ORAL HEALTH BY BLIS

NATIVE-STRAIN PROBIOTICS FOR THE MOUTH

The mouth has its own microbiome — and it helps to have strains that belong there. **BLIS M18 ™** and **BLIS K12™** are *Streptococcus salivarius* M18 and *Streptococcus salivarius* K12 — both isolated from healthy human mouths. Used in oral probiotic products across the globe, BLIS Probiotics give formulators a clinically validated, regulatorily mature platform that helps support teeth, gums, breath, and upper respiratory health.

PROBIOTICS MADE TO MATTER

SECTION 01 · THE CATEGORY

THE MOUTH IS ITS OWN MICROBIOME.

Probiotic science has spent decades focused on the gut. But the oral cavity hosts the second-most diverse microbial community in the body — and the bacteria that thrive there are different from the ones that survive transit to the colon. *Lactobacillus* and *Bifidobacterium* species, which dominate gut probiotic formulations, are not native residents of the mouth and do not colonise oral surfaces in any meaningful way.

Oral probiotics benefit from oral strains. *Streptococcus salivarius* is one of the most abundant species in a healthy human mouth.

BLIS M18™ and **BLIS K12™** are two *S. salivarius* strains isolated from healthy individuals — each selected for its ability to produce natural antimicrobial peptides that help restrict harmful bacteria in the very environment they evolved to occupy. Each strain is a distinct entity, with its own clinical evidence base and application focus.

This native-strain approach is what separates oral probiotics from gut probiotics, and it sits behind every claim in this brochure.

THE OPPORTUNITY

$425M

2029 ORAL PROBIOTICS MARKET

Forecast global market by 2029, growing at 7% CAGR — a category in early growth with breakout potential.[1]

US$12.4B

2029 PROBIOTIC SUPPLEMENTS

Forecast probiotic supplements market by 2029, growing at 6% CAGR within a wider VMS category projected to reach US$176B. [2]

110+

PUBLISHED BLIS STUDIES

Including 40+ clinical trials and over 1 billion doses consumed worldwide. [3]

WHY THE MOUTH MATTERS.

The oral microbiome doesn't stay in the mouth. Saliva carries oral bacteria into the upper respiratory tract, the gut, and the bloodstream — and an imbalanced oral microbiome is increasingly linked to systemic conditions. Published research has reported associations between poor oral microbial health and cardiovascular disease, diabetes, respiratory infection, and adverse pregnancy outcomes. [4–8]

For formulators, this is the strategic context: oral probiotics are not a niche category. They sit at the intersection of three of the largest demand spaces in supplements — preventative health, immune support, and microbiome science — and they speak to the consumer insight that brushing alone isn't enough.

ORAL–SYSTEMIC LINKS REPORTED IN PUBLISHED RESEARCH

42–47%

GUM DISEASE PREVALENCE

Of US adults are affected by gum disease — the most common chronic infection in the population. [4]

24–35%

CORONARY ARTERY RISK

Increased likelihood of coronary artery disease in people with gum disease. [5]

40%+

DIABETES RISK

Elevated diabetes risk associated with gingivitis. [6]

These associations are correlative, not causal. They explain why oral health is moving from a hygiene category into a wellness category, and why brand managers across supplement, oral care, and pet health are looking for differentiated, science-backed ingredients.

BLIS M18™

FOR TEETH, GUMS, AND DENTAL HEALTH.

BLIS M18™ is *Streptococcus salivarius* M18, a commensal bacterium isolated from the human oral cavity. It is selected for its activity against the bacteria most directly involved in dental disease — including *Streptococcus mutans* , a primary driver of caries. It produces natural antimicrobial peptides, helps regulate oral pH, and contributes to the breakdown of dental biofilm. More than 17 clinical trials have evaluated BLIS M18 ™ across paediatric, adolescent, and adult populations.

STRAIN PROFILE

STRAIN	*Streptococcus salivarius* M18 (BLIS M18 ™)
ORIGIN	Human oral cavity
FORMAT	Lozenges, sachets, powder, blends
DAILY DOSE	≥ 500 million CFU/dose
SAFETY	GRAS (GRN 000807)
DOCUMENTATION	17+ clinical trials across age groups

HOW BLIS M18™ WORKS

- Competitive exclusion in the oral cavity
- Targeted antimicrobial peptide production
- Salivary pH regulation, helping limit acidic conditions that contribute to enamel demineralisation
- Enzymatic activity against dental biofilm

AREAS OF CLINICAL SUPPORT

- Supports tooth and gum health
- Helps reduce plaque accumulation
- Helps maintain a balanced oral microbiome in children, adolescents, and adults
- Particularly relevant for paediatric formulations and orthodontic populations

Specific claims permitted vary by market. BLIS Technologies Limited supplies regulatory dossiers and claim libraries for EU, US, Canada, ANZ, and major Asian markets to support customer label development.

FROM PLAQUE TO PERIODONTAL MARKERS.

HELPS REDUCE CARIES RISK IN CHILDREN

In a 12-month controlled study in preschoolers, two 3-month courses of BLIS M18 ™ were associated with an **81% reduction in dental caries** (ICDAS) and a **73% reduction in gingivitis** (PMA index) versus control, with a 2.3× improvement in caries stabilisation. [9] A 90-day randomised study in children at high caries risk reported significantly improved cariogram outcomes and over 90% treatment tolerability. [10]

HELPS SUPPORT GUM HEALTH

A 2024 randomised clinical trial in young adults (n=61, three months) reported significant reductions in gingival bleeding index and plaque accumulation. [11] A 2025 randomised, placebo-controlled study in adults with periodontitis reported significant improvements in plaque index, bleeding on probing, and probing pocket depth across 36 weeks — with effects sustained beyond the intervention period. [12]

HELPS REDUCE DENTAL PLAQUE

A dentist-led, double-blind, placebo-controlled trial in children aged 5–10 reported significant reductions in dental plaque after three months, alongside protection against cariogenic bacteria and acid erosion. [13]

SELECTED BLIS M18™ STUDIES

STUDY	POPULATION (N)	OUTCOME
Kiselnikova & Toma 2022[9] 12 months · two 3-month courses	Preschoolers with caries (controlled)	81% reduction in caries; 73% reduction in gingivitis (PMA index)
Di Pierro 2015[10] 90 days · randomised controlled	Children at high caries risk	Improved cariogram outcomes; >90% treatment tolerability
Burton 2013[13] 3 months · randomised DB PC	Children 5–10, dentist-led	Significant reduction in dental plaque vs. placebo
Babina 2024[11] 3 months · randomised	Young adults (n=61)	Reduced gingival bleeding and plaque accumulation
Chen 2025[12] 36 weeks · randomised PC	Adults with periodontitis	Significant improvement in PI, BOP, and probing pocket depth

BLIS K12™

FOR MOUTH, THROAT, AND ENT SUPPORT.

BLIS K12™ is *Streptococcus salivarius* K12, a commensal bacterium isolated from the oral cavity of a healthy child. It produces natural antimicrobial peptides — including the lantibiotics salivaricin A2 and salivaricin B — which help inhibit pathogens such as *Streptococcus pyogenes* while leaving the commensal oral flora intact. More than 40 clinical trials, over half conducted in children, have evaluated BLIS K12 ™ across upper respiratory, ENT, and oral applications.

STRAIN PROFILE

STRAIN	*Streptococcus salivarius* K12 (BLIS K12 ™)
ORIGIN	Human oral cavity
FORMAT	Lozenges, sachets, powder, blends
DAILY DOSE	≥ 1 billion CFU/dose
SAFETY	GRAS (GRN 000591)
DOCUMENTATION	40+ clinical trials; 20+ in children

HOW BLIS K12™ WORKS

- Colonises the oral cavity and supports a balanced oral microbiome
- Produces targeted antimicrobial peptides
- Helps reduce bacteria associated with bad breath
- Helps support immune function via the upper respiratory tract

AREAS OF CLINICAL SUPPORT

- Helps maintain a healthy oral microbiome
- Supports ear, nose, and throat (ENT) health, particularly in children
- Helps maintain fresh breath when used alongside good oral hygiene
- Supports upper respiratory tract immunity

DEMONSTRATED OUTCOMES.

HELPS SUPPORT UPPER RESPIRATORY AND THROAT HEALTH

In a 90-day study in 82 children with recurrent infection, BLIS K12 ™ was associated with an approximately **90% reduction in episodes of streptococcal pharyngeal infection** compared with the prior year, alongside a 65% reduction in pharyngeal and ear infections sustained over a 6-month follow-up. [14] A 30-day randomised study in 193 healthcare workers reported a 64.8% reduction in respiratory tract infection incidence. [15]

HELPS SUPPORT ENT HEALTH IN CHILDREN

A 6-month randomised multicentre study in 222 children aged ~3 years reported acute otitis media incidence of **44.1% in the BLIS K12 ™ group versus 80.2% in control** .[16] A 2026 randomised, double-blind, placebo-controlled trial in 372 children with adenoid hypertrophy and otitis media with effusion reported significant improvements in middle ear function and hearing. [17]

HELPS MAINTAIN FRESH BREATH

Bad breath has a microbial basis — driven in part by volatile sulfur compounds (VSCs). In a 14-day study in 23 adults with halitosis, **85% of the BLIS K12™ group recorded VSC reductions exceeding 100 ppb** , vs. 30% of placebo. [18] A 2026 randomised study in 80 adults reported BLIS K12 ™ + tongue brushing produced the greatest reduction, and was the only intervention to maintain improvement four weeks after stopping. [19]

SELECTED BLIS K12™ STUDIES

STUDY	POPULATION (N)	OUTCOME
Di Pierro 2012[14] 90 days · 5B CFU/day	Children 3–12 with recurrent pathology (n=82)	~90% reduction in streptococcal pharyngeal infection vs. prior year
Di Pierro 2016[16] 180 days · 1B CFU/day	Children ~3 years, randomised multicentre (n=222)	Otitis media incidence 44.1% (BLIS K12™) vs. 80.2% (control)
Wang 2021[15] 30 days · 2B CFU/day	Healthcare workers, mean age 36 (n=193)	64.8% reduction in respiratory tract infection incidence
Burton 2006[18] 14 days · 1B CFU/day	Adults 18–69 with halitosis (n=23)	85% of BLIS K12™ group achieved >100 ppb VSC reduction vs. 30% placebo
Shi 2026[17] 12 weeks · 1B CFU/day	Children 3–6 with otitis media with effusion (n=372, R DB PC)	Significant improvement in middle ear function and hearing vs. placebo

SECTION 03 · PLATFORM

A PLATFORM BUILT FOR GLOBAL LAUNCH.

BLIS Probiotics are commercialised in oral probiotic products across more than **40 markets** , including the EU, North America, ANZ, China, Japan, Korea, and the Middle East. Both BLIS M18™ and BLIS K12™ hold US GRAS status, qualify for the EU's Qualified Presumption of Safety pathway, and are supported by full regulatory dossiers.

WHAT BLIS PROVIDES TO FORMULATORS AND BRAND TEAMS

- Two clinically validated, GRAS-affirmed strains, each with its own evidence library
- Stability data across lozenge, sachet, chewable, and powder formats
- Market-specific claims libraries for EU, US, Canada, ANZ, and major Asian markets
- Paediatric clinical evidence — over 20 trials in children — to support family and kids' brand positioning
- Co-development support through the Probi commercial network
- Finished-format options and bulk powder supply

APPLICATION AREAS

CHILDREN'S ORAL HEALTH

Caries support
Gum support
Recurrent throat & ear health
Family wellness brands

ADULT ORAL & ENT

Fresh breath
Periodontal support
Immune & URT health
Daily oral wellness

SPECIALIST SEGMENTS

Orthodontic / braces
Athletes & high-stress populations
Pet oral care
Functional oral care formats

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PROBIOTICS MADE TO MATTER.

REFERENCES.

This brochure cites a representative selection from a body of more than 110 published studies and 40+ clinical trials on BLIS strains. A full bibliography with study summaries is available on request from your BLIS Technologies Limited or Probi contact.

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