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Clinical Skin Assessment of BabyOrgano Cold Relief Roll - On: Efficacy in Cough and Cold Relief

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Abstract: ***BabyOrgano Natural Cold Relief Roll - On effective in Cough and Cold was clinically assessed for skin irritation potential on healthy human subjects by Single application patch test method (Primary Irritation Patch Test). This open - label, controlled, single - center was conducted on a group of healthy adult volunteers as per BIS 4011: 2018 guidelines with photo type III to V. A standardized patch test method was employed, wherein the BabyOrgano Natural Cold Relief Roll - On was applied to a small area of the subjects' skin. Observations were made at specific time intervals post - application, including 24, 48, and 72 hours, to assess any signs of erythema, edema, or other skin reactions. An additional follow - up period of 8 days was included, with visits scheduled at three days post - application and at T8 (one week after the initial patch removal) to monitor any delayed reactions. Screening and observations were conducted at T0 (before patch application), T1 (immediately after patch removal), T2 (24 hours after patch removal), and T8 (one week after patch removal). The primary endpoint was the change in erythema and edema scores, assessed by measuring the total irritation score 24 hours after patch removal. Three patches were used: Patch 1 with BabyOrgano Cold Relief Roll - On, Patch 2 as a negative control (0.9% saline), and Patch 3 as a positive control (1% sodium lauryl sulfate). Results showed Patch 1 and 2 were non - irritant, while Patch 3 caused irritation. All subjects completed the study without any dropouts. These findings confirm that BabyOrgano Natural Cold Relief Roll - On is non - irritant with 24 - hour Primary Irritation Patch Test for use on healthy human skin.***

Keywords: BabyOrgano, Cold Relief Roll - On**,** Dermatologically tested, Pediatrician tested**,** Skin irritation, Patch test, Allergens, Inflammatory Responses, Erythema, Oedema

1. Introduction

Cold and cough are prevalent respiratory ailments affecting individuals across all age groups, particularly during seasonal transitions or as a result of viral infections. These conditions pose a greater challenge in infants and young children, as they are unable to effectively communicate their symptoms, often leading to delayed management, which can exaggerate discomfort and respiratory distress. These conditions typically result in symptoms such as nasal congestion, coughing, throat irritation, and overall discomfort. While conventional treatments often focus on symptomatic relief through medications, there has been a growing interest in natural remedies, particularly Ayurvedic essential oils, for their holistic healing properties.

Ayurveda, an ancient system of medicine, renowned for their therapeutic properties emphasizes the use of natural herbs and essential oils such as eucalyptus, tulsi (holy basil), camphor, and peppermint to treat ailments like cold and cough. These oils work by clearing nasal passages, reducing congestion, and soothing inflammation, providing effective relief from respiratory symptoms. In addition to relieving symptoms, Ayurvedic essential oils help boost immunity and promote overall well - being without the aftereffects associated with many conventional treatments. By integrating the time - tested wisdom of Ayurveda with modern understanding, essential oils offer a natural and gentle approach to managing cold and cough, benefiting both children and adults.

BabyOrgano Natural Cold Relief Roll - On, particularly designed for babies and kids, can affect the skin's barrier properties, potentially enhancing the absorption of active ingredients. Cold and cough are common respiratory ailments that affect individuals across all age groups, especially during seasonal changes or viral infections. These conditions are especially challenging in infants and young children, as they cannot effectively communicate their symptoms, which often leads to delayed management. This delay can increase their discomfort and exacerbate respiratory distress, making timely and gentle relief crucial.

Children are more vulnerable to skin disorders due to developmental differences, with their skin being more prone to irritation, inflammation, and frequent minor injuries. Studies indicate that as children age, the softness, smoothness, and overall condition of their skin may decline, further increasing susceptibility to skin diseases. In fact, skin conditions are a significant public health concern globally, affecting more than one - third of school - aged children in some regions, including India. Exposure to pathogens, physical agents like extreme temperatures, and social interactions during school and play increase the likelihood of infectious skin illnesses. Considering these vulnerabilities, the use of cold relief roll - ons for children must carefully balance efficacy with the potential for increased dermal absorption and irritation. In the absence of specific quantitative data on skin absorption, a default assumption of 100% dermal penetration is often used in safety assessments for such products.

Skin serves as a protective barrier between the physical environment and the individual, protecting individuals from mechanical trauma, reduces the penetration of allergens and irritants, and maintains a stable water content. Therefore, the skin barrier plays an important role in human health, especially in infants (1). Skin irritation is a skin reaction

manifesting as erythema, edema, and desquamation, and is caused by the direct contact of substance with the dermal. Skin corrosion refers to the condition wherein reactions occur to the extent of irreversible tissue damage. Furthermore, the irritation reaction that occurs when the irritant initially comes into contact with the skin is called primary skin irritation, and that when the test substance comes into repeated contact is called cumulative skin irritation (2). In contrast to adult skin, infant skin may experience more problems due to the immature skin barrier. It has been reported that the stratum corneum and epidermis in babies are thinner than those in adults, by up to 30% and 20%, respectively (3; 4). At birth, babies have a higher skin surface pH, and the baby skin pH at the stratum corneum surface tends to be similar to that of adults after at least one year of development. It is important for baby skin to maintain low protease activity and enhance the synthesis of lipid lamellae, which is a fundamental element of healthy skin barriers (5; 6).

Furthermore, even when cold & cough is present, the severity is usually mild such that the skin retains a functional barrier. This paper provides a review of the literature as well as historical data on cold & cough, including the frequency of sore throat as well as the amount of skin involved and the time to resolution. The implications of cold & cough for altering the dermal penetration of chemicals is considered, recognizing that this will depend on physical - chemical characteristics such that dermal penetration is not impacted to the same extent for all chemicals. This holistic approach provides a comprehensive understanding of the implications of cough and cold for dermatological and pediatrician tested. It includes the assessment of patch tests to evaluate dermal reactions, ensuring that products like BabyOrgano Cold Relief Roll - On are beneficial for the skin, especially in infants and children.

2. Material and Methods

Evaluation of irritation potential of BabyOrgano Natural Cold Relief Roll - On on healthy human subjects by Single application patch test method. (Primary irritation patch test). The evaluation of the product **Figure 1**, to be tested was carried out versus a positive control: 1% (w/w) SLS, and versus a negative control: 0.9% isotonic solution. The trial subjects will be enrolled at one investigative site in India with approximately 24 patients who meet the trial inclusion criteria and will be given the investigational product. The maximum trial duration for each subject will be about 8 days after being provided with the written informed consent; then, the issue will undergo screening procedures. At the end of the screening period, the eligible subjects will be included in the trial, and the ineligible will be excluded from the evaluation.

Figure 1: BabyOrgano Natural Cold Relief Roll - On

2.1 Methodology of patch application

- The patch application was carried out at T0 by the CRC.
- Wash your hands with disinfectant, then begin applying the strip from the bottom, pressing upwards to release any trapped air.
- When the tape is fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation.
- The person being tested should avoid sudden movements.
- Strengthen the application of patches by applying the micro pore tape on all the four sides of patch.

During the treatment period, subjects will return to the trial site according to the trial schedule to assess compliance with the treatment regimen, concomitant medications, and adverse events (AEs).

During the treatment period, the investigator will assess the severity using the patch, and the subjects will be asked to fill the form before the screening of the trial. All the safety assessments will be done during the treatment period as mentioned in **Table No.1.**

Table 1: Trial Design

T0= (before patch application)	Patch application
T1 day= (0 hr after patch removal)	Patch removal
T2 day= (24 hr after patch removal)	Patch reading by the Pediatrician and Dermatologist
T8* = (T+1 week after 0 hr of patch removal)	Checking of the evaluation of the positive cases

2.2 Trial Endpoints

2.2.1 Primary Endpoint
Change in Skin Irritation Score - erythema and oedema.

2.2.2 Safety Endpoints
Safety endpoints include the following:
- Assessment and reporting of the Adverse Events.
- Tolerability of Test product.

2.3 Subject Population

A total of 24 subjects will be enrolled, with the goal of having all 24 complete the study for primary analysis. Each subject will be allowed to participate in the trial only once.

Before any trial - specific procedures are conducted, participants will be required to sign an informed consent form. Additionally, subjects will provide authorization for the use of their data in accordance with privacy and data protection regulations.

2.3.1 Inclusion Criteria

Subjects must meet all the following criteria to be eligible for participation in the trial:

1) Voluntary man/women between 18 and 65 years.
2) Photo type III to V.
3) Having apparently healthy skin on test area
4) For whom the investigator considers that the compliance will be correct.
5) Cooperating, informed of the need and duration of the examinations and ready to comply with protocol procedures.
6) Having signed a Consent Form.
7) Willingness to avoid intense UV exposure on test site (sun or artificial UV), during the course of the study.
8) Willingness to avoid excessive water contact (for example swimming) or activity which causes excessive sweating (that is exercise, sauna…), during the course of the study.
9) Should be able to read and write (in English, Hindi or local language).
10) Having valid proof of identity and age

2.3.2 Exclusion Criteria.

1) Pregnant/nursing mothers
2) Scars, excessive terminal hair or tattoo on the studied area.
3) Henna tattoo anywhere on the body (in case of studies involving hair dyes).
4) Dermatological infection/pathology on the level of studied area.
5) Hypersensitivity, allergy antecedent (to any cosmetic product, raw material or hair dye).
6) Any clinically significant systemic or cutaneous disease, which may interfere with study treatment or procedures.
7) Chronic illness which may influence the outcome of the study.
8) Subjects on any medical treatment either systemic or topical which may interfere with the performance of the study treatment (presently or in the past 1 month).
9) Subject in an exclusion period or participating in another food, cosmetic or therapeutic trail.

2.4 Patch Assessment

2.4.1 Patch Preparation

The patches were prepared in the morning of the application one hour before the visit i. e. at T0 as mentioned in **Table No.2**

Table 2: Patch Preparation

Products	Patch no (finn chamber)	Application frequency	Application duration
BabyOrgano Natural Cold Relief Roll - On	1	Once	24 hours
(Negative Control) - 0.9% Isotonic Saline Solution	2	Once	24 hours
(Positive Control) - 1% Sodium Lauryl Sulphate	3	Once	24 hours

2.4.2 Patch Application

1) Approx 0.04ml (40 microliter) of test sample was measured with the help of micropipette.
2) 2.0.04ml or 40 microliter of the test sample was transferred on previously numbered fin chambers.
3) Finn chamber with an appropriately sized disc of whatsman no.3 filter paper with the help of Micropipette.
4) The finn chambers with the product loaded filter paper disc were taped onto the back of the subjects.

2.4.3 Study Procedures

Principle

The patch test under occlusion is a method used to check safety in terms of irritation potential of any cosmetic or cosmeceutical formulation which is to be applied topically on healthy human subjects. Irritants are the substance that may damage the skin. The damage will depend upon the nature, concentration and duration of exposure. Irritation is manifested as inflammatory responses such as erythema (redness) and oedema (swelling) vesiculation and finally to an intense suppurate reaction without the involvement of immune system. The evaluation of the different products to be tested was carried out versus a negative control: 0.9% isotonic solution and versus positive control: 1% (w/w) SLS. The kinetic of the evaluation was as follows:

T0= (before patch application)	Patch application
T1 day= (0 hr after patch removal)	Patch removal
T2 day= (24 hr after patch removal)	Patch reading by the Pediatrician & Dermatologist
T8* = (T+1 week after 0 hr of patch removal)	Checking of the evaluation of the positive cases

Methodology of patch application

- The patch application was carried out at T0 by the CRC.
- Wash hands with disinfectant.
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape is fully in palace, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Apply the pressure to the tape and especially its edges to ensure good fixation. the person being tested should avoid sudden movements.
- Strengthen the application of patches by applying the micropore tape on all the four sides of patch.

Figure 2: Patch Application

The skin reaction was assessed under a constant artificial daylight source.

While the scoring of reactions namely erythema (including, dryness, scaliness and wrinkles) on a point scale and oedema on another 0 – 4 point scale as per Draize scale (clause observation and scoring for skin irritation test, Draize scale for scoring the treatment sites – IS 4011: 2018 methods of test for safety evaluation of cosmetics – 3rd revision)

2.5 Statistical methods and analytical plans

Being an observational Irritation study, it does not need to be evaluated by any statistical methods.

Data Sets Analyzed
All eligible subjects who were included into the study were included in the safety analysis.

Demographic and Baseline Characteristics
The following demographic variables at screening were summarized by dose level: race, gender, age, height and weight.

Sample Size
The sample size for this protocol is 24. The eligible patients will be assigned to study treatment. A total of 24 subjects were enrolled, out of which none dropouts have been considered. The design tab used to achieve this sample size is:

Power (Probability of Rejecting P ≤ P0 when P ≥ P1)	0.9
Alpha (Probability of Rejecting P ≤ P0 when P ≤ P0)	0.01
P0 (Maximum Response Rate of a Poor Treatment)	0.05
P1 (Minimum Response Rate of a Good Treatment)	0.25

3. Results & Observations

The clinical trial aimed to assess the non - irritant effect of BabyOrgano Natural Cold Relief Roll - On on healthy subjects. All 24 participants completed the study without any dropouts or adverse events. Patch application, removal, and evaluation were carried out according to a standardized protocol. Skin reactions were assessed at various intervals using the Draize scale (0 - 4), and no significant signs of erythema or edema were observed throughout the trial.

The visit schedule and assessments are summarized in **Table No.3**

Table 3: Visit Schedule and Assessments

	Screening	Visit 0 (before patch application) Patch Application day	Visit 1 (0 hour after the patch removal) Patch Removal Day	Visit 2 (24 hours after patch removal)	Visit 3: 8 Days (T+1 week after 0 hour of patch removal)
Registration	X				
Protocol Briefing	X				
Informed Consent Form	X				
Inclusion and Non - Inclusion criteria	X	X			
History Questionnaire	X				
Routine Check up	X				
Clinical observation	X				
Site identification		X			
Proscriptions and Restrictions			X	X	X
Concomitant Medication		X	X	X	X
Patch Application		X	X		
Patch Removal					
Dermatological Evaluation reading of Patch Test				X	X
AE/SAE Monitoring		X	X	X	X
					End of study

SAE = Serious adverse event; AE = adverse event.
The skin reaction was assessed under a constant artificial daylight source.

The Investigator (s) scored the reactions namely erythema **Table No 4** (including, dryness, scaliness and wrinkles) on a point scale and oedema on another 0 - 4 point scale as per Draize scale (clause observation and scoring for skin irritation test, Draize scale for scoring the treatment sites – IS 4011: 2018 methods of test for safety evaluation of cosmetics – 3rd revision)

Table 4: (including, dryness, scaliness and wrinkles) on a point scale

Score of erythema /dryness/wrinkles	Reaction	Score of oedema	Reaction
0	No reaction	0	No reaction
1	Very slight erythema / dryness with shiny appearance	1	Very slight oedema
2	Slight erythema /dryness/wrinkles	2	Slight oedema
3	Moderate erythema /dryness /wrinkles	3	Moderate oedema
4	Severe erythema / wrinkles and scales	4	Severe oedema

Erythema Scoring was done after 24 hours of Patch removal, and on day 8, the Erythema Assessment was done with a Dermatologist/Pediatrician as below Scoring **Table No 5.**

Table 5: Erythema Scoring
Oedema Scoring

Erythema 5 Point Scale [0 - 4]	Score
Score for Erythema	
No Reaction	0
Very Slight Erythema	1
Slight Erythema	2
Moderate Erythema	3
Severe Erythema	4

After the 24 hours of Patch removal, and on day 8, the Oedema Assessment was done with a Physician/Pediatrician as below Scoring **Table No 6.**

Table 6: Oedema Assessment

Oedema 5 Point Scale [0 - 4]	Score
Score for Oedema	
No Reaction	0
Very Slight Oedema	1
Slight Oedema	2
Moderate Oedema	3
Severe Oedema	4

By the end of the study (Day 8), no skin irritation was reported at the application site, confirming that the BabyOrgano Natural Cold Relief Roll - On was non - irritant to the skin.

4. Discussion

When evaluating the safety of a cold relief roll - on, particularly one containing essential oils, it is crucial to assess its potential to cause skin irritation. Essential oils, while known for their therapeutic properties, are potent and can sometimes be associated with skin sensitivity or irritation. However, in case of BabyOrgano Natural Cold Relief Roll - On, the formulation is designed for external application, typically on sensitive areas such as the chest, neck, or back, where it can deliver targeted relief from cough and cold symptoms without being absorbed systemically.

The key to ensuring that a roll - on remains non - irritating lies in its formulation. Essential oils used in these products are typically diluted with carrier oil or other skin - friendly ingredients that reduce their potential irritancy while preserving their therapeutic effects. By balancing the concentration of essential oils with suitable natural base, the formulation ensures that the roll - on provides effective relief without compromising skin integrity. Additionally, cold relief roll - ons are often subjected to clinical tests to evaluate their skin irritation potential, ensuring they are safe for use even on sensitive skin, including that of infants and young children.

An ethical method for accurately predicting the likelihood of skin irritation in many skin care product categories, including baby care items, is to conduct patch testing on healthy adult participants. Thus, a well - formulated cold relief roll - on, while containing potent essential oils, can be both effective for respiratory relief and gentle on the skin, provided it meets safety standards through rigorous dermatological testing. In conclusion, **BabyOrgano Natural Cold Relief Roll - On** was tested dermatologically as per BIS standard IS 4011: 2018 by the Pediatrician & Dermatologist and was found non - irritant with 24 - hour Primary Irritation Patch Test.

References

[1] Bonifant H, Holloway S. A review of the effects of ageing on skin integrity and wound healing. Br J Community Nurs.2019 Mar 01; 24 (Sep3): S28 - S33.
[2] Herskovitz I, Macquhae F, Fox JD, Kirsner RS. Skin movement, wound repair and development of engineered skin. Exp Dermatol.2016 Feb; 25 (2): 99 - 100.
[3] PDQ Cancer Genetics Editorial Board. PDQ Cancer Information Summaries [Internet]. National Cancer Institute (US); Bethesda (MD): Jun 25, 2024. Genetics of Skin Cancer (PDQ®): Health Professional Version.
[4] Karimkhani C, Dellavalle RP, Coffeng LE, et al. Global skin disease morbidity and mortality: an update from the global burden of disease study 2013. JAMA Dermatol.2017; 153 (5): 406–412.
[5] Vora R, Bodiwala N, Patel S, Krishna S. Prevalence of various dermatoses in school children of Anand district. National J Commun Med.2012; 3 (1): 100–103
[6] Kong F, Galzote C, Duan Y. Change in skin properties over the first 10 years of life: a cross - sectional study. Arch Dermatol Res.2017; 309 (8): 653–658.