

Tolerance of natural baby skin-care products on healthy, full-term infants and toddlers

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Purpose: To evaluate the tolerance of baby skin-care products with at least 95% naturally derived ingredients on infants and toddlers.

Materials and methods: Healthy, full-term infants and toddlers aged 1–36 months were enrolled. In study 1, a lightly fragranced natural baby hair and body wash (n=30), a lightly fragranced natural baby shampoo (n=30), or a lightly fragranced natural baby lotion (n=32) were assessed over 2 weeks. In study 2, a lightly fragranced natural baby hair and body wash and a lightly fragranced natural baby lotion (n=33) were assessed as a regimen over 4 weeks. The wash and shampoo were used three or more times per week, but not more than once daily. Lotions were applied in the morning or after a bath. Clinicians assessed the arms, legs, torso, or scalp for erythema, dryness, peeling/flakiness (study 1 only), tactile roughness, edema (study 1 only), rash/irritation (study 2 only), and overall skin condition (study 2 only) at baseline, week 1, and weeks 2 or 4. Parents completed skin assessment questionnaires. In study 2, stratum corneum hydration was measured. Subjects were monitored for adverse events.

Results: No significant changes in clinical grading scores were observed, indicating that all products were well tolerated. By the end of each study, >90% of parents/caregivers believed each product was mild and gentle. In study 2, improvement in stratum corneum hydration was observed (+37% at week 1 and +48% at week 4, $P<0.05$ for both). In study 1, one baby experienced mild erythema on the neck and scalp after using the shampoo (possibly related to treatment). In study 2, there were no product-related adverse events.

Conclusion: The natural baby skin-care products were well tolerated by infants and toddlers when used alone or as part of a skin-care regimen.

Keywords: bath, cleanser, natural, infant, lotion, shampoo

Introduction

Immediately after birth, the skin barrier of healthy, full-term neonates is competent,^{1,2} yet skin-barrier function continues to develop through at least the first year of life.^{3,4} This developing state of infant skin results in infant skin being susceptible to dryness and irritation from external factors, such as cold weather and wind, as well as harsh topical skin-care products. Therefore, it is critical that infant cleansers and moisturizers be well tolerated and not disrupt the stratum corneum. Infant skin is also exposed to other factors, such as saliva, nasal secretions, urine, feces (including fecal enzymes), and dirt, which can be irritants and result in disruption of the skin barrier. As a result of normal daily exposure to these external factors, proper skin cleansing and protection of the infant skin barrier are essential to the maintenance of skin-barrier function.⁵

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Given the importance of the skin barrier in neonates and infants, it is important to use topical skin-care products that have undergone adequate skin-tolerance studies, yet there are very few published studies^{6,7} evaluating the tolerability or efficacy of skin cleansers, lotions/emollients, and shampoos under real-world, normal conditions of use on healthy, full-term neonates or infants. Although traditional skin-cleansing, lotion, and shampoo products still comprise a large share of the personal care market, increasing numbers of consumers and health care professionals have begun scrutinizing products and product labels, which has created a sizeable market for products that contain natural ingredients. Despite the increasing popularity of natural personal care products, in our review, there do not appear to be many published studies reporting data on the tolerability of natural skin-care products used on infant or toddler skin. In this article, we report the results of two studies that evaluated the tolerability of baby skin-care products composed of at least 95% naturally derived ingredients (hair and body wash, shampoo, and lotion, alone or as a regimen) on healthy, full-term infants and toddlers with healthy skin.

Materials and methods

Study design

Two studies are described. A single-center clinical study was undertaken to determine the tolerability of a natural baby wash, natural baby lotion, and natural baby shampoo on infants and toddlers after 2 weeks under conditions of normal use (study 1). A second single-center clinical study was also undertaken to assess the tolerability and efficacy of a skin-care regimen comprised of a natural baby wash and natural baby lotion on infants and toddlers after 4 weeks under conditions of normal use. Both studies took place in a dermatology clinic, under the supervision of a board-certified dermatologist and board-certified pediatrician, and also in the routine setting of a baby's home.

Studies were carried out in compliance with the current standards and principles of the Declaration of Helsinki and the International Conference on Harmonisation Guideline for Good Clinical Practice. Parents and legal guardians gave informed consent, and an institutional review board approved the protocol (Study 1 - Allendale Investigational Review Board of RTA Inc., Old Lyme, CT, USA; Study 2 - IntegReview Ethical Review Board, Austin, TX, USA).

Study participants

Healthy, full-term male and female infants and toddlers aged 1–36 months with no dermatologic conditions (eg,

no dermatitis, eczema, psoriasis, rosacea, diaper rash, or history of recurrent diaper rash) were eligible to participate in the studies. Parents and legal guardians were eligible to enroll their child in the study if they were ≥ 18 years old and were willing to regularly apply the skin-care test products to their infant or toddler, provide a complete medical history, and complete a daily diary and study questionnaires. Subjects were excluded from participating in the studies if they had a dermatological evaluation score >0.5 for all parameters on the 4-point clinical grading scale (for rash, skin irritation, or other skin conditions [study 1]) or moderate-to-severe score (≥ 2.0 for all parameters on the 4-point clinical grading scale) for erythema, dryness, rash, or overall skin condition at baseline (study 2).

Test products

Study 1 included three commercially available products: Johnson's® Natural® Head-to-Toe™ Baby Wash, Johnson's® Natural® Baby Lotion, Johnson's® Natural® Baby Shampoo. These products are marketed by Johnson and Johnson Consumer Companies, Inc (Skillman, NJ, USA). Study 2 included two test products that were not commercially available at the time of the study. Product ingredients are listed in Table 1. All of the natural baby products were formulated with at least 95% naturally derived ingredients, and contained a low level of a naturally derived fragrance that was formulated specifically for infants and toddlers. The natural fragrance blend is composed of naturally derived ingredients and is free of known skin allergens and essential oils.

Frequency of use

The natural baby skin-care products and directions for frequency of use are described in Table 2. In study 1, participating subjects were randomly allocated equally into three groups (approximately $n=30$ subjects per group). Parents or legal guardians were instructed to use the natural baby hair and body wash (group 1) or natural baby shampoo (group 2) during bathing. In group 3, parents and legal guardians were instructed to use the natural baby lotion at least once daily in the morning. The natural baby lotion was to be used after bathing. If a child was bathed in the afternoon or evening, the test natural baby lotion was to be reapplied after bathing. The lotion was not to be used more than twice daily. In study 2, all participating subjects ($n=33$) used a skin-care regimen consisting of a natural baby hair and body wash and natural baby lotion. Parents were to use the body wash at least three times per week, but not more than once per day. The lotion was to be used once per day

Table 1 Test-product ingredients

Ingredient	Study 1			Study 2	
	Natural baby hair and body wash	Natural baby lotion	Natural baby shampoo	Natural baby hair and body wash	Natural baby lotion
Acrylates/C10-30 alkyl acrylate crosspolymer	–	–	–	x	x
Benzoic acid	–	x	–	–	–
Candelilla/jojoba/rice bran polyglyceryl-3 esters	–	x	–	–	–
Cetearyl alcohol	–	x	–	–	–
Cetyl alcohol	–	x	–	–	x
Cetyl hydroxyethylcellulose	x	x	x	–	–
Citric acid	x	–	x	x	–
Cocamidopropyl betaine	–	–	–	x	–
Coco-glucoside	x	–	x	x	–
Cocoglycerides	x	x	x	–	–
Decyl glucoside	x	–	x	x	–
Dicaprylyl carbonate	–	–	–	–	x
Dicaprylyl ether	–	–	–	–	x
Ethylhexylglycerin	–	–	–	x	x
Fragrance	x	x	x	x	x
Glycerin	–	x	x	x	x
Glyceryl laurate	–	x	–	–	–
Glyceryl oleate	x	–	x	x	–
Glyceryl stearate	–	x	–	–	–
Glycine soja (soybean) oil	–	x	–	–	x
Hydrogenated cottonseed oil	–	x	–	–	x
Hydrogenated palm glycerides	–	–	–	–	x
Phenoxyethanol	–	–	–	x	x
Polyglyceryl-10 laurate	x	–	x	x	–
Potassium cetyl phosphate	–	–	–	x	x
Sodium benzoate	x	–	x	x	–
Sodium coco-sulfate	x	–	x	–	–
Sodium hydroxide	x	–	x	x	x
Sodium stearyl lactylate	x	x	–	–	–
Water	x	x	x	x	x
Xanthan gum	x	x	x	–	–
<i>Zea mays</i> (corn) starch	–	–	–	–	x

in the morning or after a bath, but not more than twice in the same day.

In both studies, test products were provided in coded containers that did not identify the product. The subjects' parents or legal guardians and clinical evaluators did not have access to the test-product codes. In addition, the personnel dispensing

the test products or supervising their use did not participate in subject evaluation in order to minimize potential bias. The subjects and their parents or legal guardians visited the study clinic during screening, baseline, week 1, and week 2 (study 1) or week 4 (study 2). Subjects were the only individuals who were permitted to use the test products, to ensure accurate

Table 2 Products and frequency of use in studies 1 and 2

Study	Product	Skin site evaluated	Directions for frequency of use
Study 1	Natural baby hair and body wash	Scalp, torso (chest, back), arms, legs	• ≥ 3 times/week but no more than once daily
	Natural baby shampoo	Scalp	• ≥ 3 times/week but no more than once daily
	Natural baby lotion	Torso (chest, back), arms, legs	• At least once daily in the morning • If bath is given, use again after bath • No more than 2 times per day
Study 2	Natural baby hair and body wash and natural baby lotion regimen	Torso (chest, back), arms, legs	• Baby wash: ≥ 3 times/week but no more than once daily • Baby lotion: At least once daily in the morning • If bath is given, use baby lotion again after bath • Use baby lotion no more than 2 times a day

dispensing and use. Parents and legal guardians kept diaries of test-product usage habits, which were reviewed during each study visit to ensure compliance.

Clinician and parent/guardian skin assessments

In studies 1 and 2, skin assessments were made using a rating scale with the following designations: 0= none; 1= mild; 2= moderate; and 3= severe (Table 3). In addition, a 10-point scale was used to assess global/overall skin condition (1= excellent to 10= poor). Mean score and frequency distributions were calculated at baseline and weeks 1 and 2 (study 1) or baseline and weeks 1 and 4 (study 2) and were used to calculate the percentage change from baseline in skin attributes.

In both studies, parents or legal guardians completed daily diaries and provided information about their child's bathing habits, product application times, sun exposure, sunscreen use, and change in health status (eg, diaper rash, fever, illness, skin reactions, skin irritation, teething, use of medications, and use of other topical products). Parents/guardians completed skin-assessment questionnaires at baseline and weeks 1 and 2 (study 1) or baseline and weeks 1 and 4 (study 2). The skin-assessment questionnaires asked parents/guardians to rate various attributes on a scale between 1 (least or worst) and 10 (best). Similar to the clinician assessment data, scores at baseline and weeks 1 and 2 (study 1) or weeks 1 and 4 (study 2) were used to calculate percentage change (percentage improvement) from baseline. In addition, parents completed product-evaluation questionnaires at weeks 1 and 2 (study 1) or weeks 1 and 4 (study 2) that asked them to agree or disagree with statements about each product using a scale from 1 (disagree completely) to 5 (completely agree).

In study 2, stratum corneum hydration (SCH) was evaluated on the lower outer leg at each point using the Corneometer®

CM 825 (Courage and Khazaka Electronic, Cologne, Germany). The Corneometer measures moisture content in the stratum corneum by an electrical capacitance method. The measurement has no units, and increases as the skin becomes more hydrated.

Statistical analysis

In studies 1 and 2, a mean summary was performed for continuous variables (eg, age). For discrete variables, frequency distributions of raw scores were calculated. In studies 1 and 2, mean clinical grading scores were compared (percentage change from baseline) using the Wilcoxon signed-rank test. Lower scores were indicative of an improvement in grading scores. In study 2, Corneometer measurements were compared (percentage change from baseline) using a paired *t*-test. A binomial test (sign test) was performed on answers to the questionnaires. If the percentage of answers to each question was greater by a statistically significant margin, this result was indicative of positive feedback. All statistical tests were two-sided. Statistical significance was set at $P \leq 0.05$. Statistical analyses were performed using SAS version 9.2 software (SAS Institute, Cary, NC, USA).

Adverse event monitoring

During both studies, parents, legal guardians, and investigators monitored infants and toddlers for adverse events (AEs) and serious AEs. All AEs (regardless of severity or cause) were to be recorded and classified. Expected events (ie, those normally associated with use of topical products), such as irritation, erythema, dryness, itching, or stinging were not to be classified as AEs, but were to be documented on clinical evaluation case-report forms.

Results

Participants

The demographic characteristics of children included in both studies are shown in Table 4. Study 1 enrolled 99 children, 93 were qualified/enrolled, and one discontinued due to personal reasons. Study 2 enrolled 36 children and 33 completed the study. One participant was lost to follow-up, one had an AE that was determined to be unrelated to the products used, and one subject's parent requested withdrawal.

Expert grader assessments

In study 1, all of the natural baby skin-care products were well tolerated by infants and toddlers. At baseline, week 1, and week 2, no evidence of erythema, edema,

Table 3 Clinical features of the skin evaluated by expert graders to assess tolerability of the baby skin-care products

Study 1	Study 2
Assessments at baseline, week 1, and week 2	Assessments at baseline, week 1, and week 4
<ul style="list-style-type: none"> • Erythema • Edema • Dryness • Tactile roughness^a • Peeling/flakiness 	<ul style="list-style-type: none"> • Erythema • Rash/irritation • Dryness • Tactile roughness^a • Overall skin condition

Notes: ^aNot assessed for evaluations of the scalp. The skin assessments listed above used the following scale: 0= none, 1= mild, 2= moderate, and 3= severe for all assessments, except overall skin condition in study 2, which used a scale of 1= excellent to 10= poor.

Table 4 Subject demographics

	Study 1			Study 2
	Natural baby hair and body wash n=30	Natural baby shampoo n=32	Natural baby lotion n=30	Natural baby hair and body wash and lotion regimen n=33
Age, n (%)				
1–12 months	9 (30)	10 (32)	11 (37)	16 (49)
13–24 months	11 (37)	10 (32)	10 (33)	7 (21)
25–36 months	10 (33)	12 (38)	9 (30)	10 (30)
Sex, female, n (%)	14 (47)	12 (38)	12 (40)	18 (55)
Race/ethnicity				
Caucasian	11 (37)	20 (63)	19 (63)	21 (64)
African American	3 (10)	5 (16)	2 (7)	4 (12)
Hispanic	7 (23)	6 (19)	5 (17)	4 (12)
Asian	1 (3)	0	0	1 (3)
Mixed races, multiple ethnicities	8 (27)	1 (3)	3 (10)	3 (9)
Not obtained	–	–	–	1 (3)

dryness, peeling/flakiness, or tactile roughness was observed on the torso, arms, or scalp. Mean scores for all parameters were 0 (none) with the exception of a mean score of 0.1 for tactile roughness on the legs with the lotion at week 2.

In study 2, the natural baby skin-care regimen was well tolerated after 1 week and 4 weeks of use. There were no changes in clinical grading scores after 1 week or 4 weeks of use compared with those at baseline on the torso, arms, or legs for redness/erythema, rash/irritation, dryness, or tactile roughness (Table 5).

Parent/guardian assessments

Results of the parent/guardian assessments from studies 1 and 2 are shown in Figures 1 and 2, respectively. In study 1, ≥90% of parents/guardians believed that the natural baby hair and body wash, natural baby lotion, and natural

Table 5 Study 2: Expert clinical grading assessments following use of the test natural baby hair and body wash and test natural baby lotion regimen

Body location	Time point	Clinical grading assessments			
		Redness/erythema	Rash/irritation	Dryness	Tactile roughness
Torso	Baseline	0.03	0.03	0.03	0.03
	Week 1	0.00	0.00	0.00	0.00
	Week 4	0.00	0.00	0.00	0.03
Arms	Baseline	0.03	0.06	0.00	0.06
	Week 1	0.00	0.00	0.00	0.02
	Week 4	0.00	0.00	0.00	0.03
Legs	Baseline	0.03	0.03	0.06	0.03
	Week 1	0.00	0.00	0.00	0.02
	Week 4	0.00	0.00	0.00	0.03

Note: n=33.

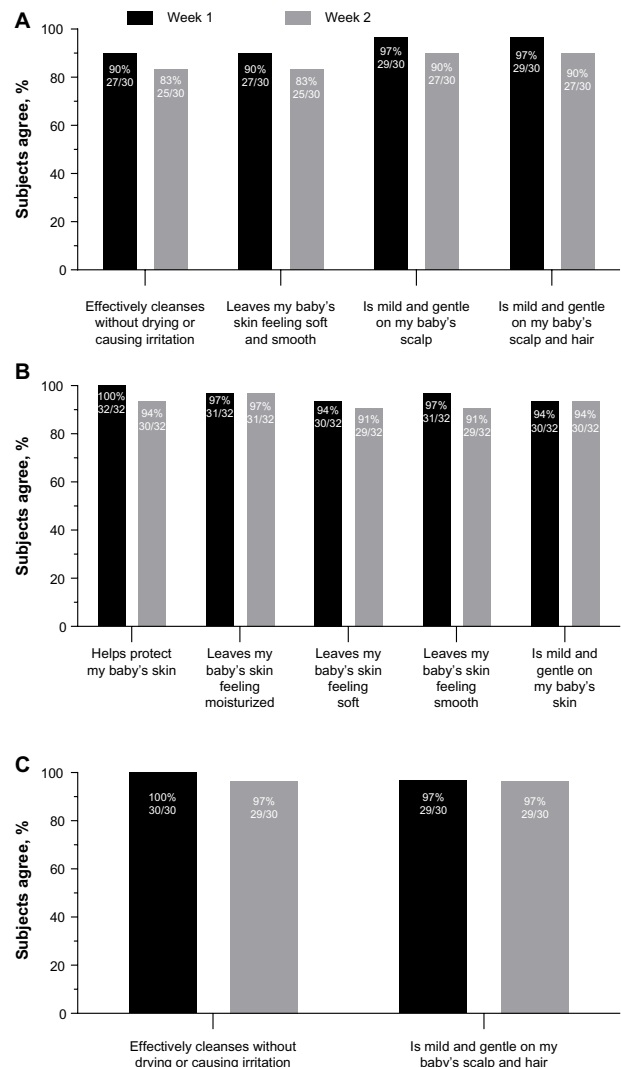


Figure 1 (A–C) Parent/guardian assessment (study 1) after 1 and 2 weeks of product use. Data shown are percentages of respondents agreeing with statements about (A) hair and body wash, (B) lotion, and (C) shampoo.

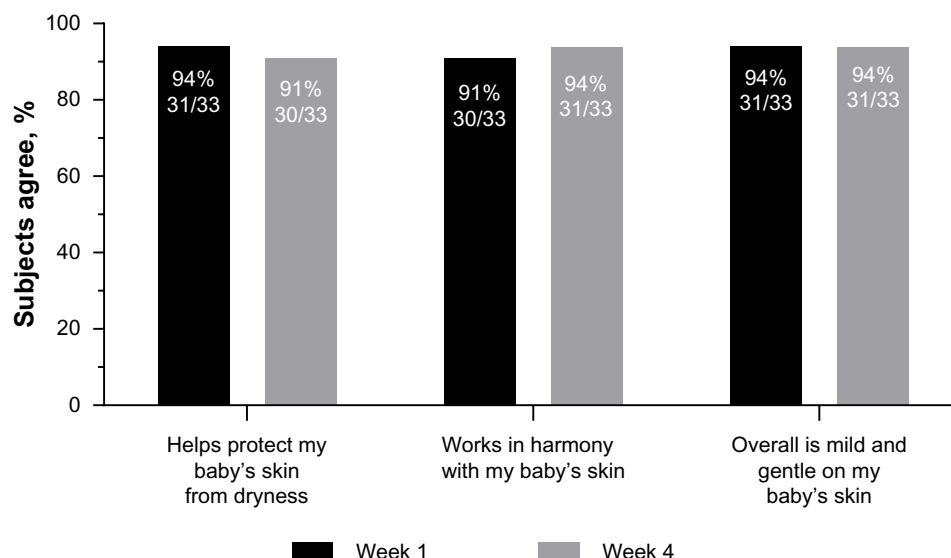


Figure 2 Parent/guardian assessment of baby wash and lotion regimen (study 2). Data shown are percentages of respondents agreeing with statements.

baby shampoo test products were mild and gentle on their baby's skin and scalp (Figure 1).

In study 2, a statistically significant number of parents/guardians believed that the skin-care regimen led to improvements in (mean \pm standard deviation) skin-condition scores for the following statements and periods: "My baby's skin looks moisturized" (weeks 1 and 4 versus baseline; $P < 0.001$; baseline: 7.39 ± 1.89 , week 1: 9.09 ± 1.01 , week 4: 8.97 ± 1.70); "My baby's skin feels soft" (week 4 versus baseline; $P = 0.016$; baseline: 9.00 ± 1.35 , week 1: 9.36 ± 1.08 , week 4: 9.58 ± 0.71); "My baby's skin feels smooth" (week 4 versus baseline; $P = 0.003$; baseline: 9.00 ± 1.25 , week 1: 9.30 ± 1.26 , week 4: 9.70 ± 0.53). Results from product-evaluation questionnaires revealed that a significant proportion of parents/guardians provided favorable responses at weeks 1 and 4 for the following statements: "This baby wash and baby lotion regimen helps protect my baby's skin from dryness," "This baby wash and baby lotion regimen works in harmony with my baby's skin," and "Overall, this baby wash and baby lotion regimen is mild and gentle on my baby's skin" (Figure 2).

Stratum corneum hydration measurements

In study 2, use of the natural skin-care regimen led to a significant improvement in SCH at weeks 1 and 4 compared with that at baseline (Figure 3).

Adverse events

In study 1, one infant experienced slight erythema on the neck and scalp for approximately 10 minutes after using the

natural baby shampoo. This mild, singular event was possibly related to the study treatment. Following clinical assessment of infant skin condition at each time point, there was no evidence of irritation in any of the test subjects. In study 2, eleven subjects were reported to have experienced a nonserious AE, including the following: viral rash, cold, acid reflux, roseola, diaper rash, ear infection, cough, seasonal allergies, fever from teething, and sinus infection. In the opinion of the study investigators, none of these nonserious AEs observed in study 2 were related to the test products.

Discussion

In these two single-center studies, the lightly fragranced natural baby skin-care products with at least 95% naturally

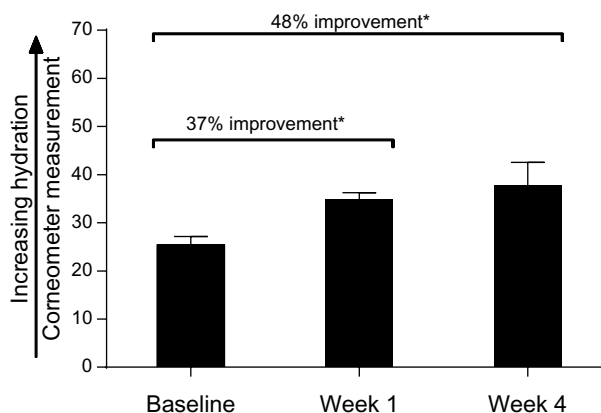


Figure 3 Stratum corneum hydration measurements following 4 weeks of skin-care regimen (study 2).

Notes: * $P < 0.05$ versus baseline. There was a statistically significant improvement in stratum corneum hydration on the right lower outer leg at weeks 1 and 4 compared with baseline. Data shown are means \pm standard error of the mean of Corneometer measurements.

derived ingredients were shown to be well tolerated by infants and toddlers with healthy skin in the routine setting of their homes. In addition, a skin-care regimen composed of a lightly fragranced natural baby hair and body wash and lightly fragranced natural baby lotion was also well tolerated. Although several studies have investigated the effects of emollient therapy on premature neonates,^{8–13} very few groups⁶ have studied the tolerability or efficacy of skin cleansers or emollients on healthy, full-term neonates or infants under conditions of normal use. Moreover, there appear to be few, if any, published studies that have reported tolerability or efficacy data following the use of personal care products derived from natural sources. The findings in our studies are important, because health care professionals and consumers alike are both looking for evidence that natural personal care products are well tolerated,¹⁴ especially when used on very young children.

In study 2, the natural baby lotion test product had moisturizing qualities that left baby skin feeling soft and smooth, when used as a regimen with the natural baby hair and body wash. This clinical observation was verified through instrumental measurements of SCH, demonstrating that after 4 weeks of the natural baby skin-care regimen, there was a 48% improvement in SCH ($P < 0.05$).

Our studies took place in subjects' homes, which is a more natural setting than a hospital or outpatient clinic. This setting also helps to provide a real-world perspective on the tolerability and efficacy of these products under conditions of normal use, which are often less than ideal (ie, unsterile environment; products are often stored in humid environments, including bathrooms).

Our studies also had limitations. They were short in duration (≤ 1 month) and did not evaluate long-term tolerability or efficacy, and the parental assessment questionnaires were not validated. Although these studies were conducted with healthy infants and toddlers, more studies could be conducted to measure the tolerability and efficacy of the test products on infants and toddlers with compromised skin (eg, atopic dermatitis, eczema). Despite these limitations, there do not appear to be other studies in the peer-reviewed literature reporting skin tolerability or efficacy data after using natural, lightly fragranced products on very young children.

In conclusion, these two studies demonstrated that appropriately formulated, lightly fragranced natural products containing at least 95% naturally derived ingredients (natural baby hair and body wash, natural baby shampoo, and natural baby lotion) were tolerated well by infants and toddlers when used alone for 2 weeks or as part of a skin-care regimen

for a 4-week period. Individual products and the skin-care regimen were shown to be mild, gentle, and acceptable for use on infants and toddlers. Furthermore, the natural baby hair and body wash, natural baby lotion, and natural baby shampoo led to an enjoyable washing experience for the majority ($>80\%$) of subjects. These studies add to a limited body of evidence demonstrating that natural personal care products, formulated specifically for infants and toddlers with healthy skin, can be mild and tolerated well under conditions of normal use.

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Disclosure

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