AKTION ZAHNFREUNDLICH

Criteria and test methods for the determination of "toothfriendly" properties of products

(V10.02.21)

Principle

The "Toothfriendly" properties of foods and other products, which are consumed for a nutritional, cosmetic or medical purpose or for pleasure and which upon ingestion come in contact with teeth, are determined by standardized in vivo pH-telemetry tests conducted by accredited test facilities. For accredited test facilities see under the heading "test centers".

A product is considered "Toothfriendly" if it lacks a significant cariogenic and erosive potential in healthy people under usual conditions of use.

Test methods

Evaluation of cariogenic potential

The cariogenic potential of a product is evaluated by measuring plaque-pH in vivo during and for thirty minutes after consumption of the product using an in-dwelling pH electrode. Using this method, the product is tested in healthy volunteers which have a 3-7-day old plaque on the electrode which is mounted in a removable, restorative dental device, it surrounded by human enamel, and is facing the sound interdental surface of an adjacent, natural tooth.

The plaque pH curve of a test product is the resultant of at least two measured pH-values per minute. A product is considered to lack a significant cariogenic potential if it does not depress the pH of the interdental plaque below 5.7 by bacterial fermentation, neither during consumption nor during a period of 30 minutes following consumption. The pH curve must clearly show the time of consumption of the test product and the 30-minute period following consumption.

The proper functioning of the plaque-pH-measuring equipment and the plaque metabolism must be checked in each test by rinsing with 10 ml sucrose solution (10%) or by the consumption of a sugar containing analogue of the test product. This positive control must depress plaque pH to values below 5.

If a range of products with different flavors is to be evaluated, one product must be tested in at least four different volunteers and each additional flavor variety in at least two different volunteers. Exceptions to this general requirement for testing may be made for products, which are substantially equivalent, with regard to the ferment-ability and acidity of their ingredients, to an already tested product of the same manufacturer.

Details of the plaque-pH test are described in a Standard Operation Procedure (SOP), which is followed by accredited test facilities for the performance of such tests.

Evaluation of erosive potential

Products suspected of having an erosive potential on dental hard tissue by virtue of their acidic components must be tested as follows. An aqueous solution of the product is made (1 g/15 ml distilled water) and its pH is measured. If the pH-value is below 5.7 or if it is impossible to make an aqueous solution of the product, the following in vivo test must be performed. Parallel or in addition to the measurement of interdental plaque pH, the pH of oral fluid is recorded during and for at least 15 minutes after consumption of the product using a clean (i.e., plaque-free) electrode. This electrode must either be placed on the buccal surface of either the maxillary canine or first premolar, or it is facing an interproximal space (i.e., is identical with the electrode used for plaque-pH measurement).

A product is regarded as not presenting a significant erosive potential if the interdental plaque pH does not fall below 5.7, and the acid exposure of the plaque-free electrode does not exceed 40µmol H^+ x min, established by calculating the area under the curve [acid concentration (in µmols H^+) x time (in minutes)]. (This value is equivalent to the exposure to a solution of pH 5 for 4 minutes).

Test centers

The accreditation criteria for test centers include the following:

The Director of the pH test centre must possess a university qualification, preferably in dental surgery or dental medicine. The test centre must have

sufficient personnel adequately trained to fulfill the technical and administrative requirements.

The test procedures must have been accepted by an ethical committee.

The test centre must be able to continually provide objective, reproducible and scientific plaque-pH measurements.

The test centre must take part in ring tests at their own cost. The ring tests will be blind and will involve pH measurements of interdental plaque and oral fluid using various test products supplied by Aktion Zahnfreundlich Schweiz.

Accredited Test Laboratories

Zurich
Prof. Dr. Th. Attin
Zentrum für Zahn-, Mund-, und Kieferheilkunde University of Zurich
Plattenstr. 11
8028 Zürich, Switzerland
Tel: +41 446343304
E-mail: thomas.attin@zzm.uzh.ch

Witten/Herdecke
Prof. Dr. Stefan Zimmer / Christian Greune Dept. of Operative and Preventive Dentistry University Witten/Herdecke
Alfred-Herrhausen-Str. 050
58448 Witten, Germany
Tel: +49 (0) 02302 926 613
E-mail: christian.greune@uni-wh.de

Beijing
Prof. Wang Xiaoling
Department of Preventive Dentistry, Peking University School of Stomatology, 22 Zhongguancun Nandajie, Haidian District Beijing 100081, PR China

Tel: +86 10 82195543
e-mail: kqwxll@gmail.com