

Acceptance Program Requirements



Cleansers for Removable Dental Appliances



Acceptance Program Requirements

This document outlines specific category requirements. Please also refer to the General Guidelines for Participation in the ADA Seal of Acceptance Program.

Category:	Cleansers for Removable Dental Appliances
Purpose:	The Acceptance Program applies to over-the-counter dental products for which safety and efficacy has been established by laboratory and/or clinical evaluations where appropriate. Accordingly, the purpose of these requirements is to provide a structure upon which cleansers for removal dental appliances can be considered for ADA Acceptance.
Scope:	These requirements apply to materials and agents used to remove soft debris from removable dental appliances, which include full and partial dentures with acrylic resin bases and partial dentures with acrylic resin bases and metal frameworks and/or clasps; to remove stains from removable dental appliances; and to eliminate unpleasant odors from these appliances.
Notice Regarding Submission of Copyrighted Materials:	To make the review of submissions to the ADA Acceptance Program as efficient as possible, the Council on Scientific Affairs provides copies of submitted materials to Council members and consultant reviewers, and also posts submitted materials to an area of the ADA's web site the access to which is restricted to Council members and staff.

By making a submission, you are representing and warranting to the Council on Scientific Affairs and the ADA that you have obtained sufficient permission(s) from the copyright owner(s) of any copyrighted material included with your submission to allow for the publication and distribution of that material by the ADA as described above, and agree to indemnify and hold ADA harmless from any and all claims arising from such publication or distribution.

Questions can be directed to adaseal@ada.org.



1. **SEAL STATEMENT**

The following statement applies to products approved under the below-listed criteria:

“The ADA Council on Scientific Affairs’ Acceptance of (Product Name) is based on its finding that the product is safe and has shown efficacy cleaning removable dental appliances, when used as directed.”

Format for product packaging:

- Helps clean removable dental appliances

2. **SUBMISSION DIRECTIONS**

- A. Submissions are to be sent in electronic format (email) to adaseal@ada.org. Additional instructions will be provided regarding shipment of necessary samples.
- B. The submission fee is a one-time, non-refundable fee and is required before review begins. Maintenance fees are billed to the company in January of every year.
- C. The review timeline for new submissions is typically 4-6 weeks after all materials have been received. The decision to award the ADA Seal to a new product is made by the Council on Scientific Affairs. Family submissions may take anywhere from 2-4 weeks to review. Eligibility criteria for Family Submissions are outlined in the Guidelines for Participation in the ADA Seal of Acceptance Program.

Note: This is an estimated timeline. Extended review time may be required if additional information or clarification is needed from the manufacturer.

- D. When a product is classified as “Accepted” and is awarded the ADA Seal of Acceptance, the Acceptance period is five years. Manufacturers will be contacted approximately six months before the expiration of the current Acceptance period to complete the requirements for the next five-year Acceptance period.
- E. Classification of a product under the Acceptance Program is subject to the conditions stated in the Agreement Governing Use of ADA Seal of Acceptance.
- F. Guidelines for the design and conduct of clinical studies are provided in Appendix I. Manufacturers interested in seeking the ADA Seal of Acceptance are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

3. **SUBMISSION MATERIALS**

All submissions must include the following information based on product type and comply with the ‘General Criteria for Acceptance’ described in the Guidelines for Participation in the ADA Seal of Acceptance Program.

A. Product Information

- i. Name of product(s)
- ii. Name of company



iii. FDA Documentation

- a) FDA registration and product listing must be provided.
- b) Evidence of FDA approval to market, if applicable (e.g., 510 (k) letter, pre-market approval, NDA/Evidence of FDA registration).

iv. Product Claims

- a) Products approved under these category requirements will receive the following Seal bullet claim: helps clean removable dental appliances. Data required to substantiate efficacy towards the Seal bullet claim is explained in Section C below. ***Please provide a list of all additional safety and efficacy claims beyond the Seal bullet claim. These claims should follow the ADA Brand Standards and must undergo review and approval by the Council on Scientific Affairs before they can be included on product packaging.*** Substantiation for any health benefit claims, outside of the Seal bullet claims, must be provided through clinical and/or laboratory data specific to the product and is not addressed in Section C below. Whether clinical or laboratory data is required depends on the nature of the claim. For any questions regarding claim substantiation, please contact the ADA Seal Program.

v. Product Specifications

- a) Chemical composition or components of the product and purpose of the various ingredients. To facilitate review, submitting the chemical composition, concentration, and purpose in tabular form is recommended.
- b) Material Safety Data Sheet (MSDS) (if applicable)
- c) Design of the product (if applicable)

vi. Product Manufacturing

- a) Describe or list the quality procedures for manufacturing or testing of the product which demonstrate compliance with Good Manufacturing Practices.
- b) Certification of Good Manufacturing Practices can also be provided.

vii. Product Instructions

- a) Include detailed instructions for product use.
- b) Include indications and contraindications for use, warnings, etc.

viii. Product Labeling/Packaging

- a) All labeling/packaging should follow the ADA Brand Standards and must be approved by the Council on Scientific Affairs before use. Companies may submit draft copy for approval. See iv. Product Claims above.

ix. Product Samples

- a) Submission requires three samples, one from three different production lots for analysis by the ADA Laboratories.

B. Safety Data

- i. Evidence must be provided that the components of the product are safe for use in the oral cavity. When appropriate, standard toxicological, mutagenic, and/or carcinogenic testing may be required. Compliance with applicable FDA standards, as well as the Generally Recognized as Safe (GRAS) list should be provided (where appropriate).
- ii. In cases where new agents that do not appear on the GRAS list have been introduced into a cleanser, at least one six-month clinical safety study may be required. See Appendix for details regarding clinical study protocols.
- iii. In products with agents with an established record of safe use in the oral cavity, clinical testing may not be required, but the manufacturer should provide supporting data and rationale for its use in the submitted product.
- iv. For cleansers meant for use outside of the oral cavity, laboratory testing data should be submitted showing that after the product has been rinsed off of the appliance following use, no dermal contact sensitization results due to residual product that might remain on the appliance. (See ANSI/ADA Standard No. 41 or ISO 7405:2025).
- v. Laboratory tests should be submitted to demonstrate that the cleanser will not adversely affect appliances and their component materials under conditions of actual use (e.g. using ASTM D543-14 for plastics, and appropriate tests to show no etching, pitting or localized corrosion of metal components).

C. Efficacy Data

- i. Supply one copy of all available physical and chemical property information developed in laboratory studies or similar materials that might be predictive of clinical use/behavior.
- ii. At least two independent 30-day clinical studies should be submitted to support each of the efficacy claims for the product (e.g. removes stains; removes plaque/mouth film and soft debris) under conditions of actual use. Additional efficacy claims (e.g. antibacterial activity) must also be supported by appropriate studies. Additional guidelines are presented in the Appendix.

- D. Supporting Literature:** Copies of the most significant articles or supporting literature demonstrating safety or efficacy of the product should be provided, where applicable.

4. REFERENCES

The following references were used in the development of these requirements and can be consulted for a more detailed discussion:

- ANSI/ADA Standard No. 41 Evaluation of Biocompatibility of Medical Devices Used in Dentistry, 2020
- ISO 7405:2025, Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry
- ASTM D543-21 Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents
- ADA Brand Standards:
https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada_seal_brand_standards_nov2024.pdf

Appendix

Clinical Protocol Guidelines for Cleansers for Removable Dental Appliances

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of dental appliance cleanser products. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of the clinical studies. The information indicated below is applicable to each independent clinical study.

Study design: Clinical trials should be randomized whenever possible, with participants allocated to treatments through a randomization process. The trials can have a parallel or a crossover design. When using a crossover design, appropriate wash-out periods must be considered for the variables being tested. Studies should be blind regarding participants, examiners and data analysts; when blinding is not possible, a justification must be provided. IRB approval is required for all studies involving human subjects. Each subject will have a complete oral cavity examination to determine eligibility for the study. The frequency of use of the product should be representative of actual use of the product in practice; and the user should be instructed in the proper use of the product, but not necessarily supervised. Measurements will be taken at baseline and at the conclusion of the study with an optional intermediate period. For those products with a directed use period, an observation immediately post-use is required.

Number of studies: At least two studies should be conducted at a different site and including a separate participant pool. Studies are expected to be independent, and free from direct control from the manufacturers. Studies are expected to adhere to the CONSORT or STROBE guidelines, as appropriate, and the checklist should be completed and uploaded with the submission. A minimum of thirty (30) day clinical studies are necessary showing safety and efficacy of the product. For products containing non-GRAS ingredients, a 6-month study for safety may be required.

Sample size: A sufficient number of subjects should be enrolled to ensure that appropriate statistical tests can be performed. The protocol should describe how sample size was determined, including all assumptions supporting the calculation and clearly defining the primary and secondary outcome variable(s) for which the study is being powered. A power of at least 80%, at an alpha error of 5%, is expected for variables leading to a Seal claim.

Eligibility criteria: Trial participants should be representative of the population for which the product is intended. Inclusion and exclusion criteria for participant's enrollment should be clearly described. All subjects should be in good physical health with no medical problems that would contraindicate participation in the clinical study. Subjects should be screened for potential participation in the study and the screening pool should be examined for balance in terms of gender and broad age distribution. Subjects must refrain from the use of any non-study related denture cleansers. Other criteria for inclusion/exclusion of subjects must be provided.

Test product and comparator: The test product should be compared with standard of care products/methods as defined by the ADA. Clear determination is to be made about the goal of the study to show superiority, equivalence or non-inferiority.

Clinical procedures: The phases of the study (lead-in, test, wash-out, when applicable) should be clearly described, preferably using a diagram. The instructions given to participants regarding any study-specific procedures should be clearly described. The duration of the study, and when assessments will be performed, must be clearly described. For studies involving evaluators, their number and calibration methods should be provided, as well as intra/inter examiner agreement data.

Assessments for efficacy: Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparator.

Assessments for safety: Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator. Evidence that the product does not adversely affect oral soft issues, oral hard tissues, or on dental restorations (e.g. composite resins, porcelain, etc.) must be provided. Subjects should be examined in the course of the study for the presence of pathologic conditions such as oral ulceration, candidiasis, or other secondary infections of the oral mucosa that may be manifestations of the proliferation of opportunistic microorganisms. All adverse events must be reported including altered oral sensations for each observation period.

Statistical analysis: Depending on the type of study (superiority, equivalence, non-inferiority), the statistical analysis plan should be described allowing for a comparison between the test product and the comparator, for all study variables, considering the predetermined power and significance level.

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