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Clinpro™ Tooth Crème

Protecting Tomorrow's smiles

The Facts

What is Clinpro Tooth Crème?

Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste is a white crème that contains 950 ppm fluoride and a functionalised tri-calcium phosphate ingredient (fTCP) with a vanilla mint flavour. This innovative formula is a one-step process requiring patients to simply brush with it once or twice daily in place of their conventional toothpaste.

Clinpro™ Tooth Crème 0.21% w/w Sodium Fluoride Anti-Cavity Paste was developed specifically for patients who need the benefits of a professionally-dispensed fluoride-containing preparation. It can be applied to enamel and exposed dentin as prescribed by a dental professional dependent on their overall oral hygiene and caries risk level. The product provides fluoride during brushing to help remineralise demineralised enamel and to aid in the prevention of tooth decay.

What is fTCP and what benefits does it offer?

fTCP is a name given to the innovative calcium-based additive we use in our preventive products. One of the major components of the additive is tri calcium phosphate. What makes it so innovative is the way in which we prepare tri-calcium phosphate so that it can co-exist with fluoride in an aqueous environment. In very simple terms, tri-calcium phosphate is specially milled with a simple organic ingredient known as "Sodium Lauryl Sulfate" (SLS) found in nearly all toothpaste formulations. During the milling process, we functionalise the TCP resulting in an organic-calcium phosphate hybrid being formed. This importantly ensures that the Calcium oxides are protected from the undesirable interactions with fluoride, which could render both calcium and fluoride inactive.

What are the clinical protocols for Clinpro Tooth Crème?

Clinpro Tooth Crème is indicated for use as part of a professional program for the prevention and control of tooth decay. We've designed this product to gently clean extrinsic stains without unnecessary abrasion, a must for patients with delicate, exposed root surfaces. Most importantly, we designed the product to be used in place of conventional toothpaste and not something that needs to be used "additionally" to their normal daily regimen.

Our experience tells us that patients are often reluctant to add steps to their daily oral hygiene routine. This product easily fits into every patient's daily routine ensuring a high level of compliance.

How is the Calcium and Flouride absorbed by the tooth?

The combination of fluoride uptake and remineralisation tells us. (A) Fluoride uptake tells us that fluoride was indeed delivered to the lesion (pH cycling is the best way to tell if it was substantive rather than just loosely bound/labile fluoride). (B) Remineralisation tells us that mineral deposition/remineralisation occurred. Again, pH cycling (exposing the tooth structure to periods of remin and demin episodes) tells us if the mineral was substantive. So, fluoride uptake basically tells us how much mineral was absorbed and remineralisation tells us about the quality of the mineral formed.

It has been well proven and documented many times that calcium alone will not prevent caries but Calcium & Fluoride will. Fluoride when applied to demineralized enamel or dentin helps form fluoroapatite. This mineral formed in the presence of fluoride is much more resistant to an acid challenge than mineral formed in its absence.

Calcium and phosphate are already abundantly available in the saliva and plaque (otherwise we'd never have calculus build-up on our teeth). The following reference should be read which confirms this point very clearly. Public health programs also recognize these facts and publish health programs that fully support ONLY the use of fluoride.

Featherstone JDB. Prevention and reversal of dental caries: role of low level fluoride. Community Dent Oral Epidemiol 1999;27:31–40. (Available upon request)

Can Clinpro Tooth Crème help in achieving remineralisation at both surface and sub-surface?

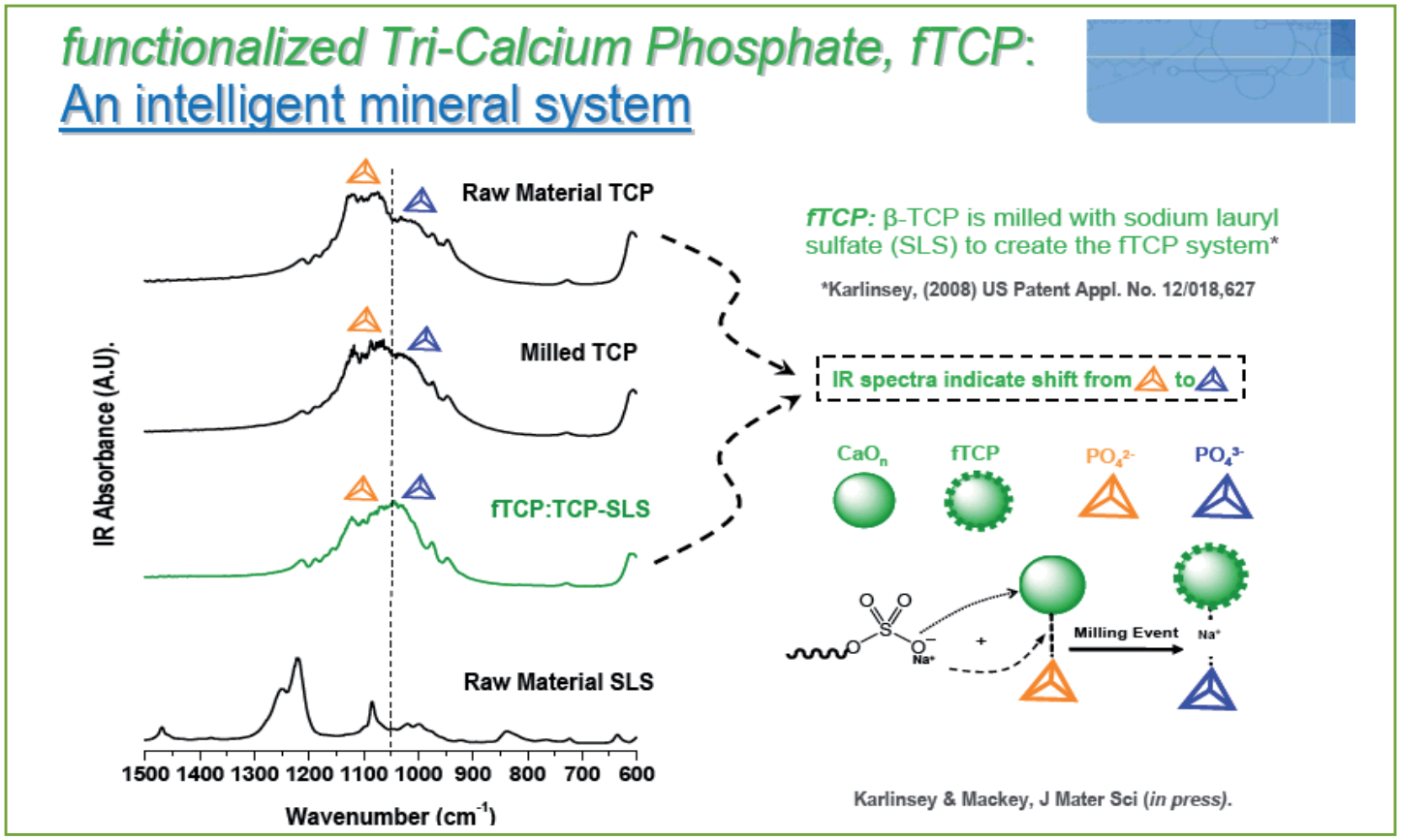
Yes. We have subsequently conducted additional experiments (DI Water Vs Normal OTC NaF toothpaste Vs Clinpro Tooth Crème) and observed locations in the body of the lesion where remineralisation occurred - What really matters is that the lesion (the subsurface) was remineralized. At all points (surface to base of the lesion) better remineralisation was observed when fTCP was added.

What is the concentration of TCP in Clinpro Tooth Crème?

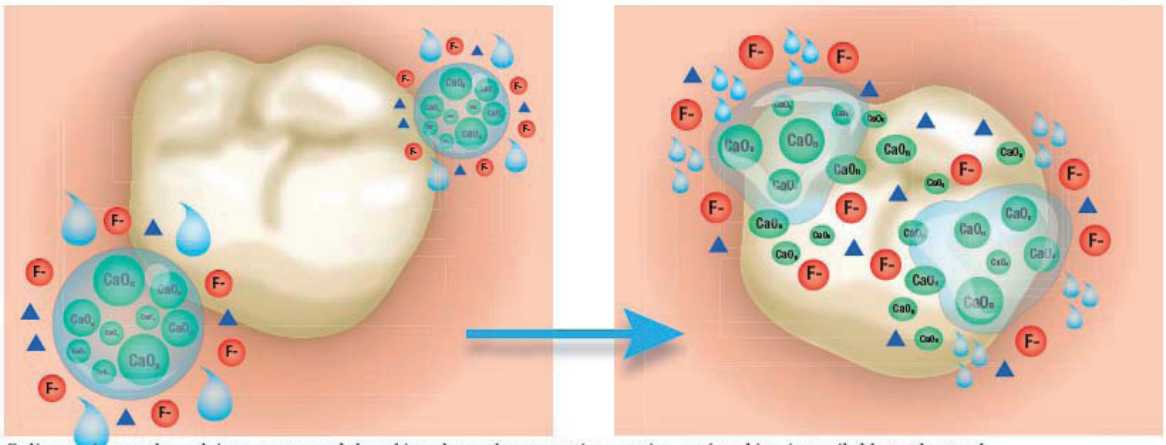
Clinpro Tooth Crème contains 500ppm tri-calcium phosphate. **More is not necessarily always better!!** In fact, the earliest clinical trials involving dentifrices with fluoride and high levels of calcium and phosphate confirmed that high levels of calcium result in clinical failure

(Stookey GK: Are all fluoride dentifrices the same? In Wei SHY (ed) Clinical Uses of Fluoride. Philadelphia, Lea & Febiger, 1985, Chapter 9, pp 105-131.)

With Tooth Crème we have created a formulation that has a good balance of the additive and fluoride so that we can maximise the performance of both components. Because the technology is built upon fluoride availability, only low amounts of fTCP were needed in order to generate the significant remineralisation benefit. Too much fTCP and you will begin to undermine the fluoride performance which inturn negates the functionality of the product.



SLS modifies the beta –TCP structure and protects calcium from prematurely interacting with ionic fluoride while coexisting in solution. It also encourages enhanced tissue integration (via calcium and phosphate) in the presence of fluoride. Because SLS has a high affinity to hydroxyapatite, the SLS molecule releases calcium for mineral integration when interfaced competitively with the enamel surface.



Saliva activates the calcium compound, breaking down the protective coating and making it available to the tooth.

I have been told that TCP is insoluble, so how can it work?

Beta TCP, in its raw material form is what we call partially or sparingly soluble. Tooth Crème contains a functionalised beta tri-calcium phosphate (fTCP). This means we have altered the basic tri-calcium phosphate ingredient to ensure we develop calcium-organic hybrids and this is confirmed through IR Spectra Analysis which shows the availability of free / unbound phosphate. This improved formulation helps build mineral in the teeth (See image bottom left).

Does Clinpro Tooth Crème work for patients with a dry mouth salivary condition?

Yes. With Tooth Crème, our functionalized TCP works synergistically with fluoride and enables high fluoride availability at normal and dry mouth salivary conditions. Unlike some other products that seem to exhibit low levels of bioavailable fluoride, or require quite a lot of water/saliva to release the contained fluoride, our product already has the fluoride released in the tube – it's not bound-up!

To inhibit further demineralisation we need to decrease the rate of metabolism of bacteria, which then results in reducing the production of acids in the plaque. Fluoride does this plus it enhances the rate of remineralisation because it induces the precipitation of calcium and phosphate.

With Tooth Crème, we have found a way to enhance remineralisation through a better formulation that includes fTCP, ensuring we maintain all of the proven benefits of Fluoride. During treatment, the sticky component in fTCP adheres to dentition to promote calcium availability (see image above).

Can SLS (Sodium Lauryl Sulfate) be used for patients with dry mouth?

Yes. People sometimes think that SLS may irritate patients with dry mouth or aphthous ulcers. SLS is a relatively common surfactant found in most toothpaste formulations. There are literally hundreds of thousands of clinical data points regarding its safety. We intentionally added a small amount of SLS because we wanted a lower foaming paste. SLS is also necessary for cleaning and plaque disruption. Patients with low salivary rates still need these agents to clean the plaque and stained pellicle.

What is the abrasive in our product?

We use hydrated silica. Most toothpastes use hydrated silica as the abrasive, which is a little softer and therefore exhibits lower abrasion on dental hard tissues.

How long is the fTCP active for after brushing?

Just like any other topically-applied fluoride preparation, the time the active ingredients remain in the mouth will depend on the patient's habits and practices. Dentifrice, oral rinses, etc. elevate fluoride levels for periods of about an hour or so. There is literature to support this.

Can we use Tooth Crème after a whitening treatment to minimize sensitivity?

Yes. Clinpro Tooth Crème treatment can be used prior to, during or after tooth bleaching treatments. Sensitivity after whitening is usually caused by dehydration of the teeth rather than an exposed root surface. The pulp chamber becomes stressed because the tooth is dehydrated (not because the tubules are opened or exposed to the oral environment). Those implying this type of sensitivity might be remedied with topically applied remineralisation agents, however might not fully appreciate the cause of the sensitivity.

To date there is insufficient evidence to prove that even a calcium phosphate combination will be able to rehydrate the tooth. We are already working on additional experiments to generate sufficient evidence before making any sensitivity claims.

Will continuous use of Tooth Crème harden the exposed root dentine?

Yes. Tooth Crème will harden the exposed root dentine. Bioavailable fluoride and our fTCP-containing formulation allow calcium and phosphate to be available to the tooth and help build mineral again.

Continued →

What Supportive Documentation is Available?

Solid-state preparation and dental application of an organically modified calcium phosphate
Robert L. Karlinsey Æ Allen C. Mackey - Journal of Materials, 2009

Dilution-Dependent Fluoride Release from NaF Dentifrices Containing Unique Forms of Calcium
Karlinsey, Pfarrer, Stookey, Caries Res (2008) 42(Abstr 135):231
2008 ORCA Meeting

In Vitro Remineralization of White-Spot Enamel Lesions from NaF Dentifrices with & without Calcium
Karlinsey, Mackey, Pfarrer, Stookey, Caries Res (2008) 42(Abstr 137):232.
2008 ORCA Meeting

Enamel remineralization and fluoride uptake from 5000 ppm fluoride pastes Karlinsey, Mackey, Pfarrer, Stookey, J Dent Res (2008) 87 (Spec Iss A) Abstr 894.Karlinsey, Frederick, Mackey, Stookey, Pfarrer, J Dent Res (2008) 87(Spec Iss A) Abstr 109.

Challenges of Implementing New Remineralization Technologies
ICNARA Conference – 2008 A. M. Pfarrer, R. L. Karlinsey

In-Vitro assessment of Dentine Tubule Occlusion by Hypersensitivity Dentifrices
A.C. MACKEY[1], R.L. KARLINSEY[1], J. GIDLEY[1], G. STOOKEY[1], and A. PFARRER[2], [1]Indiana Nanotech, Indianapolis, IN, [2]3M ESPE Dental Products, St. Paul, MN IADR Abstract – 2009

In vitro remineralisation efficacy of NaF systems containing unique forms of calcium: a pilot study.
Robert.L. Karlinsey[1], Allen C.Mackey, George K. Stookey[1], [1]Indiana Nanotech, Indianapolis. American Journal of Dentistry (In Press)

In vitro assessments of experimental NaF dentifrices containing a prospective calcium phosphate technology
Robert.L. Karlinsey[1], Allen C.Mackey, George K. Stookey[2], Aaron M. Pfarrer[3]
[1]Indiana Nanotech, Indianapolis., IN. [2]Therametric Technologies Inc, Indianapolis, IN, [3]3M ESPE Preventive Care, St.Paul, MN
American Journal of Dentistry – (In Press)

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