

# *In Oral Health Care Products*



**PYCNOGENOL®**

LOOK, FEEL, AND LIVE BETTER

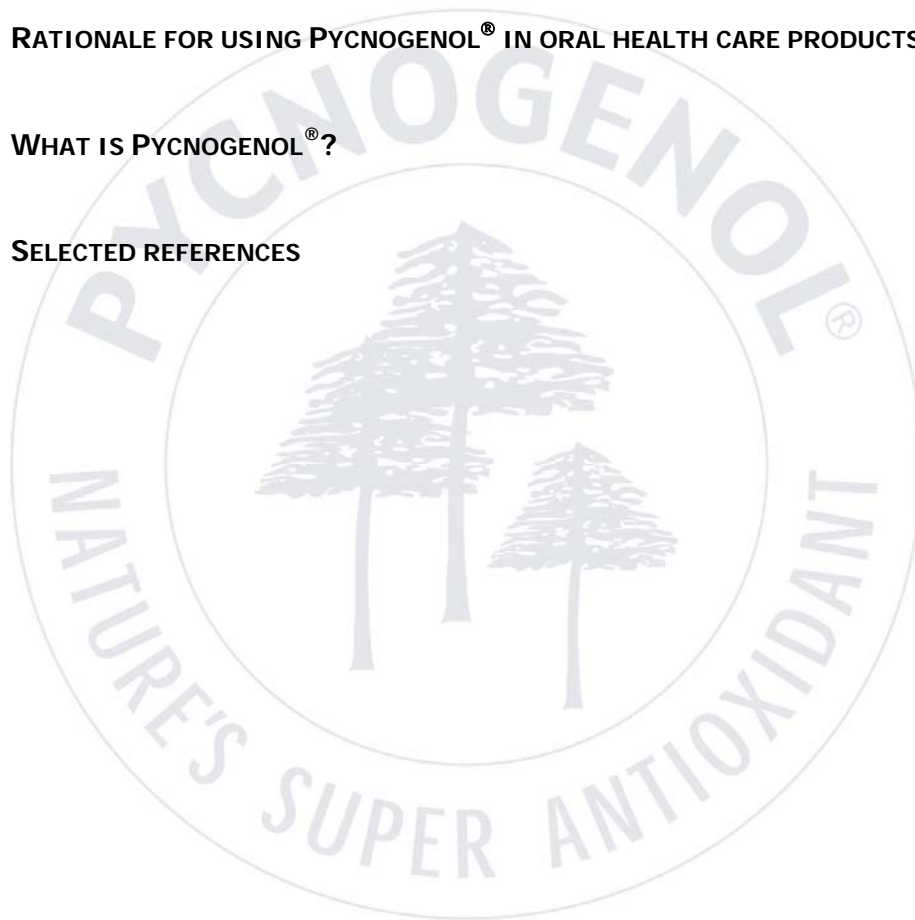
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### **Pycnogenol® in oral health care products**

Pycnogenol® is a water-soluble, standardized extract of the bark of the French maritime pine (Pinus pinaster) world-wide exclusively distributed by Horphag Research Ltd., UK.

Pycnogenol® constituents are bioflavonoids (for detailed description please see below). Pycnogenol® is a powerful antioxidant, is anti-inflammatory and strongly binds to certain proteins (e.g. collagen), the basis for its astringent taste. By virtue of its protein binding Pycnogenol® seals leaky capillaries, an effect proven in various pathological conditions in clinical studies. The anti-inflammatory action of Pycnogenol® results from the inhibition of various pro-inflammatory mediators.

Clinical studies as well as experience with existing Pycnogenol® products show that Pycnogenol®'s properties can successfully be exploited for dental care.

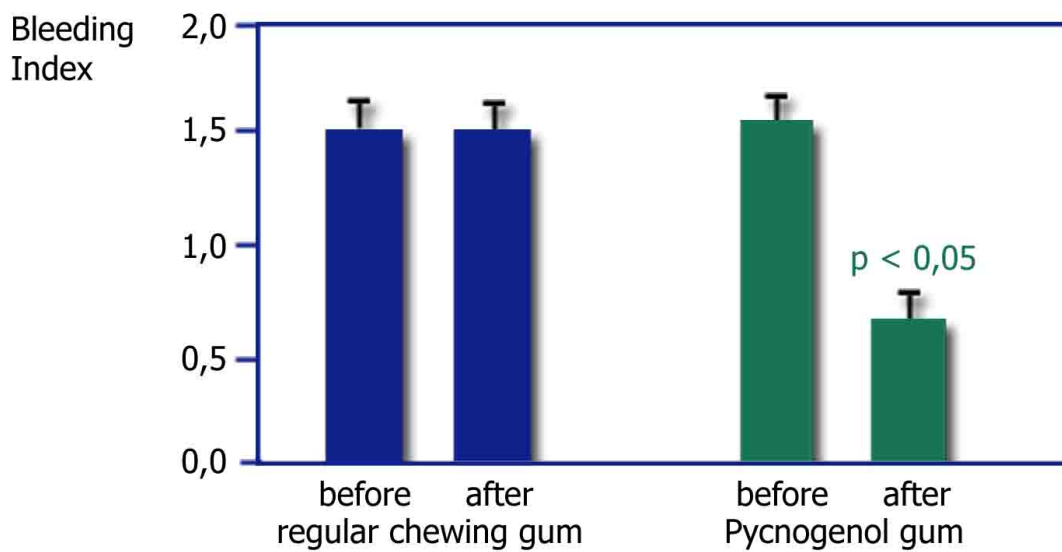
**Clinical study demonstrating that Pycnogenol® in chewing gum minimizes gingival bleeding and plaque formation**

Benjamin Lau MD, PhD (Loma Linda University, CA) explored the anti-inflammatory and capillary sealing effect of Pycnogenol® by topical application in the mouth in form of chewing gums to reduce the bleeding and plaque accumulation associated with common gingivitis [1].

Commercially available Pycnogenol® chewing gum from Finland (Fennobon Oy, Karkkila, Finland), was compared with regular sugar-free chewing gum.

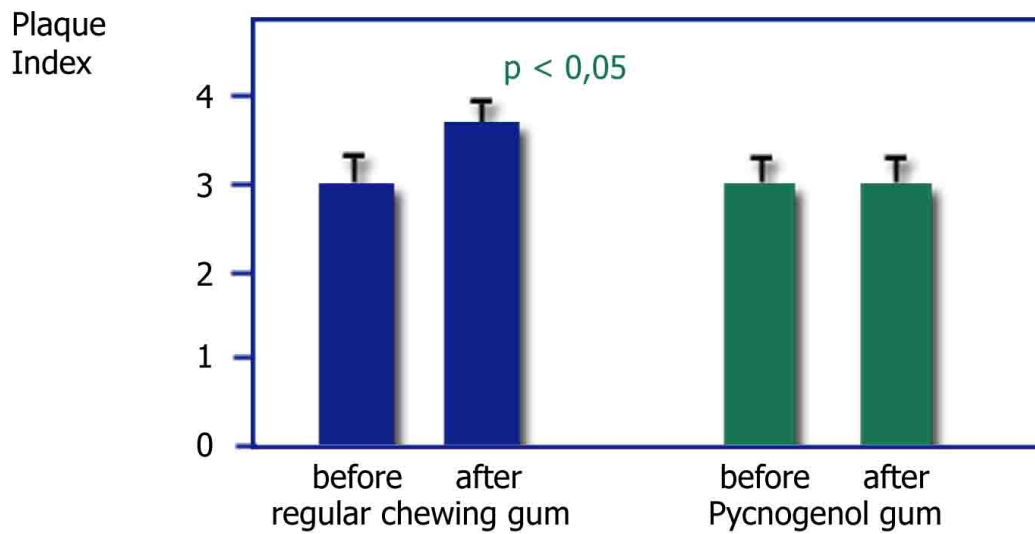
Forty dental students were chosen as subjects to ensure that the experimental protocol of the study was strictly followed. Subjects were randomly assigned to either the group receiving a popular brand chewing gum or to the other group receiving an indistinguishable chewing gum containing 5 mg Pycnogenol® per piece. This was a double blind study design in which neither the subjects nor the investigators knew the assignment to either gum type. Each subject was instructed to chew six pieces of chewing gum daily, one after each meal and three further pieces at any time, for a minimum chewing time of 15 minutes per piece.

Before and after 14 days of chewing the gum, the bleeding and plaque scores were measured using standard procedures. Bleeding scores ranging from 0 to 4 were obtained by gently holding a periodontal probe at four different positions of the gum for 30 seconds. Plaque scores were established using a plaque disclosing solution, a method reminiscent of the famous "caries tablets" given to children to mark insufficiently brushed teeth in bright pink. Throughout the study subjects wore plastic stints covering three teeth to prevent them from getting brushed. The plaque scores are presented on a scale of 0 (no plaque) up to 5 (plaque covering two thirds or more of the crown).



The subjects chewing Pycnogenol® gum showed a more than 50% reduction of gum bleeding (1.59 start; 0.71 end), while regular chewing gum proved to be ineffective (1.55 start; 1.54 end). The reduction of gum bleeding in the Pycnogenol® chewing gum group was statistically significant.

Gum bleeding of 40 subjects chewing either regular sugar-free chewing gums or chewing gums containing 5 mg Pycnogenol® per piece. After 14 days of chewing 6 pieces per day the gum bleeding in the Pycnogenol® group is statistical significantly reduced, while gum bleeding remained unaffected in the control group.



Plaque formation of 40 subjects after chewing either regular sugar-free chewing gums or Pycnogenol® chewing gums for 14 days. Subjects wore plastic stints on their teeth to prevent them from being brushed. In the group chewing regular chewing gums plaque formation was significantly increased. Pycnogenol® in chewing gums prevented plaque formation.

The group chewing regular gum had a significant increase in plaque accumulation at the end of the study (3.01 start / 3.82 end). In contrast, no plaque accumulation was observed in the group using Pycnogenol® chewing gums (start 2.95; end 2.93), suggesting that Pycnogenol® is capable of minimizing plaque accumulation normally found in individuals who don't brush their teeth.

Chewing Pycnogenol® gum not only acts locally, but will eventually be absorbed, and thus reinforce antioxidant protection throughout the body. Systemically, Pycnogenol® recycles and protects used-up vitamin C and E, thus greatly extending their activity in the body [2]. In addition, it is scientifically well established that Pycnogenol® benefits circulatory health [3].

In his research, Dr. Lau concludes that individuals who enjoy chewing gum may reduce the need of frequent tooth brushing and, at the same time, increase the benefits of maintaining gingival health.

### Experience with Pycnogenol® in dental health care

The company Hankintatukku Oy (Helsinki, Finland) manufactures a Pycnogenol® mouth spray of 30ml, containing approximately 150 spurts with 2 mg Pycnogenol® per spurt. This product has gained much popularity in elderly people who wear dentures. They use the mouth spray before putting their dentures into the mouth or after taking them out to reduce gum bleeding, swelling and inflammation in the mouth, thus improving denture fit and gum health.

Researchers in Canada discovered that Pycnogenol® *in vitro* has an antifungal activity, which was demonstrated with strains of *Candida albicans* and *Aspergillus fumigatus*. These unpublished experiments have given a minimum inhibitory concentration (MIC) of 0.1 mg/ml Pycnogenol® for both strains (Dr. Pamela C. Kibsey, personal communication). This is not a very powerful antifungal activity compared to standard antifungal drugs, however, the necessary Pycnogenol® concentration is achievable in local treatment and Pycnogenol® does not show side-effects.

A successful antifungal treatment with Pycnogenol® has been described in a patient who developed a candida infection of the oral cavity following radiation of the pharynx for treatment of his carcinoma of the left neck. He was treated with Fluconazole, a standard antifungal drug, however, without success. In a spontaneous test this patient was given Pycnogenol® tablets (25 mg each) four times daily and chewed them for approximately five minutes with 5 to 10 ml water. After 1 month the patient showed no signs of any residual infection. Two further patients with *Candida albicans* and *Candida glabrata* had their persisting infections cleared by chewing four Pycnogenol® tablets (25 mg) daily, until they had 100 tablets (Dr. Michael A. Ross, personal communication).

**Rationale for using Pycnogenol® in oral health care products**

Strengthens and seals fragile capillaries of the gum.

Minimizes gingival bleedings.

Reduces plaque accumulation on teeth.

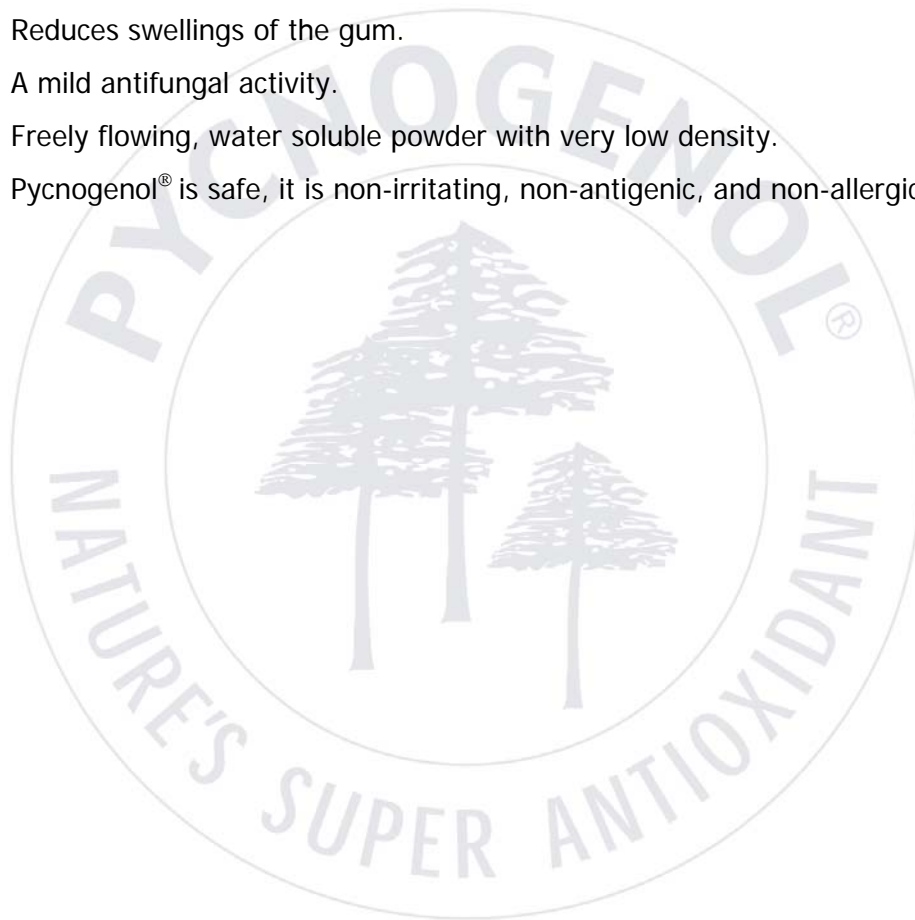
Reduces inflammations of the gum.

Reduces swellings of the gum.

A mild antifungal activity.

Freely flowing, water soluble powder with very low density.

Pycnogenol® is safe, it is non-irritating, non-antigenic, and non-allergic.



### What is Pycnogenol®?

Pycnogenol® is the water extract of the bark of French maritime pines (*Pinus pinaster* Ait.) growing in a mono-species forest – the unique source of Pycnogenol® – in the south-western coastal region of France. The pine trees from which Pycnogenol® is produced are grown entirely without pesticides, and no toxic solvents are used during the production of Pycnogenol®. Consequently, there is no trace of pesticides or toxic solvents in Pycnogenol®. No genetically modified organisms (GMOs) are used to produce Pycnogenol®.

The standardized, validated and automated extraction procedure gives a yield of  $70 \pm 5\%$  procyanidins. Additionally, Pycnogenol® contains monomeric bioflavonoids as catechin, taxifolin and various fruit acids in naturally defined constant proportions. The specifications of Pycnogenol® conform to a typical European Pharmacopoeia monograph of an herbal extract, detailing its qualitative and quantitative composition and microbial limits.

Pycnogenol® is a pink to reddish brown, freely flowing, very fine powder with a characteristic aromatic odour and astringent taste. It is soluble in water (>90%) at room temperature and is soluble in ethanol and acetone. It is moderately acidic with a pH between 2.5 and 4.4 in 1% aqueous solution. It is heat resistant and stable at room temperature for more than three years, if stored in well-closed containers away from direct exposure to light. These interesting physico-chemical properties make Pycnogenol® a versatile, easy to handle active ingredient, suitable for long-term use in a variety of formulations for topical applications.

Pycnogenol® has passed stringent international safety requirements. Extensive research on its safety has demonstrated that Pycnogenol® has a very low acute toxicity, it would require at least 300 g to produce serious toxic effects. It has a very low chronic toxicity with an NOAEL of 150 mg / kg body weight. Pycnogenol® is non-mutagenic and non-teratogenic. Four studies, one in human subjects and 3 in animals have been performed to demonstrate local tolerance of Pycnogenol® when applied topically. The conclusive result is that Pycnogenol® is well tolerated when topically applied. Pycnogenol® is non-irritating to human skin, rabbit's skin and eye. It does not produce any sensitizing or allergic reaction after topical application.

Pycnogenol® has been tested in more than 2000 human subjects/patients, in clinical research studies, without showing any incidence of severe side effects. Pycnogenol® has been approved by the British Ministry of Agriculture, Fisheries and Food (MAFF) as active food ingredient. Pycnogenol® is used as a food supplement in many countries of the world including the USA.

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**\*Referenced studies are available in the Pycnogenol® Bibliography or at Horphag Research.**