MASCOT SPINCONTROL
clinical research centre

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au coeur de la peau...

CONFIDENTIAL REPORT

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Dated: 19/04/2019

EVALUATION OF THE IRRITATION POTENTIAL OF

SKIN CARE & HAIR CARE FORMULATIONS

THROUGH:

- **Dermatological Evaluation –Single Application Patch Test Method**

TEST PRODUCTS REFERENCES:

- **Hair Conditioner (133) : Product A**
- **Body Lotion (139) : Product B**

Study Sponsor:

SLICK ORGANICS PVT. LTD.
117, 1st floor, New Delhi House,
Barakhamba Road, Connaught Place,
New Delhi – 110010.

Investigator:

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APRIL 2019

CONTENTS

1. EXPERIMENTATION SITE, PARTICIPANTS

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Date:

2. SUMMARY OF THE STUDY

2.1 OBJECTIVE

The objective of this study was to evaluate the irritation potential on healthy human subjects of Skin Care & Hair Care Formulations coded:

- **Hair Conditioner (133) : Product A**
- **Body Lotion (139) : Product B**

The evaluation was performed using:

- **Dermatological Evaluation : Single Application Patch test method***
  (*Primary irritation patch test method)

2.2 POPULATION

Twenty four (24) subjects were selected for the study.

The subjects selected for this study were healthy females and males, aged between 18 and 54 years old. In which **12 were female and 12 were male subjects.**

These subjects were selected according to the inclusion/ non-inclusion criteria listed in paragraph 3.1.

2.3 STUDY DURATION

Duration: 8 days [3days and T8 (T+1 week after 0 hours of patch removal) visit was scheduled to monitor follow up reactions].

Scheduled Procedures:

	Screening	T0 (before patch application)	T1 day (0 hours after the patch removal)	T2 days (24 hours after the patch removal)	T8 days (T+1 week after 0 hours of patch removal)
		Patch Application Day	Patch Removal Day		
Registration	■				
Protocol Briefing	■				
Consent	■				
ICF		■			
Inclusion and Non Inclusion criteria by the Dermatologist	■	■			
History Questionnaire	■				
Routine Checkup	■				
Clinical Observation	■				
Site Identification		■			
Proscriptions and Restrictions			■	■	■
Concomitant Medication		■	■	■	■
Patch Application		■			
Patch Removal			■		
Dermatological Evaluation reading of patch tests				■	■
AE/ SAE Monitoring		■	■	■	■
					End of the study

Study Schedule:

Screening /T0 (before patch application)	T1 (0 hours after the patch removal)	T2 (24 hours after the patch removal)	T8 (T+1 week after 0 hours of patch removal)
01/04/2019	**02/04/2019**	**03/04/2019**	**09/04/2019**

2.4 STUDY DESIGN

- Single application, closed, occlusive patch study
- Non comparative, single centerd study
- Subjects served as their own reference

3. STUDY PROTOCOL

3.1 SUBJECT SELECTION

Mascot Spincontrol's subject panel was composed of subjects selected on the basis of a questionnaire filled in by the Principal investigator for subjects, prior to the study that provides details of their medical history, possible allergies, skin-care and make-up habits, as well as a certain amount of administrative information.

The selection procedures were elaborated in order to guarantee that the subjects receive all possible information about the aims of the study and the consequences of their participation.
This selection procedure includes:

- A preliminary interview, during which the following points are explained to the subjects: the study's modalities, its practical considerations, possible payment, as well as any possible cosmetic benefits, inconveniences or potential risks.
- The information form which is specific to the study, including all essential information is then given to the subject to read.
- The consent form which is read and filled in freely and intentionally, approved, and signed by the subject to substantiate the fact that they freely accept the conditions of the study which has been described to them.
- The Informed Consent form which is filled in freely and intentionally by the subject after it had been fully explained to them, in the event of any claims for damages, enables them to benefit from the terms of the insurance policies taken out by Clinical Research Organization as soon as the subject is accepted into the study by the Principal Investigator /Co-Investigator.

The subject must respect the following conditions: (as well as those already mentioned)

- Available for the entire duration of the study
- Motivated to freely participate in the study
- Able to justify a permanent address
- Able to understand Hindi, Marathi, Gujarati and/or English language: i.e. only Hindi, Marathi, Gujarati and/or English speaking subjects capable of reading the consent documents and able to accept the participation conditions.
- No individual sentenced to imprisonment by a court decision or by an administrative decision, or hospitalized without consent, or admitted in a medical or social establishment.
- No minor as well as individual of age benefiting from a legal protection measure or enable to express his/her consent.

The subjects selected for the study were chosen under the supervision of the Principal Investigator and co-investigator, on the basis of the inclusion/non-inclusion criteria listed below.
A selection of 24 subjects was made for this study.
The results given included all of the present and assessable subjects at each examination.

3.1.1 Inclusion criteria

The study was conducted on subjects who fulfilled the following criteria:

Standard criteria

- Female and male Asian Indian subjects.
- Healthy human subjects (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 checkup)
- Between 18 and 65 years of age.
- Skin is healthy on the studied anatomic unit (free of eczema, wounds, inflammatory scar….)

3.1.2 Non-inclusion criteria

Standard criteria

- For female : Being pregnant or breastfeeding or having stopped to breastfeed in the past three months
- Having refused to give his/her assent by not signing the consent form
- Taking part in another study liable to interfere with this study
- Being diabetic.
- Being asthmatic.
- Following a chronic medicinal treatment comprising any of the following products: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol).
- Having cutaneous hypersensitivity (except in the case of studies with evaluation of sensitive skin).
- Having a diagnosed or highly probable allergy to one or several compounds of the cosmetic products.
- Having undergone a surgery requiring a general anaesthesia of more than one hour in the past 6 months.
- Having changed his/her cosmetic habits in the 14 days preceding the start of the study on the studied anatomic unit.
- The day of the patch application: no cosmetic product must be used (test site clean with water only).
- Refusing to follow the restrictions below during the study:
- Do not take part in another study liable to interfere with this study
- Do not take medicinal treatment comprising any of the following products: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol).
- Do not change his/her cosmetic habits apart from the particular conditions mentioned in the protocol, on the studied anatomic unit.

Specific criteria

- Having eczema, psoriasis, lichen plan, vitiligo whatever the considered area
- Having disorder of the healing (whatever the considered area)
- Having a rhinitis, allergic conjunctivitis or rhino sinusitis
- Having an allergy to perfumes and/or conservatives in cosmetic products
- Having an allergy to plaster
- Having a food allergy
- Having a cardiovascular pathology (taking a beta blocker treatment)
- Having immunosuppressive drugs, such as cyclophosphamide, methotrexate, azathioprine, etc.
- Taking a retinoid based treatment by general or oral route
- Taking specific treatment on the back
- Having taken an anti-histaminic treatment in the last 2 weeks preceding the start of the study
- Having miliaria (prickly heat) on the back.
- Presenting too many naevus on the back
- Having high pilosity on the back
- Refusing to follow the restrictions below during the study :

- During the first 24 hours(after patch application), neither cosmetic products nor water must be applied on the back
- Till the follow up period of until T8 days, only water is accepted from the first reading i.e. T2 days (24 hours after the patch removal).
- Do not practice an intensive sport activity during the first 24 hours (until the removal of the patches)
- Do not expose the back to the sun.

3.2 THE PRODUCT

3.2.1 Presentation of the products

The test products were supplied free of charge by the study sponsor.

Reference of the products	Codes	Batch/LT	Constituent form	Manufacturing Date	Expiry Date	Packaging	Capacity
Hair Conditioner (133)	A	133	Cream	02/19	02/21	Pump Bottle	200 ml
Body Lotion (139)	B	139	Lotion	02/19	02/21	Pump Bottle	200 ml

The study sponsor was in charge of product manufacturing and packaging. He / She was responsible for product identification, purity determination, composition, innocuousness, and any other characteristics of each product to be tested prior to the beginning of the study.

The study sponsor was responsible for supplying the appropriate amount of product needed to carry out the study.

For this study, the study sponsor agreed to supply:

The appropriate quantity of the product required to treat all of the subjects;
A sufficient quantity of the product for any additional subjects participating in the study;
One product per reference and per batch will be retained in the sample cabinet of MASCOT SPINCONTROL.

Products were stored in an ambient temperature away from light.

At the end of the study, the products used by the volunteers or the leftover products can be sent back to the sponsor if he has asked for it on the document attached to the quotation or by mail.
On the other hand, the investigator proceeds to eliminate the remaining products according to the method of their choice described in their procedures.

The cost of the products destruction by the investigator was charged to the sponsor.

3.2.2 Patch preparation

The patches were prepared in the morning of the application, one hour before first visit i.e. at T0 in acclimatized room temperature 20°C -25°C.

The products were stored in IP storage room (T°C between 20°C -25°C., Humidity between 40 RH and 60 RH).

Products	Codes	Patch No.	Application area	Frequency of application	Application duration	Conservation
Hair Conditioner (133)	**A**	1	Between scapula and waist	Once	24 hours	At an ambient temperature
Body Lotion (139)	**B**	2	Between scapula and waist	Once	24 hours	At an ambient temperature
Negative Control (0.9% Isotonic Saline Solution)	**-**	3	Between scapula and waist	Once	24 hours	At an ambient temperature
Positive Control (1% w/w SLS)	**-**	4	Between scapula and waist	Once	24 hours	At an ambient temperature

3.2.2.1 Patch Preparation for Test Products

a. Procedure for Patch Preparation of Hair Conditioner (133): Product A as per BIS Standard clause 4.3.1.2 ,IS 4011:2018, 3rd Revision

- 8% w/w solution of the investigational product was prepared by weighing 2g of the product and dissolving it in distilled water and making up the final weight to 25g.
- 0.04 ml or 40 µl of the prepared sample was loaded onto the filter paper disc.
- The Finn chambers with the product loaded filter paper discs was then taped onto the back of subjects

b. Procedure for Patch Preparation of Body Lotion (139): Product B as per BIS Standard clause 4.3.1.2 ,IS 4011:2018, 3rd Revision

- 0.04 ml (40 µl) of test sample was measured with the help of 1 ml syringe.
- The test product was transferred on previously numbered Aluminium Finn Chamber, with the help of syringe.

c. Procedure for Patch preparation of Negative control as per BIS Standard clause 4.3.1.2.4, IS 4011:2018, 3rd Revision

- 40 µl of 0.9% Isotonic Saline Solution was transferred to previously numbered Aluminum Finn Chamber with an appropriate sized disk of Whatman no. 3 filter paper with the help of Micropipette.

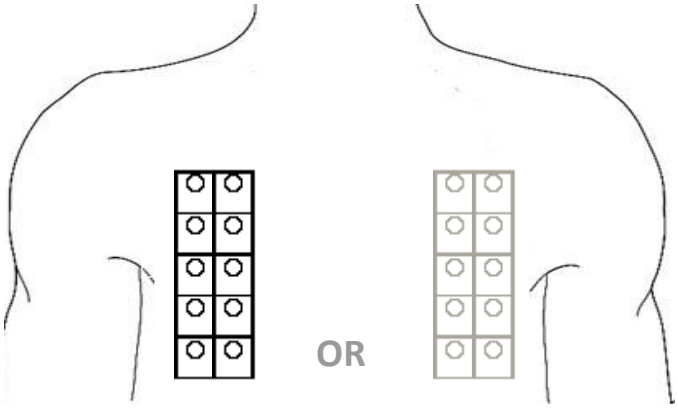
d. Patch preparation for Positive control as per BIS Standard clause 4.3.1.2.4, IS 4011:2018, 3rd Revision:

- Sodium Lauryl Sulphate solution: 1% SLS w/w solution in distilled water was prepared and 40 µl of this solution was applied on an appropriate sized disk of Whatman No. 3 filter paper & was placed in aluminum Finn chambers prefixed on micro pore tape.

Patch application

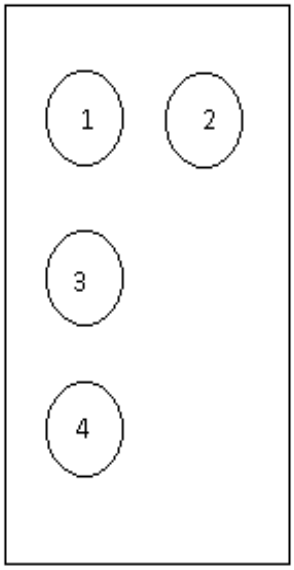
The patch application was carried out by the CRA:
For subject:

- The Dermatologist determined 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, patches were not applied on naevi.
- Location of application: Between scapula and waist.
- The application of the patches was made as follows:



For CRA

- Washed hands with disinfectant.
- Began application of the strip by the bottom, pressing the rooms up to release the air.
- When the tape was fully in place, gently press each patch 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 application of patches were strengthened by applying micro pore tape on all the four sides of patch.



3.3 STUDY DESIGN

- This is a single application closed, occlusive patch study.
- Non comparative, single centred study.
- Subjects served as their own reference.

3.4 STUDY PROCEDURE

3.4.1 Dermatological evaluation

- **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 substances 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 is carried out versus a positive control: 1 % (w/w) sodium lauryl sulfate and versus a negative control: 0.9 % Isotonic Saline Solution for leave on & liquid rinse off products.

The kinetic of the evaluation was as follows:

T0 = (before patch application)	Patch application
T1 day = (0 hrs after the patch removal)	Patch removal
T2 days =(24 hours after patch removal)	Patch reading by the Dermatologist
T8* = (T+1 week after 0 hours of patch removal)	Checking of the evolution of the positive cases

- **Methodology of patch application**

The patch application was carried out at T0 visit by the CRA.

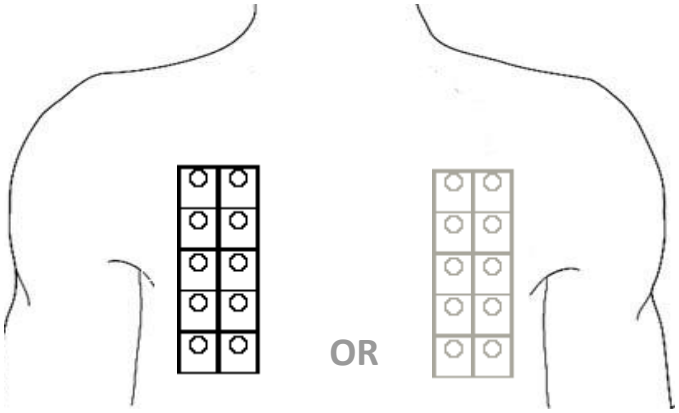
- Washed hands with disinfectant.
- Began application of the strip from the bottom, pressing the rooms up to release the air.
- When the tape was fully in place, gently press each patch containing a test product or control, to ensure an even distribution of the substance.
- Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
- The application of patches were strengthened by applying micro pore tape on all the four sides of patch.

- Studied areas and location

The patches were applied on the top of the back near the shoulder blade.

The dermatologist determined the best area to apply the patch, depending on the naevi, the pilosity and the freckles. The selected area was healthy, without an excessive pilosity, the patch was not applied on a naevi.

The patch was applied on the right or left part of the back: the side was mentioned in the CRF by the dermatologist.



- Position of the subject

It was recommended that the subject sits with the back slightly bent forward.

- **Methodology of patch removal**

The CRA removed the patch from the bottom to the top. The area was gently wipe off with a soft tissue paper.

- **Methodology of patch reading by the Dermatologist**

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

The Dermatologist scored the reactions namely erythema (including dryness, scaliness and wrinkles) on a 0-4 point scale and oedema on another 0 - 4 point scale as per Draize Scale (Clause 4.3.1.3 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)

Score For Erythema/ dryness/ wrinkles	Reaction	Score For 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/scales	4	Severe Oedema

In case of positive reaction, a photograph of the patches was made on T+2 days. Another photograph at T+8 days enabled to evaluate the evolution of the sign.

3.5 EXAMINATION SCHEDULE

The effect of the products was evaluated over a 3 - day's period and follow up visit at T8 (T+1 week after 0 hours of patch removal). The scheduled measurement procedures were as follows:

Screening

- Registration
- Protocol Briefing
- Reading and signature of the consent form
- History Questionnaire
- Routine Checkup
- Clinical Observations
- Checking of the inclusion/non inclusion criteria by the Dermatologist

***At T0* (before patch application)**

- Acclimatization at temperature 20°C - 25°C for 20 minutes.
- Acknowledgement, reading and signature of the ICF
- Concomitant Medication
- Checking of the inclusion/non-inclusion criteria by the Dermatologist
- Site Identification by Dermatologist
- Patch Application by CRA.
- AE/SAE Monitoring

***At T1* (0 hours after the patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 minutes
- Proscriptions and restrictions
- Concomitant Medication
- Patch Removal by CRA.
- AE/SAE Monitoring

***At T2* (24 hours after the patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 minutes
- Proscriptions and restrictions
- Concomitant Medication
- Dermatological Evaluation : patch test reading
- AE/SAE Monitoring

***At T8* (T+1 week after 0 hours of patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 minutes
- Proscriptions and restrictions
- Concomitant Medication
- Dermatological Evaluation : patch test reading
- Filling of Study completion form by the Dermatologist
- AE/SAE Monitoring

3.6 DATA ANALYSIS AND STATISTICS OF TECHNICAL DATA

- Carried out by Study Incharge at Mascot Spincontrol India.

The assessment was only based on the mean score obtained 24 hours after the patch removal (T2) for the technique dermatological evaluation.

Mean Score for Irritation = $\frac{\text{Total score (Erythema+ Oedema) for each sample}}{\text{Total no. of Subjects}}$

Mean score calculation for products coded Hair Conditioner (133): Product A & Body Lotion (139): Product B

Clause 4.3.1.3 Draize scale for scoring the investigational sites (IS 4011:2018 methods of test for safety evaluation of cosmetics – 3rd Revision) was used to calculate the mean score of observations made for assessing the investigational site for Skin Irritation as presented in Mean Score for Irritation:

Mean Score	Classification
2.0 / 8.0	Non- Irritant
Up to 4.0 / 8.0	Mild Irritant
Above 4.0 / 8.0	Irritant

Average score produced by each of the test sample was compared with that produced by the positive control & negative control.

Note: Positive control to give combined mean score of greater than 2.
Negative control to give combined mean score of less than 2
.
If positive control gives a combined mean score less than 2.0 and/or negative control gives a combined mean score of greater than 2.0, then the test need to be repeated on another group of newly recruited volunteers.

4. ETHICAL AND LEGAL CONSIDERATIONS

4.1 STUDY PERSONNEL

The Principal investigator assured that the Study Incharge and everyone who participated in this study have the required qualifications and abilities to carry it out.

4.2 DATA ARCHIVING

The documents are archived for a period as per recommendation of sponsor or 5 years. Dual archiving is ensured by using both paper and IT storage media.
Paper files are archived by Mascot Spincontrol until the end of the archiving period.

Electronics files are archived in 2 CD ROMs (DVD's), disks are stored for 5 years. In Mascot Spincontrol premises keep one copy of the protocol signed by the principal investigator & by the study sponsor as well as the filled case report form, questionnaire and all associated documents, consent forms & all project related documents of any type for a 5 years period following delivery of the final report.
All these documents are accessible upon request for inspection by the study sponsor, their representative or by administrative authorities.
The Principal investigator informs the study sponsor of his intention to proceed with their destruction after the 5 years period.

4.3 INSURANCE POLICY

The damages caused by the failure of the Principal Investigator or a third party shall be imputable to Mascot Spincontrol.
Adequate insurance cover of the subject for liability arising from any serious event or death during the conduct of the study will be taken by Mascot Spincontrol India Pvt. Ltd. through an insurance contract with The Oriental Insurance Company Limited, Mumbai, India. (Insurance policy number 124500/48/2019/4487).

4.4 ANONYMITY OF THE SUBJECTS

The subjects are identified for the study sponsor using a five-character alphanumeric code and a number.
The investigator makes a commitment not to raise the anonymity of the subjects.
The study sponsor cannot have access to the confidential data relative to the subjects registered in the data base of Mascot Spincontrol.

4.5 CONSENT TO PARTICIPATE IN THE STUDY

An information form is given to each subject providing full details about the study and:

- its objectives, methods, and duration;
- possible expected aesthetic benefits, constraints, and potential risks;
- The non-inclusion criteria, the amount of the payment, the right of access to data files and their later destruction.

This information enables the subjects to sign their participation consent form freely and unequivocally, in the knowledge that they are fully aware of the testing details.

4.6 USE OF IMAGE

If the study involves the use of photographs, the volunteers are informed, in the consent form, that their image without direct identification may be used by Mascot Spincontrol all over the world, with no time limit on this usage. The volunteers are also informed that Mascot Spincontrol may also provide images to the sponsor for publishing or duplication.

4.7 CONFIDENTIALITY

All the information, data, results and audio-visual recordings of informed consent process of the study are confidential. Everyone having access to such data are informed of their confidentiality.
Any medical information concerning a subject's state of health and the results of the clinical examinations carried out during the recruitment, selection and admission phases before a study is subject to the medical secrecy regulations, in no case should such information be communicated to the study sponsor using a subject's identity.

4.8 QUALITY ASSURANCE

Our quality system has been developed to meet guidelines relevant to our type of activity for ingredients and cosmetic product efficiency and tolerance testing.
As such, our Quality System is in full compliance with ICH-E6 -Good Clinical Practice (GCP) guidelines in our test companies: Mascot Spincontrol (India) and Spincontrol Tours (France).

The entire dossier of a study (protocol, results, report, and any other study-related documents) is subject to a Quality Management audit which conforms to the regulatory texts and procedures in force. Verifications of data generated in this study are performed in accordance with the Quality Assurance of the studies documents.

The investigator cooperates in ensuring any additional auditing required by the study sponsor to ensure that the study progresses in accordance with regards the protocol and the current procedures.

Sr. No.	Audit Report	Date of Auditing
1.	**Audit of study protocol**	15/03/2019
2.	**Audit of the CRF's**	19/03/2019
3.	**Audit report of the Trial Master File**	17/04/2019
4.	**Audit of the Raw Data & Results**	17/04/2019
5.	**Audit of the Study Report**	19/04/2019

4.9 REGULATIONS

This study is carried out in conformity with the most recent recommendations of the World Medical Association (Declaration of Helsinki 1964, amended in Fortaleza, Brazil, 2013).

This study complies with the "Schedules of the Drugs and Cosmetics Act".

4.10 PRACTICAL CONSIDERATIONS

A preliminary agreement between the Investigator and the study sponsor, concerned by the present contract, is necessary for any publication or communication directly concerning the two parties. They must both take the initiative to inform each other if a change is to occur.

5. RESULTS

This report is based on the exploitation of the results regarding the irritation potential of Skin Care and Hair Care formulations by Primary Irritation Patch Test Method.

5.1 PROTOCOL DEVIATIONS

The protocol has been respected as a whole.

5.2 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

At T0, 24 subjects were recruited:

Considering the information previously mentioned in the paragraph (5.1) the number of subjects considered in the expression of the results, at each examination time, presented in the following table:

Technique	T0 (before patch application)	T1 day (0 hour after the patch removal)	T2 days (24 hours after the patch removal)	T8 (T+1 week after 0 hours of patch removal)
Dermatological Evaluation	24	24	24	24

From above techniques and time points data for T2 visit (24 hrs of patch removal) – Dermatological evaluation was considered for the mean score calculation of patch test.

5.3 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of 24 healthy females and males subjects aged between 18 and 54 years old (Mean age in years: 30 Standard deviation in years: 10.2 and median age in years: 29 see detail in appendix 1) of Asian (Indian) skin type.

5.4 DERMATOLOGICAL EVALUATION

The detailed results of the dermatological evaluation are presented in appendix 2.
The studied parameters are:

1. Erythema
2. Oedema

5.4.1. Observed results at T2 days (24 Hours after the Patch Removal)

The following table summarizes the total and mean scores obtained on the exploited panel, for the erythema and oedema parameters, as well as the conclusion concerning the irritation potential of each tested material (if applicable), 24 hours after the patch removal, on the back.

	Results For T2 Days (24 Hours After The Patch Removal)Visit For Dermatological Evaluation				
Test material	**Total Score for Erythema**	**Total Score for Oedema**	**Total Score for Erythema + Oedema**	**Mean Score (Irritation)**	**Conclusion on the Irritation Assessment**
Hair Conditioner (133)	0.0	0.0	0.0	0.0	Non - Irritant
Body Lotion (139)	0.0	0.0	0.0	0.0	Non - Irritant
Negative Control (0.9% Isotonic Saline Solution)	0.0	0.0	0.0	0.0	-
Positive Control (1% SLS w/w)	45.0	12.0	57.0	2.4	-

5.4.2. Analysis

At T2 days (24 hours after patch removal) visit mean score of erythema and oedema by dermatologist is found as follows:

- 0.0 For **Hair Conditioner (133):Product A & Body Lotion (139): Product B**
- No irritative type response at T2 days (24 hours after patch removal) was observed by dermatologist.
- No reaction was observed for the negative control (i.e.0.9% Isotonic Saline Solution).
- The Mean Score for positive control 1% SLS w/w solution is 2.4

6. DISCUSSION AND CONCLUSION

In our experimental conditions, based on the incident of the response and comparison of the mean scores with positive and negative control of erythema and oedema observed for the single application of closed patch for 24 hours of the Skin Care & Hair care formulations coded **Hair Conditioner (133): Product A & Body Lotion (139): Product B** according to the Primary irritation patch test method on panel of 24 healthy human subjects (12 females + 12 males) aged between 18 and 54 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test products coded **Hair Conditioner (133): Product A & Body Lotion (139): Product B** were **dermatologically tested for safety** & can be considered as **Non- Irritant to skin**.

7. APPENDICES :

APPENDIX 1:

CHARACTERISTICS OF THE PANEL

CHARACTERISTICS OF THE PANEL

STUDY CODE: D01-6Q02-SO-MH19					
DEMOGRAPHICS					
PRODUCT REF.: **1. Patch No. 01 - Product A - Hair Conditioner (133)** **2. Patch No. 02 - Product B - Body Lotion (139)** **3. Patch No. 03 - Negative Control(0.9% Isotonic Saline Solution)** **4. Patch No. 04 - Positive Control(1% w/w SLS)**					
Sr. No.	**Subject Code**	**Subject No.**	**VB/FVB No.**	**Age**	**Sex**
1	GHEAN	001	FVB 04416	19	FEMALE
2	NABSE	002	FVB 04043	34	FEMALE
3	GUPM3	003	FVB 01655	30	FEMALE
4	PANP8	004	FVB 01654	41	FEMALE
5	SHAD5	005	FVB 02128	42	FEMALE
6	KORR1	006	FVB 01914	21	FEMALE
7	TAMS5	007	FVB 01863	28	FEMALE
8	MULSH	008	FVB 04473	33	FEMALE
9	DESAK	009	FVB 02285	54	FEMALE
10	PAT88	010	FVB 04614	42	FEMALE
11	GUP30	011	FVB 01511	36	FEMALE
12	MORA3	012	FVB 04617	44	FEMALE
13	PAT65	013	VB 02585	21	MALE
14	ADIAN	014	VB 02235	23	MALE
15	TAMD1	015	VB 02739	41	MALE
16	LONSA	016	VB 02158	33	MALE
17	CHAA7	017	VB 02892	36	MALE
18	KHUSA	018	VB 02255	21	MALE
19	PEDS2	019	VB 02460	19	MALE
20	KUPSI	020	VB 02242	20	MALE
21	CHOS6	021	VB 02922	21	MALE
22	JA121	022	VB 02921	18	MALE
23	WAIOM	023	VB 02923	21	MALE
24	BISSU	024	VB 02436	23	MALE
MEAN AGE (in years)				**30.0**	**Males:12**
MINIMUM AGE (in years)				**18**	**Females:12**
MAXIMUM AGE(in years)				**54**	
STANDARD DEVIATION (in years)				**10.2**	
MEDIAN AGE (in years)				**29**	
TOTAL SUBJECTS				**24**	

APPENDIX 2:

RESULTS OF THE STUDY

RESULTS OF THE STUDY

STUDY CODE: D01-6Q02-SO-MH19							
3.4.1 Dermatological Evaluation AT T2 (24 hours after the patch removal)							
PRODUCT REF.: **1. Patch No. 01 - Product A - Hair Conditioner (133)** **2. Patch No. 02 - Product B - Body Lotion (139)** **3. Patch No. 03 - Negative Control(0.9% Isotonic Saline Solution)** **4. Patch No. 04 - Positive Control(1% w/w SLS)**							
GRADING FOR ERYTHEMA /DRYNESS/ WRINKLES							
Sr. No.	**Subject Code**	**Subject No**	**VB/FVB No**	**Patch No.1**	**Patch No. 2**	**Patch No.3**	**Patch No.4**
1	GHEAN	001	FVB 04416	0	0	0	2
2	NABSE	002	FVB04043	0	0	0	2
3	GUPM3	003	FVB 01655	0	0	0	1
4	PANP8	004	FVB 01654	0	0	0	2
5	SHAD5	005	FVB 02128	0	0	0	2
6	KORR1	006	FVB 01914	0	0	0	1
7	TAMS5	007	FVB 01863	0	0	0	1
8	MULSH	008	FVB 04473	0	0	0	2
9	DESAK	009	FVB 02285	0	0	0	2
10	PAT88	010	FVB 04614	0	0	0	2
11	GUP30	011	FVB 01511	0	0	0	2
12	MORA3	012	FVB 04617	0	0	0	2
13	PAT65	013	VB 02585	0	0	0	3
14	ADIAN	014	VB 02235	0	0	0	3
15	TAMD1	015	VB 02739	0	0	0	1
16	LONSA	016	VB 02158	0	0	0	2
17	CHAA7	017	VB 02892	0	0	0	2
18	KHUSA	018	VB 02255	0	0	0	3
19	PEDS2	019	VB 02460	0	0	0	1
20	KUPSI	020	VB 02242	0	0	0	1
21	CHOS6	021	VB 02922	0	0	0	1
22	JA121	022	VB 02921	0	0	0	2
23	WAIOM	023	VB 02923	0	0	0	3
24	BISSU	024	VB 02436	0	0	0	2
Total Score For Erythema (E)				**0.0**	**0.0**	**0.0**	**45.0**

Scale:	
Score For Erythema	**Reactions**
0	No reaction
1	Very slight erythema/dryness with shiny appearance
2	Slight Erythema/ Dryness/ Wrinkles
3	Moderate erythema/ dryness /wrinkles
4	Severe erythema/ wrinkles/scales

RESULTS OF THE STUDY

STUDY CODE: D01-6Q02-SO-MH19							
3.4.1 Dermatological Evaluation AT T2 (24 hours after the patch removal)							
PRODUCT REF.: **1. Patch No. 01 - Product A - Hair Conditioner (133)** **2. Patch No. 02 - Product B - Body Lotion (139)** **3. Patch No. 03 - Negative Control(0.9% Isotonic Saline Solution)** **4. Patch No. 04 - Positive Control(1% w/w SLS)**							
GRADING FOR OEDEMA							
Sr. No.	**Subject Code**	**Subject No**	**VB/FVB No**	**Patch No.1**	**Patch No.2**	**Patch No.3**	**Patch No.4**
1	GHEAN	001	FVB 04416	0	0	0	1
2	NABSE	002	FVB 04043	0	0	0	1
3	GUPM3	003	FVB 01655	0	0	0	0
4	PANP8	004	FVB 01654	0	0	0	0
5	SHAD5	005	FVB 02128	0	0	0	1
6	KORR1	006	FVB 01914	0	0	0	0
7	TAMS5	007	FVB 01863	0	0	0	0
8	MULSH	008	FVB 04473	0	0	0	0
9	DESAK	009	FVB 02285	0	0	0	1
10	PAT88	010	FVB 04614	0	0	0	0
11	GUP30	011	FVB 01511	0	0	0	1
12	MORA3	012	FVB 04617	0	0	0	1
13	PAT65	013	VB 02585	0	0	0	1
14	ADIAN	014	VB 02235	0	0	0	1
15	TAMD1	015	VB 02739	0	0	0	0
16	LONSA	016	VB 02158	0	0	0	0
17	CHAA7	017	VB 02892	0	0	0	1
18	KHUSA	018	VB 02255	0	0	0	1
19	PEDS2	019	VB 02460	0	0	0	0
20	KUPSI	020	VB 02242	0	0	0	0
21	CHOS6	021	VB 02922	0	0	0	0
22	JA121	022	VB 02921	0	0	0	0
23	WAIOM	023	VB 02923	0	0	0	1
24	BISSU	024	VB 02436	0	0	0	1
Total Score For Oedema (O)				**0.0**	**0.0**	**0.0**	**12.0**

Scale:	
Score For Oedema	**Reaction**
0	No Reaction
1	Very slight Oedema
2	Slight Oedema
3	Moderate Oedema
4	Severe Oedema

RESULTS OF THE STUDY

STUDY CODE: D01-6Q02-SO-MH19

3.4.1 Dermatological Evaluation at T2 (24 hours after the patch removal) and T8 (T+1 week after 0 hours of patch removal)

PRODUCT REF.:
1. Patch No. 01 - Product A - Hair Conditioner (133)
2. Patch No. 02 - Product B - Body Lotion (139)
3. Patch No. 03 - Negative Control(0.9% Isotonic Saline Solution)
4. Patch No. 04 - Positive Control(1% w/w SLS)

GRADING FOR ERYTHEMA (E) AND OEDEMA (O)

Sr. No.	Sub. Code	Sub. No.	VB/FVB No.	Reaction	Patch No.1		Patch No.2		Patch No.3		Patch No.4	
					T2	T8	T2	T8	T2	T8	T2	T8
1	GHEAN	001	FVB 04416	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
2	NABSE	002	FVB 04043	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
3	GUPM3	003	FVB 01655	E	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0
4	PANP8	004	FVB 01654	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0
5	SHAD5	005	FVB 02128	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
6	KORR1	006	FVB 01914	E	0	0	0	0	0	0	1	1
				O	0	0	0	0	0	0	0	0
7	TAMS5	007	FVB 01863	E	0	0	0	0	0	0	1	1
				O	0	0	0	0	0	0	0	0
8	MULSH	008	FVB 04473	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0
9	DESAK	009	FVB 02285	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
10	PAT88	010	FVB 04614	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0
11	GUP30	011	FVB 01511	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
12	MORA3	012	FVB 04617	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
13	PAT65	013	VB 02585	E	0	0	0	0	0	0	3	1
				O	0	0	0	0	0	0	1	0
14	ADIAN	014	VB 02235	E	0	0	0	0	0	0	3	0
				O	0	0	0	0	0	0	1	0
15	TAMD1	015	VB 02739	E	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0
16	LONSA	016	VB 02158	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0
17	CHAA7	017	VB 02892	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0
18	KHUSA	018	VB 02255	E	0	0	0	0	0	0	3	1
				O	0	0	0	0	0	0	1	0
19	PEDS2	019	VB 02460	E	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0
20	KUPSI	020	VB 02242	E	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0
21	CHOS6	021	VB 02922	E	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0
22	JA121	022	VB 02921	E	0	0	0	0	0	0	2	0
				O	0	0	0	0	0	0	0	0
23	WAIOM	023	VB 02923	E	0	0	0	0	0	0	3	1
				O	0	0	0	0	0	0	1	0
24	BISSU	024	VB 02436	E	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	1	0

RESULTS OF THE STUDY

STUDY CODE: D01-6Q02-SO-MH19
MEAN SCORE CALCULATION
3.4.1 Dermatological Evaluation AT T2(24 hours after the patch removal)
PRODUCT REF.: 1. Patch No. 01 - Product A - Hair Conditioner (133) 2. Patch No. 02 - Product B - Body Lotion (139) 3. Patch No. 03 - Negative Control(0.9% Isotonic Saline Solution) 4. Patch No. 04 - Positive Control(1% w/w SLS)
Mean Score — Classification 2.0 / 8.0 — Non- Irritant Up to 4.0 / 8.0 — Mild - Irritant Above 4.0 / 8.0 — Irritant
Mean Score for Irritation = Total score (Erythema+ Oedema) for each sample / Total number of Subjects

Parameter	Patch No.1	Patch No. 2	Patch No. 3	Patch No. 4
Total score for erythema	0.0	0.0	0.0	45.0
Total score for oedema	0.0	0.0	0.0	12.0
Total score for Erythema + Oedema	0.0	0.0	0.0	57.0
Erythema + Oedema / 24	0.0	0.0	0.0	2.4
Conclusion	Non-Irritant	Non-Irritant	-	-

APPENDIX 3:

QUALITY ASSURANCE STATEMENT

QUALITY ASSURANCE STATEMENT

This study (D01-6Q02-SO-MH19) has been regularly monitored by the quality assurance department by way of periodic audits as recommended by Good Clinical Practice and applicable regulations. The dates of these audits and the subsequent reports to the management are listed here:

Audit Schedule :

Sr. No.	Audit Report	Audit Report Number	Date of Audits
1.	Audit of study protocol	D01-6Q02-SO-MH19-AU01	15/03/2019
2.	Audit of the CRF's	D01-6Q02-SO-MH19-AU02	19/03/2019
3.	Audit report of the Trial Master File	D01-6Q02-SO-MH19-AU03	17/04/2019
4.	Audit of the Raw Data & Results	D01-6Q02-SO-MH19-AU04	17/04/2019
5.	Audit of the Study Report	D01-6Q02-SO-MH19-AU05	19/04/2019

This report has been audited by the quality assurance department and was found to be an accurate description of such methods and procedures as were used during the conduct of the study and an accurate reflection of the raw data.

Signature: _____
Auditor(s)

Signature: _____
Auditor(s)

Signature: _____
Quality Assurance Manager

APPENDIX 4:

COPY OF STUDY PROTOCOL

SUMMARY: D01-6Q02-SO-MH19

TEST PRODUCTS: Hair Conditioner (133): Product A & Body Lotion (139): Product B

DESCRIPTION OF THE STUDY:

EVALUATION OF THE IRRITATION POTENTIAL OF SKIN CARE & HAIR CARE FORMULATIONS THROUGH:

- **Dermatological Evaluation –Single Application Patch Test Method**

NATURE OF THE TESTED PRODUCTS AND METHODOLOGY:

Product Reference	Hair Conditioner (133):Product A & Body Lotion (139): Product B
Study design	Single application Closed, Occlusive patch study, Non comparative, single centred study, Subjects served as their own reference.
Total duration of the study	8 days [3 days and T8 (T+1 week after 0 hour of patch removal) visit is scheduled to monitor follow up reactions].
Kinetics	T0 (before patch application), T1 day (0 hour after the patch removal), T2 days (24 hours after the patch removal) and T8 (T+1 week after 0 hours of patch removal).
Product application	Single application of test product, Positive control (3% SLS) & Negative control (Distilled water), under occlusion during 24 hours.
Number of volunteers	24 (12 females and 12 males)
Special selection criteria	Healthy skin on the studied anatomic unit (free of eczema, wounds, inflammatory scar….).

RESULTS AND CONCLUSION

In our experimental conditions, based on the incident of the response and comparison of the mean scores with positive and negative control of erythema and oedema observed for the single application of closed patch for 24 hours of the Skin Care & Hair care formulations coded Hair Conditioner (133):Product A & Body Lotion (139): Product B according to the Primary irritation patch test method; on panel of 24 healthy human subjects (12 females + 12 males) aged between 18 and 54 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test products coded **Hair Conditioner (133): Product A & Body Lotion (139): Product B were** dermatologically **tested for safety** & can be considered as **Non- Irritant to skin**