



Energetic & Renewal Mask

**Assessment, under dermatological control, of skin compatibility of a test item after single application:
48-hour semi-occlusive patch-test**

FINAL REPORT

Sponsor: CHIYI BIOTECH CO.,LTD.
Testing Institution: SGS Taiwan Ltd.
Ultra Trace & Industrial Safety Hygiene
Report No.: UG/2019/71013

- Note:**
1. The analytical report is the test result issued by the testing institutions as requested by the consignor. Regarding to the legitimacy of the product, it shall be determined by the authorities according to the law.
 2. Any unauthorized alteration, forgery or falsification of the content or appearance of this report is unlawful and offenders may be prosecuted to the fullest extent of the law.
 3. The results shown in this test report refer only to the test article(s) tested.
 4. The content of this report is invalid if it is not presented as the entire report.
 5. The test is conducted by the outsourcing French GLP laboratory



TABLE OF CONTENTS

STUDY SCHEDULE -----	3
ADDRESS INFORMATION -----	3
SIGNATURE OF STUDY PERSONNEL -----	4
OBJECTIVE -----	5
STUDIED TEST ITEM -----	5
VOLUNTEERS' CHARACTERISTICS -----	5
ASSESSMENT METHODS -----	5
RESULTS -----	6
CONCLUSION -----	7
TABLE -----	8
TEST ARTICLE PHOTO -----	10

STUDY SCHEDULE

Energetic & Renewal Mask

Assessment, under dermatological control, of skin compatibility of a test item after single application: 48-hour semi-occlusive patch-test

Report No.:	UG/2019/71013
Experimental starting date:	2019.09.02
Experimental completion date:	2019.09.12
Study completion date:	See Study Director's signature date in the report

ADDRESS INFORMATION

Testing Facility/Test Site

Name: SGS TAIWAN LTD. Ultra Trace & Industrial Safety Hygiene
Address: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City, 24890, Taiwan.

Study Director

Name: Benson Liu
Address: No. 38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku Dist., New Taipei City, 24890, Taiwan.

Sponsor

Name: CHIYI BIOTECH CO.,LTD.
Address: 4F-1, No. 122, Cisian 2nd Rd., Cianjin Dist., Kaohsiung City 80143, Taiwan(R.O.C.)

OBJECTIVE

Assess the degree of cutaneous compatibility of a test item by patch test performed on the external face of the arm for 48 hours; and, as a rule, to assess the ability of the product to keep the skin in good condition.

STUDIED TEST ITEM

Energetic & Renewal Mask

Code:	ID-19/08312
Batch number:	N/A
Class:	Care
Storage conditions:	Room temperature (20°C ± 5°C)
Expiry date:	2021/12/22

VOLUNTEERS' CHARACTERISTICS

20 healthy volunteers, female or male, from 18 to 65 years of age, with neither dry skin nor sensitive skin and without any dermatological lesion on tested area, should be included in the study.

ASSESSMENT METHODS

The skin compatibility of the item test was assessed after 48 hours of contact, between 30 to 40 minutes after patch removal. The clinical rating of cutaneous reactions (erythema and oedema) was spread out from 0 to 3 according to the following scales:

Rating	Erythema (E)	Oedema (Oe)
0	no erythema	no oedema
0.5	hardly perceptible erythema, slightly pink coloration on part of the patching area	hardly perceptible palpable oedema
1	slight erythema, pink coloration on all of the patching area	palpable and visible oedema
2	moderate erythema, clear coloration on all of the patching area	clear oedema with or without papules or vesicles
3	significant erythema, intense coloration on all of the patching area	significant oedema diffusing out of the patching area with or without papules or vesicles

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

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

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-CE	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.L.M. 0
 M.J.J.

Résultat non irritant
 Result non irritant

Abréviations Abbreviations

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

(a) Analyses Analysed
 X = Oui Yes
 - = Non No