



MASCOT SPINCONTROL
clinical research centre

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au coeur de la peau...

CONFIDENTIAL REPORT

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

THROUGH:

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

TEST PRODUCT REFERENCE:

- **Arata Face wash (AFW - 140) : Product A**
- **Arata Shampoo (AHR - 142) : Product B**
- **Arata Body wash(ABW - 143) : Product C**
- **Arata Hair Gel (AHG - 138) : Product D**
- **Arata Hair Cream (AHC - 139) : Product E**
- **Arata Lip Balm (ALB - 141) : Product F**

Study Sponsor:

SLICK ORGANICS PVT. LTD. (ARATA)

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JANUARY 2018

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1. EXPERIMENTATION SITE, PARTICIPANTS

1.1 EXPERIMENTATION SITE

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SPONSOR

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Date:

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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:

- Arata Face Wash (AFW - 140) : Product A
- Arata Shampoo (AHR - 142) : Product B
- Arata Body Wash (ABW - 143) : Product C
- Arata Hair Gel (AHG - 138) : Product D
- Arata Hair Cream (AHC - 139) : Product E
- Arata Lip Balm (ALB - 141) : Product F

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 **50** 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)
20/12/2017	20/12/2017	21/12/2017	22/12/2017	28/12/2017

2.4 STUDY DESIGN

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

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 are 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 unable 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 include all of the present and assessable subjects at each examination.

3.1.1 Inclusion criteria

The study was conducted on subjects who will fulfill the following criteria:

Standard criteria

- Female and male Indian subjects.
- Healthy 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 50 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:
 - For female: Do not become pregnant nor breastfeed.
 - 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
Arata Face wash	A	AFW - 140	Gel	12/2017	11/2019	Tube	125ml
Arata Shampoo	B	AHR - 142	Gel	12/2017	11/2019	White Bottle with pump	200ml
Arata Body Wash	C	ABW - 143	Liquid	12/2017	11/2019	White Bottle with pump	200ml
Arata Hair Gel	D	AHG - 138	Gel	12/2017	11/2019	Tube	125ml
Arata Hair Cream	E	AHC - 139	Gel	12/2017	11/2019	White Jar	100g
Arata Lip Balm	F	ALB - 141	Balm	12/2017	11/2019	Jar	10g

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 left over 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 the first visit i.e. at T0 in room temperature 20-25°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
Arata Face wash (AFW - 140)	A	1	Between scapulae and waist	Once	24 hours	At an ambient temperature
Arata Shampoo (AHR - 142)	B	2	Between scapulae and waist	Once	24 hours	At an ambient temperature
Arata Body Wash (ABW - 143)	C	3	Between scapulae and waist	Once	24 hours	At an ambient temperature
Arata Hair Gel(AHG - 138)	D	4	Between scapulae and waist	Once	24 hours	At an ambient temperature
Arata Hair Cream (AHC - 139)	E	5	Between scapulae and waist	Once	24 hours	At an ambient temperature
Arata Lip Balm (ALB - 141)	F	6	Between scapulae and waist	Once	24 hours	At an ambient temperature
Negative Control Distilled water	-	7	Between scapulae and waist	Once	24 hours	At an ambient temperature
Positive Control 3% w/w SLS	-	8	Between scapulae and waist	Once	24 hours	At an ambient temperature

3.2.2.1 Patch Preparation for Test Product

- a. **Procedure for Patch Preparation of Arata Face wash (AFW - 140) : Product A, Arata Shampoo (AHR - 142) : Product B, Arata Body Wash (ABW-143) : Product C**
- 8% w/w solution of the test sample in distilled water was prepared.
 - For e.g.: For preparation of 25 ml of test solution weighed 2 gm of test product and add 23 gm of distilled water. Stirred the solution to mix it well.
 - Appropriate sized disc of Whatman No. 3 filter paper were placed in Aluminium Finn chambers prefixed on micro pore tape it to avoid spillage of solution from its disc.
 - 0.04 ml (40 µl) of this solution was transferred to previously numbered Aluminium Finn Chamber, with the help of syringe.
- b. **Procedure for Patch Preparation of Arata Hair Gel (AHG – 138) : Product D, Arata Hair Cream (AHC- 139) : Product E, Arata Lip Balm(ALB – 141) : Product F**
- Measured 0.04 ml (40 µl) of test sample with the help of 1 ml syringe.
 - Transferred the test product on previously numbered Aluminium Finn Chamber, with the help of syringe.

c. Patch preparation for Negative control

- 40 µl of distilled water was transferred to previously numbered Aluminium Finn Chamber with appropriate sized disk of Whatman No. 3 filter paper with the help of Micropipette.

d. Patch preparation for Positive control

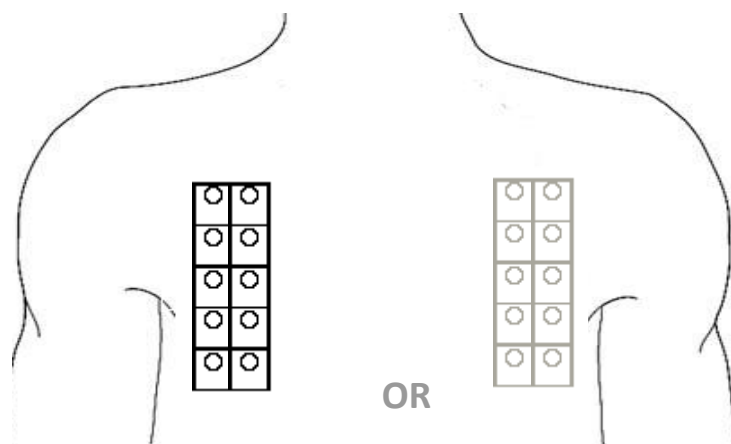
- Sodium Lauryl Sulphate solution: 3% w/w solution in distilled water was prepared and 40 µl of this solution was applied on an appropriate sized disk of Whatman No. 3 filter paper was placed in Aluminum Finn chambers prefixed on micro pore tape.

Patch application:

The patch application was carried out by the CRA:

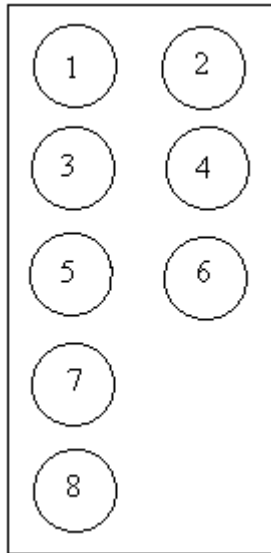
For subject:

- The Dermatologist determined the site that poses to be the most appropriate, based on moles, body hair; freckles of the selected area must be sound, without excessive hair growth. Do not apply patches on a nevus.
- Location of application: Between scapula and waist.
- The application of the patches was done as follows:



For CRA

- Hands washed 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 pressed 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 strengthen by applying micro pore tape on all the four sides of patch.



3.3 STUDY DESIGN

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

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: 3% (w/w) sodium lauryl sulfate, and versus a negative control: distilled water.

The kinetic of the evaluation is 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.

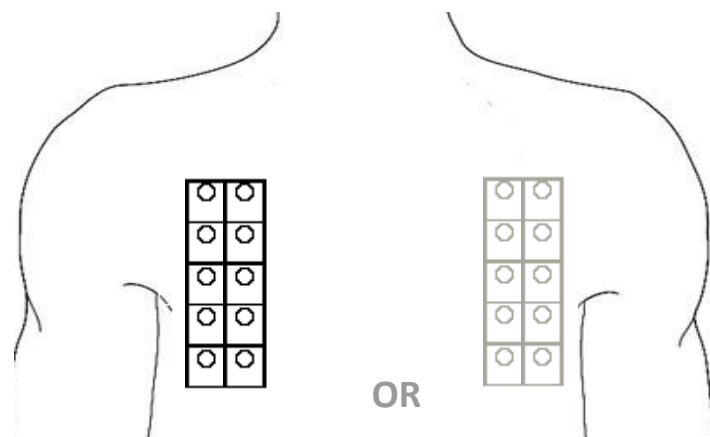
- Washed hands with disinfectant.
- Began application of the strip by the bottom, pressing the rooms up to release the air.
- When the tape was fully in place, gently pressed each patch containing a test product or Control, to ensure an even distribution of the substance.
- Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
- The application of patches were strengthen 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. Patch were 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 wiped 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

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 were captured on T2 days and on the last day of evaluation (T8 days) to track the symptom.

3.5 EXAMINATION SCHEDULE

The effect of the products were 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 mins.
- 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 mins
- 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 mins
- 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 mins
- Proscriptions and restrictions
- Concomitant Medication
- Dermatological Evaluation : patch test reading
- AE/SAE Monitoring
- Filling of Study completion form by the Dermatologist.

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.

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

Mean score calculation for product coded: Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW-143): Product C,

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.

Mean score calculation for products coded Arta Hair Gel (AHG – 138): Product D, Arata Hair Cream (AHC- 139): Product E, Arata Lip Balm (ALB – 141): Product F

The assessment of mean score was as follows:

Average score produced by each of the test sample was compared with that produced by the positive control. Toilet soaps and bathing bars showing and average score of 4 and above, a score which would be produced by 3% SLS, out of the possible maximum score of 8, are irritant.

Note: Positive control must give combined score of greater than 4.

4. ETHICAL AND LEGAL CONSIDERATIONS

4.1 STUDY PERSONNEL

The Principal investigator assures that the Study Incharge and everyone who participates 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 AMENDMENTS TO THE PROTOCOL

The study sponsor is hereby informed that any modifications requiring a protocol amendment leads to additional costs.

Each amendment includes the number of amendments and the date it is carried out. The references of the modified paragraphs appear in the amendment. To accept one amendment, the Study Sponsor and the Investigator sign it.

4.4 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 124500/48/2018/4570).

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	16/12/2017
2.	Audit of the CRF's	18/12/2017
3.	Audit report of the Trial Master File	03/01/2018
4.	Audit of the Raw Data & Results	03/01/2018
5.	Audit of the Study Report	05/01/2018

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 & Hair Care formulations by Primary Irritation Patch Test Method.

5.1 PROTOCOL DEVIATIONS

The protocol has been respected as a whole.

5.2 ABSENCES

➤ Subject n° 004, KUMVI

Reason: The subject did not reported on T+8 days visit dated 28/12/2017 due to some personal reasons as informed by the subject to the recruiters. On discussion and confirmation with the Investigator, the subject was dropped out from the study.

Impact: The data will be exploited in the global study results.

5.3 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

At T0, 24 subjects were recruited:

Considering the information previously mentioned in the paragraph (5.1 & 5.2) 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	23

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.

5.4 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of 24 healthy females and males subjects aged between 18 and 48 years old (Mean age in years: 27.5 Standard deviation in years: 10.0 and median age in years: 23 see detail in appendix 1) of Asian (Indian) skin type.

5.5 DERMATOLOGICAL EVALUATION

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

The studied parameters are:

1. Erythema
2. Odema

5.5.1 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
Arata Face wash (AFW - 140)	0.0	0.0	0.0	0.0	Non- Irritant
Arata Shampoo (AHR - 142)	0.0	0.0	0.0	0.0	Non- Irritant
Arata Body Wash (ABW - 143)	1.0	0.0	1.0	0.0	Non- Irritant
Arata Hair Gel (AHG - 138)	2.0	0.0	2.0	0.1	Non- Irritant
Arata Hair Cream (AHC - 139)	2.0	0.0	2.0	0.1	Non- Irritant
Arata Lip Balm (ALB - 141)	0.0	0.0	0.0	0.0	Non- Irritant
Negative Control (Distilled Water)	0.0	0.0	0.0	0.0	-
Positive Control (3% SLS)	59.0	40.0	99.0	4.1	-

5.5.2 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 Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C & Arata Lip Balm (ALB – 141): Product F
- 0.1 For Arata Hair Gel (AHG - 138): Product D & Arata Hair Cream (AHC -139): Product E
- No irritative type response at T2 day (24 hours after patch removal) was observed by dermatologist.
- No reaction was observed for the negative control (i.e. distilled water).
- The Mean Score for positive control 3% SLS w/w solution is 4.1.

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– Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138): Product D, Arata Hair Cream (AHC -139): Product E & Arata Lip Balm (ALB – 141) :Product F according to the Primary irritation patch test method; on panel of 24 healthy human subjects (12 females + 12 males) aged between 18 and 48 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test products coded Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138): Product D, Arata Hair Cream (AHC -139): Product E & Arata Lip Balm (ALB - 141): Product F were **dermatologically tested for safety & can be considered as Non- Irritant to skin.**

7. REFERENCES:

- 7.1 IS 4011:1997, reaffirmed (2004), Method of test for safety evaluation of cosmetics second revision
- 7.2 IS 13424:2001, Safety evaluation of bathing bars and toilet soaps – Methods of test, First revision.

8. APPENDICES :

APPENDIX 1:

CHARACTERISTICS OF THE PANEL

CHARACTERISTICS OF PANEL

01/130/17					
DEMOGRAPHICS					
PRODUCT REF.:					
1. Patch No. 01 - Arata Face wash(AFW - 140)					
2. Patch No. 02 - Arata Shampoo(AHR - 142)					
3. Patch No. 03 - Arata Body Wash(ABW - 143)					
4. Patch No. 04 - Arata Hair Gel(AHG - 138)					
5. Patch No. 05 - Arata Hair Cream(AHC - 139)					
6. Patch No. 06 - Arata Lip Balm(ALB - 141)					
7 Patch No. 07 - Negative Control - Distilled water					
8 Patch No. 08 - Positive Control- 3% SLS					
Sr. No.	Subject Code	Subject No.	VB/FVB No.	Age	Sex
1	SINH4	1	VB 02469	19	MALE
2	PATK4	2	FVB 01180	40	FEMALE
3	GUP13	3	FVB 03011	27	FEMALE
4	KUMVI	4	VB 01838	20	MALE
5	GHAS6	5	VB 02111	20	MALE
6	SINPA	6	VB 02347	19	MALE
7	GOSAB	7	VB 01953	20	MALE
8	PAT58	8	VB 02459	22	MALE
9	PALUM	9	VB 02117	21	MALE
10	MORAL	10	VB 02181	20	MALE
11	OTORA	11	VB 01842	19	MALE
12	SHEAF	12	FVB 03566	41	FEMALE
13	KUPRA	13	VB 02377	23	MALE
14	PANH5	14	VB 02467	19	MALE
15	KARAS	15	VB 02468	18	MALE
16	TIWS1	16	FVB 02034	38	FEMALE
17	MISM1	17	FVB 02037	30	FEMALE
18	MISLA	18	FVB 02038	29	FEMALE
19	HALRA	19	FVB 02427	34	FEMALE
20	MARL1	20	FVB 04213	19	FEMALE
21	SAWA4	21	FVB 02491	45	FEMALE
22	MAYP1	22	FVB 02983	45	FEMALE
23	SINHE	23	FVB 04201	25	FEMALE
24	SHLA3	24	FVB 04214	48	FEMALE
MEAN AGE (in years)				27.5	Males:12
MINIMUM AGE (in years)				18	Females: 12
MAXIMUM AGE(in years)				48	
STANDARD DEVIATION (in years)				10.0	
MEDIAN AGE (in years)				23	
TOTAL SUBJECTS				24	

APPENDIX 2:

CHARACTERISTICS OF THE PANEL

RESULTS OF THE STUDY

01/130/17											
3.4.1 Dermatological Evaluation AT T2 (24 hours after the patch removal)											
PRODUCT REF.:											
1. Patch No. 01 - Arata Face wash(AFW - 140)											
2. Patch No. 02 - Arata Shampoo(AHR - 142)											
3. Patch No. 03 - Arata Body Wash(ABW - 143)											
4. Patch No. 04 - Arata Hair Gel(AHG - 138)											
5. Patch No. 05 - Arata Hair Cream(AHC - 139)											
6. Patch No. 06 - Arata Lip Balm(ALB - 141)											
7. Patch No. 07 - Negative Control - Distilled water											
8. Patch No. 08 - Positive Control - 5% SDS											
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	Patch No.5	Patch No.6	Patch No.7	Patch No.8
1	SINH4	1	VB 02469	0	0	0	0	0	0	0	2
2	PATK4	2	FVB 01180	0	0	0	0	0	0	0	4
3	GUP13	3	FVB 03011	0	0	0	0	0	0	0	2
4	KUMVI	4	VB 01838	0	0	0	0	0	0	0	4
5	GHAS6	5	VB 02111	0	0	0	0	0	0	0	2
6	SINPA	6	VB 02347	0	0	0	0	0	0	0	3
7	GOSAB	7	VB 01953	0	0	0	0	0	0	0	2
8	PAT58	8	VB 02459	0	0	0	0	0	0	0	2
9	PALUM	9	VB 02117	0	0	0	0	0	0	0	4
10	MORAL	10	VB 02181	0	0	0	0	0	0	0	4
11	OTORA	11	VB 01842	0	0	0	0	0	0	0	4
12	SHEAF	12	FVB 03566	0	0	0	0	0	0	0	2
13	KUPRA	13	VB 02377	0	0	0	0	0	0	0	2
14	PANH5	14	VB 02467	0	0	0	0	0	0	0	2
15	KARAS	15	VB 02468	0	0	0	0	0	0	0	4
16	TIWS1	16	FVB 02034	0	0	0	0	0	0	0	2
17	MISM1	17	FVB 02037	0	0	0	0	0	0	0	1
18	MISLA	18	FVB 02038	0	0	0	0	0	0	0	2
19	HALRA	19	FVB 02427	0	0	0	0	0	0	0	4
20	MARL1	20	FVB 04213	0	0	0	0	0	0	0	1
21	SAWA4	21	FVB 02491	0	0	1	1	2	0	0	2
22	MAYP1	22	FVB 02983	0	0	0	0	0	0	0	2
23	SINHE	23	FVB 04201	0	0	0	1	0	0	0	1
24	SHIA3	24	FVB 04214	0	0	0	0	0	0	0	1
Total Score For Erythema (E)				0.0	0.0	1.0	2.0	2.0	0.0	0.0	59.0
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

01/130/17											
3.4.1 Dermatological Evaluation AT T2 (24 hours after the patch removal)											
PRODUCT REF.:											
1. Patch No. 01 - Arata Face wash(AFW - 140)											
2. Patch No. 02 - Arata Shampoo(AHR - 142)											
3. Patch No. 03 - Arata Body Wash(ABW - 143)											
4. Patch No. 04 - Arata Hair Gel(AHG - 138)											
5. Patch No. 05 - Arata Hair Cream(AHC - 139)											
6. Patch No. 06 - Arata Lip Balm(ALB - 141)											
7 Patch No. 07 - Negative Control - Distilled water											
8 Patch No. 08 - Positive Control- 3% 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	Patch No.5	Patch No.6	Patch No.7	Patch No.8
1	SINH4	001	VB 02469	0	0	0	0	0	0	0	1
2	PATK4	002	FVB 01180	0	0	0	0	0	0	0	3
3	GUP13	003	FVB 03011	0	0	0	0	0	0	0	0
4	KUMVI	004	VB 01838	0	0	0	0	0	0	0	3
5	GHAS6	005	VB 02111	0	0	0	0	0	0	0	1
6	SINPA	006	VB 02347	0	0	0	0	0	0	0	2
7	GOSAB	007	VB 01953	0	0	0	0	0	0	0	1
8	PAT58	008	VB 02459	0	0	0	0	0	0	0	1
9	PALUM	009	VB 02117	0	0	0	0	0	0	0	3
10	MORAL	010	VB 02181	0	0	0	0	0	0	0	3
11	OTORA	011	VB 01842	0	0	0	0	0	0	0	3
12	SHEAF	012	FVB 03566	0	0	0	0	0	0	0	2
13	KUPRA	013	VB 02377	0	0	0	0	0	0	0	1
14	PANH5	014	VB 02467	0	0	0	0	0	0	0	2
15	KARAS	015	VB 02468	0	0	0	0	0	0	0	2
16	TIWS1	016	FVB 02034	0	0	0	0	0	0	0	2
17	MISM1	017	FVB 02037	0	0	0	0	0	0	0	0
18	MISLA	018	FVB 02038	0	0	0	0	0	0	0	2
19	HALRA	019	FVB 02427	0	0	0	0	0	0	0	3
20	MARL1	020	FVB 04213	0	0	0	0	0	0	0	0
21	SAWA4	021	FVB 02491	0	0	0	0	0	0	0	2
22	MAYP1	022	FVB 02983	0	0	0	0	0	0	0	2
23	SINHE	023	FVB 02401	0	0	0	0	0	0	0	0
24	SHIA3	024	FVB 04214	0	0	0	0	0	0	0	1
Total Score For Oedema (O)				0.0	0.0	0.0	0.0	0.0	0.0	0.0	40.0
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

01/130/17																				
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 - Arata Face wash(AFW - 140)																				
2. Patch No. 02 - Arata Shampoo(AHR - 142)																				
3. Patch No. 03 - Arata Body Wash(ABW - 143)																				
4. Patch No. 04 - Arata Hair Gel(AHG - 138)																				
5. Patch No. 05 - Arata Hair Cream(AHC - 139)																				
6. Patch No. 06 - Arata Lip Balm(ALB - 141)																				
7. Patch No. 07 - Negative Control - Distilled water																				
8. Patch No. 08 - Positive Control- 3% 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		Patch No.5		Patch No.6		Patch No.7		Patch No.8	
					T2	T8	T2	T8	T2	T8	T2	T8	T2	T8	T2	T8	T2	T8	T2	T8
1	SINH4	001	VB 02469	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
2	PATK4	002	FVB 01180	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
3	GUP13	003	FVB 03011	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	KUMVI	004	VB 01838	E	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	4	ABS
				O	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	0	ABS	3	ABS
5	GHAS6	005	VB 02111	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
6	SINPA	006	VB 02347	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
7	GOSAB	007	VB 01953	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
8	PAT58	008	VB 02459	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
9	PALUM	009	VB 02117	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
10	MORAL	010	VB 02181	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
11	OTORA	011	VB 01842	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
12	SHEAF	012	FVB 03566	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
13	KUPRA	013	VB 02377	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
14	PANH5	014	VB 02467	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
15	KARAS	015	VB 02468	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
16	TIWS1	016	FVB 02034	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
17	MISM1	017	FVB 02037	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	MISLA	018	FVB 02038	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
19	HALRA	019	FVB 02427	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
20	MARL1	020	FVB 04213	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	SAWA4	021	FVB 02491	E	0	0	0	0	1	0	1	0	2	0	0	0	0	0	2	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
22	MAYP1	022	FVB 02983	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
23	SINHE	023	FVB 02401	E	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	SHIA3	024	FVB 04214	E	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
				O	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0

RESULTS OF THE STUDY

01/130/17								
MEAN SCORE CALCULATION								
3.4.1 Dermatological Evaluation AT T2(24 hours after the patch removal)								
PRODUCT REF.:								
1. Patch No. 01 - Arata Face wash(AFW - 140)								
2. Patch No. 02 - Arata Shampoo(AHR - 142)								
3. Patch No. 03 - Arata Body Wash(ABW - 143)								
4. Patch No. 04 - Arata Hair Gel(AHG - 138)								
5. Patch No. 05 - Arata Hair Cream(AHC - 139)								
6. Patch No. 06 - Arata Lip Balm(ALB - 141)								
7 Patch No. 07 - Negative Control - Distilled water								
8 Patch No. 08 - Positive Control- 3% 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 = $\frac{\text{Total score (Erythema+ Oedema) for each sample}}{\text{Total number of Subjects}}$								
Parameter	Patch No.1	Patch No. 2	Patch No.3	Patch No.4	Patch No.5	Patch No.6	Patch No.7	Patch No.8
Total score for erythema	0.0	0.0	1.0	2.0	2.0	0.0	0.0	59.0
Total score for oedema	0.0	0.0	0.0	0.0	0.0	0.0	0.0	40.0
Total score for Erythema + Oedema	0.0	0.0	1.0	2.0	2.0	0.0	0.0	99.0
Erythema + Oedema / 24	0.0	0.0	0.0	0.1	0.1	0.0	0.0	4.1
Conclusion	Non Irritant	Non Irritant	Non Irritant	Non Irritant	Non Irritant	Non Irritant	-	-

APPENDIX 3:

QUALITY ASSURANCE STATEMENT

QUALITY ASSURANCE STATEMENT

This study (01/130/17) 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	01/130/17-AU01	16/12/2017
2.	Audit of the CRF's	01/130/17-AU02	18/12/2017
3.	Audit report of the Trial Master File	01/130/17-AU03	03/01/2018
4.	Audit of the Raw Data & Results	01/130/17-AU04	03/01/2018
5.	Audit of the Study Report	01/130/17-AU05	05/01/2018

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:
STUDY PROTOCOL

**STUDY SUMMARY: D01-6Q01-SO-DR17
(01/130/17)**

TEST PRODUCTS: Test products coded Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138) : Product D, Arata Hair Cream (AHC -139) : Product E & Arata Lip Balm (ALB – 141) :Product F

DESCRIPTION OF THE STUDY:

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

- Dermatological Evaluation –Single Application Patch Test Method**

NATURE OF THE TESTED PRODUCT AND METHODOLOGY:

Product Reference	Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142):Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138): Product D, Arata Hair Cream (AHC -139): Product E & Arata Lip Balm (ALB – 141):Product F
Study design	Single application, closed, occlusive patch study, Non comparative, single center study, Subjects serve 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), on the back, 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– Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138): Product D, Arata Hair Cream (AHC -139): Product E & Arata Lip Balm (ALB – 141) :Product F according to the Primary irritation patch test method; on panel of 24 healthy human subjects (12 females + 12 males) aged between 18 and 48 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test products coded Arata Face wash (AFW - 140): Product A, Arata Shampoo (AHR - 142): Product B, Arata Body Wash (ABW – 143): Product C, Arata Hair Gel (AHG - 138): Product D, Arata Hair Cream (AHC -139): Product E & Arata Lip Balm (ALB - 141): Product F were **dermatologically tested for safety & can be considered as Non- Irritant to skin.**