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Date: 10.07.2020

Expertise

Examination of the Product

"iBrea Skin Relief Intense Recovery Cream"

Lot No: MWC 0206-8; Date: 20.04.28

By Repeated Open Application Test (ROAT) with initial and concluding Human Patch Test (Cosmetic Trial)

Sponsor
IBREA GLOBAL CO., LTD.
2F, 220, INHYANG-RO, GOCHON-EUP
GIMPO-SI, GYEONGGI-DO
KOREA

Performing Laboratory
Derma Consult Concept GmbH
Hermann-Wandersleb-Ring 4
53121 Bonn
Germany

Study Details

Type of study .....: Determination of irritation and/or sensitization potential by Repeated Open Application Test with initial and concluding Simple Patch Test
Study Period .....: June 2020
Study Director ....: Dr. med. H. Prieur
Test subjects .....: 30 (23-61 years; sex distribution non-standardized)
14 normal healthy, 3 eczema, 1 allergy and 12 subjects with sensitive skin
Test site.....: Inner side of forearms
Concentration.....: Undiluted

Summary Results

All participants completed the study. In the initial patch test, no reactions towards the test product were observed. None of the subjects reported on any problems or discomfort during the ROAT and no visual reactions could be observed in the scoring. Also, none of the subjects showed any reaction towards the test product in the concluding patch test. Under the test conditions, SDS (1% in water) caused positive reactions in 23 subjects in the initial patch test and in 22 subjects in the concluding patch test. The negative control water showed no reactions. On the basis of the test results and under the test conditions, the product is to be classified as 'harmless' as regards the possibility of skin irritation. In this test model there was no hint of sensitization, hence the study can help to support claims of hypoallergenicity.

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Signature:

B. Nissen
Manager Derma Consult Conept

Introduction

The initial Simple Patch Test and the Repeated Open Application Test (ROAT) allow to assess the primary skin irritation potential of cosmetic-finished products and raw materials. With an additional concluding simple patch test on the treatment area, the sensitization potential can be assessed.

To respect the SARS-CoV-2 related legal requirements in place at the time of conduct of the study, a contact minimized study protocol was employed.

Performance of Test

All the work described in this expertise was conducted in accordance with the guidelines by COLIPA (Product Test Guidelines for the Assessment of Human Skin Compatibility, Edition of 1997). Because it was a study with humans, it was carried out taking into account the principle requirements of the Declaration of Helsinki (1964) and subsequent revisions.

Experiments were carried out on 30 volunteers (14 normal healthy subjects, 3 eczema patients, 1 allergy patients, 12 subjects with sensitive skin) between the ages of 23 to 61. Sex distribution was not standardized. The volunteers were clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They gave their written informed consent before participating in the study. The participants could withdraw from the study at any time without giving any reason. The following criteria were used for selection of subjects:

Inclusion criteria

- written informed consent given
- age ≥ 18 years

Exclusion criteria

- pregnant or lactating women
- blemishes or marks (tattoos, sunburn) which interfere with scoring
- skin phototype (Fitzpatrick) > 4
- any skin disease that may interfere with the aim of the study
- any medical condition / medication that may interfere with the aim of the study

Testing was conducted according to the following schedule:

Day 0 ..... : Start of initial Simple Patch Test

Day 2 ..... : Removal of occlusion, scoring

Day 3 ..... : End of initial Simple Patch Test with scoring; start of ROAT with controlled test product application (demonstration)

Days 4-16 . : Home application (twice daily)

Day 17 ..... : Final home application & end of ROAT with dermatological examination (scoring / questioning)

Days 18-23 : Application pause

Day 24 ..... : Start of concluding Simple Patch Test

Day 26 ..... : Removal of occlusion, scoring

Day 27 ..... : End of concluding Simple Patch Test with scoring

In case reactions exceeding slight reddening / minimal scaling were observed in a subject in the initial patch test towards the test product, the ROAT was not started and the subject was excused from the study.

In case adverse reactions towards the test product were observed in a subject during the ROAT, product treatment was immediately discontinued (and the concluding patch test not started) and the subject was excused from the study.

Initial Simple Patch Test

The product was applied under occlusion undiluted in round test-chambers with 12mm diameter (Finn Chambers on Scanpor, Large – SmartPractice, USA) to the designated treatment area on the inner side of the forearms for a period of 48 hours.

Proper adherence of the patches was assured by the inclusion of sodium dodecyl sulphate (SDS) in one concentration (1 % in water) as positive control. Water was used as negative control.

Treatment sites were assessed for the presence of reactions by a trained evaluator using scoring scales for erythema, fissure, scaling and oedema listed below at 48 h (30 min after patch removal) and 72 h after patch application.

Repeated Open Application Test (ROAT)

Upon conclusion of the initial patch test, after a demonstration of the correct product application procedure by a Derma Consult staff member and initial use under supervision, the subjects used the test product at a rate of approximately 2mg/cm² twice daily (in the morning and evening) at home for the following 14 days in a manner corresponding as largely as possible to that to be practised by the future consumer in the designated area on the inner sides of the forearms of 5*5cm (relocation by template) as already used for the initial simple patch test.

For cleansing, water or a mild syndet (Eubos® flüssig – blau; manufacturer: Dr. Hobein, D-53340 Meckenheim-Merl, Germany – provided to the volunteers by the test institute) was allowed only. Use of other topical preparations, apart for the test product and the mild syndet for cleansing, was prohibited. In case of any problems with the test product or suspected adverse reactions, the subjects were advised to immediately contact the study supervisor.

After 14 days of twice daily home use, the subjects returned to the test institute (in the late afternoon, 8-12 hours after the final product application in the morning) and the treatment area was assessed for the presence of irritation by a trained evaluator using scoring scales for erythema, fissure, scaling and oedema listed below. Additionally, the subjects were questioned in-depth about the application experience with regard to any signs of adverse reactions (e.g. itching) or discomfort.

Concluding Simple Patch Test

After a treatment pause of one week, the product was re-applied under occlusion undiluted in round test-chambers with 12mm diameter (Finn Chambers on Scanpor, Large – SmartPractice, USA) to the same treatment area on the inner side of the forearms as used for the initial simple patch test and ROAT for a period of 48 hours.

Proper adherence of the patches was again assured by the inclusion of sodium dodecyl sulphate (SDS) in one concentration (1 % in water) as positive control. Water was used as negative control.

Treatment sites were assessed for the presence of reactions by a trained evaluator using scoring scales for erythema, fissure, scaling and oedema listed below at 48 h (30 min after patch removal) and 72 h after patch application.

Scoring scales

Erythema 0: no E., 1: slight E., 2: significant E., 3: pronounced E., 4: strong E.

Fissure 0: no F., 1: minimal F., 2: significantly perceptible F., 3: pronounced F., 4: ulceration

Scaling 0: no Sc., 1: minimal Sc., 2: moderate Sc., 3: significant Sc., 4: closed scale crust

Oedema 0: absence of oedema, 1: presence of oedema

Results

The test results outlining the data on a per subject base for the test product (ROAT, initial & concluding simple patch tests) and the positive and negative controls (patch tests only) are attached in tabulated form in the appendix.

Literature

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Third Edition
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Jeanne Duus Johansen, Peter . Frosch, Torkil Menné:
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Appendix: Test protocol

05. / 06.06.2020
PROTOCOL

Product: iBrea Skin Relief Intense Recovery Cream – Initial Patch Test
Lot No: MWC 0206-8; Date: 20.04.28

No.	Type	Initial Patch Test – after 48h				Initial Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	0	0	0	0	0	0	0	0
2	S	0	0	0	0	0	0	0	0
3	E	0	0	0	0	0	0	0	0
4		0	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	0	0	0	0	0	0	0	0
8		0	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	0	0
11		0	0	0	0	0	0	0	0
12		0	0	0	0	0	0	0	0
13		0	0	0	0	0	0	0	0
14	S	0	0	0	0	0	0	0	0
15		0	0	0	0	0	0	0	0
16		0	0	0	0	0	0	0	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	0	0	0	0
20	S	0	0	0	0	0	0	0	0
21		0	0	0	0	0	0	0	0
22	E	0	0	0	0	0	0	0	0
23		0	0	0	0	0	0	0	0
24	S	0	0	0	0	0	0	0	0
25	S	0	0	0	0	0	0	0	0
26		0	0	0	0	0	0	0	0
27	E	0	0	0	0	0	0	0	0
28	S	0	0	0	0	0	0	0	0
29	S	0	0	0	0	0	0	0	0
30	S	0	0	0	0	0	0	0	0
		0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4
Oedema (O): absence of oedema: 0, presence of oedema: 1

20.06.2020
PROTOCOL

Product: iBrea Skin Relief Intense Recovery Cream – ROAT Assessment

Lot No: MWC 0206-8; Date: 20.04.28

No.	Type	ROAT - day 17				ROAT – day 17, subjective evaluation			
		E	F	S	O	Redness	Itching	Discomfort	Other / Description
1	S	0	0	0	0	0	0	0	-
2	S	0	0	0	0	0	0	0	-
3	E	0	0	0	0	0	0	0	-
4		0	0	0	0	0	0	0	-
5		0	0	0	0	0	0	0	-
6	S	0	0	0	0	0	0	0	-
7	S	0	0	0	0	0	0	0	-
8		0	0	0	0	0	0	0	-
9		0	0	0	0	0	0	0	-
10	A	0	0	0	0	0	0	0	-
11		0	0	0	0	0	0	0	-
12		0	0	0	0	0	0	0	-
13		0	0	0	0	0	0	0	-
14	S	0	0	0	0	0	0	0	-
15		0	0	0	0	0	0	0	-
16		0	0	0	0	0	0	0	-
17		0	0	0	0	0	0	0	-
18		0	0	0	0	0	0	0	-
19	S	0	0	0	0	0	0	0	-
20	S	0	0	0	0	0	0	0	-
21		0	0	0	0	0	0	0	-
22	E	0	0	0	0	0	0	0	-
23		0	0	0	0	0	0	0	-
24	S	0	0	0	0	0	0	0	-
25	S	0	0	0	0	0	0	0	-
26		0	0	0	0	0	0	0	-
27	E	0	0	0	0	0	0	0	-
28	S	0	0	0	0	0	0	0	-
29	S	0	0	0	0	0	0	0	-
30	S	0	0	0	0	0	0	0	-
		0,0	0,0	0,0	0,0	0,0	0,0	0,0	

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4
Oedema (O): absence of oedema: 0, presence of oedema: 1

Redness / Itching / Discomfort: absence: 0, presence: 1

29. / 30.06.2020
PROTOCOL

Product: iBrea Skin Relief Intense Recovery Cream – Concluding Patch Test
Lot No: MWC 0206-8; Date: 20.04.28

No.	Type	Concluding Patch Test – after 48h				Concluding Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	0	0	0	0	0	0	0	0
2	S	0	0	0	0	0	0	0	0
3	E	0	0	0	0	0	0	0	0
4		0	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	0	0	0	0	0	0	0	0
8		0	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	0	0
11		0	0	0	0	0	0	0	0
12		0	0	0	0	0	0	0	0
13		0	0	0	0	0	0	0	0
14	S	0	0	0	0	0	0	0	0
15		0	0	0	0	0	0	0	0
16		0	0	0	0	0	0	0	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	0	0	0	0
20	S	0	0	0	0	0	0	0	0
21		0	0	0	0	0	0	0	0
22	E	0	0	0	0	0	0	0	0
23		0	0	0	0	0	0	0	0
24	S	0	0	0	0	0	0	0	0
25	S	0	0	0	0	0	0	0	0
26		0	0	0	0	0	0	0	0
27	E	0	0	0	0	0	0	0	0
28	S	0	0	0	0	0	0	0	0
29	S	0	0	0	0	0	0	0	0
30	S	0	0	0	0	0	0	0	0
		0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4
Oedema (O): absence of oedema: 0, presence of oedema: 1

05. / 06.06.2020
PROTOCOL

Controls – Initial Patch Test

Water

No.	Type	Initial Patch Test – after 48h				Initial Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	0	0	0	0	0	0	0	0
2	S	0	0	0	0	0	0	0	0
3	E	0	0	0	0	0	0	0	0
4		0	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	0	0	0	0	0	0	0	0
8		0	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	0	0
11		0	0	0	0	0	0	0	0
12		0	0	0	0	0	0	0	0
13		0	0	0	0	0	0	0	0
14	S	0	0	0	0	0	0	0	0
15		0	0	0	0	0	0	0	0
16		0	0	0	0	0	0	0	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	0	0	0	0
20	S	0	0	0	0	0	0	0	0
21		0	0	0	0	0	0	0	0
22	E	0	0	0	0	0	0	0	0
23		0	0	0	0	0	0	0	0
24	S	0	0	0	0	0	0	0	0
25	S	0	0	0	0	0	0	0	0
26		0	0	0	0	0	0	0	0
27	E	0	0	0	0	0	0	0	0
28	S	0	0	0	0	0	0	0	0
29	S	0	0	0	0	0	0	0	0
30	S	0	0	0	0	0	0	0	0
		0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

SDS (1% in Water)

No.	Type	Initial Patch Test – after 48h				Initial Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	1	0	0	0	0	0	0	0
2	S	1	0	0	0	1	0	0	0
3	E	1	0	1	0	1	0	1	0
4		1	0	0	0	1	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	1	0	0	0	2	0	1	0
8		1	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	1	0
11		1	0	0	0	1	0	0	0
12		0	0	0	0	1	0	0	0
13		0	0	0	0	0	0	0	0
14	S	1	0	1	0	1	0	1	0
15		0	0	0	0	0	0	0	0
16		1	0	0	0	1	0	1	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	1	0	0	0
20	S	1	0	1	0	1	0	1	0
21		1	0	0	0	1	0	0	0
22	E	1	0	0	0	2	0	1	0
23		0	0	0	0	1	0	1	0
24	S	1	0	0	0	2	0	2	0
25	S	1	0	1	0	1	0	0	0
26		0	0	0	0	1	0	0	0
27	E	0	0	0	0	1	0	0	0
28	S	1	0	0	0	0	0	0	0
29	S	0	0	0	0	1	0	0	0
30	S	0	0	0	0	1	0	1	0
		0,5	0,0	0,13	0,0	0,73	0,0	0,37	0,0

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4
Oedema (O): absence of oedema: 0, presence of oedema: 1

29. / 30.06.2020
PROTOCOL

Controls – Concluding Patch Test

Water

No.	Type	Concluding Patch Test – after 48h				Concluding Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	0	0	0	0	0	0	0	0
2	S	0	0	0	0	0	0	0	0
3	E	0	0	0	0	0	0	0	0
4		0	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	0	0	0	0	0	0	0	0
8		0	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	0	0
11		0	0	0	0	0	0	0	0
12		0	0	0	0	0	0	0	0
13		0	0	0	0	0	0	0	0
14	S	0	0	0	0	0	0	0	0
15		0	0	0	0	0	0	0	0
16		0	0	0	0	0	0	0	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	0	0	0	0
20	S	0	0	0	0	0	0	0	0
21		0	0	0	0	0	0	0	0
22	E	0	0	0	0	0	0	0	0
23		0	0	0	0	0	0	0	0
24	S	0	0	0	0	0	0	0	0
25	S	0	0	0	0	0	0	0	0
26		0	0	0	0	0	0	0	0
27	E	0	0	0	0	0	0	0	0
28	S	0	0	0	0	0	0	0	0
29	S	0	0	0	0	0	0	0	0
30	S	0	0	0	0	0	0	0	0
		0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0

SDS (1% in Water)

No.	Type	Concluding Patch Test – after 48h				Concluding Patch Test – after 72h			
		E	F	S	O	E	F	S	O
1	S	1	0	0	0	0	0	0	0
2	S	0	0	0	0	1	0	0	0
3	E	1	0	1	0	0	0	1	0
4		1	0	0	0	0	0	0	0
5		0	0	0	0	0	0	0	0
6	S	0	0	0	0	0	0	0	0
7	S	2	0	1	0	2	0	1	0
8		1	0	0	0	0	0	0	0
9		0	0	0	0	0	0	0	0
10	A	0	0	0	0	0	0	1	0
11		1	0	0	0	2	0	1	0
12		0	0	0	0	1	0	0	0
13		0	0	0	0	0	0	0	0
14	S	1	0	1	0	2	0	1	0
15		0	0	0	0	0	0	0	0
16		0	0	0	0	1	0	1	0
17		0	0	0	0	0	0	0	0
18		0	0	0	0	0	0	0	0
19	S	0	0	0	0	0	0	1	0
20	S	1	0	1	0	1	0	1	0
21		1	0	1	0	1	0	1	0
22	E	1	0	0	0	2	0	1	0
23		0	0	0	0	1	0	1	0
24	S	1	0	1	0	1	0	2	0
25	S	0	0	0	0	1	0	0	0
26		0	0	0	0	1	0	0	0
27	E	0	0	0	0	0	0	0	0
28	S	1	0	0	0	0	0	0	0
29	S	0	0	0	0	1	0	0	0
30	S	0	0	0	0	2	0	0	0
		0,43	0,0	0,2	0,0	0,67	0,0	0,43	0,0

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4
Oedema (O): absence of oedema: 0, presence of oedema: 1