Australian Competition & Consumer Commission

Final Assessment of Certification Trade Mark Application 1101569 lodged by Aktion Zahnfreundlich (Toothfriendly)

The Australian Competition and Consumer Commission (the ACCC), in accordance with the requirements of the *Trade Marks Act 1995*, has completed its Final Assessment of the above Certification Trade Mark (CTM) application.

The ACCC's Final Assessment is that it is satisfied that:

(a) the approved certifiers demonstrate the attributes necessary to competently certify the goods in respect of which the CTM is to be registered;

(b) the rules governing the use of the CTM would not be to the detriment of the public; and

(c) the rules governing the use of the CTM are satisfactory having regard to the principles relating to restrictive trade practices set out in Part IV of the *Competition and ConsumerAct* (the Act); the principles relating to unconscionable conduct, unfair practices, product safety and product information set out in the Australian Consumer Law.

Signed.....Peter Kell..... **(Deputy Chair)**

Date.....6 APRIL 2011.....

AKTION ZAHFREUNDLICK

RULES

For the issue of Licences and Certificates for the use of the Aktion Zahnfreundlich Trade Mark 1101568 (5, 30 and 32) TOOTHFRIENDLY (word mark) and 1101569 (5, 30 and 32) TOOTHFRIENDLY Tested & Device, by persons manufacturing or distributing foods and beverages which, by virtue of the absence of fermentable sugars and excessive amounts of acids, do not harm the teeth.

DEFINITIONS

1. Within the meaning of these Rules:-

Trade Marks means TOOTHFRIENDLY (word mark) and TOOTHFRIENDLY Tested & Device registered as a Certification Marks under the provisions of s.169 of the Trade Marks Act 1995 under Nos. 1101568 and 1101569;

Association means Aktion Zahnfreundlich which is an unincorporated Association and registered as a non-profit making Association which is organised and exists under the laws of Switzerland. It is registered in the Canton of Zurich under Article 60ff ZGB of the Swiss Civil Code (SCC). The purpose of the Association is to promote public awareness of the dental advantages of foods and beverages which have been shown to be non-cariogenic and non-erosive, by means of dissemination of information and education of the public in general. The Association does not use the Trade Marks on the goods.

container includes any package, bag, box or carton;

label includes any band, sticker, ticket, transfer or wrapper;

register means the register kept by the Association of the persons who are authorised users of the Trade Marks in accordance with these rules;

authorised user means other associations and manufacturers or distributors of toothfriendly products authorised by the Association to use the Trade Marks and holding a Licence Agreement;

the test criteria and test method means the criteria and method for the determination of toothfriendly properties of products outlined in Annex A of these Rules;

Licence Agreement means a written agreement between the Association and an authorised user which inter alia contains a specification of the products qualified to bear the Trade Marks;

goods or product means any of the following goods:-

Medicated lozenges including medicated throat lozenges; medicated mouth gargles and rinses and breath fresheners in class 5

Coffee, tea, cocoa, sugar, rice, tapioca, sago, artificial coffee; flour and preparations made from cereals, bread, pastry and confectionery, chewing gum, ices; honey, treacle; yeast, baking powder; salt, mustard; vinegar, sauces (except salad dressings); spices; ice being goods in class 30

Beers; mineral and aerated waters and other non-alcoholic drinks; fruit drinks and fruit juices; syrups and other preparations for making beverages being goods in class 32

2. The Trade Marks are the property in Australia of Aktion Zahnfreundlich (the Association) and cannot be used by any person except under and by virtue of permission granted by the Association.

3. The power of issuing and renewing and withdrawing and cancelling a Licence Agreement and Certificate (Annex B) is vested in the Association provided that in the event of any dispute, between the Association and an applicant to use the Trade Marks or an authorised user seeking renewal of his Licence Agreement, regarding whether any particular goods are entitled to bear the Trade Marks, or whether the applicant or authorised user is entitled to obtained certification of his goods, appeal may be made to an independent body agreed to by all parties. The decision of such independent body shall be final provided that before giving a decision the independent body shall fix a date for submitting evidence on the matter or making an appearance by the Assocation or its duly appointed representative.

4. The register shall contain (in addition to any other particulars that may from time to time be deemed necessary by the Association) the name and address of each authorised user and the description of the type of goods for which it is authorised to use the Trade Marks together with the date of its registration and particulars of renewal or cancellation of its Licence Agreement. The register shall be kept at the offices of the Aktion Zahnfreundlich, C/O Zahnarztliches Inst der Univ Zurich, Plattenstrasse 11, Postfach 8028 Zurich, Switzerland or at another place as determined by the Association from time to time. The Association shall advise any person upon request of that other place at which the register is kept for public inspection.

5. In order to qualify for use of the mark, a product must be recognised, by Expert Opinion, to be toothfriendly, ie. to lack a significant cariogenic and erosive potential. The Expert Opinion must be based on the results of an in vivo plaque - pH - telemetry test which has been conducted by an independent test centre and which has shown that the product does not depress the pH of interdental plaque below a value of 5.7 during consumption and during a period of at least 30 minutes thereafter. In addition, the product may not acidify the oral fluid to an extent that is considered to promote erosion of the tooth. (Details of the test criteria and test method are contained in Annex A).

In order to assure a state - of - the - art performance of the plaque pH telemetry test, the test centre must be accredited by the Association. The certification criteria for test centres and a list of test centres are contained in Annex A.

6. The authorised user of the Trade Marks must provide to the Association written results of the tests described and conducted in line with the conditions set forth in Annex A. Any changes in the formulation of the product to which the Trade Marks are applied makes renewed testing necessary.

Post – marketing surveillance tests are made at the expense of the authorised user to the extent that such tests are required by the official national food control authorities. Additional tests on products purchased on the market may be conducted by the Association at its own expense at any time.

7. Non-compliance with these regulations or the provisions of the Licence Agreement under which use of the Trade Marks is granted, leads to termination of the Licence Agreement. After termination of the agreement, products may no longer be distributed or sold under the Trade Marks.

8. In accordance with the Licence Agreement, the authorised users are entitled to use the Trade Marks in relation to their goods and shall apply markings (such as ®) required by the Association, to indicate that the Trade Marks are registered.

9. The authorised users shall use the Trade Marks as registered and shall make no modifications thereto except that the authorised users shall have the right to choose sizes and colours for the Trade Marks.

10. For the use of the Trade Marks the authorised users have to pay a one – time admission fee as well as a licence fee which is sufficient to cover the cost of the public information campaigns which the Association intends to launch in order to explain the meaning of the logo to the public. The admission and licence fee is not to be excessive so as to allow for the participation of small businesses.

11. Any amendments to these Rules will be submitted to the Registrar of Trade Marks.

Exhibit 1

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

Principle

Whether 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, qualify for distinction with the "Toothfriendly" mark, is determined by standardized *in vivo* pH-telemetry tests conducted by test facilities accredited by Aktion Zahnfreundlich (Switzerland).

A product is considered to qualify for distinction with the "Toothfriendly" mark 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 at least four healthy volunteers two of which have a 3-4 day old plaque and two of which have a 5–7 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 fermentability 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 all test facilities accredited by Aktion Zahnfreundlich (Switzerland) for conducting 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 interproxinal space (i.e., is identical with the electrode used for plaque-pH measurement).

For the *in vivo* test, each product must be tested in at least two volunteers. The results of the measurements must be adequately documented.

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

At present (December 20, 2004), the following independent test centers are accredited by Aktion Zahnfreundlich (Switzerland) to determine whether products qualify for distinction with the "Toothfriendly" mark:

1. Prof. Dr. Th. Imfeld
   Zentrum für Zahn-, Mund-, und Kieferheilkunde der Universität Zürich
   Plattenstr. 11
   CH-8028 Zürich

2. Prof. Dr. Dr. L. Stösser
   Klinikum der F-Schiller-Universität Jena
   Zentrum für Zahn-, Mund und Kieferheilkunde, Bereich Erfurt
   Poliklinik für Präventiv- und Kinderzahnheilkunde
   Nordhäuser Strasse 78
   D-99089 Erfurt

3. Dr. Shoko Takahashi-Abbe
   Department of Oral Biochemistry
   Tohoku University School of Dentistry
   4-1 Seiryo-machi
   Sendai, 980-8575, Japan

The accreditation criteria for test centers include the following:

The Director of the 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 procedure must have been accepted by an ethical committee.

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

The test centre must take part in ring tests at their own cost. The ring tests are blind and involve pH measurements of interdental plaque and oral fluid using test products supplied by Aktion Zahnfreundlich (Switzerland) or Toothfriendly International.

August 8, 2007

TRADEMARK LICENCE AGREEMENT

This Agreement is BY and BETWEEN:

Aktion Zahnfreundlich

an association registered in the Canton of Zürich, Switzerland, having its offices at

c/o Zentrum für Zahn-, Mund-
und Kieferheilkunde der Universität Zürich
Plattenstrasse 11
8032 Zürich
Switzerland

(herein known as "LICENSER")

AND

Toothfriendly International,

an association registered in the Canton of Basel-Stadt, Switzerland, having its offices at

Bundesstrasse 29
4054 Basel
Switzerland

(herein known as "LICENSEE").

ARTICLE 1 - BACKGROUND

1. Licenser is a non-profit association, which has been established for advancing consumer awareness of the importance of toothfriendly practices (nutrition, oral hygiene, fluoride application, dental check-ups) for oral health in Switzerland.

2. Toothfriendly International, formerly Toothfriendly Sweets International, is an association, which has been established for the purpose of the international advancement of oral health, particularly in needy regions, through preventive measures, which include regular oral hygiene, appropriate dietary habits and regular check-ups by a dentist.

3. Licenser owns all rights to the "Happy Tooth" device mark and corresponding word marks ("Happy Tooth" and similar terms in other languages), all shown in Annex A. The term "Marks" as used hereinafter, means one or several of the marks shown in Annex A.

4. The Marks may be used for the distinction of products and services, which contribute directly or indirectly to the advancement of dental health.

5. Licenser has granted Licensee a license for use of the "Happy Tooth" device mark under a license agreement dated April 29, 1993. This Agreement does not cover the word marks which Licenses has registered in the meantime, and it excludes those countries from its scope for which Licenser has granted the right to the device mark to national Toothfriendly associations under separate agreements (Germany, France), or in which Licenser is directly active (Switzerland).

Licenser and Licensee wish to continue their cooperation. Accordingly, it is agreed between the parties to adapt the terms of the license agreement so as to enable Licensee to (a) use all Marks for all applications that help achieve the common objectives of Licenser and Licensee, and (b) conclude truly global sublicense agreements with users of the Marks.

This License Agreement, therefore, supersedes the license agreement between the parties hereto of April 29, 1993.

ARTICLE 2 - GRANT

1. Licenser grants to Licensee a worldwide, exclusive and not limited license for use of the Marks:

   (a) on the label and in the advertising of products, which are consumed for a nutritional, cosmetic or medical purpose or for pleasure and which upon ingestion come in contact with the teeth;

   (b) on the label and in the advertising of ingredients used for the manufacturing of products specified under item (a);

   (c) on oral care products such as toothbrushes and toothpaste, as well as on the packaging and in the advertising of such products;

   (d) in relation to services for dental health including but not limited to the provision of educational materials, training courses for dental health instructors, as well as caries

preventive and/or prophylactic measures at community or individual level;

(e) in communications such as press releases, publications, advertisements, printed matters, stationery etc., as well as in information spread by electronic means, and

(f) on promotional items used for the direct or indirect promotion of Licensor's and/or Licensee's objectives.

2. Licenser grants to Licensee the right to sublicense the Marks to national affiliate associations, institutions pursuing similar objectives as Licenser and/or Licensee, companies producing, distributing and/or selling products or services that qualify for use of the Marks, and individuals who take a particular engagement in furthering the objectives of Licenser and/or Licensee.

3. Licensee agrees to maintain files of all sublicense agreements and to send copies of such agreements to Licenser on request.

4. Licensee accepts that Licenser retains the right to conclude license agreements for use of the Marks in Switzerland. However, such agreements shall be limited to companies producing, distributing or selling products as defined on items (a) and (c); companies, institutions or individuals rendering services as defined in item (d); as well as companies, institution and individuals, who take a particular engagement in furthering the objectives of Licenser and /or Licensee, for use in communications as defined in item (e).

5. Licensee accepts that Licenser retains the right to use the Marks for its own purposes in relation to services as defined in tem (d),

communications as defined in item (e) and promotional items as defined in item (f).

ARTICLE 3 – Requirements for use of the Marks

1. Products as specified in Articles 2(1)(a) and 2(1)(b) must be "toothfriendly", i.e. lack a significant cariogenic and erosive potential in healthy people under usual conditions of use. The criteria and test methods for determining the toothfriendly properties of such products are described in Annex B.

2. Products as specified in Article 2(1)(c) must be innocuous and effective in promoting dental health, if used as instructed.

3. Services as specified in Article 2(1)(d) must comply with good professional practice.

4. Items as specified in Article 2(1)(e) and 2(1)(f) must comply with high professional, ethical and/or other quality standards, as applicable.

5. Licenser agrees to maintain files of all pertinent specifications and test reports of products specified in Article (2)(1)(a-c) on basis of which use of the Marks was accorded to Sublicensees.

ARTICLE 4 - PRESENTATION OF THE MARKS

1. While there are no specific requirements regarding size and positioning of the Marks, the size and positioning shall be such that the Marks can be easily recognized.

   The color of the device mark is red (preferably Pantone 032) (a white tooth with a white umbrella in a red field). If the red color cannot be used, the field is black.

2. Licensee may specify details of the presentation of the device mark in a Design Manual. Approval by Licenser is required before this Manual becomes generally applicable.

ARTICLE 5 - RECOGNITION OF LICENSER'S RIGHTS IN THE MARKS

1. Licensee recognizes that Licenser owns all rights to the Marks and agrees to take no actions to impair Licenser's rights in the Marks, or question the validity of the Marks. Licensee shall not acquire or claim title to any other mark adverse to Licenser, including but not limited to the acquisition or use of any mark confusingly similar to the Marks. It is specifically recognized that all uses of the Marks by Licensee are solely for the benefit of Licenser.

ARTICLE 6 – ACQUISITION AND MAINTENANCE OF MARK REGISTRATION

1. Licenser delegates the acquisition and maintenance of trademark registrations to Licensee. Accordingly, Licensee shall take all reasonable steps and pay all fees on behalf of Licenser, which are necessary to maintain existing or hereafter acquired trademark registrations. Licenser agrees to take all reasonable steps requested by Licensee to aid in the maintenance and acquisitions of such registrations.

2. Licenser shall reimburse Licensee for all trademark registration fees and third party expenses incurred with the acquisition and maintenance of trademark registrations. Licensee will inform Licenser as early as possible if the dues under this title are likely to exceed CHF 20'000 per calendar year. Licensee shall have no right for a reimbursement of cost in excess of this yearly limit unless they are accepted on a case-to-case basis by Licenser in writing.

ARTICLE 7 – ENFORCEMENT OF MARKS

1. Licenser delegates the enforcement of the Marks to Licensee. Accordingly, Licensee shall take all actions reasonably necessary to stop unauthorized use of the Marks. Licenser shall promptly inform Licensee of any infringing use coming to his attention and agrees to provide all assistance reasonably required by Licensee in its efforts to abate any such infringement.

2. However, Licensee is under no obligation to commence legal action with respect to any infringing use or to defend against any

lawsuit brought against it regarding the subject matter of this Agreement. Licensee may, at its sole discretion, decline to defend or maintain the rights in the Mark in any country upon reasoned notice to Licensee.

3. Licenser shall reimburse Licensee for all fees and third party expenses incurred with the enforcement of the Marks. Licensee will inform Licenser as early as possible if the dues under this title are likely to exceed CHF 5'000 per calendar year. Licensee shall have no right for a reimbursement of cost in excess of this yearly limit unless they are accepted on a case-to-case basis by Licenser in writing.

ARTICLE 8 – LICENSE FEES

1. License fees collected by Licensee from Sublicensees for their use of the Marks in relation to products specified in Article 2(1) shall belong to Licensee, except for the share of license fees generated by the use of the Marks on products defined in Articles 2(1)(a) and 2(1)(c) and sold in Switzerland or a country in which a national affiliate association has been granted a non-exclusive license to the Marks by Licensee.

   Such share of license fees shall be made available by Licensee to Licenser (for the share of products sold in Switzerland) or such national affiliate association (for the share of products sold in the territory for which it has been granted the non-exclusive right to use the Marks) within 60 days of receipt of license fees.

Where such share cannot be determined from sales declarations of Sublicensee, it should be estimated by Licensee on basis of information about sales, market share or other pertinent data.

Where a dispute arises between a national affiliate association and Licensee about the estimation of such share, which cannot be resolved amicably between the parties, Licenser shall act as arbitrator and make a final decision.

2. Licensee is free to negotiate license fees and establish reasonable terms under which Sublicensees may use the Marks. However, where Sublicensee will have to pay, or can reasonably be expected to pay, license fees for products defined in Articles 2(1)(a) and 2(1)(c) in Switzerland or the territory of a national affiliate association, the license fees established, respectively, by Licenser or such national affiliate association shall apply whenever possible.

3. Licensee shall keep full and accurate records for ten years of all payments of license fees and data on basis of which license fees were calculated. Licenser has the right to inspect such records within five days of having given written notice of such inspection to Licensee.

   Licenser agrees to not divulge information and data about license fees, sales figures, specific terms of license agreements and other sensitive matter to third parties, except if required by law.

ARTICLE 9 – MEMBERSHIP FEES

1. On request by Licenser and national affiliate associations, Licensee may collect membership fees on their behalf from their respective members, in order to facilitate invoicing and accounting for all parties involved.

2. Licensee shall forward such membership fees within 60 days of receipt to Licenser and the national affiliate associations. Effective cost for the transfer of fees may be deducted by Licensee.

ARTICLE 10 – OTHER INCOME FROM USE OF THE MARKS

1. Income from use of the Marks other than that defined in Articles 8.1 and 9.1 shall belong absolutely and without limitation to Licensee.

ARTICLE 11 – TERM AND TERMINATION

1. This Agreement shall remain in force for a period of five years, effective from the date of signing of this Agreement by both parties and is renewable for subsequent five year periods, except upon written notice of non-renewal by either party to the other, given six months before the end of the then current term.

2. If either party to this Agreement is in material breach, which breach is not cured within six months notice by the non-breaching party, the party issuing such notice shall have the right to terminate this Agreement.

3. If Licensee ceases to exist as a juridical person or becomes bankrupt or insolvent, this Agreement shall terminate immediately. In such case Licenser will take over all rights and obligations from existing sublicense agreements.

4. If Licensee materially changes the statutes of its organization or the fees charged to sublicensees for use of the Marks in a way not acceptable to Licenser, this Agreement may be terminated by Licenser giving a six months advance notice to Licensee.

5. Upon termination of this Agreement, Licensee shall provide Licenser copies of all files concerning use of the Marks and payment of the fees by Sublicensees.

6. All rights to use of the Marks by Licensee and its Sublicensees shall end upon termination of this Agreement, and shall automatically revert forthwith to Licenser.

ARTICLE 12 – MISCELLANEOUS PROVISIONS

1. This Agreement shall be interpreted and enforced in accordance with the laws of Switzerland.

2. Any controversy or claim arising out of or relating to this Agreement, or a breach thereof, shall be settled by arbitration in

accordance with the Rules of Conciliation and Arbitration of the international Chamber of Commerce. Arbitration shall be a Board of three (3) arbitrators and shall be conducted in Zürich, Switzerland unless another location is agreed upon in writing by the parties.

3. Judgment upon the award rendered may be entered in any Court or Tribunal having jurisdiction, or application may be made to such Court or Tribunal for a judicial acceptance of the award and an order of enforcement as the case may be.

4. Any change or modification to this Agreement shall become effective only when agreed to in writing, signed by both parties.

IN WITNESS WHEREOF, the parties hereto have executed their Agreement as of the date first written below.

Aktion Zahnfreundlich

By

H.C. Hirzel (President)

Zurich, 22.2.2005

Place/Date

Toothfriendly International

By

Prof. B. Guggenheim (President)

Dr. A. Bär (Director)

Basel 23. 2. 2005

Place/Date

ANNEX A

Device mark

Word marks

"Happy Tooth", "Zahnmännchen", "Dentino Felice", "Diente Feliz", "Dente Feliz", "开心齿", "Toothfriendly".

Combined device word mark

ANNEX B

Criteria and test methods for the determination of dental health properties of products

Principle

The dental health 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 test facilities accredited by Aktion Zahnfreundlich (Switzerland).

A product is considered safe for teeth 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 at least four healthy volunteers two of which have a 3-4 day old plaque and two of which have a 5–7 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 fermentability 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 all test facilities accredited by Aktion Zahnfreundlich (Switzerland) for conducting 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).

For the *in vivo* test, each product must be tested in at least two volunteers. The results of the measurements must be adequately documented.

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

At present (December 20, 2004), the following independent test centers are accredited by Aktion Zahnfreundlich (Switzerland) to determine the dental health properties of products:

1. Prof. Dr. Th. Imfeld
   Zentrum für Zahn-, Mund-, und Kieferheilkunde der Universität Zürich
   Plattenstr. 11
   CH-8028 Zürich

2. Prof. Dr. Dr. L. Stösser
   Poliklinik für Präventive Zahnheilkunde
   Bachstrasse 18
   D-07743 Jena

3. Dr. Shoko Takahashi-Abbe
   Department of Oral Biochemistry
   Tohoku University School of Dentistry
   4-1 Seiryo-machi
   Sendai, 980-8575, Japan

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.