KALIDENT
ORAL CARE

Natural re-mineralization

Enamel whitening

Micro-lesions repair and reversing

Reduction of hypersensitivity

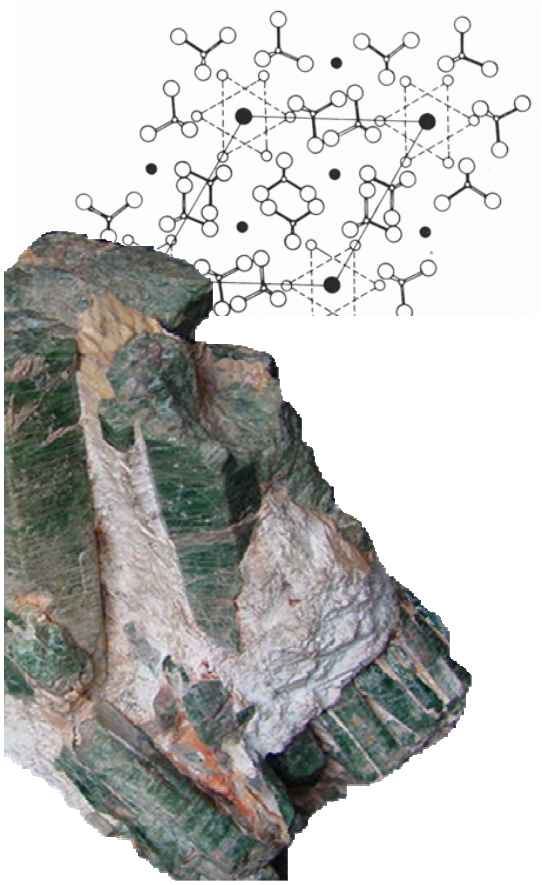
Plaque removal

Kalichem Italia s.r.l.

KALIDENT

A BIOMIMETIC ACTIVE FOR ORAL CARE APPLICATIONS

>> PRODUCTS BACKGROUND



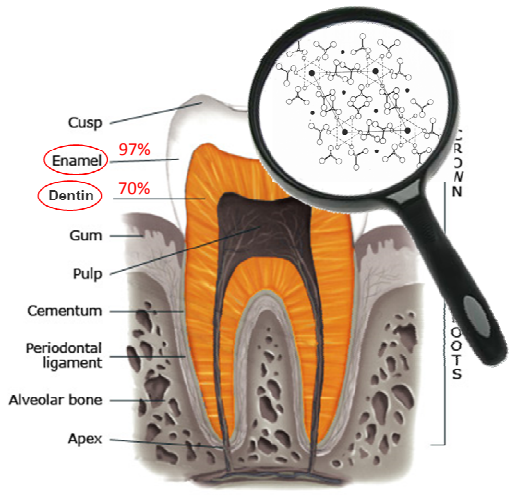
KALIDENT-Calcium Hydroxyapatite is based on a formulation designed to significantly enhance the natural salivary remineralisation of dental enamel. Each day dental enamel is demineralised by acids present in the mouth and remineralised by the calcium and phosphate ions carried in saliva. Under normal circumstances the dynamic balance between demineralisation and remineralisation is stable. This equilibrium results in healthy teeth which are not affected by caries, and are not eroded, decalcified or hypersensitive.

Poor oral hygiene, wrong dietary habits, excess consumption of carbonated beverages, occupational hazards can all increase the rate of demineralisation. The dynamic balance ions-salt can also be adversely affected by reductions in the salivary flow resulting from the normal ageing process, the use of many common drugs, the fitting of orthodontic appliances, dehydration through occupational or recreational activities and the radiotherapy and surgical interventions connected to some diseases.

Saliva is normally super-saturated in calcium and phosphate ions (i.e. saliva carries the maximum possible amount of them) hence it was not possible to increase its ions concentration in order to compensate for the loss of tooth enamel caused by any of the above circumstances. The problem of carrying high concentrations of calcium and phosphate ions directly to the tooth surface could not be solved in this way .

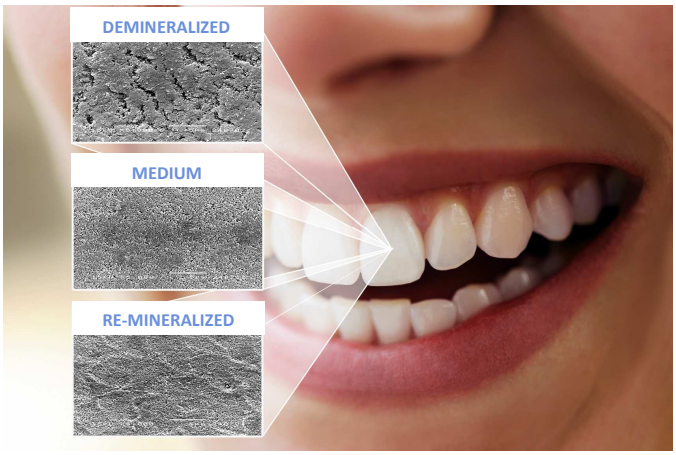
The regular use of KALIDENT-Calcium Hydroxyapatite over an extended period can do much to alleviate problems caused by excessive demineralisation of dental enamel. The use of KALIDENT-Calcium Hydroxyapatite helps prevent caries or stabilise rampant caries, counteracting the consequences of poor oral hygiene, acid foods and carbonated drinks. It can help prevent the dental consequences of xerostomia or Sjogren's syndrome. It can even assist in the reversal of dental erosion and its adverse consequences. KALIDENT-Calcium Hydroxyapatite is a good alternative to those patients unwilling to use fluorides as part of their dental care regime.

>> CLINICAL PROPERTIES



Laboratory tests indicate that the Hydroxyapatite particle is twice as effective in restoring demineralised tooth enamel as its larger-particle parent structure. Over half the dry weight of human bone, **97% of dental enamel and 70% of dentine is comprised of Calcium Hydroxyapatite.** Human saliva, rich in calcium and phosphate ions, is a saturated solution of Hydroxyapatite. Natural and synthetic Hydroxyapatite have a strong affinity with the human body, and are widely used in orthopedic and dental applications (such as bone augmentation, dental cement, coatings for implants, etc.), as well as in foods, as a readily absorbed dietary calcium phosphate supplement. A joint study carried out by the Tokyo Medical and Dental University and Gifu Dental University shows a significant reduction in new caries formation in children who brushed their teeth daily with an Hydroxypatite-based toothpaste compared with a non-Hydroxyapatite control. KALIDENT-Calcium Hydroxyapatite repairs microscopic defects in surface and subsurface tooth enamel, restoring the enamel to its original mineral density and reversing incipient caries, the beginning of tooth decay. This restoration also returns the enamel to its original optical characteristics**.**

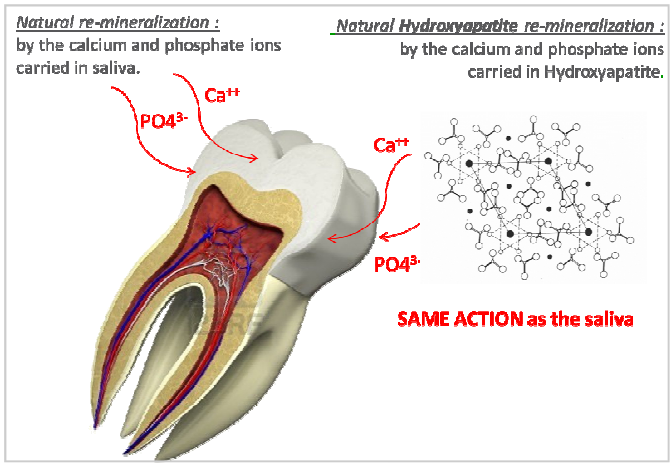
MODE OF ACTION



Demineralisation and remineralisation of tooth enamel occur naturally and constantly in the oral environment. The surface of the teeth is covered by a salivary pellicle, which can be colonized by bacteria to form dental plaque.
Minute cracks and scratches in the esame surface and spaces between the teeth that are inaccessible to a toothbrush especially Harbour plaque. The enamel itself is comprised of closely packed rods of Hydroxypatite, separated by minute channels. Plaque bacteria digest carbohydrates and produce acids which seep into the minute channels between the enamel rods, causing the enamel to dissolve and become microscopically demineralised.
Saliva however, has a restorative function, acting not only as a buffer, to reduce the acidity caused by plaque bacteria, but also as a constant source of calcium and phosphate ions. Upon neutralization of plaque acids, calcium phosphate complexes from the saliva diffuse back into the channels between the depleted enamel rods, replenishing the supply of Hydroxyapatite. So that the enamel gets remineralised.
Under optimum physiological conditions, demineralisation and remineralisation are balanced in the oral cavity, so that no net loss of mineral from the teeth occurs. But conditions such as excess plaque, inadequate saliva flow, frequent intake of acidic foods or carbohydrates can upset the balance, driving the equation overwhelmingly in the direction of demineralisation, so that cavity formation eventually occurs. It is now known, however, that early-stage demineralisation (incipient caries or “white spot lesions”) can be reversed by replenishing or reinforcing the enamel, before decay requiring medical treatment sets in.

>> NATURAL REMINERALISATION

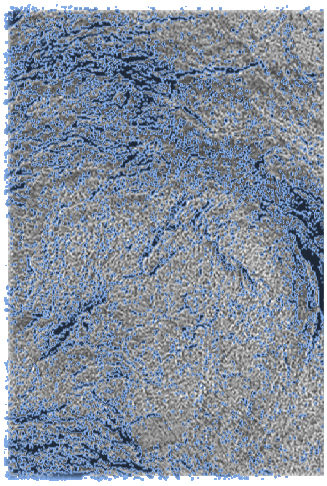
KALIDENT-Calcium Hydroxyapatite, having almost the same composition as our teeth, directly provides mineral to demineralised subsurface areas of the tooth (incipient caries), restoring the enamel to its near-natural state, without changing the composition of the enamel. This is in contrast to fluorides, which are not true remineralising substances by themselves, but promote teeth remineralisation by salivary calcium phosphate, by creating a new substance, fluorapatite, on the tooth surface. Fluorides tend to form a coating on the surface of the enamel, in contrast to Hydroxyapatite, which tends to restore subsurface lesions from the deeper part of the lesion first. This deep restorative effect has been enhanced by the reduction of the Hydroxyapatite particle size to two-figure micrometer size, facilitating their deeper penetration into the enamel.



>> ENAMEL WITHENING

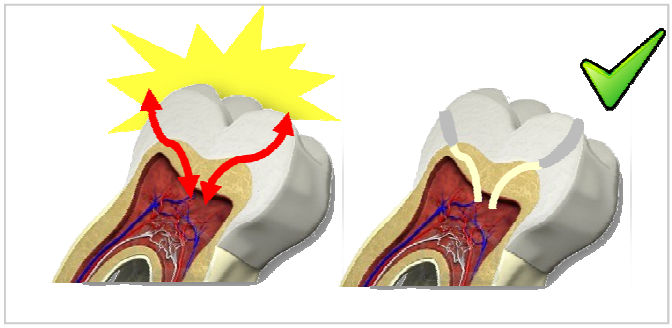
As explained above the KALIDENT-Calcium Hydroxyapatite is able to remineralize the teeth supplying useful Calcium and Phospate ions that will improve the health of the teeth. As everybody knows the teeth are naturally white and shiny. Thus, putting Hydroxyapatite on our teeth, we improve their health (remineralization) and we help them turn back to the white and shiny color. This is without any abrasion and following a regular use of the KALIDENT-Calcium Hydroxyapatite. Milder than a silica but with the same effect in the time!

>> MICRO LESIONS REPAIRING AND REVERSING



KALIDENT-Calcium Hydroxyapatite also acts as a filler, restoring minute cracks and scratches in surface tooth enamel. Reduction of its size to micrometer level has enhanced this ability of Hydroxyapatite to enter and rebuild the crystalline network at the surface defects in the enamel. This filling action is aided by the fact that the Hydroxyapatite contained in Kalident is exactly the same Hydroxyapatite contained in the tooth (Calcium Hydroxyapatite), so its interaction with the biological target is absolutely respectful of the physiological homeostasis and does not represent an invasive mechanism of enamel restoring activity. By filling minute surface lesions and restoring smoothness to the enamel, KALIDENT also reduces the number of sites on the tooth surface to which plaque is likely to adhere. Results of research in this area were presented at the IADR in early 2004.

>> REDUCTION OF THE HYPERSENSIVITY

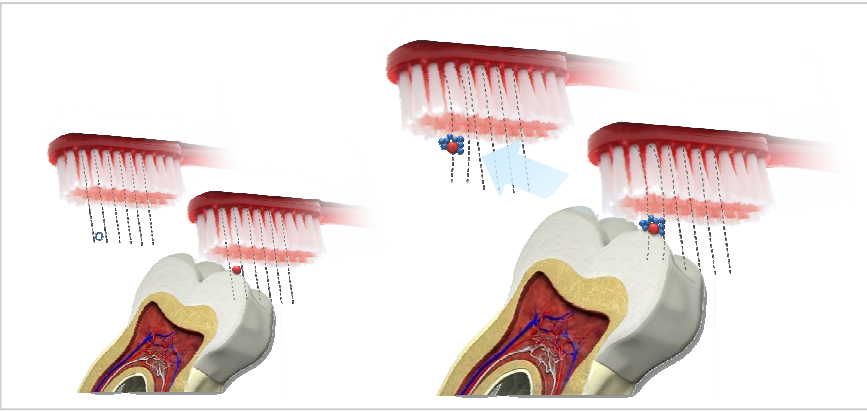


The Hydroxyapatite enamel restoring activity enables the filling the tooth micro-lesions, biological responsible for hyper-sensitivity events. This way,significantly reducingthe entity of these structural alterations of the enamel, Kalident Hydroxyapatite restores the typical physiological integrity of the tooth, carrying out a completely natural re-mineralization action, thus one can avoid the pain linked to the presence of the micro-lesions that expose the sensitive internal components of the tooth to external agents, giving back to the oral cave its natural health.

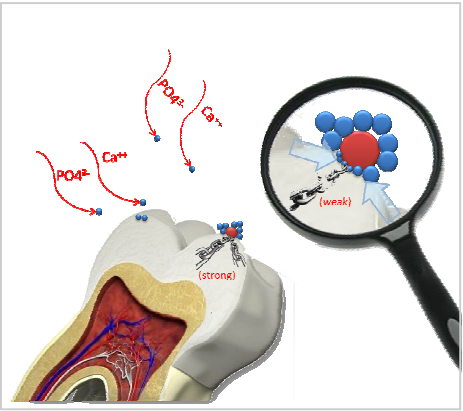
>> PLAQUE REMOVAL

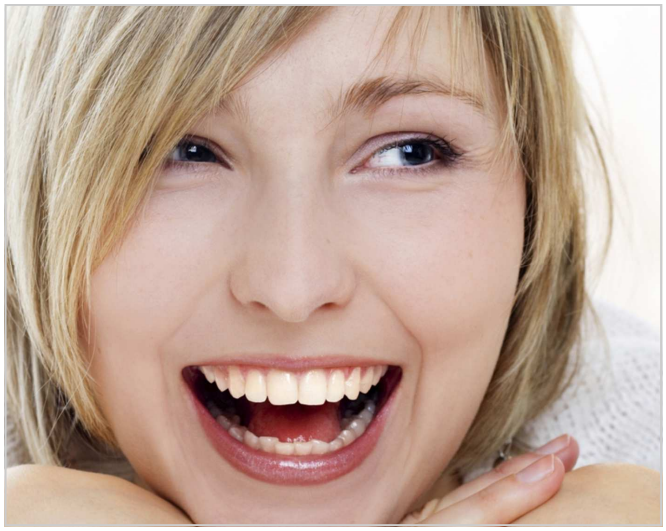
KALIDENT-Calcium Hydroxyapatite has a strong propensity to bind with proteins, and adheres to plaque bacteria and glycoproteins in the oral cavity, facilitating their removal on rinsing the mouth after brushing. This feature of the Hydroxyapatite has been enhanced by reducing of its particle size through microtechnology, so enormously increasing the surface area to which bacterial proteins can be clung to.
The interaction with the plaque is promoted by the fact that Kalident contains exactly the same Hydroxyapatite one can find on the tooth, so the presence of the same substrate tends to decrease the adhesion of the bacterial plaque to the tooth, by weakening its chemical bond (1). Beside this, one should keep in mind that bacterial plaque particles are difficultly removable by toothbrush bristles because of their dimensions: the weakening of the link between the plaque and the tooth, and the formation of a complex Hydroxyapatite-plaque (2) solves these issues, simplifying the toothbrush removing action.

1) Plaque is smaller than the toothbrush



2) Plaque strongly binds with enamel





>> STRUCTURAL TOOTH REORGANIZATION

KALIDENT-Calcium Hydroxyapatite, thanks to its affinity with structures expressed in dentin and enamel, is able to restore the physiological and homeostatic context of the tooth. This feature determines not only a repairing action of micro-lesions, but also a reorganization of the existing Hydroxyapatite in the interested affected areas. This re-organization allows a correct re-arrangement of the physiological tooth structure based on Hydroxyapatite parallel prisms disposition, a strengthening action on the existing enamel and dentin, and a stimulus to a correct "ex-novo" Hydroxyapatite crystals formation.
Toothpaste containing appropriate amounts of Calcium Hydroxyapatite proved, in fact, several physiological benefits: numerous "in-vitro" tests have demonstrated the positive influence of the micrometric particles of Kalident-Calcium Hydroxyapatite on the physiological structural re-organization of the tooth: the application of a toothpaste containing a 10% of Calcium Hydroxyapatite on experimental samples of artificial caries has proven a decreased velocity in the progress of enamel lesions and a decrease in mineral loss and depth of the enamel's lesions
These actions render the tooth more resistant to stress factors leading to hypersensitivity events, bacterial plaque formation and preservation from pathological events such as caries.

>> PREVENTION AGAINST CARIES

Caries is a degenerative disease of the tooth hard tissues, based on the aggressive action of oral cave bacteria (*Streptococcus Mutans, S. Milleri, S. Mitior, S. Sanguis and S. Actinomyces, Lactobacillus*), that adhere to the tooth forming first a bacterial plaque: this plaque, if not kept under control through the common hygiene procedures or following reduction of immune system efficiency,can dissolve the mineral and organic matrix of the tooth, by creating lesions that, if not treated in time, lead to the involvement of the dental pulp and to a consequent severe pain: in these cases surgery processes become necessary.
In order to avoid this pathological condition, it is fundamental to preserve the structure of the tooth, keeping its physiological health status.
Kalident-Calcium Hydroxyapatite supply increases the resistance of the tooth to stress factors, such as acids from food, smoke, drugs use, pathologies like Gastro-Esophagus Reflux, by preventing the erosion of dental tissue through a re-mineralization, repairing and re-organizing activity on its target.
The mechanism of action is as simple as efficient: this mineral is exactly the same of the one physiologically expressed by the tooth, so the filling action happens very easily through an affinity interaction, without providing external "non-self" molecules or unproven in-vivo activations.
This restorative action avoids the formation of all the factors leading to an increase of tooth vulnerability (micro-lesions, reduction of bacterial adherence and consequent plaque formation, decrease of hyper-sensitivity events) and helps a correct maintenance of the homeostatic balance in the oral cave, preventing caries formation.

EXAMPLES OF FORMULATION

>> REMINERALIZING TOOHPASTE

Phase	INCI NAME	% p/p
1	CELLULOSE GUM	1,5 ÷ 2
2	GLYCERIN	20
3	SORBITOL, AQUA	5
4	SILICA (AEROSIL 200)	1,0 ÷ 2,0
5	SODIUM SACCHARIN	0,15 ÷ 3
6	SILICA (SYLOBLANC 81)	14
7	SILICA (SYLOBLANC 82)	2
8	HYROXYAPATITE, AQUA	10,0 ÷ 30,0
9	SODIUM OLIVOYL GLUTAMATAE, AQUA	1,3 ÷ 1,5
10	AQUA	as needed to 100
		100.00

>> REMINERALIZING MOUTHWASH

Phase	INCI NAME	% p/p
1	AQUA	96,4
2	AMMONIUM ACRYLOYDIMETHYLTAURA TE/VP COPOLYMER	0,6
3	HYROXYAPATITE, AQUA	3,0
		100.00

PRODUCT SPECIFICATION

INCI NAME and COMPOSITION	RANGE %
HYDROXYAPATITE	25% ≤ [%] < 50%
AQUA	50% ≤ [%] < 75%

PHYSICO - CHEMICAL ANALYSIS	METHOD	LIMITS
APPEARANCE	Visual	SOLID VISCOUSE SUSPENSION
COLOUR	Visual	WHITE
ODOUR	Olfactory	SLIGHTLY CARATHERISTICS
pH DIRECT	Potentiometric	6,5 ÷ 8,0
DRY RESIDUE	2 hours 105 °C	28 ÷ 30
TOTAL MICROBE COUNT	by inclusion Ph. Eur. 7.0	0 ÷ 100

SHELF LIFE : 12 months
STORAGE CONDITIONS: Keep in original containers well closed in a cool (minimum suggested temperature 14°C max 27°C), dry, well ventilated and clean site.

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