# EFFICACY & SAFETY TESTS

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Plaque Removal with a Novel Rubber Chewing Wheel Device: Results of a Randomized Clinical Trial

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Abstract

- **Objective:** The objective of this study was to evaluate the ability of a disposable rubber chewing wheel (Rolly Brush device) to remove plaque after meals.
- **Methodology:** This was a randomized, four-armed, investigator-blinded study where subjects were assigned into tooth brushing, mouthrinse, chewing gum, and Rolly Brush groups. Plaque index was measured before and after one of the four plaque removal techniques. Questionnaires were administered to ascertain the subject’s opinion of the Rolly Brush device compared with the other plaque removal methods.
- **Results:** Rolly Brush removed plaque better than mouth rinsing (p < 0.03). Subjects reported that Rolly Brush removed plaque better than mouthrinse (p < 0.001) or chewing gum (p < 0.001), but not better than tooth brushing (p = 0.365). Subjective reports indicated that the Rolly Brush device was less likely to disrupt taste compared to mouthrinse (12% versus 30% of the subjects, respectively). Subjects randomized to the Rolly Brush group also rated the device highest in terms of ease of use, although there were no statistical differences among the methods.
- **Conclusion:** These results suggest that a disposable rubber chewing wheel, the Rolly Brush device, is an acceptable means of removing plaque after meals, and should be well tolerated by the public.


Introduction

Plaque accumulation is strongly associated with the colonization of cariogenic bacteria, gingivitis, and oral malodor. Manual disruption of plaque by tooth brushing, or a combination of tooth brushing, flossing, and oral mouthrinse use, is the optimal means of preventing plaque accumulation. These oral hygiene measures are important for promoting overall oral health. However, in today’s culture where most people are outside the home during the day, tooth brushing after each meal is inconvenient and occasionally impossible. Therefore, alternative methods for removing plaque are desirable.

Rolly Brush (SKG Italiana Spa, Italy) is a new disposable, odorless, and tasteless chewing wheel device which has been developed for plaque removal. The purpose of this randomized, investigator-blinded study was to compare the plaque reduction efficacy of Rolly Brush, tooth brushing with a dentifrice, use of a mouthrinse, and chewing gum. The null hypothesis was that there would be no difference between any of the four methods in plaque reduction. Secondary goals of this study were to determine the patient satisfaction and ease of use with the Rolly Brush device.

Materials and Methods

**Subjects and Study Design**

Three-hundred generally healthy subjects, aged 18 years and older, were enrolled in this study after reviewing and signing an IRB-approved written informed consent form, with the assistance of a study-dedicated research coordinator. Subjects were pre-screened for allergies to latex, and to the ingredients in the mouthrinse (Cool Mint Listerine®, Pfizer, Inc, New York, NY, USA), the dentifrice (Colgate® Total® Toothpaste, Colgate-Palmolive Co., New York, NY, USA), and the chewing gum (Orbit® Sugar-Free Gum, Wm. Wrigley, Jr. Co., Chicago, IL, USA). Subjects were also pre-screened to ensure there was an adequate number of anterior teeth and a plaque index greater than 1 on each tooth, by the Silness and Løe Plaque Index.

Digital photographs were obtained of the anterior teeth prior to the randomized treatment assignment. Each subject was randomized to one of the four groups. Subjects using Rolly Brush chewed on the wheel for 10 minutes, moving it around the oral cavity to cover all teeth (Figure 1). Subjects in the dentifrice group brushed their teeth with a soft-bristle toothbrush for two minutes, without additional brushing instructions. Subjects in the

![Figure 1. The Rolly Brush device. Each chewing wheel is individually packaged (right side). The device itself (center) is considerably smaller than the nickel (left side), used to show the size of the packaged and opened chewing wheel.](image-url)
mouthrinse group rinsed with 20 ml for 30 seconds. Subjects in the chewing gum group chewed one piece of gum for 10 minutes. Immediately following completion of the oral hygiene routine, the Silness and Löe Plaque Index was repeated on the same teeth by investigators blinded to the treatments used. It was stressed to the subjects not to inform the investigator which oral hygiene method they used. Digital photographs were obtained of the teeth post-randomized treatment assignment. Subjects then completed a series of questionnaires.

**Inclusion/Exclusion Criteria**

Subjects were included in the study if they were 18 years of age or older. They had to have a minimum of six teeth in the upper arch and six teeth in the lower arch, with two posterior teeth (pre-molar and/or molars). At least two teeth had to be in contact with each other. Subjects had to be generally healthy with no acute medical disorders preventing use of plaque removal products, and had to have a score of 1 or greater on the Plaque Index of Silness and Löe. Subjects were excluded from the study if they had any allergies to the ingredients in any of the test products or to latex.

**Plaque Index**

The Silness and Löe Plaque Index is scored by the following method: 0 = No plaque present; 1 = Presence of a film of plaque adhering to the gingival margin and adjacent area of the tooth; 2 = Presence of moderate accumulations of plaque within the gingival sulcus that can be seen with the naked eye, or on the tooth and gingival margin; 3 = Presence of an abundance of plaque within the gingival sulcus and/or on the tooth and gingival margin.

**Questionnaires**

**Technique-specific Questionnaire.** Subjects were asked to mark what method for plaque control they just used, and to respond to four questions about that product with either “Excellent,” “Good,” “Average,” “Poor,” or “Very Poor.” The questions were as follows: 1. How was the feeling of oral cleanliness after use? 2. How well do you think the method removed plaque? 3. Did you experience any taste disturbance? (This question had responses of “Yes” or “No,” and results were expressed as a proportion of the total population.) 4. If you were asked to use the method after every snack or meal, would you find the method easy to use? (Responses were expressed as “Very Easy,” “Somewhat Easy,” “Not Easy/Not Difficult,” “Somewhat Difficult,” or “Very Difficult.”)

**General Plaque Removal Questionnaire.** Subjects in each of the four groups were asked the following questions related to the degree of difficulty of the four methods of plaque control, regardless of which method the subject used. For example, a subject who was assigned to the mouthrinse group was asked their opinion of how difficult brushing their teeth for two minutes was, how difficult chewing gum for 10 minutes was, how difficult rinsing with mouthrinse for one minute was, and how difficult chewing a disposable small rubber wheel for 10 minutes was. Each question was answered as either “Very Easy,” “Somewhat Easy,” “Not Easy/Not Difficult,” “Somewhat Difficult,” or “Very Difficult.”

**Statistical Methods**

Data were checked for accuracy and then entered into a password-protected, study-dedicated computer. Analyses were performed with SPSS version 13 (SPSS, Chicago IL, USA). Differences in categorical responses between treatment groups were assessed by Chi-Square. Differences in means on continuous variables were analyzed with the analysis of variance (ANOVA). Significant F-tests for ANOVA were followed with post hoc Tukey’s HSD tests comparing all pairs of treatment conditions. Differences between groups for ordinal scales were analyzed using the Kruskal-Wallis ANOVA, with post hoc Bonferroni-adjusted Mann-Whitney-Wilcoxon tests for pairwise comparisons. Differences on repeated ordinal scales were evaluated by Friedman’s rank ANOVA, with Bonferroni-adjusted post hoc Wilcoxon signed rank tests for pairwise comparisons. The threshold for statistical significance was set at 0.05 for all tests.

The primary outcome variable was the Silness-Löe Plaque Index (PI), calculated as a possible score from 0 to 3, averaged over 12 teeth within each patient. The change in PI was the primary study outcome, and was defined as pre-treatment mean PI minus post-treatment mean PI for each subject. One sample two-tailed t-tests were used to assess significance in reduction in PI within each treatment group. ANOVA, followed with Tukey’s HSD post hoc test, were used to assess differences in PI reduction between groups.

The Technique-specific Questionnaire items were converted into an ordinal scale, where ratings of excellent, good, average, poor, and very poor were transformed to 1 to 5 scores, and analyzed using Kruskal-Wallis ANOVA with Bonferroni-adjusted Mann-Whitney-Wilcoxon tests for post hoc pairwise comparisons.

The General Plaque Removal Questionnaire items were also converted from the five categories of Very Difficult, Difficult, Not Easy/Not Difficult, Somewhat Easy and Easy into scores from 1 to 5, and a Friedman rank ANOVA with post hoc Wilcoxon signed rank test was used to assess differences in ratings. All subjects were asked to consider each treatment. If they had no experience with Rolly Brush, they were asked to imagine how easy it would be to use this plaque control method.

**Results**

Three-hundred generally healthy subjects, aged 18–89 years, were enrolled. There were 81 Caucasians, 146 African-Americans, 57 Hispanics, 12 Asians and four others, with 77 women and 223 men enrolled. Groups were balanced for age (p = 0.671), ethnicity (p = 0.414), and gender (p = 0.360).

The PI before tooth cleaning was assessed, and there were no differences in baseline mean plaque index scores among the four treatment groups (p = 0.191). Statistically significant reductions in plaque index were observed for each treatment group (all p < 0.001). A comparison of all four techniques demonstrated that Rolly Brush reduced plaque by 45%, the mouthrinse by 47%, chewing gum by 38%, and tooth brushing by 70% (Figures 2a,b). Tooth brushing was more effective than any of the other three methods (p < 0.01), while Rolly Brush was more effective than mouth rinsing (p < 0.03), but not chewing gum (p = 0.385). There were no statistically significant differences between the other plaque removal techniques.
The Technique-specific Questionnaire examined the subjects’ opinions of the efficacy of the plaque removal method they had used. Subjects who used Rolly Brush rated it better at removing plaque than those who used the mouthrinse (p < 0.001) or chewing gum (p < 0.001), and no different than those who used the toothbrush (p = 0.365; Figure 3). The results of the taste disturbance question demonstrated that the Rolly Brush device was less likely to disrupt taste sensation (12%) compared to the mouthrinse (30%, p < 0.01; Figure 4). The results from the feeling of cleanliness after use question revealed Rolly Brush to be rated as having a higher feeling of cleanliness than chewing gum (p < 0.03), but worse than tooth brushing (p < 0.03) and no different than mouthrinse (p = 0.492; Figure 5). Finally, the analysis of the ease of use question in the Rolly Brush group demonstrated no statistically significant differences among the different methods, though Rolly Brush was rated highest in terms of ease of use (Figure 6).
Discussion

Plaque removal after meals promotes good gingival health, and prevents caries and oral malodor. The importance of maintaining good oral health is becoming increasingly important as it has been suggested that poor oral health may be associated with certain systemic conditions, such as low birth weight infants, cardiovascular diseases, and level of diabetes control. Although tooth brushing is the most effective means of plaque removal, it is often inconvenient or impossible to perform, especially when people are away from their homes. Alternative methods of plaque removal, such as chewing gum and mouthwash, have been tried as substitutes for tooth brushing, but they have some deficiencies. Edentulous individuals have difficulty chewing gum, and some dentate adults do not enjoy chewing gum. Furthermore, use of sugar-free gum is a critical factor in using gum chewing as a plaque removal tool. Mouthrinses cause taste disturbances for many subjects that prevent them from using these products as a plaque removal technique.

This investigation examined the use of a new disposable plaque removal device, Rolly Brush, and the results suggest that it removes more plaque than either chewing gum or mouthrinse. As expected, tooth brushing still removed significantly more plaque than any of the other methods. This does not minimize the usefulness of Rolly Brush in settings where tooth brushing is inconvenient or impossible to perform. Any technique that has demonstrated effective plaque removal is preferable to no attempt at plaque removal after snacks and meals. The Rolly Brush device was relatively more effective at plaque removal than chewing gum or mouthrinse, as measured objectively by the PI, and subjects' subjective responses also indicated that Rolly Brush was effective. This latter indicator suggests that subjects could be inclined to use Rolly Brush because they reported that it was working. Another impediment to oral hygiene after snacks and meals is taste disturbance, most commonly caused by mouthrinses. Research subjects reported fewer taste disturbances after use of Rolly Brush compared to the mouthrinse. Finally, subjects who used the Rolly Brush device reported that it was as easy to use after snacks and meals as a toothbrush or mouthrinse, although more difficult than chewing gum. Thus, a device that is as easy to use as a toothbrush but does not require a sink, will provide an acceptable alternative.

In conclusion, this randomized, investigator-blinded study indicates that use of a disposable rubber chewing wheel, the Rolly Brush device, is a safe and effective method for removing dental plaque. Results from several subjective questionnaires demonstrated that subjects were satisfied with Rolly Brush's ability to remove plaque compared with other commonly used methods. Overall, these findings indicate that Rolly Brush is an efficient and effective toothbrush substitute for plaque removal after meals, where tooth brushing is impractical and subjects do not choose to chew gum.

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References
Efficacy of Plaque Removal Using a Chewing Wheel

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Location
Study conducted at the Bluestone Center for Clinical Research, NYU

Overview
The purpose of this prospective, randomized, investigator-blinded study was to determine the efficacy of plaque reduction using four methods:
- Rolly Brush®
- Tooth brushing (Colgate soft bristle toothbrush with Colgate Total® toothpaste)
- Mouth rinse (Cool Mint Listerine®)
- Chewing Gum (Orbit® Sugar free Gum)

The purpose was also to determine subject preference and likelihood of use (i.e. acceptance) for each of the four methods of plaque reduction using a questionnaire.

Methods
Three hundred (300) generally healthy subjects aged 18 years and older eligible consenting subjects were enrolled at the Bluestone Center for Clinical Research at the NYU College of Dentistry. All subjects reported no history of allergy to latex and other ingredients located in Listerine, Colgate Total toothpaste and Orbit sugar free gum.

Inclusion and exclusionary criteria were reviewed and an IRB-approved consent was signed by each subject by a study-dedicated research coordinator. Investigators then assessed the plaque index on each tooth as per the Silness and Loe Plaque Index measurement tool. Digital photographs were obtained of the teeth prior to the randomized treatment assignment. Each subject was then assigned in a randomized fashion to one of four methods of plaque removal: Rolly Brush, Cool Mint Listerine, Colgate Total toothpaste, or Orbit sugar free gum. Subjects using Rolly Brush chewed on the wheel for 10 minutes moving it around the oral cavity to cover all the teeth. Subjects using Cool Mint Listerine rinsed their mouth with 20 ml for 30 seconds. Subjects using Colgate Total Toothpaste brushed their teeth with a soft bristle toothbrush for 2 minutes. Subjects using Orbit sugar free gum chewed on 1 piece of gum for 10 minutes. Immediately following the completion of the plaque removal techniques, the Silness and Loe Plaque Index was repeated using the identical teeth as used prior to plaque removal.

Results
Analyses were performed with SAS version 9 (SAS Institute Inc., Cary NC). Differences in percents on categorical variables (e.g., gender, race/ethnicity) were determined with
chi-square tests, and differences in means on continuous variables with analysis of variance (ANOVA). Significant F-tests (p < 0.05) for ANOVA were followed with post-hoc Dunnett tests comparing Rolly Brush to each of other three treatment conditions.

Groups were balanced on age (p=0.604)(Fig 1), race/ethnicity (p=0.203)(Fig 2), and gender (p=0.394)(Fig 3). There were no significant differences among the four treatment groups in mean Plaque Index (PI) at pre-treatment (p=0.385)(Fig 4). Each group showed a significant reduction (change) in PI between pre-and post treatment (p<0.0001)(Fig 5). However, there was a significant difference among treatment groups in the amount of PI reduction (p<0.0001) with Toothbrush achieving 70% reduction from pre-treatment, Rolly Brush 42%, and Gum and Mouth Rinse similar with 34% and 32% reduction, respectively. The Dunnett test indicated that Toothbrush was significantly better than Rolly Brush (p<0.0001) in reducing Plaque, whereas, Rolly Brush was significantly better than Rinse (p=0.030) and not significantly different from Gum (p=0.313) in reducing plaque.

There were significant differences among treatment groups on each Technique-Specific Question (F-tests, p<0.011). Dunnett’s tests revealed that Rolly Brush was not significantly different from each of the three methods for “feeling of oral cleanliness after use”(Fig 6). Rolly Brush was significantly better than Gum (p<0.0001) and Rinse (p=0.0003) for “how well do you think the method removed plaque”(Fig 7), but not different from toothbrush (p=0.648). Rolly Brush did not differ significantly from the other three methods in “how easy it was to use after every snack or meal”(Fig 8). Rolly Brush was significantly less disturbing in taste compared to Rinse (p=0.009), but similar compared to Gum and Toothbrush (Fig 9)

From the General Plaque Removal Questionnaire, overall 300 subjects that participated in this study regardless of treatment assignment, Rolly Brush was deemed significantly harder to use after every snack or meal compared to Chewing Gum (p<0.0001), but similar to toothbrush (p=0.798) and mouth rinse (p=0.100) (Fig 10). The same subjects indicated that Rolly Brush was harder to use twice a day at home compared to Toothbrush (p<0.0001) and Mouth Rinse (p<0.0001), but not significantly harder than Gum (p=0.712) (Fig 11).

Conclusions
Based upon 300 subjects with similar pre-treatment levels of dental plaque, the amount of plaque reduction after treatment was statistically significant in all groups. Toothbrush was significant better than the other groups in reducing plaque. Rolly Brush achieved greater plaque reduction compared to Mouth Rinse, and similar reductions as Gum. Subjectively, subjects using Rolly Brush reported similar feelings of oral cleanliness and ease of use compared to the other plaque removing techniques. Further, subjects using Rolly Brush reported less taste disturbances compared to Mouth Rinse, and greater wellness of plaque removal compared to Mouth Rinse and Chewing Gum.

Reference

Efficacy of Plaque Removal Using a Chewing Wheel

September 28, 2005
Fig 4. Mean (+SE) Silness-Löe Plaque Indices
- Before and ▼ After Treatment

![Graph showing mean plaque index for Rolly Brush, Tooth Brush, Mouth Rinse, and Chewing Gum with bars indicating before and after treatment.]

Fig 5. Percent Change (+SE) for Silness-Löe Plaque Indices

![Graph showing percent change for Rolly Brush, Tooth Brush, Mouth Rinse, and Chewing Gum with bars indicating 42%, 70%, 32%, and 34% change.]
Fig. 6 Feeling of Oral Cleanliness After Use
(1=Excellent, 5=Very Poor)

Fig. 7 Wellness of Plaque Removal
(1=Excellent, 5=Very Poor)
Fig. 8 Ease of Use After Every Snack or Meal
(1=Excellent, 5=Very Poor)

Fig. 9. Experienced Taste Disturbance
Fig 10. Easy To Use This Method Of Plaque Control After Every Snack Or Meal
(1=Strongly Agree, 5=Strongly Disagree)

Fig 11. Easy To Use This Method Of Plaque Control Twice A Day When At Home
(1=Strongly Agree, 5=Strongly Disagree)
Fig. xx Ease Using Method of Plaque Control After Every Snack and Meal
(1=Strongly Agree, 5=Strongly Disagree)

Fig. xx Ease Using Method of Plaque Control Twice a Day at Home
(1=Strongly Agree, 5=Strongly Disagree)
Efficacy of Plaque Inhibition Using a Chewing-wheel.

study ordered by

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Short title: Plaque inhibition by a new hygiene device

Carried out through: Prof. Saxer Ulrich, P.

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Efficacy of plaque inhibition using a chewing-wheel
Abstract

In this study the plaque inhibition capacity by a new chewing-wheel, after a three day use, was evaluated. The plaque inhibiting effectiveness of the chewing wheel was tested after chewing the wheel 6 times per day. Selected tooth surface areas were tested, where plaque develops rather rapidly. These plaque areas were evaluated on the final test after staining the plaque. The plaque was scored on the selected surfaces using the Proximal Marginal Plaque Index (PMI) with the scores of the Turesky plaque Index and the planimetric amount was depicted on colour slides.

Keywords:

Plaque inhibition
Chewing-wheel
Plaque growth
Introduction

The importance of plaque in the etiology of dental caries and periodontal disease is generally accepted (König, 1988). The correct use of a toothbrush removes plaque bacteria on the buccal and lingual surfaces (Lindhe and Koch, 1967) but its effect on interdental spaces is limited (Schmid et al, 1976; Kieger et al. 1991). It has also been demonstrated that gingivitis and periodontitis are most frequent and severe in the interproximal areas (Abrams et al. 1984, Isidor et al. 1984, Papapanou, 1989). Even after thorough toothbrushing, considerable interdental plaque remains (Bergenholtz et al 1984).

In an oral health program plaque removal is imperative, but most people do not perform it completely. Therefore additional preventive measures like toothpastes and mouthwashes are indicated in order to inhibit microbial plaque activity.

During the last two decades the number of toothbrushes sold in Switzerland increased by 300% (Saxer et al. 1993, Schärer, 1988). This seems to be mainly in correspondence with the status report of Giff (1986).

Dott. T. Ravasini was interested to test the chewing wheel on the capacity to inhibit plaque growth.

The purpose of this investigation was to evaluate and compare the plaque inhibitory capacity of the chewing-wheel in dental personnel with healthy periodontal conditions in comparison to a chewing gum. The results should be compared with the same subjects and the plaque they produced during a three day period of oral hygiene abstinence (not brushing at all).
Material and Methods

Participants and study design

13 dental assistants or dental hygienists of the Prophylaxis School Zurich Nord, volunteered for this study. Their ages ranged from 20 to 30 years with an average of about 25 years. The presence of at least five teeth without crown in each quadrant, and an average sulcus depth not exceeding 3 mm served as selection criteria. The subjects were asked to maintain normal dietary habits but to refrain from the use of any kind of oral hygiene devices during the three day test periods. The subjects were advised to use a chewing-wheel or the chewing gum after each meal (breakfast, lunch and dinner) plus 3 times during the day (at 09.30, at 16.00 and before going to bed). The subjects were reminded every day and during the day they were controlled and advised repeatedly to chew the wheel at least during a 10 Min. time period.

Chewing-wheel and chewing gum
Produced and prepared by Dr. Ravasini

Experimental design

At the beginning of the study the subjects were given a professional cleaning to remove all plaque. Plaque removal was tested by staining\(^2\) (SZ). The subjects refrained from all kind of oral hygiene during the two test periods. The 13 subjects were randomly assigned to three equal groups of three to four each. During one time period half of the subjects got the chewing wheel and the other half nothing. Members of the first group who were issued the chewing wheel served in the second period as control group (no oral hygiene). In a third period of time a chewing gum was used (Tab.1). The study was designed as a double blind crossover project.

1) chewing wheel and chewing gum provided by Dr. Ravasini, Italia
2) Rondell Bla, Langsamtorkande, SVAG Peppermintsmak,
   LIC Dental, S-17183 Solna /Sweden (disclosing solution)
At the end of the 3 day study period plaque was recorded in two quadrants on 7 locations in each of the 12 test teeth, in one quadrant (I) plaque was scored buccaly and in one quadrant (III) lingually. After the plaque scoring the participants were told to clean their teeth normally until the start of the next test period. The following Tuesday, before the start of the next period plaque was again removed with a prophylaxis paste on the tested teeth and they started with the next assigned regime for the next period.

At the end of the three test periods the subjects were given 100 Swiss Franks and a free professional cleaning.

Diagnostics

1. Plaque was scored using a modified Turesky Plaque Index described by Saxer and Yankell (1998). The plaque was stained on all tested teeth and also in the forth quadrant buccaly. The scores of 0 to 5 were defined using the following criteria:

   0: No plaque on the examined surface.
   1: Single spots of plaque
   2: A thin not continuos band of plaque along the marginal gingivae
   3: A thin band of plaque visible but not exceeding 1 mm in width.
   4: A thick (> 1mm ) visible band of plaque exceeding one third but not two thirds of the surface.
   5: A thick visible band of plaque exceeding two thirds of the surface.

All plaque scoring was performed by one investigator and immediately dictated to an assistant. The data were collected immediately into a Computer system. The data was daily saved on a disc.

2. Additionally in the quadrants 1 and 4 the teeth from 15 to 13 and 45 to 43 were photographed. Semi standardised colour slides were taken in order to measure eventually (not calculated yet) the plaque extent planimetrically (Mühlemann et al.1973, Saxer 1984). Plaque extent on the buccal surfaces of the maxillary and
mandibular teeth could be planimetrically measured from paper tracings made of the slides when projected on a screen on each photograph. The extent of the plaque could be recorded using an electronic digitizer (Hewlett-Packard 9874a) connected to a computer. The buccal stained plaque content could be compared with the entire buccal surface of the depicted teeth and expressed as an average percentage per tooth in planimetric units (PU)(measurement optional, not yet done).

3. Finally, the subjective acceptance of the chewing wheel was evaluated by the volunteers after the chewing period in a questionnaire. The questions are listed in Table 6. The data of the plaque indices were statistically analyzed using the Student’s t-test.

The participants in this study agreed to the study design.

Results

Table 1

Sequence of the different measures (A = wheel, B = control, C = chewing gum).

<table>
<thead>
<tr>
<th>group</th>
<th>Period I</th>
<th>Period II</th>
<th>Period III</th>
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<td>I</td>
<td>A</td>
<td>B</td>
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<tr>
<td>II</td>
<td>B</td>
<td>C</td>
<td>A</td>
</tr>
</tbody>
</table>

Tab. 2
Total average Plaque indices (PMI) (x) and standard deviation (s) in 13 subjects refraining from tooth brushing and other mechanical oral hygiene procedures but chewing during a three day-test periods six times daily one of the chewing wheel or a chewing gum. (R=rank)

<table>
<thead>
<tr>
<th>No oral Hygiene</th>
<th>chewing gum</th>
<th>Chewing wheel</th>
</tr>
</thead>
</table>

studio SXER ups 20.4.2004 - 7 -
1) The difference between group chewing gum and the wheel was a the borderline being significant.

Tab. 3
Average Plaque indices (PMI) (x) and standard deviation (s) in buccal surfaces in 13 subjects refraining from tooth brushing and other mechanical oral hygiene procedures but chewing with the wheel or a chewing gum.

<table>
<thead>
<tr>
<th></th>
<th>No oral Hygiene</th>
<th>chewing gum</th>
<th>Chewing wheel</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td>2.67</td>
<td>2.59</td>
<td>2.21</td>
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<tr>
<td>s±</td>
<td>0.51</td>
<td>0.47</td>
<td>0.72</td>
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<td>R</td>
<td>NS</td>
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<td>p&lt;</td>
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Tab. 4
Average Plaque indices (PMI) (x) and standard deviation (s) in approximal surfaces in 13 subjects refraining from tooth brushing and other mechanical oral hygiene procedures but chewing during a three day-test periods six times daily a chewing wheel or a chewing gum. (R=rank).

<table>
<thead>
<tr>
<th></th>
<th>No oral Hygiene</th>
<th>chewing gum</th>
<th>Chewing wheel</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td>2.85</td>
<td>2.96</td>
<td>2.58</td>
</tr>
<tr>
<td>s±</td>
<td>0.82</td>
<td>0.54</td>
<td>0.66</td>
</tr>
<tr>
<td>R</td>
<td>NS</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>p&lt;</td>
<td>NS</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>p&lt; 0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Tab. 5
Average Plaqueindices (PMI) (x) and standard deviation (s) in incisal approximal surfaces in 13 subjects refraining from tooth brushing and other mechanical oral hygiene procedures but chewing during a three day-test periods six times daily a chewing wheel or a chewing gum. (R=rank).

<table>
<thead>
<tr>
<th></th>
<th>No oral Hygiene</th>
<th>chewing gum</th>
<th>Chewing wheel</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td>1.29</td>
<td>1.17</td>
<td>0.98</td>
</tr>
<tr>
<td>s±</td>
<td>0.76</td>
<td>0.58</td>
<td>0.42</td>
</tr>
<tr>
<td>R</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>p&lt;</td>
<td>NS</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>p&lt; 0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Tab. 6
Answers to the questionnaire: Plaquegrowth in different periods

<table>
<thead>
<tr>
<th>Questions</th>
<th>No Hygiene</th>
<th>Chewing gum</th>
<th>Chewing wheel</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How was the feeling of the oral cleanliness? + = good, - complains</td>
<td>1.5</td>
<td>1.75</td>
<td>1.25</td>
</tr>
<tr>
<td>2. How was the amount of plaque growth (+ fair or no; - disturbance)</td>
<td>2.25</td>
<td>2.5</td>
<td>2.25</td>
</tr>
<tr>
<td>3. Did you feel tast disturbances ? + No, - yes</td>
<td>3.25</td>
<td>3.25</td>
<td>3</td>
</tr>
</tbody>
</table>

The most favourable answer got 4 points, the second the points aso. Thus for each group the answers were summarized and divided by the number of participants. The higher the average points the better is the acceptance.

Fig. 1

Distribution of average Plaque indices (PMI) (median and 25% resp. 75% deviation presented in box-plots in all surfaces in 13 subjects refraining from tooth brushing and other mechanical oral hygiene procedures but chewing during a three day-test period six times daily one candy and using in one period a gum wheel(c) (no oral hygiene = a, chewing gum = b).
References

Birkehed D. Edwardsson S. Wikesjö U.: Effects of four days consumption of chewing gum containing sorbitol or mixture of sorbitol and xylitol on dental plaque and saliva. Caries Res. 17: 76-88, 1983


Mäkinen KK, Virtanen KK: Effects of 4.5 years use of xylitol and sorbitol on plaque.
J dent Res. 67: 441-443, 1978


Mühlemann HR, Höss D, Steiner E. Antimicrobial rinses and proximal plaque on removable gold crowns. Helv odont acta. 17: 69, 1973


Saxer UP. Plaque accumulation after rinsing with different sweetened solutions, Swiss dent. 5(Nr. 4): 33-35, 1984


Fate of Rollybrushes after accidental swallowing and during transit through the stomach and small intestine simulated in a dynamic gastrointestinal model (TIM-system)
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Approval of the report

Date: Study director
01-08-2005

Date: Head operations Physiological Sciences Dept.
12-08-2005

[Signature]
1 General

1.1 Sponsor

Sponsor: SKG France
Address: 49-51 Avenue Pierre Grenier, 92100 Boulogne Billancourt, France
Monitor: Bertrand KIEKEN
Tel / fax: +33 1 4761 8870 / +33 1 4609 0966
e-mail: bertrand.kieken@skgfrance.fr

1.2 Testing facilities

TNO Quality of Life, Physiological Sciences Department
Post address: Visitors address:
P.O. Box 360, 3700 AJ Zeist, The Netherlands Utrechtseweg 48, 3704 HE
Zeist, Netherlands
Telephone +31 30 69 44 144 (reception desk)

1.3 Responsible personnel

Study director: Robert HAVENAAR
Tel. +31 30 69 44 726
Fax +31 30 69 44 075
e-mail havenaar@voeding.tno.nl
3 Materials and Methods

3.1 Study substances

The test product (Rollybrushes; flavoured consumer product) had been supplied by the Sponsor to TNO, Zeist (contact person: Henrette Veenendaal-Hesselman). For this project 30 Rollybrushes were supplied of one similar type and batch.

3.2 Set-up of the experiments

The study was performed in the TNO dynamic, multi-compartmental system of the stomach and small intestine (TIM-1) as described above and schematically presented in Figure 3.

![Diagram](image)

Figure 3. Diagram of the dynamic, multi-compartmental model of the stomach and small intestine (TIM-1).
A. gastric compartment; B. pyloric sphincter; C. duodenum compartment; D. peristaltic valve; E. jejunum compartment; F. peristaltic valve; G. ileum compartment; H. ileo-caecal valve; I. pH electrodes; J. gastric secretion bottles with acid and enzymes; K. duodenal secretion bottles with bile, pancreatin, bicarbonate; L. secretion of bicarbonate to control the intestinal pH; M. pre-filter system; N. hollow fibre semi-permeable membrane system; O. water absorption system; P. closed dialysing system.

In the TIM-1 system the average physiological conditions of the gastrointestinal tract of young adult humans were simulated. This included the conditions in the oral cavity with saliva, followed by the conditions in the stomach with gastric acid and pepsin and followed by the conditions in the small intestine with pancreatic juice and bile. This resulted in an physiological simulation of the gastric and intestinal pH values, the composition and activity of the secretion products, the peristaltic movements of the gastrointestinal wall and transit time of the Rollybrushes. For passage of the Rollybrushes from the stomach into the small intestine, the so called ‘house keeper wave’ was simulated three hours after swallowing. This is a
physiological phenomenon for the passage of large particles or vehicles that cannot pass with the normal food and liquid contents of the stomach.

At the start of the experiments the Rollybrushes were weighed in sets of three devices.
In duplicate experiments such a set of three Rollybrushes were mixed with artificial saliva during 30 min at 37 °C and then put into the gastric compartment of the TIM-1 system. The gastric compartment contained 10 ml gastric residue (saliva and gastric acid at pH 2.0) and 100 ml drinking water at the time the Rollybrushes were put into the gastric compartment.
After 3 hours the set of Rollybrushes were transferred from the stomach into the duodenum compartment (pH 6.5) and stayed there for 15 min. After that the devices were transferred to the jejunum compartment (pH 6.8 – 7.0) and stayed there for another 3 hours.
After oral-gastro-intestinal transit (6 hours and 45 min) the set of Rollybrushes were carefully rinsed with water, dried and weighed.

As control, two sets of four Rollybrushes were weighed and put in clean water for the same period as the oral-gastro-intestinal transit time (6 hours and 45 min). After that the Rollybrushes were carefully rinsed with water, dried and weighed.
The difference in 'weight loss' between the test and control Rollybrushes, before and after the test period, was calculated.

Before and after transit of the Rollybrushes through the TIM-1 system digital pictures were made of the Rollybrushes. The same was done for the control Rollybrushes.
4 Results

The sets of Rollybrushes were weighed before and after the duplicate control (sets of 4 Rollybrushes) and the duplicate TIM-test (sets of 3 Rollybrushes). The lost of weight (difference in weight) during the control and test period (6 hours and 45 min.) was calculated per Rollybrush (Table 1). The average weight loss was somewhat more for the control Rollybrushes in comparison to the TIM-test Rollybrushes. This difference was not statistically significant. The loss of weight during the TIM-test as well as the control is most likely related to the water solubility of the flavours present on the end-product.

<table>
<thead>
<tr>
<th>Control Rollybrushes</th>
<th>tot. weight</th>
<th>weight/Rb</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>before</td>
<td>1273.60</td>
<td>318.40</td>
<td></td>
</tr>
<tr>
<td>after</td>
<td>1195.00</td>
<td>298.75</td>
<td></td>
</tr>
<tr>
<td>difference</td>
<td>78.60</td>
<td>19.65</td>
<td></td>
</tr>
<tr>
<td>before</td>
<td>1281.50</td>
<td>320.38</td>
<td>319.39</td>
</tr>
<tr>
<td>after</td>
<td>1187.90</td>
<td>296.98</td>
<td>297.86</td>
</tr>
<tr>
<td>difference</td>
<td>93.60</td>
<td>23.40</td>
<td>21.53</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIM-test Rollybrushes</th>
<th>tot. weight</th>
<th>weight/Rb</th>
<th>Average</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>before</td>
<td>961.50</td>
<td>320.50</td>
<td>320.25</td>
<td>0.25</td>
</tr>
<tr>
<td>after</td>
<td>900.80</td>
<td>300.27</td>
<td>299.47</td>
<td>0.80</td>
</tr>
<tr>
<td>difference</td>
<td>60.70</td>
<td>20.23</td>
<td></td>
<td></td>
</tr>
<tr>
<td>before</td>
<td>960.00</td>
<td>320.00</td>
<td>320.25</td>
<td>0.25</td>
</tr>
<tr>
<td>after</td>
<td>896.00</td>
<td>298.67</td>
<td>299.47</td>
<td>0.80</td>
</tr>
<tr>
<td>difference</td>
<td>64.00</td>
<td>21.33</td>
<td>20.78</td>
<td>0.55</td>
</tr>
</tbody>
</table>

Table 1. Weight (mg) of the Rollybrushes before and after the duplicate control test with sets of 4 Rollybrushes and before and after the duplicate TIM-test with sets of 3 Rollybrushes and the calculated difference per Rollybrush before and after the control and TIM-test. The average weight loss was not significantly different between the control and test Rollybrushes.

The results indicate that no materials were released from the Rollybrushes during passage through the stomach and small intestine other than water soluble compounds as released from the control Rollybrushes during their stay in water.
Thorough visual inspection of the Rollybrushes before and after transit through the TIM-1 systems did not detect any difference; among others no lost of size, form, or brushes, no signs of erosion (Figure 4). This confirms the measured data.

Figure 4. Pictures of the two sets of Rollybrushes after the control treatment (above) and after passage through the simulated conditions in the oral cavity, the stomach and the small intestine (TIM-1 system) (below). No visual difference were observed before and after treatment and between control and TIM-test.
5 Conclusion

It may be concluded from this study that during the transit of Rollybrushes through the oral cavity, stomach and small intestine (e.g. after accidental swallowing) not more compounds were released from these devices as during their stay in water for the same period of time.
It is most likely that only water soluble materials, such as flavour compounds, were released from the Rollybrushes during passage through the realistically simulated conditions of upper gastrointestinal tract of humans.
Analytical report

Project data

Analysis requested : Investigation of suitability for mouth contact using the EU and Dutch legislation on food contact materials.
Client : SKG France, Boulogne-Billancourt, France
TNO project number : 010:50873/01.22
Analyses date : August 2005
Date of issue : September 2005
Validity : September 2005 – September 2011
Evaluation : This investigation must be re-evaluated if the relevant regulation is changed, or the composition or the production process of the product is changed, or at September 2008 (whichever is the earliest).

Sample data

The following sample was analysed (hereafter called 'Sample'):
Sampled by : Client
Code client : Unknown
Description client : Rollybrush
Sample code TNO : 0939/02/0277
Sample description TNO : Green brushes
Sample received at : 14 July 2005

Legislative context

The report, the experiments described and the conditions used to obtain the results presented are based on the following legislation:
- Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands of 20 November 1979 and its amendments up to and including VGP/P&L2614264 of 12 September 2005

An interpretation of the above legislation was made for the product to be investigated, as is outlined below. The interpretation was used for the administrative check, the selection of the tests and the evaluation of the results. In
the report the legislation used for this interpretation will be referred to as 'Relevant Legislation'.

Plastic materials are regulated on European level under the EU Directive 2002/72/EC and its amendments concerning the monomers and additives. The additive list is not complete yet. To comply with article 3 of the framework regulation EC No 1935/2004 (food contact materials may not endanger human health and bring about an unacceptable change in the composition of foodstuffs), non-listed additives, catalysts, colorants etc. were tested according the requirements of the Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands.

Beside the requirements of the migration of primary aromatic amines, colorants are only regulated on European level by article 3 of the framework Regulation (EC) No 1935/2004 (food contact materials may not endanger human health and bring about an unacceptable change in the composition of foodstuffs); to ensure this the sample was tested according the requirements of the Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands, chapter I, section 4 (colorants).

To imitate the chewing, TNO has decided to immerse the 'Sample' into water and keep the 'Sample' moving by using a 'head-over-heels' apparatus. Because a food approval was requested by the client, TNO has selected which experiments had to be performed (overall and specific migrations, residual contents, extraction tests etc as described in detail in the method section) based on the information that was supplied about the composition, the application of the 'Sample' and the legislation with which the 'Sample' has to comply with.

Methods applied

Administrative check of the composition
The composition of the 'Sample' has been disclosed to TNO confidentially. Therefore the components mentioned in this report are coded.
The composition was checked against the positive lists of the 'Relevant Regulation'. For all components of the coating that are subject to restrictions, the specific migrations and/or residual contents were determined.

Experimental check of the qualitative composition
The 'Sample' was examined according to procedures prescribed in the Packaging and Food Utensils Regulation (Commodity Act) of the Netherlands.
A specimen of the 'Sample' was extracted with chloroform. The solvent was evaporated and the residue analysed by thin-layer chromatography (TLC). The various spots were, if necessary, identified with infrared spectrometry.
Migration conditions
To determine the overall and specific migration from the 'Sample', 20 brushes were immersed into 100 ml of water and stored for 30 minutes at 40°C, while simulating chewing using a 'head-over-heels' apparatus.

The simulants, contact time, and contact temperature were selected according EU Directive 82/711/EEC and its subsequent amendments up to and including EU Directive 97/48/EC and following CEN method CEN/TS 14235:2002 (23 October 2002) and CEN method EN 13130-1:2004 (26 May 2004). After the storage period the samples were analysed as is described in the overall and specific migration section.

Overall migration
After the storage period, the overall migration from the 'Sample' was determined following the CEN method ENV 1186-3 (version May 1998) (total immersion, aqueous simulant).

Specific migration
After the storage period, the specific migrations were determined. If the 'Sample' was brought into contact with several simulants, the worst case simulant for each compound was selected. The specific migrations were determined following the CEN method EN 13130-1:2004 (26 May 2004) as close as possible. A summary of the specific migrations is shown in the following table:

<table>
<thead>
<tr>
<th>Compound</th>
<th>Simulant</th>
<th>Time/temperature conditions</th>
<th>Analytical technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>water</td>
<td>Head-over-heels for 30 minutes at 40°C</td>
<td>GC</td>
</tr>
<tr>
<td>B</td>
<td>water</td>
<td>Head-over-heels for 30 minutes at 40°C</td>
<td>UVVIS</td>
</tr>
</tbody>
</table>

GC = gas chromatography, UVVIS = spectrophotometry

Results

Administrative check of the composition
The composition of the 'Sample' has been disclosed to TNO confidentially. All components are listed on the positive lists of the 'Relevant Legislation'.

Experimental check of the qualitative composition.
No additional compounds in the extract of the 'Sample' were found compared with the composition supplied.
Overall migration from the 'Sample' after contact time and temperature as described above

<table>
<thead>
<tr>
<th>Simulant</th>
<th>Overall migration (mg/item)</th>
<th>Max. number of brushes used on one day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Measurement 1</td>
<td>Measurement 2</td>
</tr>
<tr>
<td>Water</td>
<td>n.d. (&lt;1.0)</td>
<td>n.d. (&lt;1.0)</td>
</tr>
</tbody>
</table>
| n.d. = not detectable

Specific migration from the 'Sample' after a contact period and temperature as described above

<table>
<thead>
<tr>
<th>Component</th>
<th>Simulant</th>
<th>Specific migration (mg/item)</th>
<th>Specific migration limit (mg/day)</th>
<th>Max. number of brushes used on one day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Measurement 1</td>
<td>Measurement 2</td>
<td>Average</td>
</tr>
<tr>
<td>A</td>
<td>water</td>
<td>n.d. (&lt;0.47)</td>
<td>n.d. (&lt;0.47)</td>
<td>n.d. (&lt;0.47)</td>
</tr>
<tr>
<td>B</td>
<td>water</td>
<td>n.d. (&lt;0.0001)</td>
<td>n.d. (&lt;0.0001)</td>
<td>n.d. (&lt;0.0001)</td>
</tr>
</tbody>
</table>
| n.d. = not detectable

Conclusions

The composition of the 'Sample' has been disclosed to TNO confidentially. The composition provided is in accordance with the requirements specified in the 'Relevant Legislation'. The composition of the 'Sample' was checked experimentally, and was found to be in compliance with the composition supplied. Based on the information that was supplied about the composition, the application of the 'Sample' and 'Relevant Legislation', all relevant tests were selected and performed (overall and specific migrations, residual contents, extraction tests etc as described in detail in the method section).

The values obtained for the overall migrations and relevant specific migrations from the 'Sample', into water after a contact period of 30 minutes at 40°C meet the limits as specified in the 'Relevant Legislation'.

The values obtained for the relevant residual contents from the 'Sample' meet the limits as specified in the 'Relevant Legislation'.

In conclusion, the 'Sample' can be considered to be suitable for mouth contact for 30 minutes and any contact that can be considered as less severe regarding the composition, the relevant overall migrations, the relevant specific migrations, and the relevant residual contents as described above, according to the Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands of 20 November 1979 and its amendments up to and including VGP/P&L2614264 of 12 September 2005, provided that the maximum number of the 'Sample' used on one day of is not more than 12.
In conclusion, the 'Sample' is suitable for mouth contact for 30 minutes and any contact condition considered less severe regarding the composition, relevant specific migrations and the relevant residual contents according to the EU 2002/72/EC of 6 August 2002 and its subsequent amendments up to and including EU Directive 2004/19/EC of 1 March 2004 for both single and repeated use, and can be considered to be not detrimental as is required in article 3 of the Regulation (EC) No 1935/2004 (based on the fact it is in compliance with Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands) of 20 November 1979 and its amendments up to and including VGP/P&L2614264 of 12 September 2005, provided that the maximum number of the 'Sample' used on one day is not more than 12.

Supporting documents with all details of the analytical experiments will be filed for a period of six years and can be accessed by enforcement authorities upon agreement of the client.

Approved by

J.R. Veraart, Ph.D.
Project Manager Packaging Research
To whom it may concern

SKG France, Boulogne-Billancourt, France has requested TNO to verify whether their product is suitable for mouth contact for 30 minutes, in view of the EU Regulation and Dutch legislation.

For this purpose, samples as well as detailed information on the composition were provided. The sample was identified as follows (hereinafter called "Sample"):

<table>
<thead>
<tr>
<th>TNO project number</th>
<th>010.30873/01.22</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNO sample number</td>
<td>0939/02/0277</td>
</tr>
<tr>
<td>Sample description TNO</td>
<td>Green brushes</td>
</tr>
<tr>
<td>Client</td>
<td>SKG France, Boulogne-Billancourt, France</td>
</tr>
<tr>
<td>Sample code client</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sample description client</td>
<td>Rollybrush</td>
</tr>
<tr>
<td>Sampled by</td>
<td>Client</td>
</tr>
<tr>
<td>Sample received on</td>
<td>14 July 2005</td>
</tr>
<tr>
<td>Date of issue</td>
<td>September 2005</td>
</tr>
<tr>
<td>Validity period</td>
<td>September 2005 – September 2011</td>
</tr>
<tr>
<td>Evaluation</td>
<td>This investigation must be re-evaluated if the relevant regulation is changed, or the composition or the production process of the product is changed, or at September 2008 (whichever is the earliest).</td>
</tr>
</tbody>
</table>

Tests and Regulations:
The tests performed were in line with the requirements of the EU Directive 2002/72/EC of 6 August 2002 and its amendments up to and including 2004/19/EC of 1 March 2005 and the Packaging and Food Utensils Regulation (Commodity Act) of The Netherlands of 20 November 1979 and its amendments up to and including VGP/P&L2614264 of 12 September 2005 (hereinafter called 'Regulations').

The investigation comprised the following determinations:
- Administrative and experimental check of the composition of the sample.
- Overall migration into water after 30 minutes at 40°C.
- Relevant specific migrations and residual contents.

Results:
The results were described in detail in analytical report ASC 05-0905/VERA-veh. In summary it is stated that the composition of the 'Sample' is in accordance with the 'Regulations' and that the values obtained for the overall migrations, relevant specific migrations and residual contents meet the limits of the 'Regulations', provided that the maximum number of the 'Sample' used on one day is not more than 12.

Conclusion:
Given the composition and the values obtained for the relevant overall and specific migrations and residual content, the 'Sample' can be considered to be suitable for contact with mouth contact for 30 minutes and any contact condition that can be considered as less severe in view of the 'Regulations', provided that the maximum number of the 'Sample' used on one day is not more than 12.

Approved by:

J.R. Vermaat Ph.D.,
Project manager Packaging Research