

Acceptance Program Guidelines

Cleansers for Removable Appliances



Council on Scientific Affairs

Cleansers For Removable Appliances

Scope:

These Acceptance Program guidelines cover materials and agents used to remove soft debris from removable appliances, which include full and partial appliances with acrylic bases and partial appliances with acrylic bases and metal frameworks and/or clasps; to remove stains from removable appliances; and to eliminate unpleasant odors from these appliances.

I. SUBMISSION DIRECTIONS

1. General Information

- A Submissions are to be sent to the Council Office:
Director, Product Evaluations
Council on Scientific Affairs
American Dental Association
211 East Chicago Avenue
Chicago, Illinois 60611-2678
- B Submissions are to be sent in triplicate, along with one single-sided copy for duplicating purposes. Three samples of each product from different lots shall be provided. Market samples are preferred. If possible, the submission should be less than 200 pages exclusive of appendices.
- C A manufacturer is advised that the review process is complex. Typically, notification of Council action may be expected 90 to 150 days from the receipt of a complete submission by the Council. More time may be required if additional information or clarification is needed from the manufacturer.
- D When a product is classified as "Accepted," the classification is for 3 years. Renewal of the classification will be considered by the Council upon request by the manufacturer.
- E Companies with Accepted products are subject to the conditions stated in the Agreement governing use of ADA Seal of Acceptance.

II. INFORMATION TO BE SUBMITTED

1. Cover Page

A Name of company

B Product name

*2. Table of Contents

*3. Company Information

A Name of company (to be used in official list of ADA Accepted Products)

B Address (to be used in listing)

C Phone number (to be used in listing)

D Fax number

E Names of owners, officers and other individuals authorized to furnish information to the Council and represent the firm in dealing with the Council. (Foreign manufacturers must have an office or branch located in the United States, and the product must be available for purchase in the United States).

F Names and qualifications of scientific personnel responsible for formulation and testing of the product.

*4. Summary of Submission

Comprehensive summary of the information submitted on safety and effectiveness of the cleanser.

*5. Product Information

A Name of product (to be used in listing)

B Evidence¹ of FDA permission to market, e.g. 510 (k) letter or premarket approval (PMA) letter (if applicable)

C Composition of the product and the purpose of the various ingredients

D Claims of efficacy and safety

(i) List of claims of efficacy. All claims of efficacy listed must be documented (see below), including all claims in advertising and promotional materials.

(ii) The studies (or parts of studies) that provide documentation for each claim must be identified.

(iii) The FDA clearance to market must encompass all of the claims of efficacy.

E Patent title(s) and patent number(s) relating to the product

¹ This requirement may be waived by the Council during the evaluation period. Evidence must be provided prior to use of the ADA Seal if the product is Accepted.

F Instructions shall include the following:

- (i) The intended purpose of the product;
- (ii) If the product is intended to be used in combination with other materials or devices for its intended purpose, sufficient details of its characteristics should be given to identify the correct equipment and procedures to be used in order to obtain a safe combination;
- (iii) Indications and contraindications for use;
- (iv) Details of any further treatment or handling to avoid risks in connection with the use of the product, including any undesirable side effects;
- (v) Information on the environmental conditions which may adversely affect the product, such as temperature, humidity or ambient light;
- (vi) A cautionary statement is required concerning the use of soak-type cleansers with self-curing soft liners or silver solder joints. The statement shall be included in the instructions for use that soak times for removable appliances with self-curing soft liners or silver solder joints shall be limited to 15 minutes. This requirement will not be necessary for products for which evidence of prolonged safe use with these types of appliances is presented or if the product instructions expressly exclude use with self-curing soft liners and silver solder joints.
- (vii) Instructions accompanying the product shall provide adequate information on the use and hazards of cleansers for removable appliances. Items should include recommendations for use, and suitable warnings against their use, for example, for prostheses with temporary soft liners or with metal clasps.

G Labeling

- (i) The name or registered trade-mark and address of the manufacturer (or company whose name appears as owner of the brand of the product);
- (ii) A description of the contents, including the name, quantity, form (e.g., powder, liquid, paste, etc.) and the principal and active chemical constituents²;
- (iii) The batch or lot number;
- (iv) The expiration date (where appropriate) or date of manufacture;
- (v) Any special storage and/or handling conditions;
- (vi) Where appropriate, warning of the hazards of ingestion, particularly concerning children (e.g. "Denture cleansers may be hazardous. Keep out of the reach of children!");
- (vii) Information on potentially hazardous ingredients and appropriate emergency treatment should be provided.

H Packaging

I Promotional materials

***6. Quality Control Procedures for the Manufacturing of the Product**

***7. Laboratory Tests for Material Safety**

Laboratory tests should be submitted to demonstrate that the cleanser will not adversely affect appliances and their component materials under conditions of actual use.

² If the product container does not allow sufficient space for this information, it may be placed in the package insert.

8. Safety and Efficacy Data

Adequate evidence must be provided from at least one clinical investigation of at least 25 subjects with an appropriate control to show that the product can be employed under unsupervised conditions by the user to provide a high degree of denture cleanliness, e.g. lack of visible stain, deposits, or objectionable odor. Populations selected for the studies must be representative of individuals for whom the product is intended, which, in most cases, would be individuals with full or partial removable appliances. The studies also should confirm that no hazard is to be expected when the product is used according to the manufacturer's instructions.

- A Safety Data. Clinical studies should be submitted to demonstrate that the cleanser does not adversely affect the oral tissues. Such studies could utilize regimens involving exaggerated exposures over a 5-day period or daily use according to label directions for at least 30 days.

- B Efficacy Data. Clinical studies should be submitted to support each of the efficacy claims, namely, stain removal and soft debris removal (involving plaque). The studies should be controlled trials using objective, reproducible methods and assessment measures, and should be analyzed using appropriate statistical tests.

9. Comprehensive Bibliography**10. Copies of Most Significant Articles*****11. Appendices**

Detailed description of test evaluation methods and any other defined areas.

III. Requirements (performance criteria) for classification of "Accepted":

1. It is the responsibility of the investigator to develop a criteria-based rating system for evaluating the clinical parameters of the product that is objective, reproducible and relevant to the intended use of the product.

IV. statement to be used for products classified under these guidelines including qualifiers:

1. "(Product name)" is accepted for use in cleaning removable appliances as part of a program for good oral hygiene to supplement the regular professional care required for oral health."

