IR Scientific

INTRODUCING SENSI-IP

A REVOLUTION IN ORAL CARE

Sensi-IP Effectiveness

Dentin tubule occlusion studies were performed by Intertek (London, UK). The methodology used is well published and was developed by Intertek to evaluate the efficacy of commercial oral care products.

This preliminary study of Sensi-IP was to support methodological development activities between IR-Scientific and Intertek. The test examined the occlusion efficacy of Sensi-IP against commercial products including Sensodyne Complete Care, Sensodyne Repair and Protect with Novamin®, and Colgate Pro-Relief.

Test articles with Sensi-IP and commercial control articles were subjected to SEM analysis (five images at x3000 magnification, per article), in which the tubules were perpendicular to the surface.

Each x3000 magnification micrograph was examined by two single-blinded assessors for the extent of dentin tubule occlusion based on a five-point categorical scale.

The grading classification was defined as follows:

i. Occluded
ii. Mostly occluded
iii. Equal
iv. Mostly unoccluded
v. Unoccluded

Occlusion performance

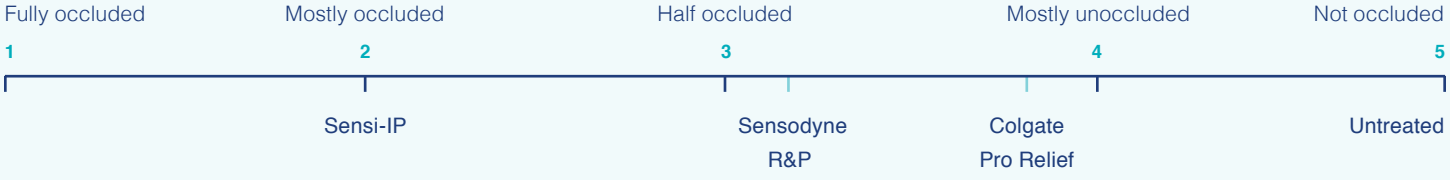
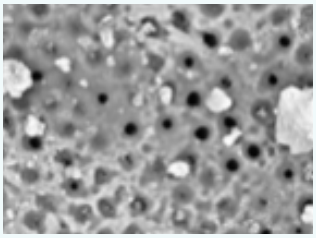
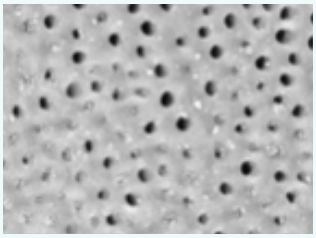


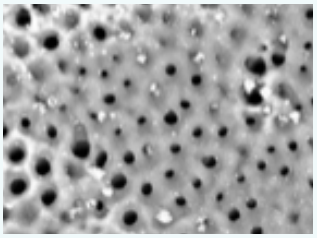
FIGURE 1: Comparative tubule occlusion of Sensi-IP versus commercial controls (grading classification score for each image in parenthesis).



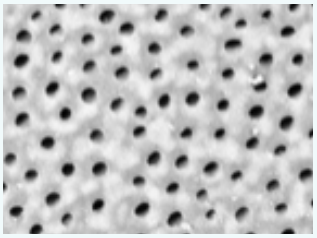
Sensi-IP (Score 2)



Sensodyne Repair and Protect with Novamin® (Score 3)



Colgate Pro Relief (Score 3.5)



Untreated (Score 4.9)

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Preliminary Independant Tubule Occlusion Efficacy (Intertek)

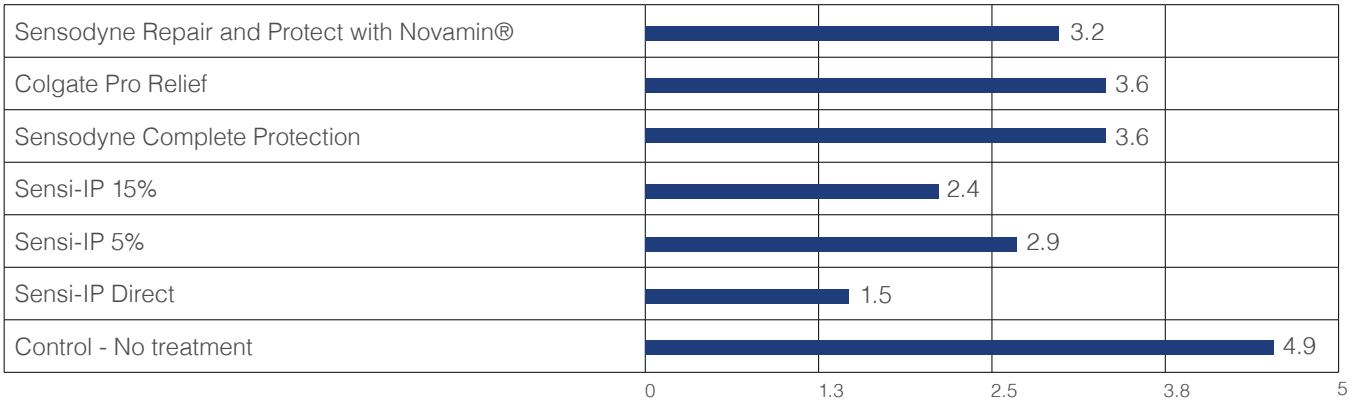

FIGURE 2: Average scoring for tubule occlusion for each test article including Sensi-IP.

Apatite Mineralization and confirmation of bioactivity

As per the TCO4 method, 0.75 g of Sensi-IP (n=3) was immersed in 50 mL of simulated body fluid (SBF) in polyethylene containers. Containers were then placed in an incubating orbital shaker at 37∞C and agitated at 120 rpm for defined periods of time (from 30mins) to investigate mineralization activity.

Subsequent to immersion in SBF, and after each time point, the test article was vacuum filtered with Whatman 42 or 5 grade filter paper (particle retention of 2.5 µm) to collect the solid material from the solution. The solids were immediately washed with distilled water and acetone to stop any further reaction.

The filtered test articles were dried in a vacuum desiccator for further analysis. Imaging of the test article was performed using a Hitachi S-4700 FEG (Hitachi, Chula Vista, Ca) scanning electron microscope operating at 3 KV and 15 mA under magnification of 300x, 1000x and 10000x [27].

Samples were mounted on stubs using double sided carbon tape and sputter coated with gold-palladium for 10s (Leica EM ACE200, Wetzlar, Germany).

Mineralization was confirmed as early as the first time points and increased with time. Figure 2 provides an SEM image confirming apatite mineralization in response to the dissolution of Sensi-IP.

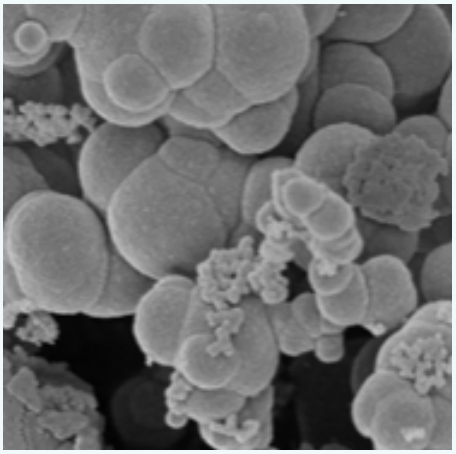

FIGURE 2: Apatite mineralization as a result of dissolution of Sensi-IP, confirmed per TC04.

Biological Risk Assessment

An independent toxicological risk assessment has been completed for Sensi-IP as an additive for toothpaste. The risk assessment was supported by information gathered from chemical characterization on the elemental composition of Sensi-IP.

This risk assessment indicates that the likelihood of adverse effects from Sensi-IP is low for all elemental exposures from material. The TRA has concluded that additional animal testing is not justified and would not follow the guidance in ISO 10993-2 Section 4.2. In addition, and based on the TRA, materials-based.

ENDPOINTS	STATUS
Genotoxicity	Endpoint Addressed (Nelson Labs)
Sub-Acute Toxicity	Endpoint Addressed (Nelson Labs)
Acute Systemic Toxicity	Endpoint Addressed (Nelson Labs)
Sub-Chronic Toxicity	Endpoint Addressed (Nelson Labs)
Chronic Toxicity	Endpoint Addressed (Nelson Labs)
Implantation effects	Endpoint Addressed (Nelson Labs)

Visit us at ir-scientific.com to learn more about the science and potential behind Sensi-IP.

Or contact Andrew Doyle directly at andrew@ir-scientific.com

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