intertek Pro Mineralizer Toothpaste Instructions

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Pro Mineralizer Toothpaste Instructions

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Contents

Pro Mineralizer Toothpaste

Laboratory Report
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Study Title: Relative Dentine Abrasively (RDA) of a Great Oral Health Toothpaste Relative to the ISO 11609 Calcium Pyrophosphate Reference Standard

Aim

To use acellular human dentine samples as the test substrate to determine the Relative Dentine Abrasively (RDA) value of a Great Oral Health Pro-Mineralizer toothpaste formulation relative to the ISO 11609 reference abrasive (Annex B).

Test Products

Table 1: Test Products
Great Oral Health Toothpaste
Pro Mineralizer
Crimp Code: 2
Exp: 5/2024
ISO 11609 Reference Abrasive:
Calcium pyrophosphate Lot: AZ7672

Overview

Oral care products such as toothpaste and tooth powders are formulated to contain abrasives (e.g. silica), which enables the mechanical removal of plaque and staining during brushing. A limitation of using abrasives is that their mechanical mode of action can also damage dental hard tissues over time. Manufacturers, therefore, need to evaluate the abrasively of a formulation, to ensure the formulation is not too abrasive and consequently damaging to teeth.

The International Standard ISO 11609 (third edition, 2017) provides manufacturers of oral care products with a method to evaluate the safety of the abrasive components of a formulation. In this ISO standard, the abrasively of the formulations is compared against the abrasively of a reference abrasive (calcium Pyrophosphate) that has a well-defined particle size and hardness.

Tooth enamel is much harder than dentine and more able to withstand daily exposures to dentifrice abrasives. Dentine, on the other hand, is softer and more susceptible to damage than enamel and is often associated with dental sensitivity. As result, many manufacturers often use RDA, rather than REA to assess whether the abrasively of a formulation lies within the safety limits of the ISO standard.

In this method, dentine samples are brushed with slurries of the toothpaste formulation and the reference abrasive under standardised brushing conditions. The post-brushing level of dentine wear is then measured, and a relative dentine abrasively value (RDA) of the oral care product is calculated relative to wear caused by the reference abrasive.

For dentine, the typical ranges for RDA values and their degree of harshness are defined as follows:
RDA = 0-70 (Low abrasivity)
RDA = 70-100 (Medium abrasivity)
RDA = 100-150 (High abrasivity)
RDA = 150-250 (Regarded as harmful limit)
RDA = > 250 (ISO recommended upper safety limit)

The abrasivity range provided above is not listed within the ISO standard but is commonly referenced with the literature.

In this study, Annex B of ISO 11609 was followed to calculate the relative dentine abrasivity of a Great Oral Health Pro-Mineralizer toothpaste formulation relative to the ISO 11609 reference abrasive to ensure the abrasivity of the formulation was within the safety limits of the standard.

Specimen Preparation

Acellular, extracted human teeth were used to prepare the dentine specimens. The radicular portions of the teeth were used for the dentine specimens, which were individually mounted in resin. Dentine samples were hand polished using [P800, P1200, P2500 & P4000] silicon carbide abrasive papers.
The flatness and surface roughness of each polished sample was checked with a 3D optical ProFilm profilometer to ensure the sample met the acceptance criteria of the ISO standard.
The surface microhardness (SMH) of each dentine sample was measured with a Vickers indenter, in accordance with the ISO standard. The hardness data of each sample was checked to ensure it met the hardness criteria defined by the ISO standard.
The SMH data was used to stratify the samples between the two treatment groups, to ensure the mean SMH of each group was approximately the same. This step reduced the biological variability of the tissue by having dentine specimens with a similar average hardness value in each treatment group.
Two pieces of adhesive electrical insulation tape were positioned across the dentine sample to expose a 3 mm window.

Preparation of the Reference Standard

A reference diluent consisting of 0.5% carboxymethylcellulose (CMC) and 10% glycerol was prepared. Reference slurries were prepared in the ratio 18g of the calcium pyrophosphate reference standard to 90 mL of the reference diluent.

Preparation of the Test Product

Test product slurries were prepared in a ratio of 1:1.6 of sample toothpaste (Great Oral Health) and RO water, with resulting measurements. Testing chambers were filled with 90ml of slurry during brushing.

Brushing

Dentine samples (8 at a time) were mounted in a V8 Cross Brushing Machine fitted with flat-headed toothbrushes. Loading was set to 150 g and the rate of brush strokes was set to 125 strokes per minute.
Samples in the reference abrasive group were brushed for 4,000 and 10,000 strokes in order to check for linearity (quality control), with fresh reference slurries used for each sample. Samples in the test product groups were brushed for 4,000 strokes with fresh test product slurries used for each sample.

Post-treatment Profilometry

Following the removal of the tape, the dentine specimens were measured using a Profilm3D optical profilometer. Specimens were scanned across the brushed region between the two taped-off areas. The ProFilm 3D software was used to calculate a wear value. From these values, means for each treatment group was calculated.
The reference abrasive is considered to have an RDA value of 100 at 4,000 strokes and 250 at 10,000 strokes. The reference abrasive mean depth was plotted against their theoretical RDA values and the following equation was used to calculate the RDA of the test dentifrices:
$y = aRDA\text{-}PE\ x$
where:

y	is the mean depth of the reference standards
x	is the RDA-PE of the reference standard (100, 250, respectively).

The mean depth of the unknown dentifrice was divided by the slope (aRDA-PE) to calculate the RDAPE value of the formulation.

Data Management

The day-to-day running of the study was documented in laboratory notebooks, which contained the study number 119-LAB-RDA-22-002. All pages of the laboratory notebooks were signed by the study analyst.
All data were entered and checked in accordance with Intertek Data Management SOPs. The Excel dataset can be found in Appendix 1.

Results

The RDA values for the reference standard and the test products can be found in Table 2.

Table 2: RDA Values for the Test Products and Reference Abrasive

Test Product	RDA Value
Great Oral Health Pro Mineralizer Toothpaste (4000 Strokes)	87.13
ISO 11609 Reference Abrasive (4000 Strokes)	100
ISO 11609 Reference Abrasive (10,000 Strokes)	250

Conclusions

- The abrasivity of the Great Oral Health Pro-Mineralizer toothpaste formulation was well below the upper safety limit defined by the ISO 11609 standard.
- The Great Oral Health Pro-Mineralizer toothpaste formulation passed the safety requirements of ISO 11609.
- The RDA value of the Great Oral Health Pro-Mineralizer formulation was 87.3, which according to the wider literature categorizes the formulation within the ‘Medium Abrasivity’ group.

Appendix 1: Excel Dataset

Reference 4000		Reference 10,000		Great Oral Health Pro-Mineralizer	
Sample number	Wear (um)	Sample number	Wear (um)	Sample number	Wear (um)
078 RDA	17.	078 RDA	41.	006 RDA	13.
050 RDA	16.	050 RDA	40.	024 RDA	12.
071 RDA	16.	071 RDA	33.	059 RDA	15.
066 RDA	11.	066 RDA	27.	016 RDA	14.
063 RDA	22.	063 RDA	42.	043 RDA	12.
030 RDA	19.	030 RDA	42.	038 RDA	11.
062 RDA	15.	062 RDA	36.	053 RDA	16.
064 RDA	15.	064 RDA	45.	070 RDA	14.
Average Wear (11m)	16.		38.		13.
RDA Value	100		250		87.

Report signature:

I declare that this report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study.
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Documents / Resources

	intertek Pro Mineralizer Toothpaste [pdf] Instructions Pro Mineralizer Toothpaste, Pro, Mineralizer Toothpaste, Toothpaste

References

- User Manual