

TEST REPORT CERTIFICATION

Certification Code: HM-230502-IR-0009-CD-58 Receipt Date: 24th April 2023
Client: SHIFT4 INC. Test Completion Date: 04th May 2023
Representative: Minho Bae
Address: 358-39 9F 903, Hosu-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Republic of Korea
Product: Vegan Comforting Suncream

Test Result			
Test Item	Inspection Standard	Result	Irritation Evaluation
By skin patch Primary irritation test	*Remark	0.02	No irritation (Excellent)
Test Methods: After wiping the subject's test area with 70% ethanol and drying it, load of the test product in Finn Chamber® and attach it on the skin for 24 hours. The dermatologist assessed whether skin irritation was present at 30 minutes and 24 hours after patch removal.			

- Summary Report: HM-230502-IR-0009-58

- Remark:

Skin Irritation Index	Irritation Evaluation
0.00 ~ 0.25	No irritation (Excellent)
0.26 ~ 1.00	Mild irritation (Good)
1.01 ~ 2.50	Medium irritation (Bad)
2.51 ~ 4.00	Strong irritation (Very Bad)

Study Director : Wonkyu Hong (Dermatologist)



19th May 2023

Human Co., Ltd. Skin Clinical Trial Center President



1005~1008, 24, Gasan digital 1-ro, Geumcheon-gu, Seoul, Republic of Korea

www.humantest.co.kr T : +82-70-5222-9663, F : +82-70-7550-9663



Summary of the results

Title	24-hours Occlusive Single Patch Test For [Vegan Comforting Suncream]		
Institute	Human Co., Ltd. Skin Clinical Trial Center		
Report No	HM-230502-IR-0009-58		
Study period	From 02 nd May 2023 to 04 th May 2023		
Report date	19 th May 2023		
Responsible researcher	Eunseok Lee / Cheif Researcher		
Objective	To evaluate the irritation potential of the [Vegan Comforting Suncream] in human skin.		
Investigational product	No*	Name of the product	Formulation
	F-8	Vegan Comforting Suncream	Cream
<i>*Location on the application of the product</i>			
Methods	<p>1. Subjects : 30 or more healthy male and female adults over the age 19 years old who met all inclusion and exclusion criteria.</p> <p>2. Evaluation methods : 24 hours single patch test, as modified by Frosch & Kligman (1979), CTFA guideline (2007) and Draize.</p> <ul style="list-style-type: none">➤ Test area: on the upper back➤ Patch duration: 24 hours occlusive patch➤ Reading and interpretation: To evaluate the test results, we removed the patch after 24 hours. The skin reactions was assessed at 30 min and 24 hours after removal. We calculated the mean skin reaction rate after each assessment and analyzed the irritation level.		

Results

1. Subjects

: This study was initially conducted with 32 Korean male and female adults who met all the inclusion criteria, exclusion criteria.

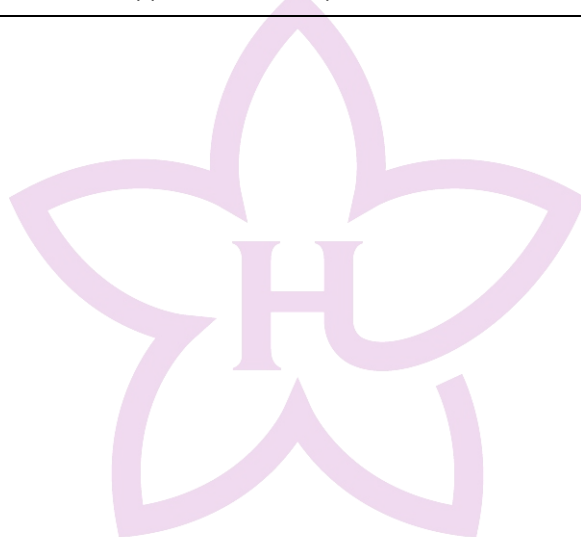
Since 0 subject has withdrawn during the test period, total 32 subjects included this test result report.

Average age of subjects is 53.03 years old, the oldest is 68 and the youngest is 25 years old.

2. Results of skin primary irritation test on human

No.*	Name of the product	Skin Irritation Index	Irritation Evaluation
F-8	Vegan Comforting Suncream	0.02	No irritation (Excellent)

**Location on the application of the product*



1. Subjects

1-1. Inclusion criteria

- Male and female adults over the age 19 years old
- Subjects who have signed consent form voluntarily after being sufficiently informed regarding the objectives of study and all related contents
- Subjects who are healthy without acute and chronic diseases including skin disorders
- Subjects who can be observed and traced throughout the entire study period

1-2. Exclusion criteria

- Subjects who is pregnant or breast-feeding
- Subject who has psychiatric disease and infectious skin disease
- Subject who has chronic disease such as asthma, diabetes, high blood pressure, etc.
- Subject who has skin lesion on the test site such as moles, pimples, erythema, scalds (burns), hemotelangiosis, and scars
- Subject who has used skin ointment containing steroid on the test site for more than one month
- Subject who has sensitive and hypersensitive skin
- Subject who has irritation history or allergy to adhesive tape
- Subject who has been part of the same clinical trial within the past 3 months
- Subject who is on contraceptive, anti-histamine and anti-inflammatory prescriptions
- Subject who has cosmetics or sunlight allergies
- Employee in this clinical trial center
- Anyone who is considered non-qualified by the investigator

1-3. Number of subjects

This study was conducted in compliance with the "Regulations on Functional Cosmetic Examination [Annex 1] Toxicity Test Method Section 7 (1) Human patch test method" by the MFDS (Ministry of Food and Drug Safety).

The results were calculated by obtaining the valid data from a minimum of 30 subjects.

1-4. Criteria for premature withdrawal and dropout from the study

The subjects who participating in this study can withdraw from the clinical trial any time, and the investigator can eliminate subjects from this test and exclude the data on the subject from the test result evaluation in the event of occurrence of one or more of the following reasons. When a subject is withdrawn, the investigator shall specify the corresponding reason and records other relevant matters to report to the principal investigator.

- (1) Voluntary withdrawal by the subject
- (2) Violation of the protocol
- (3) Occurrence of adverse event or seriously adverse event on the test site of a subject
- (4) Failure to follow up on the subject
- (5) Others

1-5. Maintenance of confidential information and duty of good faith

- (1) Confidentiality of personal information of subjects participating in the clinical trial will be maintained. However, the test data can be used for medical, academic research or marketing purposes within the scope of not disclosing the identity of the subject.
- (2) The subjects maintained confidentiality of information obtained through the clinical trial until the end of the test.
- (3) Subjects participating in the clinical trial filled out the documents related to the clinical trial sincerely and frankly.

2. Materials to conduct the study

- (1) Finn Chamber® on Scanpor® (SmartPractice®, U.S.A.)
- (2) Microman M100 (Gilson, France)
- (3) Micropore tape (3M/ Medical-Surgical Division)
- (4) Marking pen (Skin marker Slim, Sweden)

3. Methodology

This study was conducted in a temperature and humidity controlled area (indoor temperature $22\pm 2^{\circ}\text{C}$, humidity $50\pm 5\%$) within the HUMAN Co., Ltd. Skin Clinical Trial Center.

3-1. Test method and test sit

Test site was located on the flat area of the subject's back but avoiding the spine area and area where there is skin discoloration or any lesion. Test was performed in 34 healthy male and female adult subjects over the age of 19. $20\mu\text{l}$ of the coated test products and diluted test products was inserted, and the attached test product was fixed to the test area for 24 hours with adhesive tape as it was cut and attached to 1cm in width and length in Finn chamber. The skin reaction was assessed at 30 minutes and 24 hours after patch removal.

3-2. Evaluation procedure

Table 1. Evaluation procedure

Actions	Day 1	Day 2	Day 3
Admission of the subjects by the investigator	√	-	-
Application of the investigational product and giving the subjects constrains of the study	√	-	-
Remove patch	-	√	-
Observation of test site after 30 min of the patch removal	-	√	-
Observation of test site after 24 hrs of the patch removal	-	-	√

3-3. Determination of irritation

The determination of skin irritation was assessed by the dermatologist at 30 minutes and 24 hours after removal of the skin patch based on Skin Irritation Evaluation Criteria. Skin reaction was assessed according to the Frosch & Kligman and CTFA guidelines, and skin irritation index was calculated. The degree of skin irritation for test substances was categorized by referring to the skin irritation index applied with the Draize method (Table 2, 3, Fig 1).

Table 2. Skin Irritation Evaluation Criteria

Mark	Grade	Description
-	0	No reaction
+	1	Slight erythema, either spotty or diffuse
++	2	Moderate uniform erythema
+++	3	Intense erythema with edema
++++	4	Intense erythema with edema & vesicles

Fig 1. Skin Irritation Index Formula

Skin Irritation Index

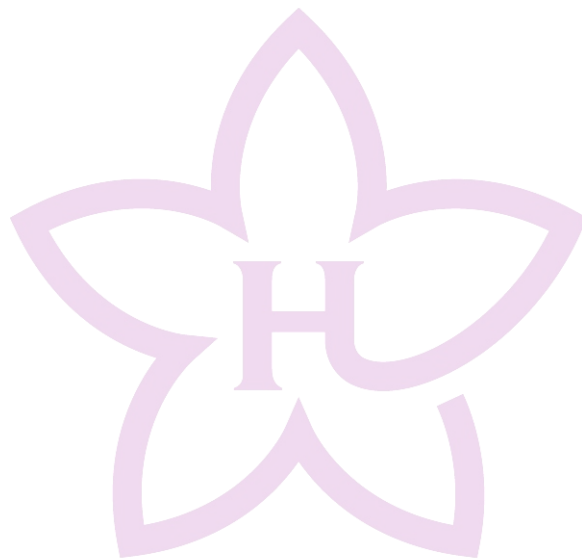
$$= \frac{\left[\left(\frac{\sum_{i=1}^n \text{Evaluation Value}}{n(\text{Number of Test Subjects})} \right) 30\text{min} + \left(\frac{\sum_{i=1}^n \text{Evaluation Value}}{n(\text{Number of Test Subjects})} \right) 24\text{hrs} \right]}{m(\text{Number of times evaluated})}$$

Table 3. Result Determination Table of Skin Patch Test

Primary Irritation Index	Irritation Evaluation
0.00 ~ 0.25	No irritation (Excellent)
0.26 ~ 1.00	Mild irritation (Good)
1.01 ~ 2.50	Medium irritation (Bad)
2.51 ~ 4.00	Strong irritation (Very Bad)

3-4. Evaluation of skin adverse event

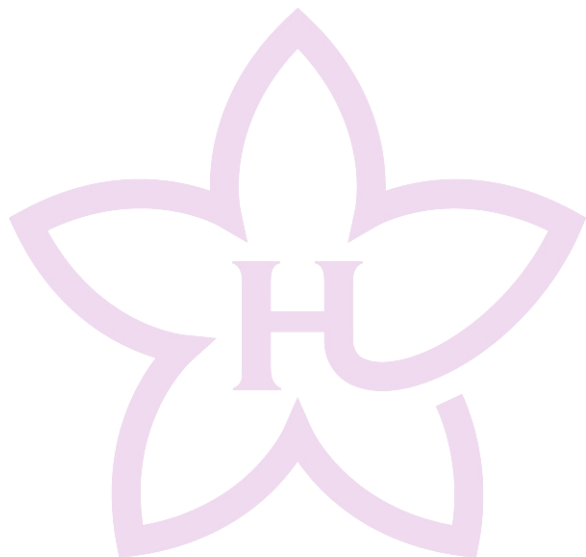
Researchers conducted visual assessment for adverse event in test area and checked for severity of symptoms at each visit. Subjects are also instructed to report immediately when they felt any abnormal symptoms during the test period, whether during visit day or not. In the case of skin adverse event report, researchers should notify the principal investigator immediately. The principal investigator would confirm the adverse event, take proper measures, and decide whether to continue participate in the clinical trial.



Appendix 1. Ingredients of the investigational products

[Vegan Comforting Suncream]

Dendropanax Morbiferus Extract(30%), Water, Propanediol, Dibutyl Adipate, Ethylhexyl Triazone, Terephthalylidene Dicamphor Sulfonic Acid, Polymethylsilsesquioxane, Butylene Glycol, Niacinamide, Tromethamine, Polyglyceryl-3 Distearate, Glycerin, Galactomyces Ferment Filtrate, Sodium Hyaluronate, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Diisopropyl Adipate, Polysilicone-15, 1,2-Hexanediol, Pentylene Glycol, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Caprylyl Methicone, Coco-Caprylate/Caprates, Poly C10-30 Alkyl Acrylate, Glyceryl Stearate, Potassium Cetyl Phosphate, Hydroxyacetophenone, Sodium Acrylates Crosspolymer-2, Methylpropanediol, Polyether-1, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glyceryl Stearate Citrate, Polyacrylate Crosspolymer-6, Adenosine, Biosaccharide Gum-1, Hydroxypropyl Methylcellulose, Acetyl Glucosamine, Sodium Hyaluronate Crosspolymer, Caprylyl Glycol, Allantoin, Madecassoside, Panthenol, Beta-Glucan, Cetearyl Alcohol, Carbomer, Disodium EDTA



Appendix 2. Subjects' information

Control No.	Initial	Age	Gender
01	PCY	58	F
02	KMO	50	F
03	KMJ	59	F
04	SBS	54	F
05	SMY	56	F
06	JKS	57	F
07	KHJ	38	F
08	YMS	66	F
09	JYJ	67	F
10	KYS	62	F
11	JMJ	43	F
12	LJH	57	F
13	PSK	68	F
14	KYG	48	F
15	KJY	48	F
16	NJY	47	F
17	PJE	25	F
18	PSY	61	F
19	KSE	54	F
20	KMS	36	M
21	LJH	39	F
22	KMS	57	F
23	JGS	51	F
24	JEY	53	F
25	LEK	43	F
26	KSH	57	F
27	SJJ	58	F
28	KYS	62	F
29	KBS	50	M
30	KEJ	52	F
31	LSY	59	F



32

KMG

62

M

