REPORT: EVALUATION OF PRIMARY SKIN IRRITATION POTENTIAL (48-HOUR PATCH TEST) OF TEST MATERIAL

Date: July 28, 2024
Sponsor: Tevo Creations Sdn Bhd
Study No: PT180624-02

1.0 SCOPE

1.1 All the work in this clinical study was conducted in accordance to Good Clinical Practice and in accordance with guidelines by COLIPA

1.2 Since it was a study tested in humans, it was carried out in accordance with the Declaration of Helsinki (1964) (World Medical Association's policy statement) and subsequent revisions.

1.3 The patch testing is intended to evaluate the capacity of cosmetic products to elicit adverse skin reaction under exaggerated consumer use condition. It will allow us to assess the primary irritation potential of cosmetic-finished products and raw materials.

2.0 OBJECTIVE

To determine the irritation potential of test materials after 48hr application to the skin of human subjects

3.0 TEST MATERIAL

3.1 TEST MATERIAL DESCRIPTION

	Test Material
1	BerryC

3.2 HANDLING:

- Samples will be retained for 6 months beyond submission of final report unless otherwise specified by the sponsors.

3.3 TEST MATERIAL EVALUATION PREREQUISITE:

- Sponsor must confirm that the manufactured test materials conforms to the local cosmetic laws and the safety assessment and toxicological profile of the test product was considered and the test product was judged safe under the normal conditions or foreseeable conditions of use.

4.0 SUBJECT SELECTION CRITERIA:

4.1 INCLUSION SELECTION CRITERIA

- Individuals 18-66 years of age
- Signed informed consent form
- Test areas with healthy skin and free of any systemic or dermatological disorder
- Individuals with uniform-colored skin on the infra scapular area of the back which would allow a discernable erythema.

4.2 EXCLUSION SELECTION CRITIRIA

- Individuals with any visible skin disease at the study site, which, would interfere with the evaluation.

- Individuals currently under steroidal treatment for asthma (non steroidal acceptable)
- Females who are pregnant, planning pregnancy or nursing a child
- Individuals whose back were prolong exposed to the sun (and especially tanned by the sun) before testing
- Individuals with known sensitivity to common cosmetics, skin care products

4.3 POPULATION DEMOGRAPHICS:

- Number of subjects enrolled: 30
- Number of subjects completing study: **30**
- Age Range: 19-62 (Average: 33.9, Median: 28.5)
- Race and Sex:

Number of subjects (%)			
Races\Sex	**Females**	**Males**	**Total**
Malay	17 (57%)	13 (43%)	**30 (100%)**

5.0 METHODOLOGY

5.1 APPARATUS & REAGENTS:

- Finn Chambers consist of aluminium chambers mounted on Scanpor tape (Actavis Norway AS, Norgesplaster Facility, Norway). The volume of the chamber is 20 µL, with 8mm inner diameter, 50 mm^2 area.
- 1 mL/cc sterile syringe will be used to deliver the test materials
- Test Materials (20 microlitre, µL):
  - Positive control: 0.5% Sodium lauryl sulphate
  - Negative control: Distilled water
  - Test materials (Leave-on: as is; Rinse-off: 1% dilution; Disinfecting Agent (with ≥50% alcohol): Semi-Open Test[5]
    - **BerryC** (1% dilution)

5.2 PROCEDURES:

- Patches containing the test materials were affixed directly to the skin of the intrascapular regions of the back for 48hr.
- Patches were removed by investigator approximately 48hr after the application, then took the readings for 3 consecutive days (at 48hr, 72hr, 96hr).
- Subjects were instructed to report any delayed reactions that might occur after the final reading.

5.3 SCORING:

Table 1 : INTERNATIONAL CONTACT DERMATITIS RESEARCH GROUP (ICDRG) SCORING SCALE

Rating	Test Reactions
0	No evidence of any effect
±	**Barely perceptible:** Minimal faints, light pink, uniform or spotty erythema, no edema/swelling
1	**Mild**: Pink, uniform erythema covering most of the contact site, no edema/swelling
2	**Moderate**: Pink/red erythema visibly uniform in entire contact area, with mild edema/swelling
3	**Marked**: Bright red erythema with accompanying edema, petechiae or papules, severe edema/swelling
4	**Severe**: Deep red with vesiculation or weeping

Note: Reaction designated with a plus (+), e.g. 1+, 2+ represent those in which the criteria for that number grade have been met, but not their severity is such that it borders on the next highest grading. Hence, it represents an "in-between" grade.

5.4 PASSING CRITERIA **(at 96hr)**

- Primary Irritation Index (Average)**: ≤ 0.16**
- % Total Population with ≥1 score**: ≤ 8%**
- Non-Parametric Mann Whitney test (*GraphPad Prism 8.0.2 software*): Positive Control Vs Tested Sample**: p<0.05**

6.0 RESULTS

6.1 TEST DATE

The study was conducted from July 20 - 24, 2024

6.2 READINGS OF INDIVIDUAL SUBJECT TO EACH PRODUCT

Table 2: 48hr patch test results of "BerryC"

Patch - Well no.	Patch 1 – Well 1		Patch 1 – Well 2		Patch 3 – Well 9	
Sample ID	**Pos ct: 0.5% SLS**		**Neg ct: Distilled water**		**BerryC**	
Subject no\Time Point	72hr	**96hr**	72hr	**96hr**	72hr	**96hr**
1	1	**1**	0	**0**	0	**0**
2	0.5	**0.5**	0	**0**	0	**0**
3	0.5	**0.5**	0	**0**	0	**0**
4	0	**0**	0	**0**	0	**0**
5	0.5	**0.5**	0	**0**	0	**0**
6	0.5	**0.5**	0	**0**	0	**0**
7	0	**0**	0	**0**	0	**0**
8	1	**1**	0	**0**	0	**0**
9	0.5	**0.5**	0	**0**	0	**0**
10	1	**1**	0	**0**	0	**0**
11	1	**1**	0	**0**	1	**1**
12	0.5	**0.5**	0	**0**	0.5	**0**
13	0.5	**0.5**	0	**0**	0	**0**
14	1	**1**	0	**0**	0	**0**
15	0.5	**0.5**	0	**0**	0	**0**
16	0.5	**0.5**	0	**0**	0	**0**
17	0.5	**0.5**	0	**0**	0	**0**
18	0.5	**0**	0	**0**	0	**0**
19	1	**0.5**	0	**0**	0	**0**
20	1	**1**	0	**0**	0.5	**0.5**
21	0.5	**0**	0	**0**	0	**0**
22	1	**1**	0	**0**	0.5	**0**
23	0	**0**	0	**0**	0	**0**
24	0.5	**0**	0	**0**	0	**0**
25	0.5	**0**	0	**0**	0	**0**
26	1	**1**	0	**0**	0	**0**
27	0	**0**	0	**0**	0	**0**
28	0.5	**0**	0	**0**	0	**0**
29	0	**0**	0	**0**	0	**0**
30	1	**1**	0.5	**0.5**	0.5	**0.5**
Primary Irritation Index	0.58	**0.48**	0.02	**0.02**	0.10	**0.07**
% Total Population with any reaction	83% (25/30)	**67% (20/30)**	3% (1/30)	**3% (1/30)**	17% (5/30)	**10% (3/30)**
% Total Population with ≥1 score	33% (10/30)	**30% (9/30)**	0% (0/30)	**0% (0/30)**	3% (1/30)	**3% (1/30)**
Mann Whitney test: Pos Ct Vs Sample			p<0.0001	**p<0.0001**	p<0.0001	**p<0.0001**
Well tolerated by skin?						**YES**

6.3 SUMMARY OF TEST RESULTS

Table 3: Summary of 48hr patch test results (30 subjects)

Patch - Well no.	Patch 1 – Well 1		Patch 1 – Well 2		Patch 3 – Well 9	
Sample ID	**Pos ct: 0.5% SLS**		**Neg ct: Distilled water**		**BerryC**	
Time Point	72hr	**96hr**	72hr	**96hr**	72hr	**96hr**
Primary Irritation Index	0.58	**0.48**	0.02	**0.02**	0.10	**0.07**
% Total Population with any reaction	83% (25/30)	**67% (20/30)**	3% (1/30)	**3% (1/30)**	17% (5/30)	**10% (3/30)**
% Total Population with ≥1 score	33% (10/30)	**30% (9/30)**	0% (0/30)	**0% (0/30)**	3% (1/30)	**3% (1/30)**
Mann Whitney test: Pos Ct Vs Sample			p<0.0001	**p<0.0001**	p<0.0001	**p<0.0001**
Well tolerated by skin?						**YES**

7.0 CONCLUSION

***BerryC* had passed all three passing criteria:**

- PII: 0.07, 3%, p<0.0001
- Product was "Dermatologically Tested" statistically less irritating than positive control, and was well-tolerated by 97% of the tested population.
- Product has low level of irritation potential and is safe for use by consumers with normal skin.

8.0 ADVERSE REACTIONS

- No unusual, serious or delayed reactions (up to 3 days after patch removal) was found or reported by the subjects.

STUDY CONDUCTED BY INVESTIGATOR

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9.0 APPENDICES

9.1 REFERENCES

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9.2 POPULATION DEMOGRAPHIC TABLE

	CODE ID	SEX	AGE	RACE
1	930901ABT-09	F	31	M
2	930101BCX-04	M	31	M
3	981101ALT-01	F	26	M
4	980601AGX-01	F	26	M
5	820601AJR-07	F	46	M
6	780101AJR-07	F	46	M
7	050801AKU-02	F	19	M
8	020901BBT-01	M	22	M
9	990801BJR-04	M	25	M
10	950601ABU-15	F	29	M
11	760101ALQ-12	F	48	M
12	750401BLR-02	M	49	M
13	000101BHW-01	M	24	M
14	981201AIU-01	F	26	M
15	631101ABU-16	F	61	M
16	890401AHT-04	F	35	M
17	960101BBU-20	M	28	M
18	970801AGS-03	F	27	M
19	940801BGV-09	M	30	M
20	641001ALT-14	F	60	M
21	010201BKV-01	M	23	M
22	691201ALT-13	F	55	M
23	950601BIV-01	M	29	M
24	990501BEV-01	M	25	M
25	991101BBB-21	M	25	M
26	981201ABT-18	F	26	M
27	960301ABT-05	F	28	M
28	941201BIW-04	M	30	M
29	620401ALQ-07	F	62	M
30	000201BCR-12	M	24	M
		Average	**33.9**	
		Median	**28.5**	

SEX (F: Female M: Male) **RACE** (M: Malay C: Chinese)

9.3 CERTIFICATE OF EACH PRODUCT (attachment)
9.4 PHOTOGRAPHS OF TESTED SITES (48hr, 72hr, 96hr) (attachment)
9.5 BACKGROUND QUALIFICATION OF INVESTIGATOR (attachment)