

PEDIATRIC DERMATOLOGICAL SAFETY OF BABYORGANO HING ROLL-ON: A CLINICAL TRIAL ON HEALTHY HUMAN VOLUNTEERS

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ABSTRACT

The skin irritation potential of BabyOrgano Hing Roll-On, a natural topical remedy designed to alleviate colic and digestive discomfort in infants, was assessed through a single-application patch test on healthy adult human subjects. In this skin irritation potential Clinical trial involving 24 volunteers. Patch testing was performed using three patches: Patch 1 with BabyOrgano Hing Roll-On, Patch 2 as a negative control (0.9% isotonic saline), and Patch 3 as a positive control (1% sodium lauryl sulfate). Patches were applied for 24 hours and skin reactions were evaluated at multiple time points: T0 (baseline), T1 (immediate post-removal), T2 (24 hours post-removal), and T8 (one-week post-removal). Reactions were assessed by both a pediatrician and a dermatologist using the Draize scale for erythema and oedema. The primary endpoint was the total irritation score 24 hours after patch removal. Results showed no

skin irritation (mean score = 0) with Patch 1 and Patch 2, while Patch 3 showed a mean irritation score of 4.33, confirming its expected irritant response. No adverse events, dropouts, or delayed reactions were observed. These findings confirm that BabyOrgano Hing Roll-On is dermatologically safe and non-irritant for application on human skin, supporting its suitability for use in pediatric populations.

KEYWORDS: BabyOrgano, Hing Roll-On, dermatologically tested, Pediatrician tested, Colic Pain, Patch test.

1. INTRODUCTION

Crying is one of the earliest and most powerful forms of communication for newborn infants. Crying connects them to their caregivers, who are their primary source for protection and nurture, this evolutionarily selected behavior probably increases infants' chances of survival.^[1,2] The pattern of early crying (during the first 3 months of life) is not modified by caretaking style, in contrast to the amount of crying later in the first year of life.^[5,6-9] Therefore, the crying of infants during the first months of life is considered to reflect physiological maturational shifts in neurobehavioral development.^[6]

At this early stage in their development, infants are not yet able to meet their own needs. Infantile colic (IC) is a common problem in infancy that induces excessive crying in infants during the first few months of life^[3,4] Crying behavior as a result of intestinal dysbiosis would be facilitated by the microbiota–gut–brain axis that links the brain with peripheral intestinal functionalities in a bidirectional manner. Various signaling pathways are involved in this interaction, including neural, endocrine, immune and humoral signaling pathways.^[10,11] Through this axis, intestinal dysbiosis can affect central and enteric neuronal function, such as detection of pain in infants^[11,12] which could potentially have a role in excessive crying.^[13] Prevalence rates in prospective studies varies from 3% to 28% and in retrospective studies from 8% to 40%. *Udarshoola* (colic) as the child rejects the breast, cries, sleeps in supine position, has stiffness of abdomen, (feeling) of cold and perspiration of face. Whereas other texts described, the significant factor responsible for the genesis of *Shoola* as *Vata* (*vayu*), detailed etiopathogenesis about 8 types of *Shoola*, and the clue for the management of *Udarshoola*. The condition is more common among first born and active babies of anxious parents or grandparents.

In *Ayurveda*, pain in and around the navel is called **colic** and is generally associated with constipation. In infants, the *dhatu* (body tissue) is still new and developing; Also, the *Agni* (digestive fire) is low or mand. This means that they cannot digest everything that is consumed by the mother or the formula food that is given to baby. Sometimes faulty feeding technique may develop Aerophagia.

BabyOrgano Hing Roll-On, specially formulated for babies and young children, is designed to support digestive comfort and ease colic-related discomfort. When applied to the abdomen, it can influence the skin's barrier properties, aiding the absorption of its natural active ingredients like *hing* (*asafoetida*), known for its soothing and carminative effects. Digestive issues such as colic, gas, and bloating are common in infants and toddlers, especially during the early stages of development when their digestive systems are still maturing. These conditions can be particularly distressing for young children, who are unable to express their discomfort clearly, often resulting in prolonged crying and parental concern. Gentle, timely intervention with a natural remedy like **BabyOrgano Hing Roll-On** can provide quick relief and comfort, helping child feel at ease without the use of harsh chemicals or oral medications.

Children's skin is more delicate and physiologically different from adult skin, making it more susceptible to irritation, inflammation, and minor injuries—particularly in areas like the abdomen, where products such as **BabyOrgano Hing Roll-On** are commonly applied. As children grow, the natural protective qualities of their skin, including softness and resilience, may diminish, increasing their vulnerability to dermatological conditions. Digestive discomfort is a common concern among infants and young children, in regions like India, often managed through traditional remedies like *Hing* (*asafoetida*). However, increased exposure to environmental factors and potential allergens necessitates careful consideration when applying topical products. The formulation of **BabyOrgano Hing Roll-On** is designed to be both gentle and effective, but due to the increased dermal absorption potential in young skin, safety assessments often assume full (100%) skin penetration in the absence of precise data. This highlights the importance of using only natural, toxin-free ingredients in pediatric products to minimize any risk while providing fast, soothing relief from colic and gas-related discomfort.

The skin acts as a critical barrier between the body and the external environment, providing protection against physical trauma, regulating water loss, and minimizing the penetration of irritants and allergens.^[14] In infants, the skin barrier is still developing, making it more susceptible to irritation and permeability changes. *Hing*-based topical applications, such as **BabyOrgano Hing Roll-On**, come into direct contact with the dermis and must be formulated with consideration for primary and cumulative irritation potential. Primary irritation refers to the response following initial contact, often manifesting as erythema or

mild inflammation, while cumulative irritation develops with repeated exposure.^[15] Infant skin, compared to adult skin, is significantly more permeable due to a thinner stratum corneum (up to 30% thinner) and epidermis (up to 20% thinner), as well as a higher surface pH at birth, which only gradually normalizes over the first year of life.^[16,17] These physiological differences increase the likelihood of dermal absorption and potential reactivity to topical products. A healthy infant skin barrier depends on adequate lipid lamellae synthesis and low protease activity—both of which are essential for maintaining skin integrity and reducing irritation risk.^[18] Therefore, BabyOrgano Hing Roll-On is formulated using natural, non-toxic ingredients to provide effective colic relief while aligning with the unique dermatological needs of infants.

Furthermore, even when colic is present, the severity is generally localized and does not significantly compromise the skin's barrier function. This paper reviews existing literature and historical data on infantile colic, including its frequency, typical duration, and associated behavioral symptoms such as prolonged crying and abdominal discomfort. The implications of colic-related stress on dermal absorption are also considered, noting that the extent of skin permeability varies depending on the physicochemical properties of applied substances. This comprehensive approach enhances our understanding of the relationship between gastrointestinal discomfort and pediatric skin health. It includes the evaluation of topical formulations through dermatologically and pediatrician-tested protocols, such as patch testing, to assess potential skin reactions. These assessments ensure that products like **BabyOrgano Hing Roll-On** are both safe and effective, providing natural relief without compromising the delicate skin of infants and young children.

2. MATERIAL AND METHODS

Evaluate the irritation potential of BabyOrgano Hing Roll On on healthy human subjects by Single application patch test method. (Primary irritation patch test). The evaluation of the product 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 problem. The investigation was approved and that informed consent was obtained.

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 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.

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

Trial Endpoints

Primary Endpoint

- Change in Skin Irritation Score- erythema and oedema.

Safety Endpoints

Safety endpoints include the following.

- Assessment and reporting of the Adverse Events.
- Tolerability of Test product.

2.1 Subject Population

24 subjects will be enrolled to provide about 24 completed subjects evaluable for the primary analysis. An individual subject will be allowed to participate in the trial once. Each potential subject will sign an informed consent document before any trial-specified procedures are performed. Subjects will provide authorization for the use of their data by the applicable regulations regarding privacy and data protection.

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

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 trial.

2.2 Investigational Product

BabyOrgano Hing Roll On

2.3 Comparator Product

1. Negative Control (0.9% Isotonic Saline Solution)
2. Positive Control (1% Sodium Lauryl Sulphate)

Testing Regimen

- Wash hands with disinfectant.
- The patch application was carried out at T0 by the CRC.
- Began application of the strip from the bottom, pressing the rooms up to release the 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.

2.4 Patch Assessment

Patch Preparation The patches were prepared in the morning of the application one hour before the visit i.e at T0.

Table 2: Patch Preparation.

Products	Patch no (finn chamber)	Application frequency	Application duration
BabyOrgano Hing 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

2.4.1 Patch Application

1. Approx. 0.04ml (40microliter) of test sample was measured with the help of micropipette.

2. 0.04ml or 40 microliters of the test sample was transferred on previously numbered fin chambers.
3. Finn chamber with an appropriately sized disc of whatsmann no.3 filter paper with the help of Micropipette.
4. The fin chambers with the product loaded filter paper disc were taped onto the back of the subjects.

The patch application was carried out by the CRC.

- The Pediatrician and the Dermatologist determined and the site that poses to be the most appropriate based on moles, body hair, freckles of the selected area was sound, without excessive hair growth.
- Location of patch application: between scapula and waist.
- The application of the patches was made as follows by the CRC:
 - Hands were washed with disinfectant.
 - The fin chambers/patches were applied.
 - Then the tape was fully in place, each patch was gently pressed containing a test product or control, to ensure an even distribution of the substance.
 - Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
 - The applications of patches were strengthened by applying micro tape on all four sides of patch.

2.4.2 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:

Table 3: Kinetic Evaluation.

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

2.4.3 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 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.



2.4.4 Studied Area and Location

The patches were applied on the on applied the top of the back of the shoulder blade. The Pediatrician and the Dermatologist determined the best area to apply the patch, depending on the naevi, the pilosity and the freckles. The selected area was the healthy, without an excessive pilosity. Patches were not applied on a back. The patches were applied on the right or left part of the back: the side was mentioned in the CRF by the investigator(s).

Position of the subject: It was recommended that the subject sat with the back slightly bent forward.

The CRA removes the patch from the bottom to the top. The area is gently wipe off with a soft tissue paper. The skin reaction was assessed under a constant artificial daylight source. The Investigator(s) scored the 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)

Table 4: Scoring of skin irritation test.

Score of erythema /dryness/wrinkles	Reaction	Score of oedema	Reaction
0	No reaction	0	No reaction
1	Very slight erythema / dryness with shinny 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

Erythema Scoring After the 24 hours of Patch removal, and on day 8, the Erythema Assessment was done with a Dermatologist/Pediatrician as below Scoring table.

Table 5: Patch Preparation.

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

Oedema Scoring

After the 24 hours of Patch removal, and on day 8, the Oedema Assessment was done with a Physician/Pediatrician as below Scoring table.

Table 6: Oedema Scoring.

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

3. RESULTS AND OBSERVATIONS

Out of 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects who underwent the testing process.

Table 7: Subject disposition details.

S. No	Variable	Number of subjects
1	No. of subjects screened for study	24
2	No. of subject's screen failure	0
3	No. of subjects enrolled in the study	24
4	Number of subjects completed the Study	24

Table 8: Study dates/schedules.

S. No	Schedule	Dates
1.	First subject ICF date	03 Feb 2025
2.	Last subject ICF date	03 Feb 2025
3.	First subject screening date	03 Feb 2025
4.	Last subject screening start date	03 Feb 2025
5.	Date of first subject completed study	11 Feb 2025
6.	Date of Last subject completed study	11 Feb 2025

Demographic and Other Baseline Characteristics The mean age of the subjects was 32.5 years. The mean height of the subjects was 157.5 cm. The mean weights of the subjects were 67 kg.

Table 9: Demographic characteristics.

S. No.	Demographics	Variable	(N=24)
1.	Age	Mean	32.5
		Min	21
		Max	43
2	Height	Mean	157.5
		Min	142
		Max	170
3	Weight	Mean	67
		Min	49
		Max	80

Dermatology Evaluation Results

Erythema Scoring (24 hours after Patch Removal).

Table 10: Project Number: CCFT480.

Products Under Experiment				
Patch 1 product- BabyOrgano Hing Roll On				
Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution				
Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate				
Scoring Day 2: Erythema/ Dryness/ Wrinkle- 5 Point scale [0-4] * 24 Hours After Patch Removal				
S.NO.	Subject ID	Patch 1	Patch 2	Patch 3
1	SM01	0	0	3
2	PR02	0	0	2
3	MA03	0	0	2
4	PR04	0	0	3
5	KH05	0	0	2
6	RI06	0	0	1
7	AH07	0	0	2
8	SO08	0	0	1
9	IT09	0	0	3
10	AZ10	0	0	2
11	AK11	0	0	3
12	AH12	0	0	2
13	SV13	0	0	1
14	TV14	0	0	1
15	SG15	0	0	2
16	VW16	0	0	3
17	KG17	0	0	2
18	PL18	0	0	3
19	PE19	0	0	2
20	DI20	0	0	3
21	VH21	0	0	3
22	SA22	0	0	1
23	VS23	0	0	3
24	AU24	0	0	1
Total erythema score		0	0	51

Oedema Scoring (24 hours after Patch Removal).

Table 11: Project Number: CCFT480.

Products Under Experiment				
Patch 1 product- BabyOrgano Hing Roll On				
Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution				
Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate				
Scoring Day 2: Oedema- 5 Point scale [0-4] * 24 Hours After Patch Removal				
S.NO.	Subject ID	Patch 1	Patch 2	Patch 3
1	SM01	0	0	2
2	PR02	0	0	2
3	MA03	0	0	2
4	PR04	0	0	3
5	KH05	0	0	2
6	RI06	0	0	1
7	AH07	0	0	2
8	SO08	0	0	2
9	IT09	0	0	3
10	AZ10	0	0	3
11	AK11	0	0	2
12	AH12	0	0	2
13	SV13	0	0	1
14	TV14	0	0	2
15	SG15	0	0	2
16	VW16	0	0	2
17	KG17	0	0	2
18	PL18	0	0	2
19	PE19	0	0	4
20	DI20	0	0	2
21	VH21	0	0	3
22	SA22	0	0	2
23	VS23	0	0	3
24	AU24	0	0	2
Total erythema score		0	0	53

Table 12: Overall Result.

Parameter- day 2 scores	Patch 1	Patch 2	Patch 3
Total Erythema Score	0	0	51
Total Oedema Score	0	0	53
Erythema + Oedema	0	0	104
Erythema + Oedema/24	0	0	4.33
Results/Conclusion	Non-irritant	Non-irritant	Irritant

Mean Score	Conclusion
Upto 2.0	Non-irritant
2.0 to 4.0	Mild -Irritant
Above 4.0	Irritant

Mean Irritation Score= (Erythema Score + Oedema Score)/Number of Test Subjects)

**Fig. 1: Irritation.**

Table 13: Project Number: - CCFT480.

Products Under Experiment								
Patch 1 product- BabyOrgano Hing Roll On								
Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution								
Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate								
S. No.	Subject Id	TEST (E/O)	Patch 1		Patch 2		Patch 3	
			Day2	Day8	Day2	Day8	Day2	Day8
		E	0	0	0	0	3	0
1	SM01	O	0	0	0	0	2	0
		E	0	0	0	0	2	0
2	PR02	O	0	0	0	0	2	0
3		E	0	0	0	0	2	0
	MA03	O	0	0	0	0	2	0
4		E	0	0	0	0	3	0
	PR04	O	0	0	0	0	3	0
5		E	0	0	0	0	2	0
	KH05	O	0	0	0	0	2	0
6		E	0	0	0	0	1	0
	R106	O	0	0	0	0	1	0
7		E	0	0	0	0	2	0
	AH07	O	0	0	0	0	2	0
8		E	0	0	0	0	1	0
	SQ08	O	0	0	0	0	2	0
9		E	0	0	0	0	3	0
	IT09	O	0	0	0	0	3	0
		E	0	0	0	0	2	0
10	AZ10	O	0	0	0	0	3	0
11		E	0	0	0	0	3	0
	AK11	O	0	0	0	0	2	0
12		E	0	0	0	0	2	0
	AH12	O	0	0	0	0	3	0
13		E	0	0	0	0	1	0
	SV13	O	0	0	0	0	2	0
14		E	0	0	0	0	1	0
	TV14	O	0	0	0	0	2	0
		E	0	0	0	0	2	0
15	SG15	O	0	0	0	0	1	0
16		E	0	0	0	0	3	0
	VW16	O	0	0	0	0	2	0
17		E	0	0	0	0	2	0
	KG17	O	0	0	0	0	2	0
18		E	0	0	0	0	3	0
	PL18	O	0	0	0	0	2	0
		E	0	0	0	0	3	0
19	PE19	o	0	0	0	0	2	0
20		E	0	0	0	0	2	0
	DI20	O	0	0	0	0	2	0
21		E	0	0	0	0	3	0

	VH21	o	0	0	0	0	4	0
22		E	0	0	0	0	1	0
	SA22	O	0	0	0	0	2	0
23		E	0	0	0	0	3	0
	VS23	O	0	0	0	0	3	0
24		E	0	0	0	0	1	0
	AU24	O	0	0	0	0	2	0

4. DISCUSSION

Out of 24 subjects screened, none were found screen failures, none were dropouts. 24 subjects underwent the Trial.

The mean age of the subjects was 32.5 years. The mean height of the subjects was 157.5 cm. The mean weights of the subjects were 67 kg. Data from all 24 subjects who completed the study were analyzed.

The primary end point change in the Erythema & Oedema Score was calculated as total irritation score was measured at 24 hours after the patch removal.

Patch 1 product- BabyOrgano Hing Roll On showed/was found non-Irritant to the skin.

Patch 2 product (Negative Control)- 0.9% Isotonic Saline Solution showed/was found non-Irritant to the skin.

Patch 3 product (Positive Control)- 1% Sodium Lauryl Sulphate showed/was found Irritant to the skin.

There were no subjects lost to follow up.

There was no subject who withdrawn the consent.

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