SELIM PRODUCT DEVELOPMENT SERVICES INC.
MOFFETT CAMPUS
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March 4, 1995

Mr. Robert A. Bevilacqua
Health-Dent International, Inc.
122A Kirkland Circle
Oswego, IL 60543

Dear Mr. Bevilacqua:

Selim has completed the preliminary comparison that you requested, of the Miles' Gluma Desensitizer to the Health-Dent Desensitizer. In this comparison we explored vendor data relative to the functionality of the ingredients unique to each product. In order to do this, we obtained literature from the known raw materials suppliers and then discussed this literature with the appropriate company's technical expert or tech service department. The following is a summary of the findings from this survey.

As noted above, the first step taken in this study was to identify the ingredients used in each Desensitizer. The ingredients used in Gluma were identified from the product's patent (US 4,593,054), MSDS, company literature, and journal articles. You provided the ingredient list for the Health-Dent product. A summary of the ingredient information for both products can be found in Attachment 1.

From this summary, it is obvious that at least two major differences exist between the products. The first is that Health-Dent's product contains Fluoride and Gluma does not. As you well know, the major advantage of having Fluoride present in a dental product is to aid in the control of cavities. Slow release of the Fluoride ion over time is an especially preferred delivery mechanism for cavity control. Although we have no confirmatory test data, we believe some of the Fluoride in your product is "encapsulated" in a HEMA residual coating and would be available for slow release onto the treated tooth. You may want to explore this phenomena in some future study.

The second major difference is that Health-Dent has chosen Benzalkonium Chloride as it antimicrobial agent while Gluma utilizes Glutaraldehyde. According to the Nakabashii Theory bacterial is the culprit behind tooth sensitivity. The role of the antimicrobial agent in desensitizers is to eliminate this bacteria related irritation. Both Benzalkonium Chloride and Glutataldehyde are effective disinfectants. However, discussions with Lonza and Stepan Chemical on the efficacy of "Quat" (quaternary ammonium compounds) type products have confirmed that are equal usage levels Benzalkonium Chloride is a much more efficient and faster acting antimicrobial agent than Glutaraldehyde.

In addition, other comments from Lonza and general literature references indicate Benzalkonium Chloride at dilute levels should exhibit no oral tissue irritation unlike, Glutaraldehyde. This should not be a surprise since dilute solutions of various "Quats" have been employed for years in medicines to sterilize skin, conjunctivae and mucous membranes.

One final advantage associated with using Benzalkonium Chloride is its potential for crosslinking with HEMA to form a "temporary" coating on the treated tooth. Although the Quat manufacturers provide no hard data to of this action, they both indicated that Benzalkonium Chloride and other Quats perform this function. As with the Fluoride release phenomena this potential for crosslinking should be explored in a future study.

A possible third difference is the presence of an antioxidant in the Health-Dent product is present to stabilize the formula's ingredients over its use life. The lack of an equivalent ingredient in the Gluma formulation my indicate the use life of Gluma is significantly shorter than that of Health-Dent's product.

Using the information obtained for the above comparison, I feel we can now theorize as to the potential functional mechanism of the Health-Dent Desensitizer. Once the product is applied to the surface of the tooth, the combination of the Benzalkonium Chloride and HEMA reduce the surface tension of the water solution to aid in "wetting out" the treatment area. As the solution wets out, the Benzalkonium Chloride comes in contact and kills the bacterial present on the surface of the tooth or in the tooth's tubules. Killing the bacterial eliminates the source of tooth sensitization. In a short period of time the desensitizing solution starts to dry allowing the Benzalkonium Chloride and HEMA to crosslink onto the dentin or enamel of the tooth. During this time the Fluoride ion is available to react with the tooth surface. Once the solution has dried, some of the Fluoride ion is encapsulation in the HEMA coating and may be available for slow release overtime.

When you have finished reviewing the above findings, please give me a call so that we can discuss this in more detail. I believe the Heath-Dent Desensitizer is an excellent formulation which offers a number of advantage over the current state of the art represented by the Gluma product.

Sincerely,

Michael Endres

Michael Endres
President

ATTACHMENT
KNOWN FORMULATION COMPONENTS

RAW MATERIALS	HEALTH-DENT	GLUMA
Water	Yes	Yes
HEMA	Yes	Yes
Glutaraldehyde	No	Yes
Benzalkonium Chloride	Yes	No
Sodium Fluoride	Yes	No
Antioxidant	Yes	No