

At the end of the study, a mean irritation index (M.I.I.) was calculated according to the following formula:

$$\text{M.I.I.} = \frac{\text{Sum of skin reactions (E + Oe)}}{\text{Number of analysed volunteers}}$$

Any other skin reaction (dryness, desquamation, roughness, soap effect...) was assessed according to the following scale and reported in a descriptive manner:

- 0 : no reaction
- 0.5 : very slight
- 1 : slight
- 2 : moderate
- 3 : important

The M.I.I. allowed to classify arbitrarily the test item using the scale in the table below:

M.I.I. ≤ 0.20	Non irritant
0.20 < M.I.I. ≤ 0.50	Slightly irritant
0.50 < M.I.I. ≤ 2	Moderately irritant
2 < M.I.I. ≤ 3	Very irritant

RESULTS

1. Conditions of the study

Number of subject:

- A. Included: 21
- B. Analysed: 21
- C. Patch: semi-occlusive (True med[®])
- D. Quantity: 160 µL (or 0.16 g)
- E. Dilution: pure

2. Events during the study course

A. Adverse event

No adverse event was recorded during the study.

B. Non-analysed volunteers

File	Inclusion no.	Raison / Reason
52497	5	Exclusion from the study (unstuck patch)

C. Protocol deviation

No protocol deviation was recorded during the study.

D. Other(s) event(s)

None.

3. M.I.I.

The Mean Irritation Index (M.I.I.) of the test item is:0.



CONCLUSION

The test item Energetic & Renewal Mask code ID-19/08312 can be considered as non-irritant after an application for 48 consecutive hours on 21 volunteers.

This result is conform to that obtained for the test items of same class in accordance with our database.

TABLE

Etude N° 237029 Code 1.01_48H Dossier 52497 Du 02/09/2019 Au 04/09/2019 Talence
 Study # File From To

Produit ID-19/08312 Dilution pur pure
 Product ENERGETIC & RENEWAL MASK - REF : UG/2019/71013

Caractéristiques des volontaires

Réactions cutanées

Characteristics of volunteers

Skin reactions

Inclusion N°	Initiales	Sexe	Age	Traitement	Réaction sur le site produit	Score individuel du produit	Réaction sur Témoin 1	Réaction sur Témoin 2	Remarque	(a)
#	Initials	Sex	Age	Treatment	In-situ reaction of product	Individual score of product	In-situ reaction on Control site 1	In-situ reaction on Control site 2	Remark	
1	MO-PA	F	19	-	-	0,00	-	-		X
2	RI-SY	F	57	-	-	0,00	-	-		X
3	BR-AU	F	36	-	-	0,00	-	-		X
4	FR-PI	M	22	-	-	0,00	-	-		X
5	MI-CA	F	59	-	-	0,00	-	-	Sortie d'essai - Exclusion from the study	-
6	CO-EL	F	31	-	-	0,00	-	-		X
7	MU-BA	F	30	-	-	0,00	-	-		X
8	GU-LÉ	F	19	-	-	0,00	-	-		X
9	FR-MA	F	40	-	-	0,00	-	-		X
10	BO-ZA	F	60	-	-	0,00	-	-		X
11	CA-RO	F	29	-	-	0,00	-	-		X

Nombre de volontaires inclus 11 Nombre de volontaires analysés 10
 Number of included volunteers Number of analyzed volunteers

L.I.M. 0
 M.I.L.

Résultat non irritant
 Result non irritant

Abréviations

Abbreviations
 E = Erythème Erythema
 O = Oedème Oedema
 P = Papules Papulae
 V = Vésicules Vesicles
 B = Bulles Blisters

(a) Analysés

Analysed
 X = Oui Yes
 - = Non No

Etude N° 237030 Code 1.01_48H Dossier 52884 Du 03/09/2019 Au 12/09/2019 Talence
 Study # File From To
 Produit ID-19/08312 Dilution pur pure
 Product ENERGETIC & RENEWAL MASK - REF : UG/2019/71013

Caractéristiques des volontaires Réactions cutanées

Characteristics of volunteers

Skin reactions

Inclusion N°	Initiales	Sexe	Age	Traitement	Réaction sur le site produit	Score individuel du produit	Réaction sur Témoin 1	Réaction sur Témoin 2	Remarque	(a)
#	Initials	Sex	Age	Treatment	In-situ reaction of product	Individual score of product	In-situ reaction on Control site 1	In-situ reaction on Control site 2	Remark	
1	ME-AY	F	51	-	-	0,00	-	-		X
2	CO-YU	F	42	-	-	0,00	-	-		X
3	GO-JO	M	62	-	-	0,00	-	-		X
4	MU-VI	F	24	-	-	0,00	-	-		X
5	LO-CE	F	20	-	-	0,00	-	-		X
6	VA-LI	F	35	-	-	0,00	-	-		X
7	TA-NA	F	59	-	-	0,00	-	-		X
8	MA-CÉ	F	42	-	-	0,00	-	-		X
9	VI-MO	F	38	-	-	0,00	-	-		X
10	SA-TH	F	20	-	-	0,00	-	-		X
11	MO-IN	F	19	-	-	0,00	-	-		X

Nombre de volontaires inclus 11
 Number of included volunteers

Nombre de volontaires analysés 11
 Number of analyzed volunteers

I.I.M. 0
 M.I.I.

Résultat non irritant
 Result non irritant

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