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

Study sponsor:	Sr. Enrique Romero
Reference of client:	HRIPT
Reference of EUROFINS:	R.14000069
Tested product:	GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330

Technical Manager
AURORA BENAIGES

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STUDY SUMMARY

TITLE : SENSITIZING POTENTIAL STUDY OF A PRODUCT «DNNPPAÑAL REF: 2014-03.01 BATCH 1 (457426)» ACCORDING TO MARZULLI-MAIBACH METHOD, ON 50 SUBJECTS DURING 6 WEEKS - FINAL CLINICAL SECURITY TEST

STUDY REFERENCE : ES-1180

PRODUCT : GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)

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 sensitizing potential of a product (diluted at 5%) under dermatological control and under the conditions defined by study's sponsor.

SUBJECTS : 50 healthy subjects with normal skin corresponding to the inclusion and non-inclusion criteria defined by LISKIN.

STUDY SCHEDULE : February 3rd to March 14th, 2014

EXPERIMENTAL DESIGN : simple blind and monocentric study.

MAIN TOLERANCE PARAMETERS :

- Irritation potential (Induction Phase)
  Erythema, edema, 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 KG	**Irritation potential**	**Sensitizing potential**
GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)	Mean rate of 0,000 = non-irritating	No allergic reaction

CONCLUSION :

Under these study conditions, the product «GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)» can be considered non-irritating and non-sensitizing.

1. METHOD

1.1. STUDY PRODUCT

The product supplied by EUROFINS ATS, has the following characteristics :

Product name	Product presentation	Study ref	EUROFINS ATS REF.
GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)	opaque blue liquid	CC	457426

The product was delivered on January 20th, 2014.
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.

1.2. CLINICAL METHODS

1.2.1. 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.

1.2.2. Experimental design

This was an open study.

1.2.3. Study subjects

Inclusion criteria

- Healthy subject of Caucasian origin, male or female,
- Age between 18 and 70,
- Phototype II, III or IV,
- Sensitive 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 50 subjects completed the study. The table below presents the information 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	38 F 12 M	46 ± 2	II : 50 III : 0 IV : 0	cf. Table in APPENDIX II	

3.3 MATERIAL

The patches used are “FINN CHAMBERS ON SCANPOR®“ which ensures a good occlusion.

2. PRODUCT APPLICATION

Application area	Scapular zones: homolateral (induction zone) and controlateral (challenge zone)
Quantity and Concentration	25 µl diluted at 5% in water
Frequency &	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 product «GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330(457426)» was applied like an occlusive patch to the subject's back. The 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 take a shower on Sunday, after patches removing, and pay attention not to put a detergent product on all tested zones. During all Challenge Phase, no washing and no any product application take place on controlateral zone.

3. STUDY SCHEDULE

The study was carried out according to the following diagram:

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

W1:

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**		

W2:

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**		

W3:

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)
W4:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D22	D23	D24	D25	D26	D27	D28

W5:

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)
W6:

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

4. ASSESSMENT CRITERIA

4.1. 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
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.

4.2. 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 edema	+	1
Erythema, edema and vesicles	++	2
Severe reaction with blisters	+++	3

(*) - International Contact Dermatitis Research Group

4.3. ASSESSMENT METHOD

4.3.1. Irritating potential - Induction Phase

At the conclusion of the 8 readings of the induction phase, the average score of every volunteer 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	Strongly irritating
1,600 ≤ score	Very strongly irritating

4.3.2. 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 patchs removal and 48 hours later.

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) in the absence of added irritation phenomenon.
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”.

4.4. 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 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.

4.5. PROTOCOL AMENDMENT

None

5. RESULTS

5.1. 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 KG	J3	J5	J8	J10	J12	J15	J17	J19	Conclusion
GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)	Results - number of subjects								**non-irritating** (IRR = 0,000)
	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	T+ : 0 0 : 50	
	Results - Percentage								
	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	T+ : 0% 0 : 100%	

C+ = Positive control IRR = global irritation MV = missing value

Under these study conditions, the product «GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)» showed a score lower than 0.080, so it can be considered non-irritating under the conditions of this study (score below 0,008).

5.2. 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 : KG	Zones	score	Day of the reading				Global result
			D38		D40		
			n	%	n	%	
GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)	Homolateral zone readings	T+ :	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	T+ :	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	

CC = GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)
T+ = Positive control
VM = missing value
n = number of subjects
% = % of subjects

Under these study conditions, no reaction ++ (2) nor +++ (3) were observed, so the product «GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)» can be considered non-sensitizing.

6. CONCLUSION

Under the study conditions, the product «GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)» can be considered non-irritating and non-sensitizing.

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TABLE OF READING - CHALLENGE PHASE

APPENDIX I

RESULTS AUTHENTIFICATION SHEET

Applus LGAI

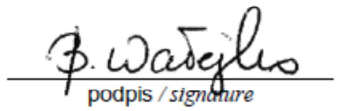
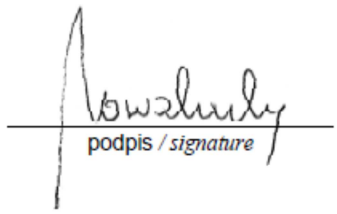
PROCOS

KARTA AUTENTYCZNOŚCI REZULTATÓW
FICHE D'AUTHENTIFICATION DES RESULTATS
AUTHENTIFICATION PAGE

Według posiadanych przeze mnie informacji, badanie Nr :
A ma connaissance l'étude N° :
I am aware that the study N° :

ES – 1180

było przeprowadzone zgodnie PROTOKOŁEM oraz KARTĄ PARAMETRÓW TESTU.
a été conduite en accord avec le PROTOCOLE et la FICHE DES PARAMETRES D'ETUDE.
has been conducted according to the PROTOCOL and to the STUDY PARAMETERS PAGE.

Mgr inż. Barbara WAŁEJKO Odpowiedzialna za badania *Responsable d'unité* Unit head	 podpis / *signature*	*14/03/2014* data */date*
Dr Marlena NOWAKOWSKA Lekarz dermatolog *Dermatologue* Dermatologist	 podpis / *signature*	*14/03/2014* data */date*
Mgr Magdalena KUREK Odpowiedzialna za jakość *Responsable qualité* Responsible for quality control	 podpis / *signature*	*14/03/2014* data */date*
Barbara SZULC Asystentka *Assistante* Medical	 podpis / *signature*	*14/03/2014* data */date*

APPENDIX II

SUBJECTS CHARACTERISTICS

SUBJECTS CHARACTERISTICS

Subject number	Subject code	Age	Sex **F** ou **M**	Phototype	Skin type (**N**ormal or **S**ensitive)	Medical or surgical events and medical treatments	
						before the study	before the study
1	PORBO	55	F	II	N	-	-
2	DMUMA	34	F	II	N	-	-
3	LAPEL	47	F	II	N	-	-
4	BIESY	48	M	II	N	-	-
5	SWIBA	64	F	II	N	-	-
6	CHRHA	60	F	II	N	-	-
7	ZEMEW	59	F	II	N	-	-
8	WLOKA	29	F	II	N	-	-
9	JAGJA	58	M	II	N	-	-
10	MIEAL	44	F	II	N	-	-
11	DABJU	33	F	II	N	-	-
12	KOZBO	41	F	II	N	-	-
13	ANDDA	49	M	II	N	-	-
14	ZAKAU	45	F	II	N	-	-
15	MALIG	54	M	II	N	-	-
16	SZARY	58	M	II	N	-	-
17	LOPMA	33	F	II	N	-	-
18	JANJO	30	M	II	N	-	-
19	PIOLU	65	F	II	N	-	-
20	KAMBE	52	F	II	N	-	-
21	KAMWA	45	M	II	N	-	-
22	WROJA	37	F	II	N	-	-
23	MACIR	37	F	II	N	-	-
24	GRZUR	45	F	II	N	-	-
25	GLUAN	57	F	II	N	-	-
26	WIKIW	55	F	II	N	-	-
27	STABA	58	F	II	N	-	-
28	GAWMA	61	F	II	N	-	-
29	OLEIR	53	M	II	N	-	-
30	JEDRE	53	F	II	N	-	-

UN = untraceable

SUBJECTS CHARACTERISTICS - (continuation)

Subject number	Subject code	Age	Sex **F** ou **M**	Phototype	Skin type (**N**ormal or **S**ensitive)	Medical or surgical events and medical treatments	
						before the study	before the study
31	SUJWI	58	F	II	N	-	-
32	TALMA	39	F	II	N	-	-
33	OLSJO	58	F	II	N	-	-
34	WOJAN	47	F	II	N	-	-
35	SIEWO	49	M	II	N	-	-
36	SADKA	54	F	II	N	-	-
37	GORBO	31	M	II	N	-	-
38	MARBE	50	F	II	N	-	-
39	TRUMO	32	F	II	N	-	-
40	KWIAN	51	M	II	N	-	-
41	KEDKR	51	F	II	N	-	-
42	KLOMO	33	F	II	N	-	-
43	GRUEW	27	F	II	N	-	-
44	GADEW	29	F	II	N	-	-
45	KUTDA	27	F	II	N	-	-
46	WOZMA	28	F	II	N	-	-
47	PALKA	53	F	II	N	-	-
48	GODEL	25	F	II	N	-	-
49	ROSTE	59	F	II	N	-	-
50	SOTKR	27	M	II	N	-	-

UN = untraceable

APPENDIX III

TABLE OF READING

INDUCTION PHASE

TABLE OF READING - Induction Phase

Subject number	D3		D5		D8		D10		D12		D15		D17		D19	
	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC
1	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
3	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
5	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
7	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
9	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
11	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
13	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
15	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
17	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
19	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
21	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
23	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
25	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
27	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
29	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

UN = untraceable
C = control
CC = GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)

TABLE OF READING - Induction Phase (continuation)

Subject number	D3		D5		D8		D10		D12		D15		D17		D19	
	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC	C	CC
31	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
33	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
35	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
37	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
39	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
41	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
43	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
45	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
47	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
49	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

UN = untraceable
C = control
CC = GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)

APPENDIX IV

TABLE OF READING

CHALLENGE PHASE

EUROFINS PRODUCT TESTING SPAIN S.L.
C/ De la Font del Carme s/n
08193 Bellaterra (Barcelona)
Campus de la UAB
Tlf. 93 5202054 Fax: 93 567 20 01

TABLE OF READING - Challenge Phase

Subject number	D38 Homolateral zone		D38 Controlateral zone		D40 Homolateral zone		D40 Controlateral zone	
	C	CC	C	CC	C	CC	C	CC
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	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	0	0	0	0	0	0	0	0
7	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	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	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	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0

UN = untraceable
C = control
CC = GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)

EUROFINS PRODUCT TESTING SPAIN S.L.
C/ De la Font del Carme s/n
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Tlf. 93 5202054 Fax: 93 567 20 01

TABLE OF READING - Challenge Phase

Subject number	D38 Homolateral zone		D38 Controlateral zone		D40 Homolateral zone		D40 Controlateral zone	
	C	CC	C	CC	C	CC	C	CC
31	0	0	0	0	0	0	0	0
32	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0

UN = untraceable
C = control
CC = GEL VERDE NATURA DE IMPREGNACIÓN BG-22 BATCH S-0001330 (457426)