SADA Seal of Approval Program

SADA Seal of Approval Program

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1 - What is the SADA Seal of Approval?
SADA Seal of Approval (SOA) is issued by the SADA Seal of Approval Panel (SOA Panel) and indicates the acceptance of a product, following considerations of an application in accordance with this program, as being generally safe and of benefit when used by those for whom it is indicated in accordance with the applicant's recommendations and under reasonably foreseeable conditions of use. It also implies that the claims made by the applicant are justified and based on sound evidence.

- SOA will not be taken to mean that the SOA Panel and/or SADA is expressing a view on the value of the product to the individual nor on its value for money;
- Where products are subject to a Statutory Scheme, any assessment of an application will consider findings relating to safety, quality or efficacy made under such a regulatory scheme.
- Subject to the provisions of the program, once a product has been formally approved by the SOA Panel, applicants may use the SOA statement and logo on their packaging and other promotional material. All packaging and promotional material of an approved product, whether or not it bears SADA's name or logo, must comply with the Code for Advertising and Marketing as described in this document;
- A product in this program refers to "a unique product formulation or design or a group of product formulations or designs produced by the same applicant which, in the opinion of the SOA Panel, do not differ materially".
- The Seal of Approval Panel **('SOA Panel')** formed by SADA will approve products in defined categories.
- The SAO Panel also determines the safety, quality and efficacy as well as disseminates information on products, materials and equipment that are offered to the public or the profession and further critically evaluate statements of efficacy and advertising claims.
- Applicants are invited to apply for SOA of products according to the following guidelines.

2 - Objectives
The objectives of accreditation are;

- to assist the consumer and dental health professionals in the choice of safe products of reliable quality and effectiveness which perform in accordance with the applicants claims;
- to encourage research and development into the manufacture of products which promote oral health and high standards in dentistry;
- to improve the quality of information available to users regarding oral health care issues.

3 - Approval Terms

- Approval is granted for a renewable period of three (3) years.
- Approval is renewable and may be reconsidered at any time.
- If there is a change in the ingredients, manufacturing, clinical trials, product information, formulation, and any information of a material nature relating to the product, the period of accreditation will terminate automatically.
- Products which are obsolete, markedly inferior, ineffective, or dangerous to the health of the user will be declared unaccepted.
- Approval shall apply only to the distribution, sale and marketing of a product within the Republic of South Africa, unless otherwise determined.
- All applications for approval shall be submitted to the Head of Clinical Support Services who undertakes to forward the application to the SOA Panel. Additional experts may be added to the SOA Panel where this is considered desirable and is at the sole discretion of SADA.
- The names of the SOA Panel members, whose interests are declared in writing and are lodged with SADA, are available to Applicants on request.
- Wherever possible, the same SOA Panel will be convened for review of applications for products of a similar type. When it is in the best interests of the public or the profession, SADA may submit reports on unaccepted products to the Editor for publication in the SA Dental Journal (SADJ).

4 - Confidentiality
It is the policy of SADA and/or the SOA Panel to treat all information and data relating to the *application, which is supplied by the applicants, as confidential.*
The SOA Panel shall make no use of, except for the purpose of product approval, save that this restriction shall not apply to any of the information:

- which was lawfully in SADA's possession and was known to SADA without restriction as to its use, prior to disclosure of it by the applicants;
- which at the time of disclosure by the applicants was in the public domain;

- which becomes part of the public domain through no act or default on the part of SADA or becomes available to SADA from a third party otherwise than breach of a legal obligation of confidentiality owed to the applicants in respect thereof;
- which SADA deems it necessary to disclose to the appropriate authority to protect public oral health.
- SADA is not liable to the applicant for any damages arising from the acts or omissions of its employees and/or the SOA Panel.

5 - Guidelines for Approval

In making its judgment on the acceptability of a product the SOA Panel will consider the following –

- evidence of the safety and efficacy of the product which must be demonstrated by scientific evidence copies of such papers to be supplied;
- the product's formulation or design;
- information on the properties of all ingredients;
- the product's compliance with the relevant national and international compositional standards and labeling requirements;
- where applicable the existence of a product license granted by the South African licensing authority and fulfillment of the conditions under which the license was granted;
- evidence of compliance that manufacturing and laboratory control facilities are under the supervision of qualified personnel, are adequate to assure purity and uniformity of products and that the products are produced in compliance with the relevant Codes of Good Manufacturing Practice. The applicant shall permit representatives of SOA Panel to visit the laboratories and factories upon request;
- the claims made in relation to the product;
- the relevance of the product to health especially oral health;
- the packaging and promotional material (including safety of containers packaging, instructions for use and any health advice);
- that such products are clearly positioned as only one part of the total oral health program;
- the dental profession is not portrayed as promoting or endorsing any specific commercial product, other than the endorsement of safety and efficacy implicit in the approval.
- The SOA Panel reserves the right to request any additional information it deems necessary from time to time from the applicant.
- Guidelines specific to particular product categories will be available from time to time.

6 - Application for Approval

- All applications for approval shall be made in writing confirming that the applicant agrees to be bound by the terms and conditions set out in this document and should be addressed to the Head of Clinical Support Services. Application forms are annexed to this document.
- In the case of products already on the market, as many copies as the SOA Panel may require all relevant clinical, scientific and manufacturing materials, and any other additional material in support of the application shall be provided. In addition, information on adverse reactions/faulty products and complaints of a material nature, examples of the products in its current packaging and copies of all alternative packaging. Examples of all current and projected advertising and promotional material, including any associated health literature or package inserts, shall also be supplied.
- In the case of new products not yet on the market, the supply of information described above may be phased in that packaging and promotional material may be provided at a later stage, but before approval is granted.
- Evidence should be submitted on the existence of patents.
- Claims made for the product, which the SOA Panel is required to assess, shall be enumerated.
- The SOA Panel shall as far as reasonably possible aim to complete its consideration of the application and to notify the applicant of its decision within sixteen (16) weeks of receipt, provided adequate information has been submitted at the time of application.
- All necessary requests for additional information from the applicant may cause a delay to this timetable. It may be necessary for the SOA Panel to interview the applicant's representatives, in which case the applicant will be required to confirm in writing any new information which may have come to light. It is envisaged that there will be a dialogue with the applicant during this process.
- SADA will acknowledge receipt of the application.

7 - Acceptance and rejection of an application

- Once approval of a product has been confirmed in writing to the applicant, the applicant may use the approval statement and/or logo provided that in all cases the text and its means of dissemination comply with SADA's Code of Practice for the Advertising and Marketing of SADA Seal of Approval Products which Code is annexed to this document.
- Once approval of a product has been granted the applicants will undertake to notify the panel immediately of any confirmed adverse effects associated with the product's use, whether by the public or in further clinical trials or otherwise, and any claims or proceedings threatened or pending against the applicant arising from the

product's use. In relation to product/s which are subject to product licenses, this is without prejudice to any conditions of those licenses requiring them to inform the Licensing Authority in those circumstances.

- Where an application for accreditation is rejected, the SOA Panel will supply the applicant with a confidential summary of the reasons for rejection.
- The decision of the SOA Panel will be final, and it will not be required to enter into correspondence or discussion once an application has been rejected.
- Applicants whose application for approval has been rejected may re-apply in relation to the same product after six (6) months or such shorter period that the SOA Panel may decide.

8 - Renewal

- Seal of Approval is granted for a period of three (3) years unless otherwise requested, in which case the applicant will be given additional guidelines for the extension of the approval by the SOA Panel.
- Applicants will be required to seek a renewal of approval in writing at least six (6) months before the expiry of the current term of approval.
- Where a possibility then known to the SOA Panel arises of approval not being renewed, the SOA Panel will at this time inform the applicant in confidence. The applicant may have the opportunity to discuss the matter with the SOA Panel in confidence to resolve problems before final decisions are taken.
- In applying for renewal, applicants will supply information updating that which was supplied at the time of the initial application or of the most recent renewal. To this end, the applicant shall supply to the SOA Panel and on request grant access to, all information in the applicant's possession relating to reports of adverse reactions/faults in respect of the product and information on all material complaints received in respect of safety and efficacy in relation to any of the SOA criteria.
- Applicants who do not renew SOA, must as soon as possible but in any event within six (6) months of expiry of accreditation or such shorter period that the Panel may decide, withdraw all products showing SADA accreditation from sale, supply from the applicant's warehouse as well as all packaging, package inserts, advertising and other promotional literature and take steps, whether by legal proceedings or otherwise, at their own expense, to prevent the unauthorized distribution or sale by or to third parties.
- Applicants will in any event, notify SADA of any suspected unauthorized use of SADA SOA Logo and/or statement by third parties and agree to take such action as SADA may request and authorize to take legal proceedings in the name and at the expense of the applicant to prevent such misuse.
- If the applicant is liquidated or declared insolvent or enters into compromise with its creditors, SADA may forthwith withdraw approval at its sole discretion immediately or at any time afterwards and in that event no trustee, liquidator or administrator, creditor, agent or representative of the applicant shall have the right to dispose of any of the approval products without the prior written consent of SADA.

9 - Changes in claims, composition, name or ownership of product

- Any material change in information provided at the time of granting approval to a particular product must be submitted in writing to the SOA Panel for review and approval before a modified product or change of name is marketed as an approved product, or before a product is marketed as an approved product by a different company.
- The Panel reserves the right to take the full sixteen (16) weeks or such longer time it deems necessary before granting or refusing approval, but it is not envisaged that this would normally be necessary.
- The decision of the SOA Panel as regards what constitutes a new product or a different company and therefore a new application will be final.

10 - Withdrawal of Seal of Approval

- If the SOA Panel's approval of a product is withdrawn, the SOA Panel shall be entitled to immediately terminate or suspend without prejudice to any other rights which the Panel may have the Applicant's rights to display the Seal of Approval logo or approval statement.
- The SOA Panel may also withdraw approval forthwith in any of the following circumstances:
    - where any of the terms of Part 9 are not complied with (changes in claims, composition, name and ownership);
    - where the approval statement and/or SOA logo are used in material of any kind in a manner, which does not comply with SADA's code of practice for advertising and approved products.
    - At the expiry of the approval period where it is not otherwise formally renewed;
    - if, in the view of the SOA Panel at its absolute discretion believe that current scientific evidence demonstrates the product is no longer safe or efficacious or if the product becomes obsolete or markedly inferior or dangerous to the health of the user;
    - if the applicant fails to comply to a material extent with all relevant codes of good manufacturing practice and/or engages in illegal, immoral or otherwise disreputable activities;
    - if there is a deterioration in manufacturing and laboratory control procedures which are either serious and/or continuous and/or recurrent;
    - otherwise at the discretion of SADA.

- Applicants must agree to withdraw any reference to SADA approval from all existing product labeling, packaging and package inserts, advertising and other promotional material as soon as practicable and no longer than six (6) months after written notification of accreditation withdrawal.
- This includes the name of SADA, its approval statement, and/or logo. Forthwith, upon withdrawal of approval, there must be no new reference to accreditation.
- Notwithstanding the provisions hereof, the SOA Panel shall at all times be entitled to require the Applicant to remove the Approval from the products and any SOA Panel approved statements within such shorter time it deems necessary from the standpoint of safety and efficacy of the product or if the reason for termination is the Applicant's misuse of the approval.

11 - Liaison Officer

- The applicant will always undertake to appoint a liaison officer responsible for the submission of all applications to the SOA Panel, and any changes in liaison officer will be reported to the SADA offices immediately. The applicant will also ensure that the liaison officer is fully informed of the requirements of the Seal of Approval Program.

12 - Advertising and Marketing of Approved Products

- All advertising, packaging and promotional material bearing the name, approval statement and/or Seal of Approval logo of SADA must comply with SADA's Code of Practice for Advertising and Marketing annexed hereto.
- Advertising must comply with the Codes of Advertising and Sale Promotion and such other codes, which may be appropriate.
- The Applicant will notify SADA of any suspected infringement of SADA's intellectual property rights, and SADA may sue in the Applicant's name, subject to the Applicant's prior approval.

13 - Indemnity

- Applicants must at their own cost take out fully comprehensive public liability and employers' liability insurance in respect of approved products.
- Any payment made by an insurance company pursuant to the public liability policy required above shall be assigned by the applicant to SADA to the extent of foreign indemnity.
- Applicants will agree in writing to indemnify SADA and the members of the SOA Panel in full respect of any claim which may be made against it in respect of its approval of their product. This includes all actions, suits, claims, demands and costs arising in connection with the supply or manufacture of an approved product, but it excludes those which may arise because of any act or omission of the SOA Panel caused solely by its own fault or negligence.
- The applicant shall notify SADA promptly upon receipt of any of the claims mentioned herein.

14 - Reference to the Profession

- The approved advertising may not use the word "dentist" or refer to SADA in such a way as to mislead by implying a relationship with, or endorsement by SADA and its members.
- SADA's name may be used only to vouch for those facts that are directly related to oral health. Any such use must be in good taste and in keeping with professional dignity and in these matters SADA and/or the SOA Panel shall be deemed to be the sole arbiter.

15 - Costs

- Applicants applying formally for approval of a product will be charged with a non-refundable fee as set out in the document. See Part18 Seal of Approval Program Costs.
- The Applicant accepts that in the event of a failure to obtain approval in respect of a product or withdrawal of an application after acceptance for consideration, the application fee is non-refundable.

16 - Disputes

- The provisions of this program are to be interpreted according to the laws of South Africa.
- Any dispute or difference between the parties in connection with this scheme shall, though not obliged to and only if both parties agree, be referred to arbitration in Johannesburg on the terms to be agreed by both parties.
- In the event of failure to agree on referral to arbitration or the terms of arbitration, the dispute shall be determined in accordance with the laws of the Republic of South Africa and for this purpose the Applicant hereby consents to the jurisdiction of the Johannesburg Magistrate's Court and/or the jurisdiction of the Johannesburg High Court.

17 - Miscellaneous Provisions

- It will not be the function of the SOA Panel or SADA to examine whether the manufacture or marketing of a product and its packaging comply with legislative requirements applying to them and responsibility for those matters remains wholly with the applicant.

- It is the responsibility of the applicant to ensure that all claims made in respect of a product are accurate and in accordance with the entirety of current available scientific evidence.
- In making an application in respect of a product, the applicant warrants that the product complies in all respects with all relevant industry and safety standards.
- SOA Panels' members and officers of SADA will not take part in any promotional activity in respect of any approved product on behalf of applicant(s).

18 - Variations in the provisions of the program

- SADA reserves the right to vary the provisions of the program upon three (3) months' notice to and after consultation with applicants of approved products.

19 - Seal of Approval Program Costs

- Before a product is considered for approval, an Applicant is requested to agree in writing that in the event of approval being granted, a three-year agreement will be entered into with SADA to take up SADA Seal of Approval on specified terms and conditions.

- **Non-refundable application fee (VAT inclusive) per item**

Original Submission	Supplementary Submission
R20 000.00	R10 000.00

- **Annual Seal of Approval Fees for Approved Products (VAT inclusive)**

Product Group	Annual Fee per Brand*	Annual Fee per Variant**
Toothpaste	R50 000.00	R15 000.00
Mouthrinses/Fresheners	R50 000.00	R15 000.00
Toothbrushes – Manual	R50 000.00	R15 000.00
Toothbrushes – Electric	R50 000.00	R15 000.00
Dental Floss/Tape	R50 000.00	R15 000.00
Gum	R50 000.00	R15 000.00
Oralgiene (Tongue Cleaner)	R20 000.00	Not applicable
Toothpaste Dispenser	R20 000.00	Not applicable
3D Printer	R60 000.00	Not applicable
Pacifiers and feeding devices	R50 000.00	R15 000.00
Athletic Mouthguards	R30 000.00	R15 000.00
Removable Prostheses Cleaner	R30 000.00	R15 000.00
Denture adherents	R30 000.00	R15 000.00
Manual interdental cleaners	R30 000.00	R15 000.00
Oral irrigators	R50 000.00	R15 000.00
Tooth stain removal products	R30 000.00	R15 000.00

SOA Form 2 - STRICTLY CONFIDENTIAL

Seal of Approval Program – Panel Members
Consumer Dental Health Products and Related Products

SOA Form 3 - STRICTLY CONFIDENTIAL

Seal of Approval Program – Guidelines for Applicants
Consumer Dental Health Products and Related Products

General Guidelines for Applicants seeking approval of consumer dental health products
The general rules of the SOA Program explain that approval can be granted to products which can, in the opinion of the SOA Panel formed by SADA for this purpose, demonstrate safety, quality and efficacy in formulation or design.

- Program rules go on to say that SOA Panel will take account of the following in reaching their decisions: -
  - evidence of the safety and efficacy of the product which must be demonstrated by scientific evidence copies of such papers to be supplied;
  - the product's formulation or design;
  - information on the properties of all ingredients;
  - the product's compliance with the relevant national and international compositional standards and labeling requirements;
  - where applicable the existence of a product license granted by the South African licensing authority and fulfillment of the conditions under which the license was granted;
  - evidence of compliance that manufacturing and laboratory control facilities are under the supervision of qualified personnel, are adequate to assure purity and uniformity of products and that the products are produced in compliance with the relevant Codes of Good Manufacturing Practice. The applicant shall permit representatives of Panel to visit the laboratories and factories upon request;
  - the claims made in relation to the product;
  - the relevance of the product to health especially oral health;
  - the packaging and promotional material (including safety of containers, packaging, instructions for use and any health advice);
  - that such products are clearly positioned as only one part of the total oral health program;
  - the dental profession is not portrayed as promoting or endorsing any specific commercial product, other than the endorsement of safety and efficacy implicit in the approval.
- The SOA Panel reserves the right to request any additional information it deems necessary from time to time from the applicant.
- In addition, the SOA Panel has drawn up specific guidelines for certain categories of product, to assist applicants in preparing evidence for the SOA Panel's consideration. These guidelines appear on the following pages and should be used alongside the general requirements listed above. They will be revised from time to time in the light of changes in current knowledge, and comments are welcome and will be considered.
- Applicants are requested to submit copies of published supporting papers rather than simply listing references.

Product Descriptors
Dentifrices

1. The approval of dentifrices will be based upon a scientific review of laboratory and/or clinical data on each submitted product. Scientific data submitted by the applicants must support the efficacy and safety (including abrasiveness) of each product and the claims made.
2. All claims made in relation to formulation should be supported by two clinical trials conducted by independent investigations using that formulation or a very similar formulation.
3. The SOA Panel reserves the right to request that at least one of the clinical trials should be performed using South African population.
4. Data from laboratory, in support of a product's equivalence to a previously tested, clinically effective product(s) may be used for some products.
5. The SOA Panel is concerned with clinical claims only, and will not express opinions on claims substantiated subjectively by users about taste, breath freshness etc.
6. The SOA Panel will not expect any claims about gingival health to be made from data about plaque control alone and would normally expect plaque control claims to be supported by evidence of an effect on gingival health.
7. The SOA Panel is required to view the packaging; package insert and tube wordings. These should include clear instructions for safe use of fluoride toothpastes by children, on packaging, inserts and tubes, except for brands which are unlikely to be used by this age group.
8. Packaging inserts and tubing should show all active ingredients, and their concentrations, in legible size, with fluoride concentrations being shown.
9. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Mouthrinses

1. The approval of mouthrinses will be based upon a scientific review of laboratory and/or clinical data on each submitted by the applicants which must support the efficacy and safety of each product and the claims made.
2. All claims made in relation to a formulation should be supported by two clinical trials conducted by independent investigators using that formulation or a very similar formulation.
3. The SOA Panel reserves the right to request that at least one of the clinical trials should be performed using South African population.
4. Data from laboratory, animal and in vivo experimentation in support of a product's equivalence to a previously tested, clinically effective product(s) may be used for some products.
5. The SOA Panel are concerned with clinical claims only, and will not express opinions on claims substantiated subjectively by users about taste, breath freshness etc.
6. The SOA Panel will not expect any claims about gingival health to be made from data about plaque control alone and would normally expect a plaque control claim to be supported by evidence of an effect on gingival health in addition to evidence of reduction of plaque.
7. The SOA Panel expects mouthrinse trials to be based on a realistic level of use. Trials based on use more than twice a day will not normally be considered.
8. Mouthrinses containing alcohol should have clear warnings against use by children and against swallowing.
9. Containers should show all active ingredients and their concentrations, in legible size, fluoride concentrations being shown.
10. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Manual Toothbrushes

1. The approval of toothbrushes will be based primarily upon scientific review of laboratory, manufacturing, design, and clinical data to demonstrate safety in normal use. All relevant safety data should be submitted.
2. Brushes should normally be soft; stiffness being assessed on the basis of filament length, diameter and material, which should be specified. Data on these filament features should therefore be submitted for each brush type covered by an application.
3. In assessing the safety of toothbrushes, in relation to filament stiffness, references will be made to the SABS specifications.
4. Filaments should be end-rounded at all parts of the brush.
5. Brush handles should be designed to allow a comfortable and firm grip in normal use;
6. Handle material should be durable and tested to show durability in normal usage. Customer complaints data about breakage will be required.
7. Head size and configuration should be appropriate for the intended user.
8. Applicants should note that other safety data will be considered, including filament retention.
9. All promotional claims proposed for a product must be submitted. Claims of superior efficacy in plaque removal and promotion of gingival health will not normally be accepted.
10. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Electric Toothbrushes

1. The aim of these guidelines is to approve electric toothbrushes proven to be safe and efficacious in normal use to promote oral and gingival health.
2. Electric toothbrushes should comply with points 1 to 5 of the requirements for manual toothbrushes, but in addition the following applies.
3. Brush heads should be replaceable with a simple, yet firm means of connection to the handle.
4. Head size and configuration should be appropriate for the intended user.
5. Handle/head material should be durable and tested to show durability and reliability in normal use. The number and details of customer complaints about breakage or mechanical failure will be required in relation to the total number of sales.
6. Electric motors should produce a consistent movement of the brush head or filaments under the loads required to produce efficient cleaning of the tooth surface. These loads should be achievable by the average user.
7. Head action should be compatible with the use of conventional toothpaste. Laboratory and or clinical evidence should demonstrate no deterioration in head action over a period equivalent to three (3) months usage of a single head.
8. Clinical data will be required to support claims of cleaning action other than the mechanical action of filaments on the teeth.
9. Units should satisfy safety of household electrical appliances and for battery-powered toothbrushes and their charging and battery assemblies, and the specification for oral hygiene appliances connected to the mains supply through a safety isolating transformer.
10. Switches should be readily accessible to allow the unit to be turned off rapidly if necessary.

11. Units should give reasonable time of operation between charging or replacement of batteries, for example, capable of fourteen (14) brushing cycles of at least two (2) minutes each.
12. data will be required to show the relationship between brush stiffness, mode, frequency and amplitude of vibrator to hard to soft tissue abrasion.
13. Applicants should note that other safety data will be considered, including filament retention.
14. Detailed instructions for use should be clear and understandable in everyday language, with appropriately labeled diagrams. These should include instructions on recharging procedures if appropriate.
15. All promotional claims proposed for the product must be submitted. Claims of superior efficacy in plaque removal and promotion of gingival health will not normally be accepted.
16. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Tape and Floss

1. These guidelines recognize that flossing can significantly benefit oral hygiene and gingival health but that there can also be detrimental effects from the uninstructed use of floss, especially in children.
2. The approval of floss and tape will be based primarily on a review of data to demonstrate safety in normal use. All relevant safety data should be submitted. Particular attention will be paid to data on the effect of flossing on gingival attachment levels.
3. Packaging should explain the circumstances in which flossing may be desirable and recommend that, before use, professional advice should be taken on the need for flossing and the method of use, especially in relation to any fixed orthodontic appliances or crown and bridgework.
4. Both waxed and unwaxed floss and tape will be considered for approval.
5. Flosses and tapes containing therapeutic or preventive agents claiming to provide adjunctive benefits to dental or gingival health will not be accepted without evidence derived from suitable clinical studies relating directly to the product submitted.
6. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Gum

1. These guidelines recognize that the chewing of gum can contribute to mechanical plaque removal and stimulate salivary flow, thereby aiding oral cleanliness and neutralizing plaque acids. However, overuse or inappropriate use may cause temporomandibular joint (TMJ) discomfort in some individuals.
2. Approval will be based on safety data demonstrating that the product does not adversely affect teeth, restorations, or oral soft tissues.
3. Packaging and labelling should clearly state whether the gum is sugar-free and, if containing active agents (e.g., xylitol or fluoride), provide substantiating evidence of efficacy.
4. Claims regarding therapeutic or preventive benefits will only be accepted if supported by appropriate clinical trials conducted with the product as marketed.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Oralgiene (Tongue Cleaner)

1. These guidelines acknowledge that tongue cleaning can assist in reducing oral malodour and contribute to improved overall oral hygiene.
2. Approval will depend on demonstration of product safety and absence of trauma to soft tissues during normal use.
3. Packaging should include clear instructions for gentle use to avoid mucosal injury and advise that professional guidance may be sought for persistent halitosis.
4. Claims of bacterial reduction or oral health improvement must be supported by appropriate in vivo data.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Toothpaste Dispenser

1. These guidelines recognize the hygienic and dosage-control benefits of toothpaste dispensers in minimizing contamination and waste.
2. Approval will require demonstration that materials used are non-toxic, durable, and do not react adversely with toothpaste formulations.
3. Instructions for cleaning and maintenance must be clearly provided on packaging.
4. Any claims related to improved oral hygiene or infection control must be substantiated with relevant data.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

3D Printer (Dental Applications)

1. These guidelines apply to 3D printers used for dental models, appliances, or prostheses, recognizing their role in advancing precision and patient-specific care.
2. Approval will require documentation of material biocompatibility, dimensional accuracy, and sterilization compatibility.
3. Manufacturers must provide data verifying that printed products meet relevant safety and performance standards for intraoral use.
4. Use should be limited to trained dental professionals under validated workflows ensuring quality control and traceability.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Pacifiers and Feeding Devices

1. These guidelines recognize that pacifiers and feeding devices may influence orofacial development and oral hygiene in infants.
2. Approval will be based on safety, non-toxicity of materials, and resistance to deformation or fracture under normal use.
3. Packaging should advise regular inspection and replacement of worn or damaged products and warn against sweetening agents on pacifiers.
4. Claims regarding orthodontic or developmental benefits must be supported by independent clinical studies.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Athletic Mouthguards

1. These guidelines recognize the protective role of mouthguards in preventing dental and soft-tissue injuries during sports.
2. Approval will depend on demonstration of material safety, shock absorption, and adequate fit without respiratory restriction.
3. Packaging should advise professional fitting for best protection and replacement after deformation or significant wear.
4. Any claims of superior impact protection or antimicrobial benefits must be supported by credible laboratory or clinical evidence.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Removable Prostheses Cleaner

1. These guidelines recognize that proper cleaning of removable prostheses is essential to maintaining oral health and preventing microbial colonization.
2. Approval will depend on demonstration of cleaning efficacy and absence of damage to acrylic or metal components.
3. Packaging should provide clear instructions for use and warnings against prolonged soaking or use with incompatible materials.
4. Claims of antimicrobial or whitening action must be supported by validated laboratory or clinical data.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Denture Adherents

1. These guidelines recognize the role of denture adherents in improving comfort, retention, and patient confidence.
2. Approval will depend on biocompatibility and safety under normal oral conditions.
3. Packaging must clearly describe application instructions and cleaning requirements to avoid bacterial contamination.
4. Claims of antimicrobial or therapeutic benefit will only be accepted with appropriate supporting clinical data.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Manual Interdental Cleaners

1. These guidelines recognize that manual interdental cleaners contribute to plaque control and gingival health when properly used.
2. Approval will be based on safety data demonstrating no trauma to gingival tissues or tooth surfaces.
3. Packaging should recommend professional advice for correct size and use, especially in patients with orthodontic or periodontal conditions.
4. Products claiming additional therapeutic benefits must provide supporting clinical evidence.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Oral Irrigators

1. These guidelines recognize that oral irrigators may assist in plaque removal and gingival health maintenance, particularly in patients with orthodontic appliances or prostheses.
2. Approval will depend on data demonstrating safety and absence of adverse effects on gingival attachment levels.
3. Packaging should include usage instructions emphasizing that irrigation does not replace brushing and should be used under professional guidance.
4. Claims of therapeutic or preventive benefit must be substantiated by controlled clinical studies.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Tooth Stain Removal Products

1. These guidelines recognize that tooth stain removal products can enhance aesthetics and confidence but may pose risks of enamel abrasion or sensitivity if improperly used.
2. Approval will depend on safety and efficacy data, particularly concerning enamel integrity and soft-tissue tolerance.
3. Packaging must provide clear usage directions and warnings regarding overuse or inappropriate application.
4. Claims of whitening or stain prevention must be supported by well-designed clinical studies relevant to the product.
5. The SOA Panel expects data of the same quality and comprehensiveness as would be submitted to a regulatory body, in order that an independent view can be formed.

Reminder

Any published supporting papers specifically relevant to the above guidelines should be submitted in full, rather than being listed as references.

SOA Form 4 - STRICTLY CONFIDENTIAL

Seal of Approval Application
Consumer Dental Health Products and Related Products – PART A

Applicants are requested to complete Parts A and B of this form and send it to
The South African Dental Association
Private Bag 1, Houghton, 2041
with supporting literature and samples of the product for which the application is made.

Company Name	
Full Postal Address	
Telephone Number	
Fax Number	
E Mail Address	
Person Responsible for Application	
Position	
Name of Liaison Officer (if different from person responsible for application)	
Product	**Brand:** **Variant:**

We hereby apply for Seal of Approval (referred to hereafter as SOA) of the above mentioned product by The South African Dental Association (see Part B for claims and supporting evidence) and certify that should the SOA of the above product be granted, the Applicant will comply in every respect with the Association's SAO Program and with any changes to the Program subsequently notified to the Applicant, as well as with any changes to the Association's Code of Practice for the Advertising and Marketing of SADA Seal of Approval Program.

We also confirm that in the event of SOA, we will arrange for indemnity insurance cover in accordance with Part 12 of the SOA Program and agree to indemnify the Association and the members of the SOA Panel in full from any claim which may be made against us in respect of its SOA of our products.

The Applicant's shall immediately settle the invoice supplied in respect of the application. The application will only continue with processing once the invoice is settled.

We understand that the fee is not refundable even if our application is not accepted for consideration for accreditation or the application is rejected.

In the event of accreditation being granted, we undertake to pay SADA for the Annual SOA Fee as set out in the SADA Seal of Approval Program Costs (plus VAT) annually in advance for each of the three (3) years of the initial SOA term.

If for any reason we decide, after being granted SOA, not to take it up, we will not disclose the Panel's decision or use it or the Association's name in any form of product promotion.

Print Name:	**Signature:**
Position:	**Date:**

SOA Form 5 - STRICTLY CONFIDENTIAL

Seal of Approval Application
Consumer Dental Health Products and Related Products – PART B

Applicants are requested to complete sections 1–14 and supply supporting literature where appropriate and supporting literature to:
The South African Dental Association, Private Bag 1, Houghton, 2041.

1	**Company**			
2	**Brand name of product seeking SOA**			
3	**Variant of product seeking SOA**			
4	**List claims/therapeutic indications being made for the product**			
5	**Does the product have a license?**	YES	NO	
5a	**If yes to 5 above, please supply the license number and the indications for which the license was given**			
6	**List all ingredients of product**			
7	**List the active ingredients of the product**			
8	**Supply details of the product formulation**			
9	**Supply details of the clinical trials cited in support of the claims made for the product in item 3 above**	Number of volumes	Number of pages	
10	**Supply details of the toxicology data for the product in item 3 above**	Number of volumes	Number of pages	
11	**Supply details of any warnings included in the package insert or on the package or product**			
12	**Supply details of package size/s**			
13	**Supply details of shelf life before and after opening**	Before	After	
14	**If applicable, does the product have a child resistant closure (CRC)?**	NOT APPLICABLE	YES	NO
15	**Please supply any additional information which SADA Seal of Approval Panel must be made aware of**			

Please supply information on a separate sheet if there is not enough space on this form.

I can confirm that the information given above is correct and complete

Print Name:	**Signature:**

Position:	Date:

SOA Form 6 - STRICTLY CONFIDENTIAL

Seal of Approval Program – Advertising & Marketing Code
Consumer Dental Health Products and Related Products

Preamble

- In applying for the Seal of Approval of product by the SOA Panel, applicants undertake, once the approval has been confirmed by the SOA Panel, to comply in every respect with the terms of the SADA Seal of Approval Programs Rules and this Code. This code forms an integral part of the SADA Seal of Approval Program Rules and should be read in conjunction with it. In the event of inconsistency arising between the provisions of the Program Rules and the Code, the provisions of the Program Rules shall prevail.
- The Code was devised as an aid, and its objective is to dispense with the need for prior approval of a copy which would be burdensome and cause unnecessary delay. The applicant is responsible for the observance of this Code, whether promotional activities are delegated to an advertising agency or other intermediary.
- The aim of the Code is to ensure high standards of promotional practice in the industry and to protect the public, the dental profession, and the Association.

Scope and Definition

- The Code applies to all items and activities of promotion, distribution, advertising and marketing of a product, whether they are aimed at the public, the profession, sales staff, wholesalers, retailers and all other persons, individually or collectively. Such activities include broadcast and print media, advertisements, cinema and audio-visual material, informational and marketing literature and material, posters, leaflets, all packaging including exhibition material, public relations material and press statements. They also include staff and distributor training, publicity and sales promotion material as well as material aimed at the dental profession. The expressions 'promote', 'promotion', 'promotional material and activities' are used in this Code to include any or all of these or similar terms.

Promotional Material

- Claims made in promoting a product must strictly comply with those which have been substantiated to the SOA Panel. There shall be no reference to tests or trials unless these have formed part of the accreditation application and have been accepted by the SOA Panel as valid.
- No statement shall be made which implies that the Association has considered the value of the product to an individual nor its value for money.
- Applicants must ensure that their promotional material complies with the appropriate legislation.
- Promotional material:
    - including claims made, must be accurate and in accordance with current available scientific evidence.
    - must be legal, decent, honest, and truthful. It should be factual, clear, and unambiguous. Applicants should maintain a sense of responsibility to and should not exploit the knowledge or lack of knowledge of the consumer.
    - should not depict dentistry, dentists or dental treatment as frightening or painful and should not in any way be in a form which might discourage the public from attending dental practices or from practicing good oral hygiene.
    - should not contain comparisons with nor disparage, directly or by implication, other products, as permitted by law.

Definition

Brand: Unique design, sign, symbol, words, or a combination of these, employed in creating an image that identifies a product and differentiates it from its competitors. Over time, this image becomes associated with a level of credibility, quality, and satisfaction in the consumer's mind (see positioning). Thus, brands help harried consumers in crowded and complex marketplaces, by standing up for certain benefits and value. The legal name for a brand is a trademark and, when it identifies or represents a firm, it is called a brand name.
Source: http://www.businessdictionary.com

Variant: A form or version of something that differs in some respect from other forms of the same thing or from a standard.
Source: https://en.oxforddictionaries.com

Use of SADA Seal of Approval Symbol and Statement

- The symbol must be reproduced exactly as shown above but may be in any single color. Once approval is granted, the symbol will be provided by SADA or its representative in the format the Applicant requires.
- Applicants may vary the statements or make other reference to SADA or to SADA for approval and joint statements within the spirit of approval but only after specific prior approval has been obtained from SADA on each occasion, in writing. Such a statement may stand alone or with the logo but not appear as part of another copy.
- The symbol and/or statement must not form the focal point of any promotional material. In printed form, the dimension of the boundary of the symbol shall not be less than 1.3cm x 0.9cm and shall not exceed 4.5cm x 3.5cm. The maximum dimension of the boundary of the symbol when used in exhibition promotional material shall be in an acceptable proportion to the applicant's product; the SOA Panel retains the sole discretion in this regard.
- The symbol and/or statement may only appear in relation to approved products and must not suggest the approval of any other product.
- The symbol and/or statement may be used only after confirmation by SADA that a product has been approved.
- There should be no comments on promotional material on the significance of the symbol or statement, unless the comments are approved by the SADA Seal of Approval Program.
- In broadcast material, the symbol and statement may appear both visually and orally.
- A copy of all promotional material relating to SADA approved products must immediately upon availability be sent to SADA for information. It will not necessarily be retained for future reference.
- The symbol and/or statement may not appear on any items or in connection with any activities which at the same time also use any logo and/or statement or endorsement in any form granted by another body, except with SADA's prior approval.

Promotion of newly approved products

- Applicants must advise SADA in advance of the manner in which a newly approved product is to be promoted or of any proposed change in the manner in which the approved product is to be promoted, so that SADA can if necessary be in a position to respond effectively to any media or public outcry.

Complaints

- Complaints made to SADA about the promotion of an approved product shall state the clauses of the Code which are believed to have been breached and the precise grounds of the complaint.
- Such a complaint shall be reported to the SOA Panel and its decision on whether any promotional activity warrants withdrawal either of material or of approval of any or all of Applicant products shall be final.
- The SOA Panel will give the Applicant an opportunity to respond to any complaint in respect of the relevant approved product and will take these responses into account in reaching its decision regarding the complaint.

February 2026