent to which a toothpaste is able to remove existing stains and prevent new stains from forming. The cleaning power of a toothpaste can be achieved either chemically, mechanically or through a combination of both. Mechanical prevention or removal of stains is usually accompanied by increased dentin abrasivity (RDA and REA values).

The cleaning effect is determined by the procedure described by STOOKEY et al. (1982). This method determines the relative cleaning effect of a toothpaste as the Pellicle Cleaning Ratio (PCR) in relation to the ADA-reference paste, which is specified as 100. The following rating scale is applied:

PCR	cleaning efficiency
≥ 100	= very good
70 x < 100	= good
50 x <70	= satisfactory
30 x <50	= sufficient
> 30	= insufficient

Only toothpastes with a least "good" cleaning efficacy can be awarded the Toothfriendly logo.

2. Children's toothpastes

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 and, 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 cariespreventive efficacy and (b) changes of the bioavailable fluoride content due to inappropriate storage conditions and storage time of the toothpaste.

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.

The fluoride content and the recommended conditions of use are as follows:

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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: 950 ppm (Tolerance value +- 50 ppm)
Recommended use:
at 500 ppm: up to full length of brush (250 mg – 500 mg), twice per day
at 950 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

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.

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).

Provisions on labelling:
The instructions of use shall be clearly legible (type size, color, contrast) and be shown in a conspicuous place of the toothpaste tube.

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.

The terms „pea-size" and „smear" 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.

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Additional Provisions:
Excluded from the use of the Toothfriendly certification is children's toothpaste with:

- bactericidal or bacteriostatic ingredients except permitted preservatives, fluorides as well as extracts and essential oils of plant origin.

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

3. Mouth rinse

Mouth rinses serve a range of primary purposes that are listed below. The manufacturer must present evidence from a controlled clinical study or in situ study that shows a statistically significant and clinically relevant effect. No medical or dental adverse effects, especially erosion, should be associated with the product. For certain products the evidence may also derive from laboratory studies. Depending on the purpose, mouth rinses should preferably contain 200 – 500 ppm bioavailable fluoride. The Toothfriendly logo cannot be awarded if the mouth rinse contains triclosan.

- Caries protection: The main anti-caries effect is caused by the fluoride content of the mouth rinse. Antibacterial ingredients alone do not qualify a mouth rinse as caries-protective.
- Erosion protection: The anti-erosive effect has to be proven in a controlled clinical study or in situ study, published in a peer-reviewed journal with impact factor. The study must clearly show a preventive effect against demineralisation under erosive conditions (a reduction of erosion associated softening of at least 40% compared to a negative control must be achieved).

For other types of mouth rinses, the following desired effect should be proven in a registered and published clinical study.

- Gingivitis/periodontitis: Reduction of plaque and bleeding scores has to be proven in a controlled clinical study of at least 28 days duration, published in a peer-reviewed journal with impact factor (a reduction of plaque and bleeding scores of at least 40% compared to a negative control must be achieved; initial plaque score shall not exceed 80%).

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- Hypersensitivity: Reduction of Schiff and VAS scores has to be proven in a controlled clinical study, published in a peer-reviewed journal with impact factor (a reduction of Schiff and VAS scores of at least 40% compared to a negative control must be achieved).
- Halitosis: Reduction of olfactoric or Halimeter test scores has to be proven in a controlled clinical study, published in a peer-reviewed journal with impact factor (a reduction of olfactoric or Halimeter test scores of at least 40% compared to a negative control must be achieved).

4. Interdental brushes

The Toothfriendly logo can be awarded if the manufacturer provides user trainings for professionals in order to avoid harm to the soft and hard tissues. Furthermore, the cleaning effect should be proven in a controlled clinical study, published in a peer-reviewed journal with impact factor. No adverse effects should be reported (plaque scores should be reduced by 25% or more after one stroke; bleeding scores should be reduced by 40% compared to a negative control).

5. Dental floss

Due to the many possibilities that exist for using dental floss incorrectly and thus causing damage to the periodontium, dental floss is not awarded the Toothfriendly logo.

6. Manual toothbrushes

The Toothfriendly logo can be awarded if the manufacturer provides user trainings (e.g., videos, written instructions or pictograms) in order to avoid harm to the soft and hard tissues. Furthermore, manual toothbrushes must have either rounded or tapered synthetic bristles (scanning electron microscopy evidence).

7. Electric toothbrushes

The Toothfriendly logo can be awarded if the manufacturer provides user trainings (e.g., videos, written instructions or pictograms) in order to avoid harm to the soft and hard tissues. Furthermore, the following requirements have to be fulfilled:

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1) Bristles
Either rounded or tapered synthetic bristles (scanning electron microscopy evidence).

2) Abrasion
Abrasion is a multifactorial effect influenced by the combination of oscillation frequency, contact pressure, brush field design, toothpaste abrasivity, oscillation amplitude and the tooth substrate itself. Overall, a very low abrasivity must result on non-eroded human or bovine dentin specimens. The company must recommend a specific toothpaste (in the instructions) to be used with their electric toothbrush; with this toothpaste and the highest power output of their electric toothbrush an RDA/RDA-PE <150 and an REA/REA-PE <15 must be achieved. Furthermore, a warning must be included in the instruction that with other toothpastes than the recommended an increased abrasivity might result. There must additionally be evidence of very little gingival injury in the porcine model. Tests performed by a reputable testing centre will be accepted for the abrasivity measurement and the quantification of gingival injury. Recommendations for universities that conduct the test are available on request.

Electric toothbrushes should bear a CE or equivalent mark.

Cleaning and non-contact cleaning effect should be proven in a controlled clinical study, published in a peer-reviewed journal with impact factor. No adverse effects should be reported (plaque scores and bleeding scores should be reduced by 50% compared to a negative control, whereby the initial plaque score shall not exceed 80%).

8. Pacifiers

Pacifiers can be awarded the Toothfriendly logo if a prospective controlled clinical study has provided evidence that no open bite is induced. The study must show a significant difference ($p < 0.05$) from the control, have sufficient power (alpha 0.05; beta 0.8) and be published in a peer reviewed journal with an impact factor. A controlled clinical study or an equivalence study can be carried out with the AZS pacifier, that has already been certified.

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9. Saliva-substitute solutions

Saliva-substitute solutions are used to lubricate the oral cavity if the patient is unable to produce sufficient saliva due to illness or following radiation therapy. These saliva-substitute solutions must have a neutral pH (pH 6.8 - 7.2), or, if the saliva substitute solution is acidic, the pH must not be below pH 6 and must have a fluoride content 4-10 ppm fluoride. The pH value should be measured in a laboratory, i.e., extra-orally.

Dry mouth products
Products that are marketed as dry mouth products should document their effectiveness against xerostomia (subjective assessment by respective patients) and their harmlessness in a controlled clinical trial. Furthermore, the products should not be erosive (demineralization shall not cause more than 5 KHN measured in enamel in an in vitro study).

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