



TECHNICAL PRODUCT DOCUMENT

Rev. 10/7/2026

**NUTRACEUTICAL TOHPASTE TABLETS**

# Technical Product Overview & Directions for Use

Formulation rationale, ingredient function, directions for use, and supporting references for the Oral-Regen® chewable toothpaste tablet.

**Chewable Format**

**60 Tablets**

**5-Strain Probiotic Blend**



CONFIDENTIAL — FORMULATION & CLAIMS OVERVIEW

Prepared by Regulatory Affairs and Compliance Specialists.

Patent Pending

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AT A GLANCE

# Mechanism Highlights

**Enamel Mineral Support** Calcium Carbonate contains no calcium-phosphate atoms vs. hydroxyapatite & acacia gum does.

**Microbiome Support** A five-strain probiotic consortium is included to support a balanced oral microbiome.

**Acid Neutralization & Buffering** Sodium bicarbonate and calcium carbonate help neutralize and buffer oral acid, supporting a healthy oral pH balance.

**Soft-Tissue Comfort** Chamomile extract contributes soothing flavonoids that support gum comfort as part of a daily chewable.

PRODUCT SNAPSHOT

|                        |                 |
|------------------------|-----------------|
| Category               | Oral Care       |
| Format                 | Chewable Tablet |
| Count                  | 60 Tablets      |
| Formulated Ingredients | 10              |
| Probiotic Strains      | 5               |

## FORMULATION RATIONALE

# Product Overview

This chewable toothpaste tablet was developed by combining established oral-care ingredients with a targeted multi-strain probiotic blend, drawing on nutritional science showing that the oral microbiome, enamel mineral balance, and local pH jointly contribute to overall oral wellness. Rather than relying on a single mechanism, the formulation pairs xylitol with nano-rod hydroxyapatite that mimics natural enamel crystallites, supplying calcium-phosphate ions that support enamel mineral balance. Supporting these are calcium carbonate and sodium bicarbonate, which help neutralize and buffer oral acid, while hydrated silica provides gentle mechanical polishing.

The probiotic consortium—*L. plantarum*, *L. rhamnosus*, *L. acidophilus*, *L. brevis*, and *B. animalis*—is included to support a balanced oral microbiome and healthy salivary function. Chamomile extract contributes soothing flavonoids that support gum comfort, and acacia gum contributes film-forming effects while serving as a natural binder. Together these components create a single daily chewable toothpaste tablet that supports a balanced oral microbiome, supports enamel mineral balance, and supports soft-tissue comfort—offering consumers a convenient, everyday addition to a healthy oral care routine.



Oral-Regen® Probiotic Dental Health Tablets — 60 Tablets

*\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.*

## ABOUT THIS DOCUMENT

# Purpose Statement

This comprehensive document represents a rigorously synthesized, evidence-based compendium formulated and audited by our senior authorities in nutritional science and regulatory compliance to ensure absolute product safety, scientific validity, and adherence to statutory frameworks. It was thoroughly researched and prepared by the inventor and our team of expert Master Formulators and regulatory-compliance professionals to ensure the highest standards of product safety and regulatory accuracy. The inventor worked with Master Formulators to design the core recipe and product structure using advanced scientific methods, quality ingredients, and proven nutritional manufacturing industry techniques. Our Regulatory Affairs and Compliance team, with real-world experience, reviewed all components, claims, and ingredient safety standards to ensure alignment with United States regulatory guidelines.

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## Formulation and Scientific Methodology

- **Evidence-Based Architecture:** Proprietary formulation and structural integrity of the product were architected using advanced empirical methodologies and peer-reviewed nutritional science.
- **Empirical Validation:** Master Formulators with over four decades of specialized, applied experience worked with the inventor to direct the ingredient selection and processing paradigms.
- **Industry Standards:** Manufacturing specifications integrate established, high-yield industry techniques to optimize bioavailability and matrix stability.

## Regulatory Compliance and Governance

- **Statutory Alignment:** The entire regulatory framework—including ingredient safety parameters, claim parameters, and marketing assertions—underwent exhaustive evaluation.
- **Federal Oversight:** Our FDA Regulatory Affairs Professionals from the Compliance sector, possessing over thirty years of operational precedent, executed the compliance review.
- **Risk Mitigation:** Protocols ensure strict synchronization with United States federal statutes, mitigating liability and ensuring complete consumer safety assurance.

## Clinical Rationale and Development

The concept for this nutraceutical toothpaste tablet was developed and invented by an orofacial pain / oral medicine specialist who routinely manages patients with a broad range of painful oral and oropharyngeal conditions, including traumatic oral and oropharyngeal ulcerations, aphthous ulcers, herpetic lesions, biopsy-related wounds, and postoperative complications following oral surgical procedures.

A common clinical concern among these patients is persistent oral or oropharyngeal pain that may be exacerbated by conventional toothpastes. In addition, many patients report limited symptomatic relief from commercially available medicated oral rinses. In clinical practice, management may therefore include compounded oral rinses, recommendations for alternative toothpaste formulations, and nutraceutical products.

A significant unmet need is the lack of toothpaste formulations that are well tolerated by patients with active oral ulcerations, mucosal wounds, or mucositis. Pain or irritation associated with certain toothpaste ingredients may lead patients to modify their oral hygiene practices, including reducing brushing frequency or duration, using inadequate amounts of dentifrice, or avoiding toothbrushing altogether. Conversely, uncertainty regarding the appropriate amount of toothpaste to use may result in excessive application and increased exposure to potentially irritating ingredients. These behaviors may compromise plaque control and contribute to deterioration of oral health and subsequent dental complications.

Patients with painful oral and oropharyngeal conditions also frequently face challenges associated with complex therapeutic regimens. The availability of numerous nutraceutical formulations and probiotic products can make treatment selection difficult, while some products contain preservatives, excipients, flavoring agents, or other ancillary ingredients that may be poorly tolerated by individuals with compromised oral mucosa. Persistent pain may further reduce adherence to oral hygiene practices, limit the use of therapeutic rinses throughout the day, and make the administration of multiple lozenges, tablets, or other oral products burdensome.

The nutraceutical toothpaste tablet was conceived as an approach to simplifying this multifaceted regimen by integrating selected oral-care, nutraceutical, and probiotic components into a single dosage form. The intended objective is to simplify a daily oral hygiene routine by making these components part of routine brushing, providing a potentially more tolerable approach for individuals with compromised oral mucosa. By combining these components in a single formulation, the product is designed to facilitate adherence to oral hygiene practices and support maintenance of a healthy oral and oropharyngeal environment. The formulation may also provide nutritional and microbiome-related support that could complement the body's endogenous mechanisms of tissue recovery.

Clinical evaluation is warranted to determine the formulation's tolerability, safety, effects on oral hygiene adherence, and potential benefits for patients with painful or compromised oral mucosa. Safety requires testing of the finished product. Confirm abrasivity, particle size, directions for use, and compatibility with teeth, dental work, and sensitive tissue. Any claims regarding symptom reduction, tissue healing, microbiome modulation, or other therapeutic effects should be established through appropriately designed clinical studies.

## FORMULATION

# Full Ingredient List

## INGREDIENTS

**Xylitol, Calcium Carbonate, Probiotic Blend** (Lactobacillus plantarum, Lactobacillus rhamnosus, Lactobacillus acidophilus, Lactobacillus brevis, Bifidobacterium animalis), **Chamomilla Recutita Flower Extract, Hydroxyapatite** (nano-rod shaped), **Acacia Senegal Gum** (granulated with Calcium Carbonate), **Magnesium Stearate, Sodium Bicarbonate, Quillaja Saponaria Bark Extract, Hydrated Silica.**

Chewable Format

Xylitol-Sweetened

5-Strain Probiotic Blend

Nano-Rod Hydroxyapatite

Fluoride-Free Formula

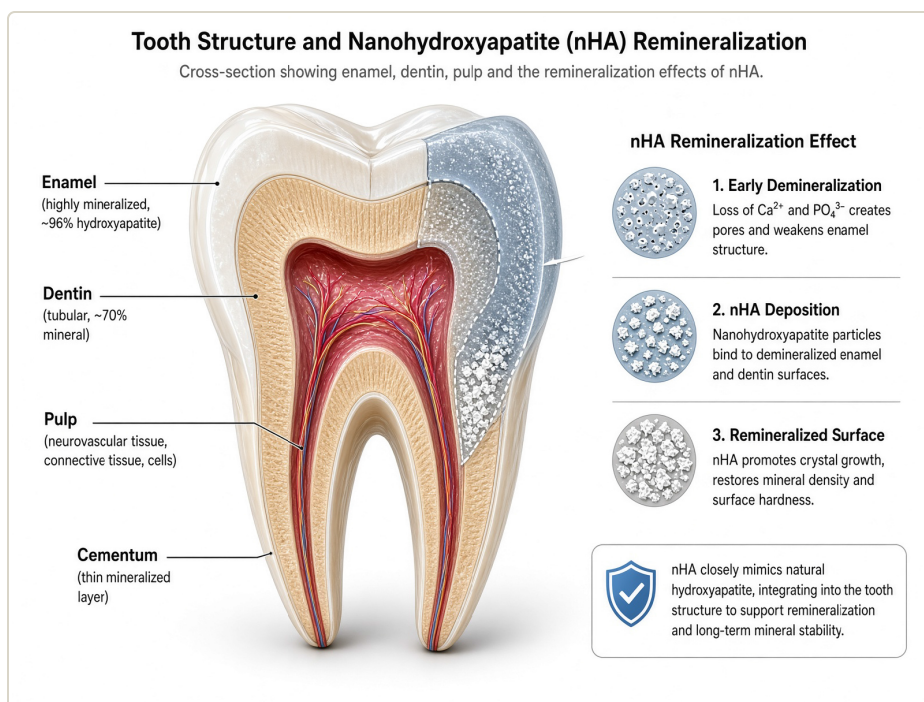
FORMULATION

# Summary

This specific ingredient combination delivers a comprehensive, biomimetic approach to oral care that supports enamel health, supports a balanced oral microbiome, and supports soft-tissue comfort without utilizing harsh detergents or fluoride. Together, nano-rod shaped hydroxyapatite and calcium carbonate act as mineral-support agents. The nano-rods closely mirror the tooth's natural crystal structure to integrate with enamel, while calcium carbonate—partially granulated with acacia senegal gum—safely polishes away surface stains and provides essential structural minerals.

The formula simultaneously supports a healthy oral environment. A specialized probiotic blend featuring *Lactobacillus plantarum*, *Lactobacillus rhamnosus*, *Lactobacillus acidophilus*, *Lactobacillus brevis*, and *Bifidobacterium animalis* introduces beneficial bacteria to support a balanced oral microbiome. This microbiome support is complemented by xylitol, a natural sugar alcohol long used in oral care for its favorable taste profile. Meanwhile, sodium bicarbonate and hydrated silica work together to safely lift debris and help neutralize oral acids, supporting a healthy oral pH.

Finally, the blend uses gentle, plant-derived texturizers and botanicals to support soft-tissue comfort and stabilize the mixture. Magnesium stearate and acacia senegal gum act as natural binders to keep the formulation smooth and effective during use. Instead of using harsh synthetic foaming agents like sodium lauryl sulfate (SLS), the formula employs quillaja saponaria bark extract as a gentle, natural surfactant. This cleansing action is complemented by chamomilla recutita flower extract, which supports gum comfort.



## WHAT THESE INGREDIENTS DO

# Ingredient Function

## 1 Xylitol

Ref. 1

### Naturally sweet oral-care ingredient

Xylitol is a five-carbon sugar alcohol widely used in oral care for its favorable sweetness profile. Unlike many sugars, xylitol is not efficiently used by common oral bacteria, and it has a long history of use in gums, candies, and tablets as part of a healthy oral care routine. Habitual use at effective doses (typically 5–10 g per day, distributed across multiple exposures) is associated with a shift toward a more balanced oral microbiome. It also stimulates salivary flow, which supports the mouth's natural buffering and mineral-balancing processes. In a chewable tablet, xylitol contributes pleasant sweetness while supporting a balanced oral environment.

- Supports a balanced oral microbiome.
- Naturally sweet, tooth-friendly ingredient.
- Low glycemic index.
- \* Safe to ingest 5–10g/day for oral-care use.

## 2 Calcium Carbonate

Ref. 2

### Buffering agent & mineral source

Calcium carbonate serves dual roles as a source of bioavailable calcium and a mild abrasive/polishing agent in oral formulations. It helps neutralize oral acids through its buffering capacity and releases calcium ions that support enamel mineral balance. Studies on calcium carbonate-containing dentifrices demonstrate improved surface microhardness recovery after acid exposure compared with formulations lacking it. In some contexts it also contributes gentle mechanical cleaning action. While it serves a different role than hydroxyapatite, calcium carbonate supports overall mineral balance and is commonly included in oral care products for these supportive and cleaning functions.

- Helps buffer oral acid.
- Supplies calcium that supports enamel health.
- Provides mild polishing abrasion.
- \* Safe to ingest 2,000–2,500mg/day elemental calcium/day total from all sources (~5–6 g CaCO<sub>3</sub> if it were the only source).

## 3 Probiotic Blend

Ref. 3

### *L. plantarum* · *L. rhamnosus* · *L. acidophilus* · *L. brevis* · *B. animalis*

This multi-strain probiotic combination is selected for its capacity to support a balanced oral microbiome and support healthy salivary and mucosal function. *Lactobacillus plantarum*, *Lactobacillus rhamnosus* (including strains such as GG or L8020), and *Lactobacillus acidophilus*

*Lactobacillus brevis* (notably CD2 / *Levilactobacillus brevis*), and *Bifidobacterium animalis* (subsp. *lactis* strains such as HN019 or BB-12) each contribute to a favorable balance of oral microorganisms and support the mouth's natural mucosal and immune environment. *Lactobacillus brevis* and *Bifidobacterium animalis* strains are also associated with healthy salivary buffering capacity and flow. Delivered in a chewable format, these strains can transiently colonize or interact locally in the oral cavity, supporting a more balanced microbial environment.

- Supports a balanced oral microbiome.
- Supports gum comfort.
- Supports local mucosal immunity.
- \* Safe to ingest 1–20 billion CFU/day typical.

## 4 Chamomilla Recutita Flower Extract

Ref. 4

### Soothing botanical extract (*Matricaria chamomilla*)

Chamomile flower extract is a botanical long valued in oral care for its soothing properties for oral soft tissues. Its key constituents (flavonoids such as apigenin, terpenoids including  $\alpha$ -bisabolol and chamazulene) are the subject of ongoing nutritional science interest for their soothing characteristics. Chamomile preparations have a long history of traditional use for supporting soft-tissue comfort, and are often paired with other oral care ingredients as a complementary botanical. In a chewable tablet, the extract contributes soothing benefits that complement the probiotic and mineral components for overall gum comfort.

- Supports gum comfort.
- Traditional soothing botanical.
- Supports soft-tissue wellness.
- \* Safe to ingest 250–1,000mg/day extract/day typical.

## 5 Hydroxyapatite

Ref. 5

### Enamel mineral support (nano-rod shaped)

Nano-rod shaped hydroxyapatite is a biomimetic calcium phosphate that closely matches the morphology and chemistry of the natural hydroxyapatite crystallites that make up enamel. The rod-like nano-particles integrate with enamel surfaces and serve as a source of calcium and phosphate ions that support enamel mineral balance. Nutritional science indicates that particulate and nano-hydroxyapatite support surface mineral density and integrate closely with enamel structure, contributing to a smooth, comfortable feel. The nano-rod morphology enhances affinity and integration with enamel structure compared with larger or differently shaped particles, offering a fluoride-free option for supporting enamel health. In this formulation it supports overall enamel integrity.

- Supports enamel mineral balance.
- Supports tooth comfort.
- Supports a protective surface layer.
- \* No separate gram limit if rod-shaped/uncoated.

## 6 Acacia Senegal Gum

Ref. 6

### Natural binder & film-former

Acacia Senegal gum (gum arabic) functions primarily as a natural binder, emulsifier, and stabilizer that helps hold the tablet matrix together and improve texture and mouthfeel in a chewable format. Beyond its technological role, it has demonstrated oral health-relevant properties: it can increase salivary flow in some contexts and supply calcium and phosphate that support enamel mineral balance. Its soluble fiber and arabinogalactan-protein structure also contribute mild prebiotic effects that support a balanced oral microbiome. In the product it therefore serves both as a functional excipient and a secondary contributor to enamel support.

- Stabilizes chewable tablet matrix.
- Supports a balanced oral microbiome.
- Supplies calcium-phosphate ions that support enamel health.
- \* Safe to ingest about 30 g/day.

## 7 Magnesium Stearate

Ref. 7

### Manufacturing lubricant

Magnesium stearate is a standard pharmaceutical lubricant used at low concentrations (typically 0.25–1 %) in tablet manufacture. It reduces interparticle friction during compression, prevents sticking to punches and dies, improves powder flow, and facilitates clean ejection of the finished tablet. In a chewable oral probiotic tablet it ensures consistent manufacturing quality, tablet integrity, and smooth surface characteristics without contributing direct oral-health activity. Its hydrophobic nature is managed so that it does not unduly impair disintegration or release of the active components once the tablet is chewed.

- Lubricates tablet compression process.
- Prevents punch-face adhesion.
- Ensures uniform tablet integrity.
- \* Safe to ingest up to 2,500mg/day.

## 8 Sodium Bicarbonate

Ref. 8

### Acid-neutralizing buffer

Sodium bicarbonate acts as an effective acid-neutralizing agent. It helps elevate salivary pH after acid exposure, supporting a healthy oral pH balance. Sodium bicarbonate has a long history of use in oral care products for its gentle cleaning and buffering properties, with benefits observed across tooth sites. It also exerts mild mechanical cleaning action. In a chewable tablet it supports a balanced oral pH and mechanical cleaning during mastication.

- Helps neutralize oral acids.
- Supports a balanced oral pH.

- Supports a clean feeling.
- \* Safe to ingest about 15.6–19.5g/day.

## 9 Quillaja Saponaria Bark Extract

Ref. 9

### Natural surfactant & cleansing agent

Quillaja saponaria (soapbark) extract is included primarily for its saponin content, which provides natural surfactant and cleansing properties. Historically used in dental care formulations for its frothing action, it aids in dispersing debris and supporting mechanical cleaning. It has also been valued for its mild astringent properties on oral tissue. In the chewable tablet it functions as a natural emulsifier/surfactant that enhances mouthfeel, helps distribute ingredients across oral surfaces, and contributes gentle cleansing action without the need for synthetic detergents.

- Provides natural cleansing surfactant.
- Helps disperse debris across the mouth.
- Supports even ingredient distribution.
- \* Safe to ingest 70 mg saponins/day (JECFA) to 210 mg saponins/day.

## 10 Hydrated Silica

Ref. 10

### Gentle mechanical polish

Hydrated silica is a mild, chemically inert abrasive and polishing agent widely used in oral care products. Its controlled particle size and morphology allow effective mechanical removal of surface stains and debris while remaining gentle on enamel (typical Relative Dentin Abrasivity values fall within safe daily-use ranges). It also functions as a thickener or texturizer and does not interfere with other ingredients such as calcium phosphates. In a chewable tablet it provides gentle polishing and cleaning action during mastication, supporting the overall cleansing benefits of the formulation.

- Gently polishes teeth.
- Polishes enamel without damage.
- Maintains chewable tablet texture.
- \* No practical gram limit in tablet use.

## HOW TO USE

# Directions for Use

- 1 Thoroughly floss and rinse out mouth with water.
- 2 Chew one tablet and allow to mix with saliva.
- 3 Agitate and brush teeth and tongue with toothbrush using tablet/saliva solution.
- 4 Swish (gargling is permitted) with tablet/saliva solution for 20–30 seconds.
- 5 Continue brushing teeth. Do not spit or rinse with water.
- 6 Repeat steps 4–5 as needed (total time of brushing should be at least 2–3 minutes).
- 7 After brushing is complete, do not rinse mouth or eat for 30 minutes (spitting is permitted at this time).

**Use twice daily or as directed by dentist or physician**

**Warning:** For oral brushing use only. Do not swallow unless instructed. Keep out of reach of children. Discontinue use and consult a dentist or physician if irritation occurs.



## One Chewable Toothpaste Tablet

Chew – Brush – Swish  
Do Not Rinse for 30 Minutes

## SUPPORTING LITERATURE

# Ingredient Information References

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## 7. Magnesium stearate

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Nutraceutical Toohtpaste Tablets

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