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CONFIDENTIAL REPORT

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EVALUATION OF THE IRRITATION POTENTIAL OF

SKIN CARE FORMULATIONS

THROUGH:

- Dermatological Evaluation – Single Application Patch Test Method

TEST PRODUCTS REFERENCES:

- Safelife Hand Sanitizer (028) : Product A
- Safelife Hand Wash (002) : Product B
- Gel Real Bathing Bar (069) : Product C

Study Sponsor:

Reliance Retail Limited.
3rd Floor, Court House,
Lokmanya Tilak Marg,
Dhobi Talao,
Mumbai 400 002, INDIA.

OCTOBER 2019

Investigator:

MASCOT SPINCONTROL INDIA PVT. LTD.
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3.2 THE PRODUCTS

3.2.1 Presentation of the products

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

References of the Products	Codes	Batch / LT	Constituent Form	Manufacturing Date	Expiry Date	Packaging	Capacity
Safelife Hand Sanitizer (028)	A	028	Liquid	09/19	08/21	Pet Jar	50 ml
Safelife Hand Wash (002)	B	002	Liquid	09/19	08/21	Pet Jar	50 ml
Get Real Bathing Bar (069)	C	069	Soap	09/19	08/21	Carton	125 gm

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 supplied:

The appropriate quantity of the products 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 were 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 is 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 acclimatized room 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
Safelife Hand Sanitizer (028)	A	1	Between scapulae and waist	Once	24 hours	At an ambient temperature
Safelife Hand Wash (002)	B	2	Between scapulae and waist	Once	24 hours	At an ambient temperature
Get Real Bathing Bar (069)	C	3	Between scapulae and waist	Once	24 hours	At an ambient temperature
Negative Control (0.9% Isotonic saline solution)	-	4	Between scapulae and waist	Once	24 hours	At an ambient temperature
Negative Control (Distilled water)	-	5	Between scapulae and waist	Once	24 hours	At an ambient temperature
Positive Control (1% w/w SLS)	-	6	Between scapulae and waist	Once	24 hours	At an ambient temperature
Positive Control (3% w/w SLS)	-	7	Between scapulae and waist	Once	24 hours	At an ambient temperature

3.2.2.1 Procedure for Patch Preparation

a. **Procedure for Patch Preparation of Safelife Hand Sanitizer (028) : Product A, as per BIS Standard clause 4.3.1.2, IS 4011:2018, 3rd Revision:**
For the ease of procedures, the technique is modified as below:

- 1cm2 disc of Whatman no. 3 filter paper was placed on the back of subjects.
- 0.02 ml or 20 µl of test product was loaded onto the filter paper disc in a drop wise manner and was allowed to evaporate prior to loading the remaining 0.02 ml or 20 µl of test product in a similar manner.
- Once the product got completely evaporated, the Whatman no. 3 filter paper was lifted and the site was left as it is for up to half an hour prior to occluding the patch.

b. Procedure for Patch Preparation of Safelife Hand Wash (002) : Product B, 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 was dissolved 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.

c. Procedure for Patch Preparation of Get Real Bathing Bar (069): Product C as per BIS Standard clause 2.2.4, IS 13424:2001, Safety evaluation of bathing bars and toilet soaps-Methods, of test, First revision:

- 8% w/w solution of the investigational product was prepared by weighing 2g of the product and dissolved 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 taped onto the back of subjects.

d. Patch preparation for 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 Aluminium Finn Chamber with an appropriate sized disc of Whatman No. 3 filter paper with the help of Micropipette.
- The Finn chambers with the 0.9% isotonic saline solution loaded filter paper discs was then taped onto the back of subjects.

For soaps: As per BIS Standard clause 2.2.5, IS 13424: 2001, First Revision:

- 40 µl of distilled water was transferred to previously numbered Aluminum Finn Chamber with appropriate sized disk of Whatman No. 3 filter paper with the help of Micropipette.
- The Finn chambers with the distilled water loaded filter paper discs was then taped onto the back of subjects

e. 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% 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.
- The Finn chambers with the 1% SLS loaded filter paper discs was then taped onto the back of subjects

For soaps: As per BIS Standard clause 2.2.5, IS 13424: 2001, First Revision:

- 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.
- The Finn chambers with the 3% SLS loaded filter paper discs was then taped onto the back of subject

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5. RESULTS:

This report is based on the exploitation of the results regarding the irritation potential of Skin 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° 001, PATK4** was absent at T+1 day visit.

As the interpretation of results is based on T+1 day visit, hence the data of the subject is not 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	23	23	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 23 healthy females and males subjects aged between 18 and 49 years old (Mean age in years: 27.3 Standard deviation in years: 10.5 and median age in years: 22 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. Oedema

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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**
Safelife Hand Sanitizer (028)	0.0	0.0	0.0	0.0	Non-Irritant
Safelife Hand Wash (002)	1.0	0.0	1.0	0.0	Non-Irritant
Get Real Bathing Bar (069)	18.0	0.0	18.0	0.8	Non-Irritant
Negative Control (0.9% Isotonic saline solution)	0.0	0.0	0.0	0.0	-
Negative Control (Distilled water)	0.0	0.0	0.0	0.0	-
Positive Control (1% w/w SLS)	53.0	17.0	70.0	3.0	-
Positive Control (3% w/w SLS)	67.0	27.0	94.0	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 **Safelife Hand Sanitizer (028): Product A, Safelife Hand Wash (002): Product B.**
- 0.8 For **Get Real Bathing Bar (069): Product C**
- 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. 0.9% Isotonic Saline Solution).
- No reaction was observed for the negative control (i.e. Distilled water).
- The Mean Score for positive control 1% SLS w/w solution is 3.0.
- The Mean Score for positive control 3% SLS w/w solution is 4.1.

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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 formulations for products coded **Safelife Hand Sanitizer (028): Product A, Safelife Hand Wash (002): Product B & Get Real Bathing Bar (069): Product C** according to the Primary irritation patch test method on panel of 23 healthy human subjects (11 females + 12 males) aged between 18 and 49 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test products coded **Safelife Hand Sanitizer (028): Product A, Safelife Hand Wash (002): Product B & Get Real Bathing Bar (069): Product C** were **dermatologically tested for safety** & can be considered as **Non- Irritant to skin**.

7. APPENDICES :

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