

## Pre-Submission Package: Technical Summary for Dragon's Breath Oral Care Formulation

### 1. Introduction and Product Purpose

Dragon's Breath is an innovative, dual-component oral care system developed by Plaque Slayer Inc., comprising a daily-use toothpaste and an instant-action mouth spray. This formulation is engineered to provide a comprehensive, multi-modal approach to oral hygiene, specifically targeting advanced biofilm management, sustained malodor control, and enhanced enamel integrity. The product aims to deliver superior cleanliness and a heightened sensory experience, empowering users with confidence through an uncompromising oral care regimen. It is designed to be a significant advancement over conventional oral hygiene products by integrating novel active principles for an aggressive yet safe therapeutic effect.

### 2. Product Composition and Mechanism of Action

The Dragon's Breath system leverages a scientifically formulated blend of active ingredients and functional excipients to achieve its intended benefits.

#### 2.1. Dragon's Breath Toothpaste

- **Nano-hydroxyapatite Complex:** A biomimetic crystalline structure designed to integrate directly with tooth enamel. This complex promotes effective remineralization of demineralized areas, thereby enhancing enamel hardness, reducing surface porosity, and increasing overall resistance to acid erosion. This contributes to the repair of early caries lesions and reduction of dentinal hypersensitivity.
- **Capsicum Extract (Standardized):** Included for its unique thermogenic properties, which provide a distinct heat-activated sensation during brushing. This sensation is perceived as an intense, deep clean, psychologically reinforcing the product's efficacy. While primarily sensory, capsaicinoids have been observed in some *in vitro* studies to exhibit mild antimicrobial activities, potentially contributing to biofilm modulation.
- **Citrus Terpenes (Proprietary Blend):** A precisely calibrated blend of natural terpenes, specifically selected for their potent ability to neutralize volatile sulfur compounds (VSCs). VSCs, such as hydrogen sulfide and methyl mercaptan, are primary metabolic byproducts of anaerobic bacteria in the oral cavity and are the leading cause of halitosis. These terpenes chemically bind to or convert VSCs, effectively eliminating their malodorous presence.
- **Abrasive System:** A finely milled, non-damaging silica-based abrasive system formulated to effectively remove extrinsic stains and mechanically disrupt supragingival plaque biofilms without compromising enamel or dentin.
- **Surfactants and Excipients:** Contains standard oral-grade humectants, binders, foam-generating surfactants (e.g., sodium lauryl sulfate), flavorants, and preservatives, all conforming to regulatory safety standards and designed to ensure product stability, texture, and user compliance.

#### 2.2. Dragon's Breath Instant-Action Mouth Spray

The mouth spray formulation is designed for rapid delivery and immediate impact. It features a concentrated solution of:

- **Citrus Terpenes (Proprietary Blend):** Identical to the toothpaste, these terpenes provide immediate and potent VSC neutralization upon application, offering rapid relief from oral malodor.
- **Capsicum Extract (Standardized):** Delivers an instant thermogenic sensation, signaling immediate freshness and cleanliness.
- **Aqueous Base and Excipients:** Formulated with a pH-balanced aqueous base, humectants for oral mucosal hydration, and taste-masking agents to ensure palatability, along with necessary preservatives for product integrity.

### 3. Testing Conducted

Comprehensive testing protocols were implemented to ascertain the efficacy and safety profile of the Dragon's Breath formulations.

#### 3.1. In Vitro Efficacy Assessments

- **Biofilm Disruption and Reduction Assays:** Multi-species oral biofilm models (e.g., *Streptococcus mutans*, *Porphyromonas gingivalis*) were utilized to evaluate the toothpaste's capacity to inhibit biofilm formation and disrupt established biofilms. Results demonstrated a significant reduction ( $p < 0.001$ ) in bacterial viability and biomass within treated biofilms compared to untreated controls, indicative of robust anti-plaque activity.
- **Volatile Sulfur Compound (VSC) Neutralization Studies:** Headspace gas chromatography-mass spectrometry (GC-MS) analysis was employed to quantify the reduction of key VSCs following exposure to the citrus terpene blend. Both toothpaste and mouth spray formulations exhibited rapid and substantial reductions ( $>90\%$ ) in hydrogen sulfide and methyl mercaptan within minutes of application, with effects sustained over several hours.
- **Enamel Remineralization Analysis:** *In vitro* pH cycling models and microhardness testing, coupled with Scanning Electron Microscopy (SEM) and Energy-Dispersive X-ray Spectroscopy (EDX), were performed on demineralized enamel specimens. The nano-hydroxyapatite complex in the toothpaste demonstrated a statistically significant increase in enamel surface microhardness and visible re-deposition of mineral structures, confirming its remineralization capabilities.

#### 3.2. Consumer-Use Evaluation (Clinical Trial)

A randomized, double-blind, placebo-controlled clinical trial was conducted over a 4-week period involving 120 healthy adult participants. Participants were instructed to use Dragon's Breath toothpaste twice daily and the instant-action mouth spray as needed.

- **Objective Endpoints:**
  - **Plaque Index (Turesky modified Quigley-Hein):** At week 4, the Dragon's Breath group showed a statistically significant reduction in plaque scores (mean reduction of 35%,  $p < 0.001$ ) compared to baseline and placebo, indicating superior plaque removal and control.
  - **Gingival Index (Löe and Silness):** A significant reduction in gingival inflammation was observed in the Dragon's Breath group (mean reduction of 25%,  $p < 0.005$ ), suggesting an improvement in overall gingival health.
  - **Halitosis Assessment:** Organoleptic scores and portable sulfide monitor readings demonstrated a significant and sustained reduction in oral malodor in the Dragon's Breath group (mean reduction of 70% in VSCs,  $p < 0.001$ ) compared to placebo.

- **Subjective Endpoints:** Validated questionnaires indicated that participants in the Dragon's Breath group reported a statistically significant increase in perceived oral cleanliness, a fresher mouthfeel, and enhanced confidence in social interactions compared to placebo users ( $p < 0.001$ ). Overall product satisfaction was also notably higher.

### 3.3. Non-Irritation and Safety Assessments

- **Oral Mucosal Irritation Studies:** Conducted using human reconstructed oral mucosal models and *in vivo* patch testing, adhering to ISO 10993 guidelines. Both formulations demonstrated excellent compatibility with oral tissues, exhibiting no signs of irritation, erythema, or edema.
- **Cytotoxicity Assays:** *In vitro* assessments on human gingival fibroblasts and oral epithelial cells confirmed the non-cytotoxic profile of Dragon's Breath formulations at intended use concentrations.
- **Clinical Safety Monitoring:** Throughout the 4-week clinical trial, continuous monitoring for adverse events revealed no significant oral or systemic adverse reactions attributed to Dragon's Breath. Participant compliance was high, and product tolerability was excellent.

## 4. Observed Benefits

Based on the rigorous testing outlined above, Dragon's Breath provides the following observed benefits:

- **Supports Exceptional Oral Cleanliness and Biofilm Management:** The synergistic action of its abrasive system and active ingredients effectively disrupts and reduces oral biofilm accumulation, leading to demonstrably cleaner tooth surfaces and a significant reduction in plaque burden.
- **Helps Reduce Surface Debris and Extrinsic Stains:** The optimized formulation effectively dislodges and removes food particles, superficial debris, and extrinsic stains, contributing to a visibly brighter and smoother enamel surface.
- **Contributes to a Sustained Fresher Mouthfeel and Malodor Control:** Through the rapid and potent neutralization of volatile sulfur compounds by its proprietary citrus terpenes, complemented by the unique thermogenic sensation of capsicum extract, Dragon's Breath delivers immediate and long-lasting oral freshness, actively combatting halitosis at its source.
- **Enhances Enamel Integrity and Resilience:** The nano-hydroxyapatite complex actively facilitates the remineralization of early enamel lesions, fortifying the tooth structure, improving surface smoothness, and increasing its resistance to demineralization and acid challenges.

## 5. Conclusion

Dragon's Breath represents a scientifically advanced and clinically supported oral care solution. Its innovative dual formulation, combining the therapeutic benefits of nano-hydroxyapatite, VSC-neutralizing terpenes, and a unique sensory experience from capsicum extract, delivers superior cleaning, potent malodor control, and enhanced enamel protection. The comprehensive *in vitro* and *in vivo* testing confirms the product's efficacy and favorable safety profile, positioning Dragon's Breath as a robust and compelling option for individuals seeking an elevated standard of oral hygiene and confidence.