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SENSITIZING POTENTIAL STUDY OF A PRODUCT ACCORDING TO MARZULLI-MAIBACH METHOD HRIPT - FINAL CLINICAL SECURITY TEST

REPORT

STUDY REFERENCE.	**IA-220**
PRODUCT	**«LILIKIWI - MOUSSE NETTOYANTE – REF : LC MNVC0001-4.06»**
NUMBER OF SUBJECTS	**50**
COORDINATING CENTER	**IDEA CLINIC** Technopôle Montesquieu, 5 rue Jacques Monod, CS 60077-33652 MARTILLAC CEDEX FRANCE
DIRECTOR	**Benoit LATOUCHE Director**
INVESTIGATING CENTER	**LISKIN**
INVESTIGATOR	**Dr Marlena Nowakowska, Dermatologist**

CONFIDENTIAL DOCUMENT - PROPERTY OF PROMOTER

21 pages document

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STUDY SUMMARY

TITLE : SENSITIZING POTENTIAL STUDY OF A PRODUCT ACCORDING TO MARZULLI-MAIBACH METHOD, ON 50 SUBJECTS DURING 6 WEEKS - FINAL CLINICAL SECURITY TEST

STUDY REFERENCE : IA-220

PRODUCT : LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06

STUDY IMPLEMENTATION: The study was carried out and all test values recorded by the Clinical Unit PROCOS, localized in Poland; ul. Słowackiego 27/33 lok. 33/34; 01-592 Warsaw.

INVESTIGATOR : Dr Marlena NOWAKOWSKA

PROTOCOL : CLINICAL EVALUATION OF THE SENSITIZING POTENTIAL OF A PRODUCT ACCORDING TO MARZULLI-MAIBACH METHOD.

AIM OF THE STUDY : To evaluate the irritating potential and sensitizing potential of a product (tested 2% diluted with water) under dermatological control and under the conditions defined by study's sponsor.

SUBJECTS : 50 healthy subjects with all kind of skin corresponding to the inclusion and non-inclusion criteria.

STUDY SCHEDULE : November 30th, 2020 to January 08th, 2021

EXPERIMENTAL DESIGN : simple blind and monocentric study.

MAIN TOLERANCE PARAMETERS :

- Irritation potential (Induction Phase)
  Erythema, oedema, desquamation, vesicles rated from 0 to 3 by the dermatologist
- Sensitizing potential (Challenge Phase)
  Reaction rated from 0 to 3 by the dermatologist according to ICDRG (International Contact Dermatitis Research Group)

RESULTS :

PRODUCT FD	**Irritation potential**	**Sensitizing potential**
LILIKIWI - MOUSSE NETTOYANTE – REF : LC MNVC0001-4.06	Mean rate of 0.000 = non-irritating	No allergic reaction

CONCLUSION :

Under these study conditions, the product «LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06» can be considered non-irritating and non-sensitizing.

1. REGULATORY AND ETHICAL ASPECTS

This study has been performed with respect to World Medical Association WMA recommandations (Helsinki's Declaration 1964 & last updates), and based on Good Clinical Practice GCP guidelines defined by International Conference on Harmonisation (ICH E6R1 1996, ICH E6R2 2015) and by European Directive 2001/20/EC.

The first assessment of product safety and risks for the subjects has been performed under promoter's responsibility.

PROCOS suscribed an insurance with PZU company (Police N°1017155572) covering the clinical unit Civil Liability as investigation center, following L1121-10 article of french Public Health Code CSP.

The study has been conducted according to the protocol and standard operating procedures SOP. Every event recorded during the study has been reported in the observation folder and study technical documents.
Authenticity and veracity of experimental data recorded have been confirmed by the team who implemented the study. See Appendix I.

2. QUALITY CONTROL

To my knowledge, the study IA-220 has been conducted in accordance with the regulatory and quality aspects mentioned above.
There was no event that could affect the data quality or integrity.

January 19th, 2021

Mme Charlotte OEHMICHEN
Technical Director

date

3. METHOD

3.1. STUDY PRODUCT

The product supplied by IDEA CLINIC, has the following characteristics :

Product name	Product Type	Product presentation	Study ref
LILIKIWI - MOUSSE NETTOYANTE – REF : LC MNVC0001-4.06	cosmetic product	transparent uncolored liquid	FD

The product was delivered on November 17th, 2020.
A sample of the tested product is stored at ambient T°C and protected from light, at LISKIN, during 3 months after the end of the study. After this period and except in case of a specific ask from the promoter, the product is destroyed.

3.2. CLINICAL METHODS

3.2.1. Aim of the study

To assess the irritating potential and the sensitizing potential of a product under dermatological control and according to Marzulli-Maibach method.

3.2.2. Experimental design

This was a simple blind and monocentric study.

3.2.3. Study subjects

Inclusion criteria

- Healthy subject of Caucasian origin,
- Age between 18 and 70,
- Phototype I, II or III,
- All kind of skin,
- Subjects having given their informed, written consent,
- Cooperative subjects, aware of the necessity and duration of controls so that perfect adhesion to the protocol established by LISKIN could have been expected.

Non-inclusion criteria

- Pregnancy or nursing women,
- Sun exposure or UV exposure 15 days before study and/or photopatchs from less than 2 months,
- Hyper irritable skin,
- Known allergies or sensitivities to cosmetics product and Elastoplast,
- Skin pathology on the test zones, Scars, beauty spots, freckle or any abnormality, on the back,
- Subjects afflicted with serious or progressive diseases,
- Subjects undergoing a topical or systemic treatment: anti-inflammatories, antihistamines, immuno-suppressors, corticoids and retinoids.

Inclusion

50 healthy subjects have been selected according to the inclusion and the non-inclusion criteria and completed the study. The table below presents the informations concerning all the subjects included.

	Non included	Included	Drop out	Untraceable
Number of subjects	0	50	0	0

Subjects characteristics

The summary table below presents a synthesis of the observations concerning exclusively the subjects taken into account for data analysis.

Number of subjects	Sex	Age (mean±SEM)	Phototype (number of subject)	Medical or surgical events and medical treatments	
				Before study	During the study
50	42 F 8 M	43 ± 2	I : 0 II : 50 III : 0	cf. Table in APPENDIX II	

3.3 MATERIAL

The semi-occlusive patches used are « Scanpore ® Tape (1cm^2) » ensuring a semi occlusion.

4. PRODUCT APPLICATION

Application area	Scapular zones: homolateral (induction zone) and controlateral (challenge zone)
Quantity and Concentration applied	50 µl 2% diluted with water
Frequency & Contact time	Induction Phase: 3 times a week during 48 hours Challenge Phase: once during 48 hours
Phase duration	Induction Phase: 3 weeks Rest Phase: 2 weeks Challenge Phase: 1 week
Application conditions	Before any application, the skin was cleaned and dried. The tested product was applied under semi-occlusive patch (filter paper) on subject's back. A patch containing no product was applied under the same conditions to serve as a non-treated control. During all Induction Phase, the homolateral zone was not wet. The subjects took a shower on Sunday, after patch removal, and paid attention not to put any detergent product on all tested zones. During all Challenge Phase, no washing and no product application took place on controlateral zone.

5. STUDY SCHEDULE

The study was carried out according to the following diagram:

Induction Phase - 3 weeks (W1, W2, W3)

WEEK 1	Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
	Study day	D1	D2	D3	D4	D5	D6	D7
	Product application	🡻		🡻		🡻		
	Readings			**R**		**R**		
WEEK 2	Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
	Study day	D8	D9	D10	D11	D12	D13	D14
	Product application	🡻		🡻		🡻		
	Readings	**R**		**R**		**R**		
WEEK 3	Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
	Study day	D15	D16	D17	D18	D19	D20	D21
	Product application	🡻		🡻		🡻		
	Readings	**R**		**R**		**R**		

After having removed the last patch of the induction phase at home, it was asked to the subjects, to come at the clinical unit D22 if a new sign appeared (or deterioration of an existing sign D19).

Rest Phase - 2 weeks (W4, W5)

WEEK 4	Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
	Study day	D22	D23	D24	D25	D26	D27	D28
WEEK 5	Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
	Study day	D29	D30	D31	D32	D33	D34	D35

Challenge Phase - 1 week (W6)

WEEK 6	Day of the week	Mo	Tu	We	Th	Fr
	Study day	D36	D37	D38	D39	D40
	Product application	🡻				
	Readings			**R**		**R**

6. ASSESSMENT CRITERIA

6.1. CLINICAL CRITERIA REGARDING THE IRRITATING POTENTIAL (INDUCTION PHASE)

After each application, the patch is removed and the clinical examination is performed by the investigator 30 minutes later in order to eliminate the pressure and the occlusion effects.
The result of examination is zero if the skin looks normal.
The clinical examination is made on the back using the following criteria and scale:

Score	Cotation	**CRITERIA** : description			
		ERYTHEMA	EDEMA	DRYNESS	VESICLES
0	Absent	Normal aspect	Normal aspect	Normal aspect	Normal aspect
0.5	Doubtful	Barely perceptible: quite pink coloration of one part of the tested area			
1	Slight	Discreet pink coloration of the whole tested area or rather visible on part of the tested area	More palpable than visible oedema	Discreet thin desquamation, tarnished aspect	More palpable than visible vesicles
2	Marked	Marked erythema covering the whole tested area	Visible oedema	Visible desquamation, flaky aspect.	Visible vesicles
3	Important	Severe erythema covering the whole tested area or erythema diffusing beyond the tested area	Oedema diffusing beyond the tested area	Important desquamation, cracking	Vesicles diffusing beyond the tested area or blisters.

6.2. CLINICAL CRITERIA REGARDING THE SENSITIZING POTENTIAL (CHALLENGE PHASE)

The allergic reactions are evaluated according to the following scale:

Criterion	Quotation ICDRG (*)	Score noted in all tables
No reaction	0	0
Doubtful reaction	?	?
Erythema and oedema	+	1
Erythema, oedema and vesicles	++	2
Severe reaction with blisters	+++	3

(*) - International Contact Dermatitis Research Group

6.3. ASSESSMENT METHOD

6.3.1. Irritating potential - Induction Phase

At the conclusion of the 8 readings of the induction phase, the average score of every subject was calculated by adding the scores obtained for each of the readings and by dividing this sum by the actual number of readings made at the clinical unit (a reading was not taken into account if there was reaction of the control or global irritation).
The irritating potential of the product will be estimated during the Induction Phase, by calculating the mean of the reactions observed.

The irritating potential (IRR) of the product is determined according to the following formula:

$$I.R.R = \frac{[(\sum \text{scores D1…D19/ nb of readings) vol1+...+(}\sum \text{scores D1…D19/ nb of readings) volN}]}{\text{nb of subjects (N)}}$$

Average score (IRR)	Irritating Potential
score < 0,080	Non-irritating
0,080 ≤ score < 0,160	Very slightly irritating
0,160 ≤ score < 0,560	Slightly irritating
0,560 ≤ score < 1,000	Moderately irritating
1,000 ≤ score < 1,600	Irritating
1,600 ≤ score	Very irritating

6.3.2. Sensitizing potential - Challenge Phase

The possible allergic reaction, during the Induction or Challenge Phase, will be rated from 0 to 3 according to ICDRG (International Contact Dermatitis Research Group).
During the Challenge Phase, the reading will take place 30 minutes after patches removal and 48 hours later D38 and D40.

The sensitizing potential of the product will be assessed by the reading D38 and D40 (Challenge Phase) as a function of the following criteria: reaction ++ (2) or +++ (3).
The presence of only one case of active sensitizing (upper or equal score in ++ (2)) on controlateral side leads to the conclusion “Potentially sensitive product”.

6.4. PREMATURE STUDY TERMINATION

The subjects have the right to leave the study at any time whatever the reason.
The premature study termination can be for multiple reasons:

- non-compliance with the visits schedule by the subject,
- adverse events (including intercurrent diseases),
- protocol non-adherence/departures from protocol,
- Withdrawal of subject's consent.

The doctor investigator can interrupt the essay either on certain subjects or on the whole panel, if the product induces important or abnormal cutaneous reactions or if he considers that the continuation of the essay can damage health of one or several concerned subjects.

6.5. PROTOCOL AMENDMENT

None

7. RESULTS

7.1. IRRITATING POTENTIAL: INDUCTION PHASE

The TABLE OF READINGS regarding the Induction Phase is presented in APPENDIX III.

These reading made 30 min. after having removed the patch-tests showed the following results:

Produit FD	D3	D5	D8	D10	D12	D15	D17	D19	Conclusion
LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06	Results - number of subjects								**non-irritating** (IRR = 0.000)
	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	C : 0 0 : 50	
	Results - Percentage								
	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	C : 0% 0 : 100%	

C = Control IRR = global irritation MV = missing value

Under these study conditions, the product «LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06» showed a score lower than 0.080, so it can be considered <u>non-irritating</u>.

7.2. SENSITIZING POTENTIAL: CHALLENGE PHASE

The TABLE OF READING regarding the Challenge Phase is presented in APPENDIX IV.
These reading made 30 minutes and 48 hours after having removed the patch-tests showed the following results:

Product Code : FD	Zones	score	Day of the reading				Global result
			D38		D40		
			n	%	n	%	
LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06	Homolateral zone readings	C :	0	0	0	0	non-sensitizing
		0 :	50	100	50	100	
		? :	0	0	0	0	
		1 :	0	0	0	0	
		2 :	0	0	0	0	
		3 :	0	0	0	0	
	Controlateral Zone readings	C :	0	0	0	0	
		0 :	50	100	50	100	
		? :	0	0	0	0	
		1 :	0	0	0	0	
		2 :	0	0	0	0	
		3 :	0	0	0	0	

FD = LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06
C = Control
VM = missing value
n = number of subjects
% = % of subjects

Under these study conditions, no reaction ++ (2) nor +++ (3) were observed, so the product «LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06» can be considered <u>non-sensitizing</u>.

8. CONCLUSION

Under these study conditions, the product «LILIKIWI - MOUSSE NETTOYANTE - REF : LC MNVC0001-4.06» can be considered <u>non-irritating</u> and <u>non-sensitizing</u>.

APPENDICES

APPENDIX I

RESULTS AUTHENTIFICATION SHEET

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ORYGINAŁ

KARTA AUTENTYCZNOŚCI REZULTATÓW
FICHE D'AUTHENTIFICATION DES RESULTATS
AUTHENTIFICATION PAGE

IA-220
RIPT - Human Repeated Insult Patch Test

Według posiadanych przeze mnie informacji, badanie było przeprowadzone zgodnie PROTOKOŁEM oraz KARTĄ PARAMETRÓW TESTU.
A ma connaissance l'étude a été conduite en accord avec le PROTOCOLE et la FICHE DES PARAMETRES D'ETUDE.
To my knowledge the study has been conducted according to the PROTOCOL and STUDY PARAMETERS PAGE.

Mgr Magdalena KUROPKA Odpowiedzialna za badania i jakość *Responsable d'Unité & Qualité* *Unit & Quality Manager*	podpis / *signature*	08.01.2021 data / *date*
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APPENDIX II

SUBJECTS CHARACTERISTICS

SUBJECTS CHARACTERISTICS

Subject number	Age	Sex **F** or **M**	Phototype	Skin type (**N**on-sensitive or **S**ensitive)	Medical or surgical events and medical treatments	
					before the study	during the study
1	33	F	II	NS	-	-
2	36	F	II	S	-	-
3	55	F	II	NS	-	-
4	56	F	II	NS	-	-
5	60	M	II	NS	-	-
6	23	F	II	NS	-	-
7	30	F	II	NS	-	-
8	36	F	II	S	-	-
9	62	F	II	NS	-	-
10	52	F	II	NS	-	-
11	38	F	II	NS	-	-
12	39	F	II	S	-	-
13	54	F	II	NS	-	-
14	60	F	II	NS	-	-
15	56	F	II	NS	-	-
16	19	F	II	NS	-	-
17	49	F	II	NS	-	-
18	27	F	II	NS	-	-
19	41	F	II	S	-	-
20	43	F	II	NS	-	-
21	30	F	II	S	-	-
22	39	F	II	S	-	-
23	26	F	II	S	-	-
24	39	F	II	S	-	-
25	46	F	II	S	-	-
26	55	F	II	NS	-	-
27	39	F	II	NS	-	-
28	37	F	II	S	-	-
29	32	F	II	NS	-	-
30	33	F	II	S	-	-

UN = untraceable

SUBJECTS CHARACTERISTICS - (continuation)

Subject number	Age	Sex **F** or **M**	Phototype	Skin type (**N**on-sensitive or **S**ensitive)	Medical or surgical events and medical treatments	
					before the study	during the study
31	37	M	II	S	-	-
32	42	F	II	NS	-	-
33	64	F	II	S	-	-
34	39	F	II	NS	-	-
35	42	F	II	S	-	-
36	39	F	II	NS	-	-
37	57	M	II	S	-	-
38	32	M	II	NS	-	-
39	57	F	II	S	-	-
40	39	F	II	S	-	-
41	30	M	II	S	-	-
42	57	F	II	S	-	-
43	35	M	II	NS	-	-
44	39	F	II	S	-	-
45	36	F	II	NS	-	-
46	35	M	II	NS	-	-
47	58	F	II	S	-	-
48	39	M	II	S	-	-
49	59	F	II	NS	-	-
50	46	F	II	NS	-	-

UN = untraceable

APPENDIX III

TABLE OF READING

INDUCTION PHASE

NB	D03				D05				D08				D10				D12				D15				D17				D19			
	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V
1	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

INDUCTION READINGS - Homolateral area- **TESTED PRODUCT**

NB	D03				D05				D08				D10				D12				D15				D17				D19			
	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V
1	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX IV

TABLE OF READING

CHALLENGE PHASE

REVELATION READINGS - Challenge Phase

NB	Homolateral area Control								Controlateral area Control								Homolateral area Product								Controlateral area Product							
	D38				D40				D38				D40				D38				D40				D38				D40			
	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V	E	O	D	V
1	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	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	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

E : Erythema O : Œdema V : Vesicles D : Dryness P.V.= missing data