**VOHC Pre-Trial Protocol**

**Submit your Pre-trial Protocol for VOHC Review using this form.**

**Use the blue, underlined links to obtain further information from the VOHC website**

Insert the appropriate information in the tan space, then submit the completed form to [VOHC@AVDC.org](mailto:VOHC@AVDC.org) as an attachment **in Word format to allow comments from the VOHC Director** to be added to the form. The tan cells will expand to accommodate additional text. You can provide additional information within the form or as email attachments.

Additional data, such as halitosis scores, can be obtained as part of the trial but will not be reviewed by VOHC; include a brief mention of additional data in the final item in this protocol form.

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| **GENERAL** | |
| State **Product Name** and **Company Name** |  |
| Provide **Name** and **Contact Information** for the Company correspondent for this review. |  |
| State [VOHC Claim](http://vohc.org/dental_product_claims.html) requested:Plaque, Tartar or Plaque & Tartar. |  |
| **VOHC Required Items** | |
| Provide a **Description of the product,** including mode of dental action (mechanical, chemical), and the population of animals for which the product will be marketed.  Describe **Specific instructions or limitations for use of the product** that are or will be stated on the package (frequency of use, minimum number or amount to be used, body weight range of animals per size). |  |
| **Describe the** [Types of Trial](http://vohc.org/protocol_details.html#Required) **required for this product after reviewing the webpage information via the link.**  **If the Product is a** [Product Line](http://vohc.org/dental_product_line.html)**,** describe the difference in the products in the product line (different sizes, shapes, ingredients etc.). |  |
| **Safety Issues raised by use of the Product:**  **Oral health following use of the product is addressed in specific items listed below. If there are e.g. systemic or distant organ health issues that could potentially be caused by use of the product (e.g. systemic toxic effects), describe them here.** |  |
| State the [Number of Trials](http://vohc.org/protocols_submissions.html#Two)to be used:  **Single Product:** Two trials required, with no overlap in population of animals.  [Product Line](http://vohc.org/dental_product_line.html)**:** For products marketed in **different sizes**, two trials are required, with no overlap in population of animals, plus one trial in another size of the product; each trial must be conducted in animals within the body weight range designated for that size of the product.  *If the difference in the products is related to the dental effectiveness and is* ***something other than the size of the product****, contact VOHC to confirm what specific trials are required.*  *If the product will be marketed in e.g. different flavors, or with additional ingredients designed for e.g. joint health or skin health, additional trials are not required provided that the company has informed VOHC of the differences and received confirmation that VOHC accepts that the* ***differences will not affect the dental effectiveness*** *of the product.* |  |
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| **TRIALS DETAILS** | |
| Describe the[Trial Design](http://vohc.org/protocols_submissions.html#Types)**:** Parallel groups or cross-over design in which each animal acts as its own control.  If you will be using a pre-trial period to determine plaque scores for the purpose of reducing variability between groups, describe the pre-trial procedures. |  |
| Describe the **Site** (location) and **Proposed Start** and **End dates** of the trials. |  |
| State the **Personnel involved**:  **Investigator/supervising veterinarian**. Provide a brief CV.  [Scorer](http://vohc.org/protocol_details.html#Scorers)(s): With summary of relevant training and experience.  **Statistician,** if used**:** Brief summary of qualifications. |  |
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| **CARE of the ANIMALS** | |
| Describe the **Housing** and **General Care of the Animals.**  Describe the **Pre-trial** **Veterinary Examination** to ensure general health of the animals. |  |
| [Control Diet](http://vohc.org/protocol_details.html#Control-diet): Must be an AAFCO-maintenance kibble dry food – state the diet to be used and confirm that it will be **fed dry.** |  |
| **For laboratory-housed animals**, state that review of animal care procedures and the purpose of the trial has been approved by e.g. IACUC. State whether the facility is USDA- or AALAC- (or equivalent) approved.  [For client-owned animals](http://vohc.org/protocol_details.html#Client-owned), provide a copy of the Owner Document (consent form and instructions for participants in the trial) and Owner Daily Report Form as separate attachments. |  |
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| **POPULATION and RANDOMIZATION** | |
| [Population](http://vohc.org/protocol_details.html#Population)**:** Indicate the source, age, weight range, breed, and sex of the animals to be recruited. The final VOHC submission is to include the ID # or name of individual animals listed, with group assignments.  For products marketed in more than one size, each trial must be conducted in subjects that are within the weight-range recommended for that size of the product. |  |
| State the[Number of subjects per group](http://vohc.org/protocol_details.html#Statistics)**.** There is no minimum # required by VOHC, however, if each group consists of fewer than 20 animals, the statistical analysis must include demonstration of normal distribution of the data, or non-parametric analyses must be used. |  |
| Describe the [Randomization](http://vohc.org/protocol_details.html#Statistics) process used to assign animals to the trial groups. |  |
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| **TRIAL PROCEDURES, DURATION** | |
| Describe the[Pre-trial awake oral examination](http://vohc.org/protocol_details.html#Pre-trial)**:** All VOHC teeth must be present and intact, with no F3 furcations present.  State that the mouth is to be observed for **non-gingival inflammation, oral ulceration** and **laceration** on Day zero and at the final scoring episode. |  |
| Describe the **Scaling procedure** to be used to create the ‘[clean tooth model](http://vohc.org/protocol_details.html#Clean-tooth)’. Include mention of the anesthesia protocol, intubation and use of post-scaling disclosing solution to confirm absence of plaque and calculus on day zero and between cross-over periods. |  |
| [Method of application](http://vohc.org/protocol_details.html#Use-of-product) of the product in the trials is to be described; this must match the method recommended for use of the product as marketed. |  |
| State the[Duration](http://vohc.org/protocol_details.html#Duration) of trials. 28 days minimum for each arm (or each leg of a cross-over trial). |  |
| Confirm that[no drugs or access to oral hygiene products](http://vohc.org/protocol_details.html#Other)are to be allowed, includinglocally applied or lickable antiseptics or chew toys or other dental treats other than the test product during the trials. |  |
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| **SCORING** | |
| State that the **‘**[VOHC set’](http://vohc.org/protocol_details.html#Teeth-scored)of teeth will be scored, and confirm that only the buccal surfaces of the teeth will be scored:  **Dog**: Max: I3, C, P3, P4, Ml. Mand: C, P3, P4, Ml.  **Cat**: Max: C, P3, P4. Mand: C, P3, P4, Ml.  [Gingivitis](http://vohc.org/protocol_details.html#Gingivitis), and [plaque](http://vohc.org/protocol_details.html#Scoring-plaque) and/or [tartar](http://vohc.org/protocol_details.html#Scoring-tartar) indices are to be scored at the start and end of trial. Briefly describe and provide references for standard indices or provide detailed justification if a new method is to be used.  **Plaque and Calculus:** Either the whole buccal surface of each tooth is scored, or teeth can be visually divided horizontally, but only the gingival half is to be scored. A combination index of extent and thickness is permitted. Consult [Scoring](http://vohc.org/protocol_details.html#Scoring) for additional information.  **Plaque**: Disclosing agent is to be applied and the teeth rinsed prior to scoring.  **Calculus**: Teeth are to be air-dried before scoring. Detecting the edge of calculus with a dental explorer is recommended but not mandated; if not used, what method is to be used to confirm the edge of calculus deposits, e.g. brushing and rinsing following scoring of plaque?  [Random presentation of subjects for scoring](http://vohc.org/protocol_details.html#Presentation)is to be confirmed.  [Scorers blinded](http://vohc.org/protocol_details.html#Scorers). State that scorers will be blinded to the group assignment. Two scorers can be used, but each index must be scored by the same scorer at the end-of-trial scoring episode in every animal.  [Timing of final day scoring](http://vohc.org/protocol_details.html#Final-score)**:** State that the final scoring episode is to be within +/- 3 hours of when the next treatment would have been given if the trial had continued (e.g. 21-27 hours after the last treatment for a product that is given daily). |  |
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| **ANALYSIS** | |
| [Statistical analysis](http://vohc.org/protocol_details.html#Statistics) procedures are to be described in sufficient detail that a statistician consulted by VOHC could repeat the analysis from the description and data provided. |  |
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| **OTHER ITEMS** | |
| **Describe areas in which the submission does not meet VOHC requirements**, and reasons why VOHC should consider such departures from its stated policies or requirements. |  |
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| **Other Items Not Required by VOHC**  Include here a brief description of other observations, e.g. halitosis, that will be included in the trials.  VOHC will restrict its review to Plaque, Calculus and Gingivitis scores - please do not include other observations in the material submitted to VOHC for review following completion of the trials. |  |
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| **DIRECTOR’S COMMENTS TO BE FORWARDED TO THE COMPANY FOR RESPONSE PRIOR TO APPROVAL OF THE PRE-TRIAL PROTOCOL** | |
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