

RESEARCH ARTICLE

Low Dermatitis Potential of Five Cocoa-Based Cosmetic Products Using Repeat Insult Patch Test On the Normal Individual

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Abstract

Background: Cosmetics based on cocoa fruit gaining traction due to its natural origins. Thus, in collaboration with the Malaysian Cocoa Board, a line of cocoa-based cosmetic namely COPHORIA products were produced.

Aim: To evaluate the potential of COPHORIA products namely Liquid Foundation, BB Cushion, Blusher Cushion, Compact Powder and Loose Powder under test to induce elicit Type IV skin sensitization reactions (that is allergic contact dermatitis) in humans.

Methods: Each COPHORIA product was tested using a human repeat insult patch test. A sample of the product and control material (distilled water) were applied to human skin. The study was conducted in two phases, the induction phase (3 weeks) and the challenge phase (4-days). Scoring was based on the standard scoring criteria of the North American Contact Dermatitis Research Group (NACDRG).

Results: A total of 153 subjects, all female (46.40 ± 8.81 years) were enrolled on five COPHORIA product test groups (30 – 31 subjects per product). All subjects in each product test group had a final score of not more than 1.5 during the induction phase and challenge phase. All products were identified to be non-irritating to skin based on the mean cumulative irritation index (MCII) for each COPHORIA product; Liquid Foundation (0.06), BB cushion (0.006), blusher cushion (0.000), compact powder (0.003) and Loose powder (0.043).

Conclusion: There is no clinical evidence of the presence of chemical additives at the level that may induce Type IV allergy in all COPHORIA products tested.

Keywords: cocoa-based, cosmetics, human repeat insult patch, makeup

Introduction

Cocoa consumption, either orally or topically, can protect human skin from damaging UV rays. This is because cocoa has antioxidant, anti-inflammatory, and photoprotective properties that are good on the skin. Primarily, cocoa polyphenols have been identified to inhibit the induction of COX-2, activation of MAPKs and NF- κ B signalling which are known to be linked to ROS overproduction during skin exposure to UV [1-2]. Cocoa polyphenol has been shown to positively affect skin elasticity and skin tonus namely, glycosaminoglycans and collagen I, III and IV. Furthermore, the antioxidants in cocoa aid in the prevention of premature ageing of skin cells by reducing oxidative stress [2-3]. Cocoa also improves skin density and hydration by increasing blood flow to the cutaneous and subcutaneous regions [4]. From these studies, cocoa has potential as an anti-ageing agent [1-5]. Due to these advantages, cocoa-based cosmetic was developed by Proxima Technologies PLT with the help of the Malaysian Cocoa Board.

Proxima Technologies PLT cocoa-based cosmetic products (COPHORIA) contained a high percentage of cocoa powder (refer to Appendix I for full COPHORIA product ingredients), apart from other standard cosmetic ingredients such as talcum [6] and Ethylhexyl methoxycinnamate [7]. Patch testing of cosmetic products is a standard activity to diagnose allergic contact dermatitis from the product [8-10]. To detect Type IV skin sensitization reactions (that is allergic contact dermatitis) in humans that might arise from ingredients in the COPHORIA products, multiple human repeated insult patch tests (HRIPT) were conducted.

The HRIPT is over half a century old but is still used in several countries as a confirmatory test in the safety evaluation of skin sensitizers. Sensitization is the process by which a person becomes, over time, increasingly allergic to a substance through repeated exposure to that substance. It is very different from irritation because it involves an immune response, the reactions become worse with repeated exposure, and it is usually specific to individuals. The HRIPT consist of 2 phases [8-9].

Phase I is the Induction Phase where the product is applied to the skin a few times during a week. This is followed by an approximately 3 weeks' rest period after which the skin is exposed to the product again in Phase II or the Elicitation Phase. A response in Phase II is usually an allergic reaction and Phase III is used to verify and better define the reaction [8-9]. In this study, COPHORIA products namely COPHORIA Liquid Foundation, COPHORIA BB Cushion, COPHORIA Blusher Cushion, COPHORIA Compact Powder and COPHORIA Loose Powder were tested to evaluate potential products under the condition of test to induce and elicit Type IV skin sensitization reactions (allergic contact dermatitis) in human.

Methods

The test was performed by Healthmedic Research Sdn. Bhd. and conducted in compliance with the Helsinki Declaration and written informed consent from the subject. For each COPHORIA product tested, the study received human ethic approval from Healthmedic Research Ethic Committee (HMREC); COPHORIA Compact Powder (HMREC-HMR-25-2021), COPHORIA BB Cushion (HMREC-HMR-26-2021), COPHORIA Blusher Cushion (HMREC-HMR-27-2021), COPHORIA Loose Powder (HMREC-HMR-34-2021),

COPHORIA Liquid Foundation (HMREC-HMR-35-2021). The test was performed on different non-sensitized adults (Figure 1) between November 2021 and May 2022. A written consent form was signed before enrolment into the study.

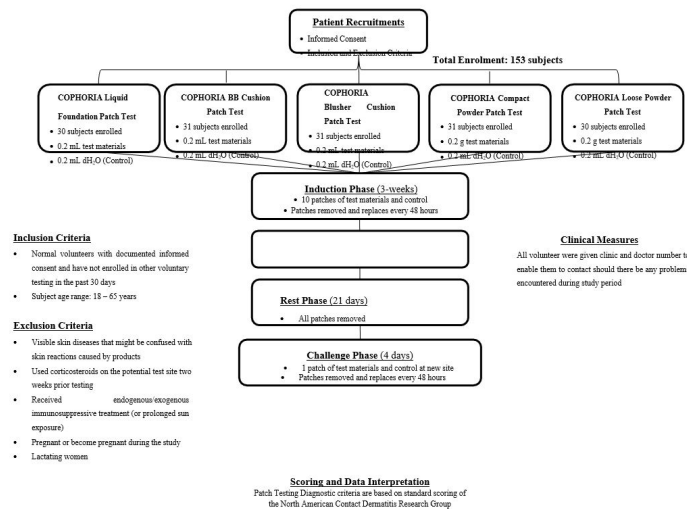


Figure 1: Subject Recruitment and Study Procedure Flowchart

The procedures for recruitment involve a thorough explanation of the purpose and conduct of the study and any possible risks or consequences resulting from their participation in the study. Each subject read and countersigned the consent form before recruitment into the study. The selection of the subjects was made according to the inclusion and exclusion criteria (Figure 1).

The test material was tested on human skin. The study was conducted in two phases. For each COPHORIA product tested, a sample of the test materials (Figure 1) was applied onto a minimum surface area of 0.8 cm by 0.8 cm of the skin of each test subject. The test material was patched onto the upper back area and continuously secured on the edges with a nonreactive adhesive tape, and micropore whilst ensuring the complete occlusion of the patch. A neutral control patch was also applied with a 2 cm by 2 cm Kendall Webril pad wetted with 0.2 mL distilled water. The induction phase of the test includes the application of ten patches of test material each Monday, Wednesday and Friday. The test material was removed and replaced with a new one at the same site every 48 hours for a total of ten changes. Patches applied on Friday were removed on Monday. Any signs of erythema, oedema or dryness (scaling) or any allergic reaction, if any, were recorded. Subjects that developed a reaction that occurred to an initial induction test patch, were considered pre-sensitised individuals. Reaction observed after placement of the second patch in the induction phase was generally considered an irritation.

At the end of the three-week induction period, the tenth test patch was removed and no further test materials were applied to the test subjects for approximately 21 days until the challenge patches were applied. After the rest period, 2 consecutive 48 hours of challenge patches, of the same test material, a minimum of 0.8 cm by 0.8 cm in surface area were applied consecutively to a virgin site. The test was evaluated again for signs of erythema, oedema or dryness (scaling) or any allergic reaction, if any, at the time of each patch removal and again 2 to 4 days after removal of the second patch. All adverse events observed during the study period were reported. All findings were recorded in the case record form.

Test results were evaluated by investigators and scored based on standard scoring of the North American Contact Dermatitis Research Group (NACDRG) as conducted by Jeffrey *et al.* [10]. The mean cumulative irritation index (MCII) was used to grade the degree of severity of cutaneous reaction towards the test material. The score is graded according to ISO 10993-10:2010 (E) by following Equation (1).

Mean Cumulative irritancy index (MCII) = Sum of irritation score/number of readings (1)

Results

A total of 153 human subjects were patched with test material and control material. Thirty subjects were recruited into COPHORIA Liquid Foundation and Loose Powder test group each while 31 subjects were recruited into COPHORIA BB Cushion, Blusher cushion and Compact Powder each. The age range of the study subjects was between 19 – 58 years (mean 45.85 ± 9.28 years). All subjects were female and Malay (Figure 1).

All subjects had a final score of skin reaction not more than 1.5 during the Induction Phase and the Challenge Phase (Table 1-5, Supplementary Table 1-5). No skin reaction was observed on the control material (data not shown) when tested with COPHORIA products. The mean cumulative irritation index (MCII) for all subjects for all COPHORIA products was less than 0.0 (Table 6-10). The lowest MCII for COPHORIA products were found to be from blusher cushion (MCII = 0.000, Table 6), followed by compact powder (MCII = 0.003, Table 8) and BB cushion (MCII = 0.006, Table 3). The highest MCII for COPHORIA products were found to be from the liquid foundation (MCII = 0.06, Table 1) follow by loose powder (MCII = 0.043, Table 10). The results of the final score are summarized in Table 11 while Table 12 summarised the percentage of positive reactions in the duration of the induction and challenge test.

Table 1: Scoring of skin reaction induced by the COPHORIA Liquid Foundation patches in 30 non-sensitised subjects.

Day	Induction Phase											Challenge Phase 48 hours			
	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
0	30	28	25	28	30	29	29	28	29	27	25	30	28	26	25
0.5	0	1	4	1	0	1	1	1	1	2	5	0	1	3	4
1	0	1	1	1	0	0	0	1	0	1	0	0	1	1	1
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2: Scoring of skin reaction induced by the COPHORIA BB Cushion patches in 31 non-sensitised subjects.

Day	Induction Phase											Challenge Phase 48 hours			
	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31
0	31	29	31	31	31	31	31	31	31	31	31	31	30	31	31
0.5	0	2	0	0	0	0	0	0	0	0	0	0	1	0	0
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 3: Scoring of skin reaction induced by the COPHORIA Blusher Cushion patches in 31 non-sensitised subjects.

Day	Induction Phase											Challenge Phase 48 hours			
	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31
0	31	31	31	31	31	31	31	31	31	31	31	31	31	31	31
0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table4

Table 5: Scoring of skin reaction induced by the COPHORIA Loose Powder patches in 30 non-sensitised subjects.

Day	Induction Phase											Challenge Phase 48 hours			
	1	3	5	8	10	12	15	17	19	22	24	1	3	5	8
Patch no (removal)		1	2	3	4	5	6	7	8	9	10				
Total Score	30	30	30	30	30	30	30	30	30	30	30	30	30	30	30
0	30	29	25	29	30	27	30	30	30	27	27	30	30	28	26
0.5	0	1	5	1	0	3	0	0	0	3	3	0	0	2	4
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 6: Tabulation of Daily Total Irritation Score (TS) of Cutaneous Reaction and its Mean Cumulative Irritancy Index (MCII) for COPHORIA Liquid Foundation.

Score Value	Day 1	Day 3	Day 5	Day 8	Day 10	Day 12	Day 15	Day 17	Day 19	Day 22	Score frequency	Score value x frequency
0	30	28	25	28	30	29	29	28	29	26		
1	0	2	5	2	0	1	1	2	1	4	18	18
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
No of Subjects	30	30	30	30	30	30	30	30	30	30		
TOTAL CUMULATIVE SCORE											18	
COPHORIA Liquid Foundation MCII = Sum of irritation score/number of readings											0.06 (Non-irritating)	

Table 7: Tabulation of Daily Total Irritation Score (TS) of Cutaneous Reaction and its Mean Cumulative Irritancy Index (MCII) for COPHORIA BB Cushion patches.

Score Value	Day 1	Day 3	Day 5	Day 8	Day 10	Day 12	Day 15	Day 17	Day 19	Day 22	Score frequency	Score value x frequency
0	31	29	31	31	31	31	31	31	31	31		
1	0	2	0	0	0	0	0	0	0	0	2	2
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
No of Subjects	31	31	31	31	31	31	31	31	31	31		
TOTAL CUMULATIVE SCORE											2	
COPHORIA BB Cushion MCII = Sum of irritation score/number of readings											0.006 (Non-irritating)	

Table 8: Tabulation of Daily Total Irritation Score (TS) of Cutaneous Reaction and its Mean Cumulative Irritancy Index (MCII) for COPHORIA Blusher Cushion material.

Score Value	Day 1	Day 3	Day 5	Day 8	Day 10	Day 12	Day 15	Day 17	Day 19	Day 22	Score	Score value x frequency
0	31	31	31	31	31	31	31	31	31	31		
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
No of Subjects	31	31	31	31	31	31	31	31	31	31		
TOTAL CUMULATIVE SCORE											0	
COPHORIA Blusher Cushion MCII = Sum of irritation score/number of readings											0.000 (Non-irritating)	

Table 9: Tabulation of Daily Total Irritation Score (TS) of Cutaneous Reaction and its Mean Cumulative Irritancy Index (MCII) for COPHORIA Compact Powder material.

Score Value	Day 1	Day 3	Day 5	Day 8	Day 10	Day 12	Day 15	Day 17	Day 19	Day 22	Score frequency	Score value x frequency
0	31	31	31	31	31	31	31	31	31	31		
1	0	0	1	0	0	0	0	0	0	0	1	1
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
No of Subjects	31	31	31	31	31	31	31	31	31	31		
TOTAL CUMULATIVE SCORE											1	
COPHORIA Compact Powder MCII = Sum of irritation score/number of readings											0.003 (Non-irritating)	

Table 10: Tabulation of Daily Total Irritation Score (TS) of Cutaneous Reaction and its Mean Cumulative Irritancy Index (MCII) for COPHORIA Loose Powder material.

Score Value	Day 1	Day 3	Day 5	Day 8	Day 10	Day 12	Day 15	Day 17	Day 19	Day 22	Score frequency	Score value x frequency
0	30	29	25	29	30	27	30	30	29	28		
1	0	1	5	1	0	3	0	0	0	3	13	13
2	0	0	0	0	0	0	0	0	1	0	1	2
3	0	0	0	0	0	0	0	0	0	0	0	0
No of Subjects	30	30	30	30	30	30	30	30	30	30		
TOTAL CUMULATIVE SCORE											15	
COPHORIA Loose Powder MCII = Sum of irritation score/number of readings											0.05 (Non-irritating)	

Table 11: Final score of the skin reaction induced by the test patches during the challenge phase in non-sensitised subjects for all COPHORIA products.

Sample	Total Score	Number of Subjects
COPHORIA Liquid Foundation	Score less than 1.5	30
	Score more than 1.5	0
COPHORIA BB Cushion	Score less than 1.5	31
	Score more than 1.5	0
COPHORIA Blusher Cushion	Score less than 1.5	31
	Score more than 1.5	0
COPHORIA Compact Powder	Score less than 1.5	31
	Score more than 1.5	0
COPHORIA Loose Powder	Score less than 1.5	30
	Score more than 1.5	0

Table 12: Summary of percentage of positive reaction during the induction phase and challenge phase for all COPHORIA products and the control sample.

Description	Number of subjects	Percentage of positive reaction in non-sensitized subjects	
		Induction	Challenge
Test Material: COPHORIA Liquid Foundation test material Control Material: Kendal Webril pad wetted with distilled water	30	0%	0%
	30	0%	0%
Test Material: COPHORIA BB Cushion Control Material: Kendal Webril pad wetted with distilled water	31	0%	0%
	31	0%	0%
Test Material: COPHORIA Blusher Cushion Control Material: Kendal Webril pad wetted with distilled water	31	0%	0%
	31	0%	0%
Test Material: COPHORIA Compact Powder Control Material: Kendal Webril pad wetted with distilled water	31	0%	0%
	31	0%	0%
Test Material: COPHORIA Loose Powder Control Material: Kendal Webril pad wetted with distilled water	30	0%	0%
	30	0%	0%

Discussions

The cosmetics products tested contained cocoa powder processed by the Malaysian Cocoa Board. A previous study using cocoa has shown cocoa is non-toxic to skin cells and even helps reduce wrinkles on the skin after application [11]. Other ingredients used to formulate each COPHORIA product (e.g. talcum, Ethylhexyl methoxycinnamate), which are potential allergens materials already have been proven to be safe for human skin [12-14]. Apart from the mentioned ingredients, there is no known chemical component in COPHORIA products that may induce Type IV allergy such as parabens and thiomersal which are common allergens in cosmetic products [15]. From the results obtained, all COPHORIA products show negative results in inducing Type IV skin contact dermatitis.

A patch test is the primary diagnostic tool for evaluating cosmetic products inducing allergic contact dermatitis. Primarily, HRIPT is used to simulate and exaggerate the everyday situation of product application on the skin [8 - 9]. Based on the result obtained, none of the subjects in each test group showed excessive reactions towards the COPHORIA products tested. It can be interpreted that there is no allergen causative agent exist or that the existence of allergen has no clinical effects on the skin of the study subjects. Thus, it can be expected that the potential of the COPHORIA product to induce chemical sensitization in the user population is less than 1.5%.

The ingredients of cosmetic products usually contain other chemical constituents apart from their main active ingredients such as a preservative agent and/or colouring and fragrance agent. This is also true for COPHORIA products which contain other ingredients apart from cocoa such as talcum, Ethylhexyl methoxycinnamate. However, the North American Contact Dermatitis Group (NACDG) and various other dermatological groups have already conducted large screening series to detect positive reactions of various allergens that are commonly found in cosmetic products such as talcum and Ethylhexyl methoxycinnamate

which is also found in COPHORIA product [12-14]. Since there are no positive reactions were observed in all subject tested from the COPHORIA products' containing talcum and Ethylhexyl methoxycinnamate, thus COPHORIA products are suitable to be used by human as it meets the criteria of low dermatitis potential.

Conclusion

The human repeated insult patch test for all COPHORIA products is negative. There was no clinical evidence in all COPHORIA products of the presence of residual chemical additives at the level that may induce Type IV allergy in the unsensitised human. The cocoa-based cosmetic products provide an alternative for users that prefer fruit-based ingredients in their cosmetics.

Conflict of Interest Declaration

Ainil Hawa Jasni and Dasyariwani Sariah Daud are the directors of Proxima Technologies PLT. and Dr. Ahmad Kamil Mohd Jamil (Deputy Director General of Malaysian Cocoa Board) declares no conflicts of interest. Malaysian Technology Development Corporation had sponsored the study.

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Supplementary

Supplementary Tables 1: Repeat Insult Patch Test Tabulation of scoring: COPHORIA Liquid Foundation – Basic and Supplemental Score of cutaneous reaction that occurred during the Induction and Challenge Phase. (ST, Skin type according to Fitzpatrick Skin Type; B, Basic Score; S, Supplemental Score)

No.	Age	ST	Induction Phase																				Challenge Phase									
			Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8	
			B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	55	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0
2	38	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	48	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	52	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	38	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	47	III	0	0	0.5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0.5	0
8	44	IV	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0.5	0.5	0	0	0	0	0	0	0	0	0.5	0
9	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0.5
10	19	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	30	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	49	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	45	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	55	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0
19	48	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	28	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0.5	0	0	0	0	0	0	0	0	0	0
22	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0
24	58	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0
25	56	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	47	IV	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0.5	0	0.5	0
28	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	52	IV	0	0	1	0	1	0	1	0	0	0	0.5	0	0.5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	43	IV	0	0	0	0	0.5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Supplementary Tables 2: Repeat Insult Patch Test Tabulation of scoring: COPHORIA BB Cushion – Basic and Supplemental Score of cutaneous reaction that occurred during the Induction and Challenge Phase. (ST, Skin type according to Fitzpatrick Skin Type; B, Basic Score; S, Supplemental Score)

No.	Age	ST	Induction Phase															Challenge Phase																		
			Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8					
			B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
2	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
3	52	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
4	42	III	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
5	58	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
6	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
7	47	IV	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
8	48	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
9	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
10	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
11	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
12	49	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
13	42	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
14	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
15	45	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
16	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
17	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
18	19	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
19	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
20	30	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
21	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
22	38	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0
23	44	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
24	55	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	56	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	51	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	46	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	28	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	38	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	22	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

31	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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Supplementary Tables 3: Repeat Insult Patch Test Tabulation of scoring: COPHORIA Blusher Cushion – Basic and Supplemental Score of cutaneous reaction that occurred during the Induction and Challenge Phase. (ST, Skin type according to Fitzpatrick Skin Type; B, Basic Score; S, Supplemental Score)

No.	Age	ST	Induction Phase																Challenge Phase															
			Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8			
			B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S
1	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	52	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	42	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	58	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	48	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	49	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	42	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	45	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	19	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	30	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	38	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	44	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	55	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	56	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	51	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	46	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	28	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

29	38	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	22	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Supplementary Tables 4: Repeat Insult Patch Test Tabulation of scoring: COPHORIA Compact Powder – Basic and Supplemental Score of cutaneous reaction that occurred during the Induction and Challenge Phase. (ST, Skin type according to Fitzpatrick Skin Type; B, Basic Score; S, Supplemental Score)

No.	Age	ST	Induction Phase																Challenge Phase														
			Day 1		Day 3		Day 5		Day 8		Day 10		Day 12		Day 15		Day 17		Day 19		Day 22		Day 24		Day 1		Day 3		Day 5		Day 8		
			B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	B	S	
1	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	52	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	42	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5	58	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	48	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	53	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	45	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	49	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	42	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	46	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	45	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	53	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	57	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	19	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	54	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	30	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	47	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	38	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	44	III	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	55	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	56	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	51	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

27	48	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
28	47	IV	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0
29	43	IV	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	42	IV	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0