

## SF Bubble Shampoo

**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/2019/71012

- 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.
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  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

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## STUDY SCHEDULE

### SF Bubble Shampoo

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

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Report No.:	UG/2019/71012
Experimental starting date:	2019.09.09
Experimental completion date:	2019.09.12
Study completion date:	See Study Director's signature date in the report

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## ADDRESS INFORMATION

### Testing Facility/Test Site

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

### Study Director

**Name:** Benson Liu  
**Address:** No. 38, Wu Chyuan 7<sup>th</sup> 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.)

## SIGNATURE OF STUDY PERSONNEL

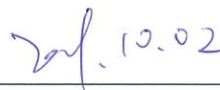
### SF Bubble Shampoo

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

Approval Signatory:



Benson Liu / SGS Taiwan Ltd.

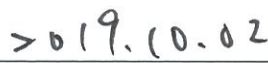


Date

Laboratory Head:



Shin Jyh Chen / SGS Taiwan Ltd.



Date

\* Approval signatory of this study is the study director.

## 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

### SF Bubble Shampoo

Code:	ID-19/08318
Batch number:	N/A
Class:	Hair care
Storage conditions:	Room temperature (20°C ± 5°C)
Expiry date:	2022/06/03

## 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:

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

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. $\leq$ 0.20	Non irritant
0.20 < M.I.I. $\leq$ 0.50	Slightly irritant
0.50 < M.I.I. $\leq$ 2	Moderately irritant
2 < M.I.I. $\leq$ 3	Very irritant

## RESULTS

### 1. Conditions of the study

Number of subject:

- A. Included: 22
- B. Analysed: 22
- C. Patch: semi-occlusive (True med®)
- D. Quantity: 160  $\mu$ L (or 0.16 g)
- E. Dilution: diluted at 2%

### 2. Events during the study course

A. Adverse event

No adverse event was recorded during the study.

B. Non-analysed volunteers

All the included volunteers were analysed.

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 SF Bubble Shampoo code ID-19/08318 can be considered as non-irritant after an application for 48 consecutive hours on 22 volunteers.

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

## TABLE

Etude N° 237027 Code 1.01\_48H Dossier 52720 Du 09/09/2019 Au 11/09/2019 Talence  
 Study # File From To

Produit ID-19/08318 Dilution dilué à 2 % diluted at 2%  
 Product SF BUBBLE SAMPOO - REF : UG/2019/71012

## Caractéristiques des volontaires

Characteristics of volunteers

## Réactions cutanées

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	RE-MA	F	51	-	-	0.00	-	-		X
2	BL-ER	M	58	-	-	0.00	-	-		X
3	EL-LA	F	36	-	-	0.00	-	-		X
4	LE-MI	F	21	-	-	0.00	-	-		X
5	SC-NA	F	43	-	-	0.00	-	-		X
6	GA-AU	F	41	-	-	0.00	-	-		X
7	BO-NI	M	25	-	-	0.00	-	-		X
8	GO-CE	F	45	-	-	0.00	-	-		X
9	CE-EL	F	55	-	-	0.00	-	-		X
10	VA-AD	M	19	-	-	0.00	-	-		X

Nombre de volontaires inclus 10  
 Number of included volunteers

Nombre de volontaires analysés 10  
 Number of analyzed volunteers

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

Résultat non irritant  
 Result non irritant

## Abréviations

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

## (a) Analysés

X = Oui Yes  
 - = Non No



Etude N° 237028 Code 1.01\_48H Dossier 52719 Du 10/09/2019 Au 12/09/2019 Talence  
Study # File From To

Produit ID-19/08318 Dilution dilué à 2 % diluted at 2%  
Product SF BUBBLE SAMPOO - REF : UG/2019/71012

## 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	KA-SA	F	31	-	-	0,00	-	-		X
2	BE-AU	F	53	-	-	0,00	-	-		X
3	SO-CH	F	64	-	-	0,00	-	-		X
4	EL-BA	F	53	-	-	0,00	-	-		X
5	MO-LA	F	23	-	-	0,00	-	-		X
6	ME-MY	F	62	-	-	0,00	-	-		X
7	TA-DA	F	19	-	-	0,00	-	-		X
8	BO-SY	F	43	-	-	0,00	-	-		X
9	AR-AM	F	20	-	-	0,00	-	-		X
10	AL-SA	F	38	-	-	0,00	-	-		X
11	BA-ST	F	40	-	-	0,00	-	-		X
12	QU-BO	F	44	-	-	0,00	-	-		X

Nombre de volontaires inclus 12  
Number of included volunteers

Nombre de volontaires analysés 12  
Number of analyzed volunteers

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

Résultat non irritant  
Result non irritant

## Abréviations Abbreviations

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

## (a) Analysés Analysed

X = Oui Yes  
- = Non No