Skin Research and Technology 2001; 7: 98–104
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Skin Research and Technology
ISSN 0909-752X

A comparative study of the effects on the skin of a classical bar soap and a syndet cleansing bar in normal use conditions and in the soap chamber test

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Background/aims: The skin irritation potential of a body cleansing product is often compared under exaggerated test conditions, although the product is intended to be used at home with repetitive and brief contact with the skin. The aim of this study was to determine how much patch testing is predictive of the clinical, sub-clinical and subjective cutaneous effects of products used at home by consumers for their normal hygienic cleansing.
Methods: A double-blind comparative study of the normal use of an alkaline soap bar and a syndet at home during 10 consecutive weeks was performed on two identical groups of 25 healthy female subjects. The eventual skin changes observed at different anatomical skin sites were evaluated by clinical visual examination and by bioengineering measurements before the start of the study and then every 2 weeks. The objective measurements were compared with the subject's perceptions of dryness, tightness and product irritancy during the testing.
Results: The bioengineering measurements did not show any significant changes on all the anatomical skin sites, except for a small increase in skin pH with the classical soap bar. However, a trend appeared, showing that the alkaline soap bar is perceived by the subjects themselves as more of an irritant than the syndet bar. In the soap chamber test, the bar soap showed a significantly higher irritancy than the syndet bar.
Conclusion: This study showed that cutaneous irritation induced by cleansing products in patch testing is not necessarily predictive of the irritation likely to occur in normal use conditions. Finally, a clear relationship could be demonstrated between the results of the soap chamber test and the consumer perception of both cleansing bars.

Key words: soap – syndet – skin irritation – home use test – bioengineering methods

Accepted for publication 31 October 2000

MANY EXPERIMENTAL in vivo procedures have been developed for assessing the potential skin irritancy/mildness of body cleansing products, such as soap and syndet bars (1–3). These irritancy tests include: i) various single or repetitive occlusive patch tests, such as the 24-h occlusive patch test (4, 5), the Frosch-Kligman soap chamber test (6) and its variant (7), the 21-day cumulative irritation test (8) and the 4-h occlusive patch test (9); ii) exaggerated wash and in-use tests, such as the forearm wash test (10), the flex wash test (11) and the hand/forearm soaking tests (12); and iii) home or in-use tests for longer periods (3).

Several important point can be made about the methodology of the occlusive patch tests and the exaggerated wash tests. Although these exaggerated applications of the products on the skin are able to predict the irritation potential of ingredients or finished products and classify them as very mild, mild, or irritating in comparison with reference products, their ability to predict mildness/irritancy in normal use is often questioned. Furthermore, modern skin cleansing products (soap and syndet bars) possess cleaning properties but also present claims of hydration, soothing, and protection. However, it is usually impossible to demonstrate these supplemental benefits because they are usually masked by the irritancy potential of the surfactants that is generated in these unrealistic conditions.

Using cleansing products under mild application conditions (e.g., normal use at home) for an extended period is often necessary to overcome the weaknesses of the exaggerated protocols and avoid the irritating effects of some of the ingredients while revealing the beneficial properties to the skin.

The general objective of this study was to determine the irritancy potential of a classical alkaline bar soap and a syndet bar on the skin by using two different

experimental procedures: the soap chamber test on the forearm (7) and normal use on the whole body for several weeks. This study also aimed to optimize the experimental procedure of the in-use test in order to obtain the best discrimination between the two different personal care products. More specifically the purposes of this study were:

- to evaluate the sensitivity of different instruments in detecting slight skin modifications;
- to assess the sensitivity of different skin sites in discriminating between a soap and syndet in normal use conditions;
- to correlate the objective clinically and instrumentally observed skin changes with the subjective perception of skin changes determined by means of questionnaires; and
- to correlate the data obtained under these conditions of normal use with the results obtained in the soap chamber test.

Subjects and Methods

Study population

In-use test

Fifty healthy female Caucasian volunteers, between the ages of 18 and 50 (mean age 26±7) years participated in the in-use test. The subjects were divided into two balanced groups based on baseline measurements of transepidermal water loss (TEWL) and skin hydration, on reactions of after-sun exposure (crude rating of phototype) and on individual washing habits (Table 1). Each group received one of the two products in a double blind fashion.

TABLE 1. Evaluation of the baseline skin condition (sensitivity of the skin and phototype) and washing habits (type of washing products and frequency of weekly washing) of the two groups before the start of the in-use testing

Skin conditions	Group A	Group B
Sensitive skin: 0 (not) – 10 (very)	4.6±2.4	4.5±2.1
Number of past experiences of irritancy with soaps, shower gels, shampoos and day/night creams	14	14
Phototype (1–4)	2.5±0.7	2.6±0.7
Use of daily washing products		
Soap	22	18
Syndet	3	2
Shower gel	13	10
Bath foam	3	2
Body lotion	2	5
Number of weekly washings	6.5±3.2	7.1±2.9

Soap chamber test

Twenty healthy female and male Caucasian volunteers, between the ages of 18 and 55 (mean age 37±9) years participated in the soap chamber test.

All the subjects gave informed written consent to participate in these experiments. Test protocols were approved by local Ethics Committee.

Test products

Three commercially available soap bars were used in this study. Products were a solid syndet bar, a classical soap bar, and an irritant reference alkaline soap bar (soap chamber test only). The pH of 2% aqueous solutions in tap water for the soap chamber test was 6.9 for the syndet, 9.6 for the classical soap and of 10.5 for the alkaline reference soap. The pH of tap water was almost neutral at 7.4.

In-use test

The subjects used the products at home for 10 consecutive weeks, with a visit to the laboratory every 2 weeks (±1 day). Ten bars were provided for the subjects (two at the beginning and then two each 2 weeks when coming to the laboratory for evaluations). The subjects were asked to return the old bars and to take new ones at each visit, in order to control their use. The cleansing bars had to be used at least once a day on the whole body. Subjects were not allowed to use any other body cosmetic product, such as gel, cream, lotion, or milk. Subjects were requested not to introduce a major lifestyle change during the study, such as winter holidays and swimming. The testing was performed from January to April in Brussels, Belgium, under medical supervision.

Clinical evaluations

Clinical evaluations and bioengineering measurements were performed by an experienced evaluator 15 days before starting product use (first baseline), the day before the first use of the product (second baseline), and then every 2 weeks (±1 day) for 10 weeks. Evaluations were performed at least 3 h after personal hygiene washing, and during the hour before evaluation the subjects were asked to avoid wetting the test sites with water. Furthermore, at their first baseline visit, subjects answered a short questionnaire on their washing habits, on their skin reactions after exposure to sun (crude classification as phototype), on their skin sensitivity to cosmetics and on their experience with skin irritation from cleansing products.

Skin assessments (visual objective ratings and instrumental measurements) were made on five distinct sites located only on the right side of the body: the

back of the hand (site between the thumb and the index), the middle part of the volar forearm, the middle part of the outer upper arm, the lateral side of the neck (regio cervicalis lateralis), and the middle part of the dorsal median of the foreleg.

Clinical assessments of erythema, dryness, and roughness on the respective skin sites were performed according to a numerical scale of 0 to 10.

Instrumental measurements

All instrumental measurements were carried out as follows: two baseline visits and additional visits every 2 weeks. The same evaluator performed all the instrumental evaluations. Skin reflectance colorimetry was measured using a Minolta Chroma Meter CR-200 (Minolta, Tokyo, Japan) with the *L*a*b** color space coordinates. The *a** color parameter correlates with skin redness (13). Skin hydration was measured by the capacitance method using the Corneometer CM 825 (Courage-Khazaka, Cologne, Germany). The electrical capacitance of the upper layers of the epidermis (arbitrary Corneometer units) is related to the hydration level of the horny layer (14). The integrity of the barrier function of the horny layer was measured by transepidermal water loss (TEWL) using the Tewameter TM 210 from Courage-Khazaka (15, 16). Skin pH was measured using a special flat surface electrode (Ingold LoT 453-S7) with a Radiometer PHM80 pH meter (Radiometer, Copenhagen, Denmark) (17). All instrumental measurements were taken after the panelists had rested for 20 min with their forearms, arms, neck and forelegs exposed to an air temperature of 20±2°C and a relative humidity of 45±5%.

Panelists perceptions

Subjective perceptions were obtained through a questionnaire at the baseline visits and at each subsequent visit. These perceptions were made on four distinct sites located on the right side of the body only: back of the hand, the total forearm, the lateral side of the neck, and the foreleg. The questionnaire focused on the panelists' perception of skin dryness (look and feel) or tightness for each skin site separately, and on their overall perception of the irritancy/mildness of the cleansing product (not at the baseline visit) on their skin. The subjects scored each of the properties on a 0–10 linear scale.

Soap chamber test

The modified soap chamber test (7) was performed on 20 healthy female (n=17) and male (n=3) volunteers. Hill Top Chambers® (19 mm) were applied on the volar part of both forearms in a double-blind, randomized application. One hundred and fifty microliters of a 2% aqueous solution of the syndet, classical soap, and a very alkaline soap were applied to the chambers. Tap water alone and the very alkaline soap were included as the negative and positive controls, respectively. The schedule for the test was as follows:

Day 0: Baseline clinical assessments and bioengineering measurements were made and followed by the first application of the soap chambers on the forearms.

Day 1: 24 h later, the chambers were removed, and the sites were rinsed with water. The sites were patted dry with a tissue without rubbing. After 3 h, clinical assessments and bioengineering measurements were made and the soap chambers were applied.

Day 2: 21 h later, the chambers were removed and the sites were rinsed with water. The sites were patted dry with a tissue without rubbing. After 3 h, clinical assessments and bioengineering measurements were made.

Day 3: Clinical assessments and bioengineering measurements were made 24 h after removal of the second patch.

Clinical assessments

Dryness, redness, and roughness were evaluated visually by a trained evaluator using a numerical scale of 0 to 4. Edema was determined as present or absent.

Instrumental measurements

Measurements of skin color, hydration, and the integrity of the barrier function of the horny layer by TEWL were performed with the same instruments as described above. All instrumental readings were taken after the panelists had rested for 20 min with their forearms exposed to an air temperature of 20±2°C and a relative humidity of 45±5%.

Data treatment and statistics

All data were tested for normality using the Kolmogorov goodness of fit test. Differences between the in-use curves obtained for the two products were analyzed using the MANOVA procedure, evaluating the effect of the product and the effect of time within each test. For the pH measurements on the skin, a t-test analysis was applied between the soap and syndet treated skin sites. The significance level was set at 5%.

TABLE 2. Bioengineering measurements using TEWL, Chroma Meter a parameter, and Corneometer values for the syndet group and the soap group before treatment*

Product	Hand	Forearm	Upper arm	Neck	Leg
TEWL (g/h · m^2)					
Syndet	19.4±1.2	10.7±0.5	10.7±0.5	13.2±0.5	13.2±0.8
Soap	19.8±1.7	11.0±0.8	10.6±0.7	13.3±0.6	13.7±0.7
Chroma Meter *a**					
Syndet	8.8±0.4	5.5±0.2	7.3±0.3	9.2±0.4	7.4±0.3
Soap	8.5±0.4	5.6±0.3	6.7±0.3	9.2±0.5	7.6±0.4
Arbitrary Corneometer hydration units					
Syndet	55±2	63±2	54±2	82±2	53±2
Soap	58±2	66±2	52±1	82±2	55±2

Results

In-use tests

Instrumental measurements

The baseline values of TEWL, *a**, hydration, and skin surface pH, observed at the different skin areas, can be considered as normal values (Table 2) and are in agreement with previously published data (18–20). No differences were observed between the baseline values of the syndet and the soap groups, indicating that the two groups were balanced.

For all the skin areas, no significant differences in the instrumental measurements of integrity of barrier function (TEWL), hydration and redness were observed between the daily use washing with either the syndet or the soap. Only pH measurements show a small but significant increase in pH after 10 weeks treatment with the soap on the upper arm, neck and lower leg (Table 3). Furthermore, the daily use of either the soap or the syndet during 10 weeks did not induce any significant modifications in skin color (*a** redness parameter) and barrier function of the horny layer (TEWL) on all skin sites (data not shown). A small but significant dehydration effect was noticed for both cleansing products on the hand and lower leg (data not shown).

TABLE 3. Influence of syndet and soap on the pH of the skin surface

Time	Product	pH of the skin surface				
		Hand	Forearm	Upper arm	Neck	Leg
Base	Syndet	5.4±0.1	5.4±0.1	5.5±0.1	5.3±0.1	5.3±0.1
	Soap	5.4±0.1	5.5±0.1	5.5±0.1	5.4±0.1	5.4±0.1
W10	Syndet	5.5±0.1	5.5±0.1	5.6±0.1	5.3±0.1	5.6±0.1
	Soap	5.7±0.4	5.7±0.1	6.0±0.1	5.6±0.1	6.0±0.1
		NS	NS	S	S	S

Baseline values (Base) and after 10 consecutive weeks washing with the syndet or the soap (W10) are shown. S: significant @ $P \leq 0.05$, NS: not significant @ $P > 0.05$. The comparison is between soap and syndet at each timepoint.

Clinical visual evaluations

The clinical ratings of redness and dryness (on a 0–10 numerical scale) at the five skin sites confirmed the instrumental results, which indicated almost no signs of redness and dryness on all skin sites before the start of the study. Only the lower legs showed moderate signs of dryness, which are consistent with the cold and dry weather conditions between January and April (data not shown).

No significant differences in the degree of redness (Table 4) and dryness (not shown) (0–10 numerical scale) were observed between the daily use washing with either the syndet or the soap, confirming the in-

TABLE 4. Objective observations of skin redness and subjective perception of product irritancy at different skin sites

Time	Product	Hand	Forearm	Upper arm	Neck	Leg
Clinical objective evaluation of redness						
Base	Syndet	1.0±0.3	0.8±0.2	1.0±0.2	1.0±0.2	1.1±0.3
Base	Soap	1.0±0.2	0.7±0.2	1.6±0.3	1.5±0.3	1.1±0.3
		NS	NS	NS	NS	NS
W10	Syndet	2.5±0.3	1.2±0.1	1.7±0.2	1.5±0.2	1.8±0.2
W10	Soap	1.9±0.3	1.0±0.1	1.3±0.2	1.3±0.2	1.2±0.1
		NS	NS	NS	NS	S
Subjective evaluation product irritancy						
W8	Syndet	2.7±0.5	2.2±0.4	–	2.2±0.4	3.1±0.5
W8	Soap	3.2±0.6	3.2±0.6	–	2.4±0.5	4.1±0.7
		NS	NS		NS	NS
W10	Syndet	2.5±0.5	1.9±0.5	–	1.6±0.4	2.5±0.6
W10	Soap	3.3±0.6	3.1±0.5	–	2.1±0.5	3.6±0.6
		NS	NS		NS	NS

Objective redness is evaluated before (Base) and after 10 weeks (W10) daily washing with the syndet or the soap. Subjective perception of irritation is estimated after 8 and 10 weeks (W8, W10) daily washing with either the syndet or the soap. S: significant @ $P \leq 0.05$, NS: not significant @ $P > 0.05$. The comparison is between soap and syndet at each timepoint.

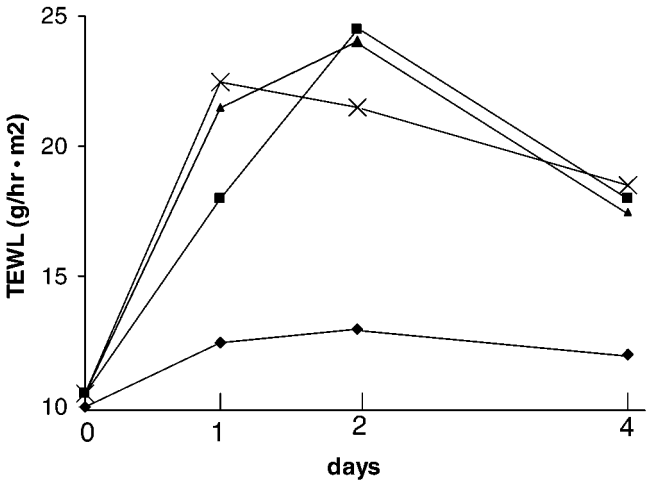

Fig. 1. TEWL measurements of the forearm in the soap chamber test. Measurements were performed before application and after two consecutive applications of the Hill Top chambers [syndet (■), soap (▲), reference soap C (X), and water (◆)].

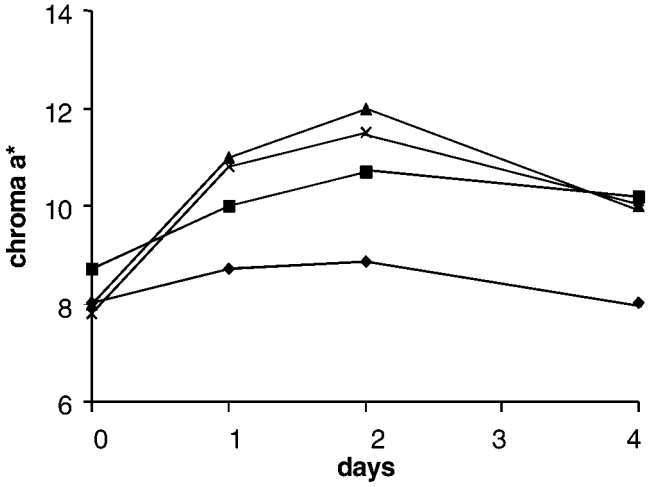

Fig. 2. Chroma Meter a* *color parameter measurements of the forearm in the soap chamber test. Measurements were performed before application and after two consecutive applications of the Hill Top chambers [syndet (■), soap (▲), reference soap C (X), and water (◆)].*

strumental readings. Daily use of both products did not induce any visible clinical changes.

Subjective perceptions

The subjective ratings (on a 0–10 numerical scale) of the look and feel of dryness, of the look of redness, and of the feeling of tightness at the four skin sites indicated almost no signs of redness and dryness on all skin sites before the start of the study, except for moderate signs of dryness on the lower leg (data not shown). This confirms the clinical assessments and the instrumental results. When comparing the subjective ratings, the look and feel of dryness and the feeling of tightness, with the clinical ratings of a trained evaluator, reasonably good agreement was observed in the rank order of the various skin sites: forearms–neck<hand<leg. However, in general, the subjective ratings were somewhat more severe than the objective visual assessments.

The results of the subjective perceptions of product irritancy by the volunteers for four skin sites are shown in Table 4. The objective clinical and bioengineering observations were not confirmed by the perception of the consumers during the 10 weeks of use. As shown in Table 4, the subjective perception of product irritancy at the four anatomical sites clearly indicates a general trend (statistically non-significant) that the soap induces more changes than the syndet in the skin at all sites.

Soap chamber test

The results of the bioengineering measurements with the soap chamber test are shown in Fig. 1 for TEWL and in Fig. 2 for *a**. The results of redness (*a**) at days 1 and 2 and TEWL at day 1 allow clear ranking of irritancy: water<syndet<classical soap<irritant soap. By TEWL, a similar ranking was observed after the first patch test and, partially, after the second one. It was not possible to establish a ranking of the products based on hydration measurements (data not shown). The results of the clinical assessments of erythema, dryness (Table 5) and roughness, were in good agree-

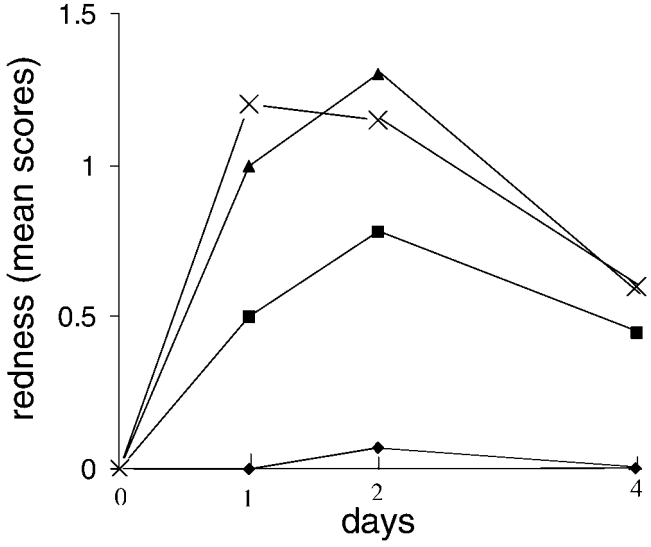

Fig. 3. Visual assessments of the redness (0–4 numerical scale for severity) of the forearm in the soap chamber test. Measurements were performed before application and after two consecutive applications of the Hill Top chambers [syndet (■), soap (▲), reference soap C (X), and water (◆)].

TABLE 5. Visual assessments of erythema, dryness, and roughness on the forearm in the soap chamber test

	Syndet	Soap	Reference soap	Water
Redness				
Day 0	0	0	0	0
Day 1	0.5±0.6	1.0±0.6 S	1.2±0.5 S	0
Day 2	0.8±0.7	1.3±0.5 S	1.1±0.6 NS	0.1±0.4
Dryness				
Day 0	0	0	0	0
Day 1	0.8±0.6	1.1±0.6 S	1.1±0.6 S	0
Day 2	1.4±0.5	1.6±0.5 NS	1.6±0.5 NS	0
Roughness				
Day 0	0	0	0	0
Day 1	0.7±0.7	1.1±0.6 S	0.9±0.6 NS	0
Day 2	1.3±0.7	1.6±0.5 NS	1.6±0.6 NS	0

Clinical evaluations were carried out before application (day 0) and after each of 2 consecutive applications of the Hill Top chambers (days 1 and 2). Aqueous solutions (2%) of a syndet, a soap, a reference soap, and water were applied. S: significant @ $P \leq 0.05$, NS: not significant @ $P > 0.05$. The comparison is with the syndet at each timepoint.

ment with the bioengineering measurements. All visual ratings at days 1 and 2 allow a clear ranking of irritancy: water<syndet<two soaps. With both instrumental and clinical observations, significant differences between the effects on the skin of the syndet and the soaps were detected; however, the values obtained for the visual ratings of symptoms of irritancy in the soap chamber test were moderate: maximal values of 1.5 on a 0–4 scale. These data clearly suggest that the symptoms of irritancy are rather low, suggesting rather mild cleansing products.

Discussion

Usually an "in-use test" should be performed on a large number of subjects (ideally 50–100 subjects). However, considering the complex methodology employed during this in-use test – namely 1) evaluations during 10 consecutive weeks, 2) examination of 4–5 different skin areas by objective clinical assessments, 3) use of various complementary instrumental measurements, and 4) use of subjective perception – it was difficult for technical reasons to perform this study on such a large group of subjects. To overcome the problem of two groups of only 25 subjects, extreme precautions were taken in the selection of the two groups to obtain two similar balanced groups with no differences in style of washing habits, in phototype, in sensitivity to cleansing products, and in baseline values of instrumental data. Furthermore, a careful follow-up of the two groups every 2 weeks was established with no use of any other body cosmetic product, such as gel, cream, lotion, or milk on the body. Similar use of the syndet and soap was monitored by weighing the used bars. No big changes in lifestyle were allowed during the duration of the study, such as winter holidays and swimming. All these precautions indicate that this in-use study could be considered as valid and significant.

In this normal use test, it was not possible to detect, by visual assessments or by instrumental measurements, any significant changes in the skin at the different anatomical skin sites or to discriminate between the effects of the two cleansing bars, with the exception of skin pH. However, these objective clinical and bioengineering observations were not confirmed by the subjective evaluations. From the questionnaires, a general trend can clearly be identified. The soap induced more perceived changes in the skin than the syndet at all skin sites but, in particular, on the leg and the hand. This clear trend was, however, not statistically significant.

On the other hand, the soap chamber test was more sensitive for the detection and discrimination of irritancy. All cleansing bars are significant irritants compared to water. This technique allowed the ranking of the irritant properties of, respectively: water<the syndet<two soaps. The two soaps were significantly more irritating to skin than the syndet bar.

This study showed also that skin irritation induced by soap bars in an exaggerated application test, such as the soap chamber test, is not necessarily predictive of an irritation likely to occur under the conditions of normal use over a 10-week period. Comparable results have also been obtained by Keswick et al. (21), who compared the use of a syndet and a soap bar under the conditions of normal use and in two exaggerated use tests (the forearm wash test and the flex wash test). It must also be noted that modern cleansing bars, even soap bars, are nowadays very complex mixtures that are generally very mild on the skin. The potential irritancy of the alkaline surfactants present in the soap cleansing bar are neutralized by the addition of humectants, filmogen and emollient ingredients. Furthermore, modern syndets contain very mild amphoteric and/or nonionic emulgators with the same hydrating and soothing ingredients. As a consequence, it is quite normal that when testing these products under the conditions of normal use for a long period, almost no effects on the skin are noticed. This study suggests that the evaluation of skin irritation induced by cleansing products should be tested using several different testing methods.

Acknowlegdements

The authors thank Ms. E. DeKegel, Ms. G. Machtelings, Ms. I. Vanbeneden, Mr. F. Brebaer and Mr. R. Lambrecht for technical assistance in both studies.

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