

Evaluating the dermal safety and skin compatibility of personal care cosmetic products formulated with natural ingredients: An in-vivo primary irritation patch test study.

Manisha Mishra¹, Nayan Patel², Ipsa Pandya³, Raji Patil⁴, Maheshvari Patel^{5*}

¹Medical Advisor, Department of Medical Advisors, Vedistry Private Limited. 21, Evergreen Industrial estate, Shakti mills lane, Mahalaxmi, Mumbai, India

²Medical Director, Department of Clinical Trials, NovoBliss Research Private Limited, Shaligram Lakeview, Nr. Vaishnodevi Circle, Khoraj, Gandhinagar, India

³Consultant Dermatologist, Department of Consumer Research, Clantha Research, Garden View, Auda Garden, Bodakdev, Ahmedabad, India

⁴Dermatologist, Department of Clinical Research, MASCOT-SPINCONTROL INDIA PVT. LTD., Kohinoor Estate, Lower Parel-West, Mumbai – 400013, India.

⁵Director Operations, Department of Clinical Trials, NovoBliss Research Private Limited, Shaligram Lakeview, Nr. Vaishnodevi Circle, Khoraj, Gandhinaga, India

Abstract

Background: Cosmetic products have been widely used by the public for an extended period, emphasizing the high importance of ensuring their safety. Although cosmetic ingredients undergo skin irritation testing before entering the market, there is no obligatory mandate for producers to conduct final formulation testing.

Objective: The aim of this investigation was to assess the potential dermal irritation in individuals with diverse skin types when exposed to cosmetics and personal care formulations with natural ingredients. This evaluation utilized a single 24-hour application patch test method on healthy human subjects.

Methods: The dermal irritation potential of 26 personal care products of Vedistry Private Limited was tested following ethical principles and guidelines for Good Clinical Practice, IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics, CHD 25: Soaps and Other Surface-Active Agents Sectional Committee (first revision) and IS 13424:2001 Safety evaluation of bathing bars and toilet soaps. The products were applied on the subject's back region i.e., between the scapula and waist. Application sites were evaluated for scoring the reaction, namely, erythema, dryness, wrinkles on a 0–4-point scale separately for each parameter and oedema on another 0–4 points scale as per the Draize Scale after 30+5 minutes of patch removal, 24±2 hours. The mean irritation score was computed through an excel-based calculation method.

Results: At both 30 minutes and 24 hours after removing the patches containing test products and controls, all 26 test products with a mean irritation score below 2.0 were determined to be non-irritating and safe for skin use. The negative control, showing a mean irritation score below 2.0, was confirmed as non-irritant. Conversely, the positive controls, which exhibited a mean irritation score surpassing 2.0, were identified as mild irritants at both the 30-minute and 24-hour assessments following patch removal. No subjects experienced serious adverse events or test product-related adverse event.

Conclusion: Vedistry's moha: Personal care product line, crafted with natural ingredients for both skin and hair care, adheres to dermatological safety standards. Following a 24-hour primary irritation patch test conducted under occlusion, these products are classified as non-irritating, skin-compatible, and safe for diverse skin types-ranging from oily and mixed to dry, normal, and sensitive.

Keywords: Natural Ingredients, Cosmetics, Patch Testing, Irritation, Personal Care, Dermal Safety, Dryness.

*Correspondence to: Maheshvari Patel, Department of Clinical Trials, NovoBliss Research Private Limited, Ahmedabad, India. E-mail: maheshvari@novobliss.in, maheshvaripatel3@gmail.com

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Introduction

The increasing use of cosmetics and personal care products is driven by the desire for improved skin texture and enhanced attractiveness, addressing emotional and self-esteem concerns. With the growing popularity of these products, there's a rise in the incidence of unwanted effects, primarily mild to moderate skin irritation reactions. Hence, cosmetic product used in the market since the long period of time by the public, and the safety of the cosmetic products are more important. While cosmetic ingredients undergo skin irritation testing before marketing, there's no mandatory requirement for final formulation testing by producers [1,2]. Personal care products formulated with natural ingredients have gained popularity in recent years due to their perceived benefits. Additionally, these products are believed to be safer and better for the environment than synthetic alternatives [3]. Clinical studies evaluating the efficacy of personal care products formulated with natural ingredients have been conducted. For instance, a study evaluated the use of natural antioxidant extracts in personal care products such as hand cream, body oil, shampoo, clay mask, body exfoliating cream, and skin cleanser. The study found that these products were well-received by participants and showed promise in terms of their antioxidant properties [4]. Herbal personal care products contain natural antioxidants like vitamin-C [5]. Thus, natural products are believed to be gentler on the skin and less likely to cause irritation or allergic reactions.

Different types of patch test are used to evaluate the safety of the cosmetic products like single patch test, in-use patch test, human repeated insult patch test (HRIPT). Patch test is mainly used to identify the etiological factors of allergic contact dermatitis. This is one of the most scientific method used for the investigation of contact dermatitis [6]. Patch testing is standard approach to evaluate the irritation and sensitization. In-Vitro testing, animal experiments and human experiments are used to evaluate the safety of the cosmetics. The human patch test is useful method to test the primary irritation in the human body caused by direct contact with the skin [7].

Several patch testing studies were undertaken to evaluate the safety of different ranges of personal care products formulated based on natural ingredients for skin and hair including moha: Herbal Face Wash, moha: Herbal Scrub, moha: Aloe Vera Gel, moha: Rose Mist, moha: Herbal Lip Balm, moha: Herbal Sunscreen Lotion With SPF 50, moha: Moisturizing Lotion, moha: Soap, moha: Rose And Almond Soap, moha: Scrub Soap, moha: Herbal Shower Gel, moha: Rejuvenating Massage Oil, moha: Foot Care Cream, moha: Nail Care Cream, moha: 5 In 1 Hair Oil, moha: Anti- Dandruff Hair Oil, moha: Herbal Shampoo, moha: Herbal Anti-Dandruff Shampoo, moha: Sulfate Free Herbal Shampoo, moha: Herbal Hair Conditioner, moha: Herbal Hair Serum, moha: Herbal Radiance Face Mask, moha: Overnight Lotion, moha: Skin Cream, moha: Hydrating Face Serum, moha: Sunscreen Spray. The details of these study test products are provided in (Table 1).

These investigations involved adult participants spanning the age range of 18 to 65 years, encompassing diverse skin types such as sensitive, oily, dry, combination, and normal.

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Material and Methods

Study design and ethical consideration

The dermal safety studies were conducted at a single center and had a blinded dermal evaluator designated to assess the safety of the test products on healthy adult human subjects aged 18-65 years with varied skin types (oily, dry, normal and combination) and only sensitive skin for one test product. The studies adhered to ethical standards outlined by the Indian Council of Medical Research (ICMR), Good Clinical Practice (GCP) R2, the Declaration of Helsinki, and the method adhered to Bureau of Indian Standards (BIS), including PCD 19: Cosmetics (third revision) and IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics [8]. Additionally, compliance was ensured with CHD 25: Soaps and Other Surface-Active Agents Sectional Committee (first revision) and IS 13424:2001 Safety evaluation of bathing bars and toilet soaps [9].

Before commencing the study, a thorough review of essential documents, including the master Protocol (Version#01 - Final), Informed Consent Form (Version#01 - Final), Case Report Form (Version#01 - Final), Log-sheets (Version#01 - Final), protocol appendices were undertaken and approval from an Independent Ethics Committee (IEC) was successfully obtained. The studies were officially registered with the Clinical Trial Registry India (CTRI) except for few products (Table 2). Subjects provided written, informed consent before being enrolled in the study.

Participation criteria

The subjects were pre-screened per inclusion and exclusion criteria. The female and male subjects aged 18-65 years having healthy skin (free of eczema, wounds, inflammatory scar) on the studies anatomic site with no infectious and evolutive pathology which could make the subject vulnerable and stop the study, no pathology which could interfere with the study, no symptom in the process of an exploratory check-up were enrolled in the study. Subjects who had history of diabetes, asthma or Chronic obstructive pulmonary disease (COPD), skin disease including eczema, atopic dermatitis, lichen planus, vitiligo or active cancer and mastectomy involving removal of lymph nodes within past year, or treatment of any active type of cancer within the last 6 months or with known allergy to perfumes or any cosmetic products, plaster, food, having miliaria, too many naevus, or high pilosity on the back were excluded. For Sunscreen spray, additional criteria included the evaluation using Baumann's questionnaire to identify the subjects with sensitive skin.

Patch application and removal of test products

Total 26 test products were tested in different studies along with the positive control i.e. 1% SLS solution and 3% SLS solution and negative control i.e. 0.9% isotonic saline solution. The description of the study products is shown in (Table 3). The test sites were cleaned with distilled water and water before the test product application.

To apply the Sunscreen Spray, a 1cm 2 disc of Whatman number 3 filter paper was positioned on the subjects' backs.

Table 1: Details of the products.

Sl.No	Name of the Product	Key Ingredients
1.	moha: Herbal Face Wash	Neem, Aloe Vera, Rose, Cucumber, Liquorice
2.	moha: Herbal Scrub	Walnut shell, Orange Peel, Nutmeg Oil, Rose, Olive Oil
3.	moha: Aloe Vera Gel	Aloe Vera, Rose, Cucumber
4.	moha: Rose Mist	Rose, Aloe Vera
5.	moha: Herbal Lip Balm	Apricot Oil, Almond Oil, Wheatgerm Oil, Olive Oil, Honey
6.	moha: Herbal Sunscreen Lotion with SPF 50	Aloe Vera, Sunflower Oil, Rice Bran Oil, Wheatgerm Oil
7.	moha: Moisturizing Lotion	Almond Oil, Sunflower Oil, Aloe vera
8.	moha: Soap	Aloe Vera, Neem, Tulsi
9.	moha: Rose and Almond Soap	Rose, Almond Oil, Wheatgerm Oil, Pomegranate
10.	moha: Scrub Soap	Almond Oil, Honey, Walnut Shell
11.	moha: Herbal Shower Gel	Aloe Vera, Tea Tree Oil, Argan Oil, Orange Peel
12.	moha: Rejuvenating Massage Oil	Almond Oil, Olive Oil, Jojoba Oil, Evening Primrose Oil, Sunflower Oil
13.	moha: Foot Care Cream	Aloe Vera, Papaya, Peppermint Oil, Kapurkachri
14.	moha: Nail Care Cream	Almond Oil, Flaxseed Oil
15.	moha: 5 In 1 Hair Oil	Coconut Oil, Almond Oil, Jojoba Oil, Argan Oil, Wheatgerm Oil, Hibiscus Oil, Tea Tree oil, Sesame Oil
16.	moha: Anti- Dandruff Hair Oil	Neem, Rosemary Oil, Hibiscus Oil, Water Lily Oil, Tea Tree Oil
17.	moha: Herbal Shampoo	Amla, Aloe Vera, Brahmi, Bhringraj
18.	moha: Herbal Anti-Dandruff Shampoo	Tea Tree Oil, Hibiscus Oil, Neem Oil, Kapurkachri Oil
19.	moha: Sulfate Free Herbal Shampoo	Hydrolysed Keratin, Aloe Vera, Sunflower Oil, Argan Oil, Green Tea
20.	moha: Herbal Hair Conditioner	Aloe Vera, Wheatgerm Oil, Jojoba Oil, Almond Oil, Olive Oil
21.	moha: Herbal Hair Serum	Hibiscus Oil, Flaxseed Oil, Water Lily Oil
22.	moha: Herbal Radiance Face Mask	Multani Mitti, Mulberry, Aloe Vera, Orange Peel, Manjistha, Liquorice, Turmeric
23.	moha: Overnight lotion	Olive Oil, Aloe Vera, Papaya, Wheatgerm, Avocado, Shallaki, Soya, Liquorice
24.	moha: Skin Cream	Aloe Vera, Almond Oil, Wheatgerm Oil
25.	moha: Hydrating Face Serum	Hyaluronic Acid, Papaya Extract, Liquorice Extract, Rice Bran Extract, Bamboo Extract
26.	moha: Sunscreen Spray	Rice Bran Oil
Storage Details of All Test Products		
Storage condition		The test product was stored in cool and dry place below 25 ° C.
Route of Administration		Topical
Manufactured by		Charak Pharma Private Limited
Marketed by		Vedistry Private Limited, Vedistry is a part of Charak Pharma, pioneers for Ayurveda an herbal medicine.

Table 2. Study Test Products, Site Information with CTRI Registration Numbers.

Sl.No	Study Test Product Name	Study Site	Study Period	CTRI Registration No.
1	moha: Herbal Face Wash	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
2	moha: Herbal Scrub	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
3	moha: Aloe Vera Gel	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
4	moha: Rose Mist	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
5	moha: Herbal Lip Balm	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
6	moha: Herbal Sunscreen Lotion with SPF 50	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
7	moha: Moisturizing Lotion	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
8	moha: Soap	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
9	moha: Rose and Almond Soap	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
10	moha: Scrub Soap	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
11	moha: Herbal Shower Gel	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
12	moha: Rejuvenating Massage Oil	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
13	moha: Foot Care Cream	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
14	moha: Nail Care Cream	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
15	moha: 5 In 1 Hair Oil	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
16	moha: Anti- Dandruff Hair Oil	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
17	moha: Herbal Shampoo	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
18	moha: Herbal Anti-Dandruff Shampoo	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
19	moha: Sulfate Free Herbal Shampoo	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
20	moha: Herbal Hair Conditioner	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783
21	moha: Herbal Hair Serum	Cliantha Research	10 Nov 21-17 Nov 21	CTRI/2021/11/037783

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22	moha: Herbal Radiance Face Mask	Cliantha Research	11 Mar 22–18 Mar 22	CTRI/2022/03/040961
23	moha: Overnight lotion	Cliantha Research	11 Mar 22–18 Mar 22	CTRI/2022/03/040961
24	moha: Skin Cream	Cliantha Research	11 Mar 22–18 Mar 22	CTRI/2022/03/040961
25	moha: Hydrating Face Serum	Mascot-Spincontrol India Pvt. Ltd.	20 Sep 23–28 Sep 23	Not Registered
26	moha: Sunscreen Spray	Mascot-Spincontrol India Pvt. Ltd.	20 Sep 23–28 Sep 23	Not Registered

Table 3. Products Description.

Sl.no	Product Name	Batch#	Type of Product	Mfg. Date	Exp. Date	Concentration of test product applied
1	moha: Herbal Face Wash	CF041	Gel	Jun-21	May-23	8% w/v sample solution
2	moha: Herbal Scrub	CR025	Cream	Jul-21	Jun-23	Neat
3	moha: Aloe Vera Gel	CE025	Gel	Jul-21	Jun-23	Neat
4	moha: Rose Mist	LRO018	Clear Liquid	Feb-21	Jan-23	Neat
5	moha: Herbal Lip Balm	CL004	Semisolid	Jan-21	Dec-23	Neat
6	moha: Herbal Sunscreen Lotion with SPF 50	CU008	Lotion	Jan-21	Dec-23	Neat
7	moha: Moisturizing Lotion	CM019	Lotion	Apr-21	Mar-24	Neat
8	moha: Soap	EMH059	Soap	Jun-21	May-23	8% w/v sample solution
9	moha: Rose and Almond Soap	EMR002	Soap	Aug-21	Jul-23	8% w/v sample solution
10	moha: Scrub Soap	EMS006	Soap	May-21	Jul-23	8% w/v sample solution
11	moha: Herbal Shower Gel	CW029	Clear Liquid	Apr-21	Mar-23	8% w/v sample solution
12	moha: Rejuvenating Massage Oil	ORE031	Oil	Apr-21	Mar-24	Neat
13	moha: Foot Care Cream	CC006	Cream	Aug-21	Jul-24	Neat
14	moha: Nail Care Cream	CN003	Cream	Jul-21	Jun-24	Neat
15	moha: 5 In 1 Hair Oil	OMH024	Oil	Jul-21	Jun-24	Neat
16	moha: Anti- Dandruff Hair Oil	OAN027	Oil	Jan-21	Dec-22	Neat
17	moha: Herbal Shampoo	CS047	Clear Liquid	May-21	Jul-23	8% w/v sample solution
18	moha: Herbal Anti-Dandruff Shampoo	CA016	Clear Liquid	May-21	Jul-23	8% w/v sample solution
19	moha: Sulfate Free Herbal Shampoo	CP001	Clear Liquid	Feb-21	Jan-23	8% w/v sample solution
20	moha: Herbal Hair Conditioner	CH021	Cream	Aug-21	Jul-23	8% w/v sample solution
21	moha: Herbal Hair Serum	CI006	Oil	Feb-21	Jan-23	Neat
22	moha: Herbal Radiance Face Mask	CJ001	Face Mask	Jan-22	Dec-23	Neat
23	moha: Overnight lotion	CB001	Lotion	Jan-22	Dec-23	Neat
24	moha: Skin Cream	CK001	Cream	Jan-22	Dec-23	Neat
25	moha: Hydrating Face Serum	WBSF0010	Liquid	Aug-23	N/AV	Neat
26	moha: Sunscreen Spray	PS001	Aerosol	Feb-23	Jan-25	Neat

About 0.02mL or 20µL of the test product was carefully deposited onto the filter paper disc in a drop wise fashion, and the remaining 0.02ml or 20µL was similarly applied. After complete evaporation of the product, the whatman#3 filter paper was removed, and the site was left undisturbed for up to thirty minutes before proceeding to occlude the patch.

For rinse-off products including moha: Soap, moha: Rose and Almond Soap, moha: Scrub Soap, moha: Herbal Shower Gel, moha: Herbal Face Wash, moha: Herbal Shampoo, moha: Herbal Anti-Dandruff Shampoo, moha: Sulfate Free Herbal Shampoo, and moha: Herbal Hair Conditioner, 0.04 mL of 8% w/v solution of test samples in distilled water was dispensed onto the centre of an appropriately sized filter paper placed in the designated IQ/Finn chambers prefixed to a micropore tape and was applied onto the back of the subjects [Figure 1].

Leave-On products i.e. moha: Herbal Scrub, moha: Aloe Vera Gel, moha: Rose Mist, moha: Herbal Lip Balm, moha: Herbal Sunscreen Lotion with SPF 50, moha: Moisturizing Lotion, moha: Rejuvenating Massage Oil, moha: Foot Care Cream, moha: Nail Care Cream, moha: 5 In 1 Hair Oil, moha: Anti- Dandruff Hair Oil, moha: Herbal Hair Serum, moha: Herbal Radiance Face Mask, moha: Overnight lotion, moha: Skin Cream, moha: Hydrating Face Serum were applied neat

onto the filter paper and were applied on the subject's back. Positive controls (1% SLS and 3% SLS) and negative control were applied in a similar fashion.

Single 24-hours application of test products along with positive and negative controls were kept in contact with the skin of subjects under complete occlusion for at least 24 hours (+2 hours). Subjects were informed to follow study instructions and were asked return to the facility on day-2 for the patch removal process followed by application site cleaning with distilled water to remove any residue of test products. Irritation scoring was done 30 minutes and 24 (+2 hours) post patch removal on day-2 and day-3 respectively.

Dermal irritation scoring post patch removal

The total study duration was 9 days from the patch application day. Application sites were evaluated for scoring the reaction, namely erythema, dryness, wrinkles on 0-4 points scale separately for each parameter and oedema on another 0-4 points scale as per Draize scale mentioned in (Table 4), after 3+5 minutes and 24±2 hours of patch removal as mentioned in Methods of test for safety evaluation of cosmetics, reaffirmed (2004), Bureau of Indian Standards, PCD 19: Cosmetics [Third revision and IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics]. Subjects were

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contacted telephonically after 168±2 hours of patch removal for any signs of erythema, dryness, oedema and wrinkles and confirmation for the same have been taken from the subjects.

The highest score of erythema, dryness and wrinkles were taken for calculation of Mean Irritation Score (MIS). Mean Score for Irritation = Total score (highest score from erythema, dryness, wrinkles + oedema) for each sample / total no. of subjects.

The determination of final results for test products, positive, and negative controls was based on the Mean Irritation Score (MIS) obtained, following the guidelines outlined in BIS: PCD 19: Cosmetics (third revision) and IS 4011:2018 Methods of Test for Safety Evaluation of Cosmetics, specifically in accordance with clause 4.3.1.3. The test products with mean score less than 2.0/8.0, 2.0-4.0/8.0, and above 4.0/8.0 were considered as non-irritant, mild irritant and irritant respectively.

Scoring of irritation was conducted using a 100-watt incandescent blue bulb lamp as the artificial light source to illuminate the patch areas. The light lamp was 1 ft distance away from application site. The scorer was blinded as to treatment assignments and any previous scores.

Statistical methods

Subjects' demographic details were presented using descriptive statistics. For qualitative variables, frequencies and percentages were reported. Quantitative variables were summarized using means, medians, standard deviations, minimum and maximum values.

Results

The demographic characteristics of subjects such as gender, age, skin type was included in all the studies as shown in (Table 5).

There were total of 26 cosmetics and personal care products tested where out of twenty skin care products there was one

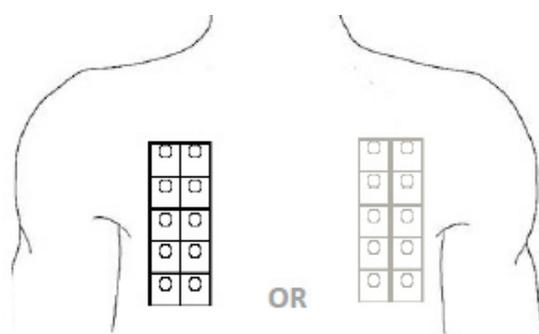


Figure 1: Patch Application.

Table 4: Draize Scale for Irritation Scoring.

Score for Erythema/ Dryness/ wrinkles (1)	Reaction-2	Score for Oedema (3)	Reaction-4
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/ wrinkle	3	Moderate oedema
4	Severe erythema/ wrinkle/ scale	4	Severe oedema

Table 5: Demographic inclusive to Age and Skin Type Distribution of Enrolled Subjects.

Demographic Details of Completed Subjects(N=26, Female = 13(50.00%) and Male = 13(50.00%)									
Sl.No	Name of the Product	Age distribution(%)			Skin Type n(%)				
		Mean(SD)	Median (Years)	Min, Max(Years)	Combination	Dry	Normal	Oily	Sensitive
1.	moha: Herbal Face Wash	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
2.	moha: Herbal Scrub	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
3.	moha: Aloe Vera Gel	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
4.	moha: Rose Mist	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
5.	moha: Herbal Lip Balm	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
6.	moha: Herbal Sunscreen Lotion with SPF 50	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
7.	moha: Moisturizing Lotion	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
8.	moha: Soap	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
9.	moha: Rose and Almond Soap	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
10.	moha: Scrub Soap	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)

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11.	moha: Herbal Shower Gel	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
12.	moha: Rejuvenating Massage Oil	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
13.	moha: Foot Care Cream	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
14.	moha: Nail Care Cream	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
15.	moha: 5 In 1 Hair Oil	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
16.	moha: Anti- Dandruff Hair Oil	39.(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
17.	moha: Herbal Shampoo	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
18.	moha: Herbal Anti-Dandruff Shampoo	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
19.	moha: Sulfate Free Herbal Shampoo	39.(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
20.	moha: Herbal Hair Conditioner	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
21.	moha: Herbal Hair Serum	39.5(9.85)	37	18, 58	7(26.92%)	6(23.08%)	7(26.92%)	6(23.08%)	0(0.00%)
22.	moha: Herbal Radiance Face Mask	38.76(11.18)	38	20, 58	7(26.92%)	6(23.08%)	6(23.08%)	7(26.92%)	0(0.00%)
23.	moha: Overnight lotion	38.76(11.18)	38	20, 58	7(26.92%)	6(23.08%)	6(23.08%)	7(26.92%)	0(0.00%)
24.	moha: Skin Cream	38.76(11.18)	38	20, 58	7(26.92%)	6(23.08%)	6(23.08%)	7(26.92%)	0(0.00%)
25.	moha: Hydrating Face Serum	25.8(8.1)	22	19, 44	0(0.00%)	0(0.00%)	26(100.00%)	0(0.00%)	0(0.00%)
26.	moha: Sunscreen Spray	30.60(10.30)	30	18, 53	0(0.00%)	0(0.00%)	0(0.00%)	0(0.00%)	26(100.00%)

Table 6: Mean Irritation Scores [MIS] for Each Tested Formulation.

Sl.No	Products Name	Mean Irritation Score		Irritancy Level	
		[Visit 02] 30 mins post-patch Removal	[Visit 03] 24 hours post-patch Removal	[Visit 02] 30 mins post-patch Removal	[Visit 03] 24 hours post-patch Removal
Clinical Study Conducted at Cliantha Research					
1	moha: Herbal Face Wash	0	0	Non-Irritant	Non-Irritant
2	moha: Herbal Scrub	0	0	Non-Irritant	Non-Irritant
3	moha: Aloe Vera Gel	0	0	Non-Irritant	Non-Irritant
4	moha: Rose Mist	0	0	Non-Irritant	Non-Irritant
5	moha: Herbal Lip Balm	0	0	Non-Irritant	Non-Irritant
6	moha: Herbal Sunscreen Lotion with SPF 50	0	0	Non-Irritant	Non-Irritant
7	moha: Moisturizing Lotion	0	0	Non-Irritant	Non-Irritant
8	moha: Soap	0.2	0.1	Non-Irritant	Non-Irritant
9	moha: Rose and Almond Soap	0.3	0.3	Non-Irritant	Non-Irritant
10	moha: Scrub Soap	0.3	0.3	Non-Irritant	Non-Irritant
11	moha: Herbal Shower Gel	0	0.1	Non-Irritant	Non-Irritant
12	moha: Rejuvenating Massage Oil	0	0	Non-Irritant	Non-Irritant
13	moha: Foot Care Cream	0	0	Non-Irritant	Non-Irritant
14	moha: Nail Care Cream	0	0	Non-Irritant	Non-Irritant
15	moha: 5 In 1 Hair Oil	0	0	Non-Irritant	Non-Irritant
16	moha: Anti- Dandruff Hair Oil	0	0	Non-Irritant	Non-Irritant
17	moha: Herbal Shampoo	0	0	Non-Irritant	Non-Irritant
18	moha: Herbal Anti-Dandruff Shampoo	0	0	Non-Irritant	Non-Irritant
19	moha: Sulfate Free Herbal Shampoo	0	0	Non-Irritant	Non-Irritant
20	moha: Herbal Hair Conditioner	0	0	Non-Irritant	Non-Irritant
21	moha: Herbal Hair Serum	0	0.1	Non-Irritant	Non-Irritant
22	Positive Control (1% SLS)	2.9	2.7	Mild-Irritant	Mild-Irritant
23	Positive Control (3% SLS)	4	3.8	Mild-Irritant	Mild-Irritant
24	Negative Control	0	0	Non-Irritant	Non-Irritant
Clinical Study Conducted at Cliantha Research					
25	moha: Herbal Radiance Face Mask	0	0	Non-Irritant	Non-Irritant
26	moha: Overnight lotion	0.1	0	Non-Irritant	Non-Irritant
27	moha: Skin Cream	0.1	0	Non-Irritant	Non-Irritant
28	Positive Control (1% SLS)	3	3.4	Mild-Irritant	Mild-Irritant
29	Negative Control	0	0	Non-Irritant	Non-Irritant
Clinical Study Conducted at Mscot SpinControl					
30	moha: Hydrating Face Serum	-	0.1	Non-Irritant	Non-Irritant

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31	Positive Control (1% SLS)	-	2.6	Mild-Irritant	Mild-Irritant
32	Negative Control	-	0	Non-Irritant	Non-Irritant
Clinical Study Conducted at Mscot SpinControl					
33	moha: Sunscreen Spray	-	0.4	Non-Irritant	Non-Irritant
34	Positive Control (1% SLS)	-	0	Non-Irritant	Non-Irritant
35	Negative Control	-	3.3	Mild-Irritant	Mild-Irritant

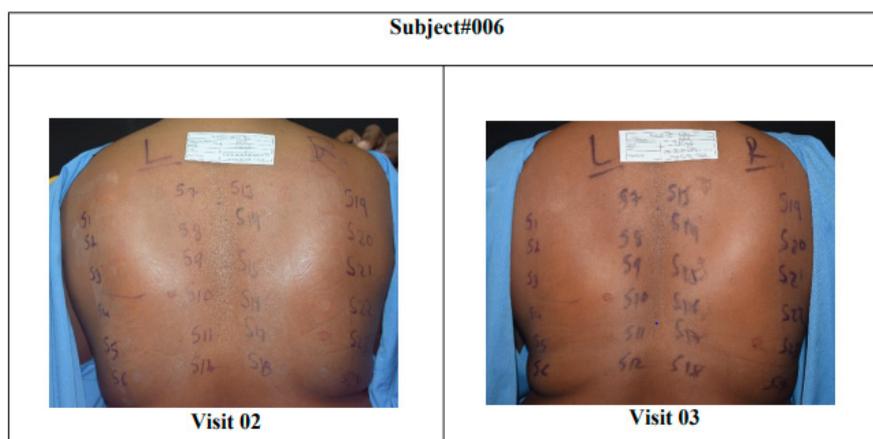


Figure 2: Images at 30 minutes and 24 hours Post Patch Removal.

face wash, one scrub, one gel, one mist, one lip balm, three lotion, three soap, one shower gel, one massage oil, one foot care cream, one nail care cream, two serum, one face mask, one cream, one sunscreen spray that included moha: Herbal Face Wash, moha: Herbal Scrub, moha: Aloe Vera Gel, moha: Rose Mist, moha: Herbal Lip Balm, moha: Herbal Sunscreen Lotion with SPF 50, moha: Moisturizing Lotion, moha: Soap, moha: Rose And Almond Soap, moha: Scrub Soap, moha: Herbal Shower Gel, moha: Rejuvenating Massage Oil, moha: Foot Care Cream, moha: Nail Care Cream, moha: Herbal Hair Serum, moha: Herbal Radiance Face Mask, moha: Overnight Lotion, moha: Skin Cream, moha: Hydrating Face Serum, moha: Sunscreen Spray and 6 hair care products i.e. two hair oil, three shampoo, one conditioner including moha: 5 In 1 Hair Oil, moha: Anti- Dandruff Hair Oil, moha: Herbal Shampoo, moha: Herbal Anti-Dandruff Shampoo, moha: Sulphate Free Herbal Shampoo, moha: Herbal Hair Conditioner, had mean irritation score less than 2.0 and hence were found to be non-irritant and safe on skin. The negative control with mean irritation score less than 2.0 and positive control with mean irritation score more than 2.0 had been found to be non-irritant and irritant respectively (**Table 6**).

Images of 30 minutes and 24 hours post patch removal have been shown in [Figure 2].

Safety Assessments

Adverse events

Throughout the study, no adverse events were reported by any of the subjects, leading to the conclusion that the products were safe for use and well-tolerated.

Discussion

The human skin is a very good barrier that is protective against environmental factors and different chemicals present

in pharmaceutical formulations and cosmetic products. Evaluation of the skin irritation and/or corrosion potential of the ingredients of a cosmetic product is necessary in order to assess its toxic effects and safety. Skin irritation can be seen after dermal use of cosmetic and personal care products. Other than skin irritation, allergic reactions and acne can also be seen after the use of cosmetics. Evaluating the skin irritant and/or corrosive properties of the end product can also be helpful in describing the potential hazard [10].

Numerous studies have highlighted that skincare products, including moisturizing and cleansing cream, lotion, are frequently implicated in cases of contact allergy to cosmetics. However, drug patch tests can be particularly valuable in identifying the specific ingredient or drug associated with various medical conditions. Soaps and shampoos are the most important types of cosmetics responsible for adverse reactions [11]. In this conducted study the cosmetic products including skin care and hair care products were tested for irritation potential and were found to be safe and non-irritant in nature on the study population. It is highly recommended that the cosmetic companies test the cosmetic product's ingredient for skin irritation potential before they market them but unfortunately, these end-product testing are not usually performed by the cosmetic companies. The regulatory authority should encourage these testing before providing permission to market the products to be used by the population.

Further, natural personal care products have proven to be safe to use than conventional beauty products. Dermatologists have tested and confirmed that they are hypo-allergenic and safe to use, since they do not cause problems like skin rashes or itchy skin. Parabens, the most common preservative in cosmetics, penetrate the skin, and are suspected of disrupting hormone function. Herbal products do not contain parabens. All skin types can use natural personal care products [12].

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However, not all products marketed as being natural are equally safe to use. Since cosmetic product labelling regulations are lax, a product labelled as "natural" may contain undesirable synthetic chemicals, on top of the natural ingredients. Also, pesticides and other harmful chemicals may have been applied to the raw natural procurements that were used to make a "100% natural" personal care product [13]. Vedistry's moha range of skin and hair care products are all regular synthetic with herbal actives.

Conclusion

In summary, the dermal safety assessments conducted on Vedistry's moha range skincare and haircare products formulated with natural ingredients, including moha: Herbal Face Wash, moha: Herbal Scrub, moha: Aloe Vera Gel, moha: Rose Mist, moha: Herbal Lip Balm, moha: Herbal Sunscreen Lotion With SPF 50, moha: Moisturizing Lotion, moha: Soap, moha: Rose And Almond Soap, moha: Scrub Soap, moha: Herbal Shower Gel, moha: Rejuvenating Massage Oil, moha: Foot Care Cream, moha: Nail Care Cream, moha: 5 In 1 Hair Oil, moha: Anti-Dandruff Hair Oil, moha: Herbal Shampoo, moha: Herbal Anti-Dandruff Shampoo, moha: Sulfate-Free Herbal Shampoo, moha: Herbal Hair Conditioner, moha: Herbal Hair Serum, moha: Herbal Radiance Face Mask, moha: Overnight Lotion, moha: Skin Cream, moha: Hydrating Face Serum, and moha: Sunscreen Spray, affirm their non-irritating nature with skin compatibility and safety for diverse skin types-ranging from oily and mixed to dry, normal, and sensitive.

Conflict of Interest

Dr. Ipsa Pandya and Dr Raji Patil affirms that they have no conflicts of interest regarding providing scientific insights and designing the clinical study. Dr Manisha Mishra is an employee of Vedistry Private Limited. Dr Nayan and Maheshvari Patel were part of scientific writing have no conflict of interest. The authors declare that any association have not influenced the work reported in this paper.

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Ethical Approval: Yes, the studies were approved by the Independent Ethics Committees.

CTRI Registration: Yes, refer Table#2.

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