



TEST RAPPORT



- CE
- EU Approved
- FDA Rapport
- Product test rapport

2020
EDITION

CE



Sungo FDA

CE CERTIFICATION

December 2020



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Owner/Operator Number: 10061396
Device Listing#: See annex

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Love2smile,
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**Fiscal Year 2020
CERTIFICATION OF REGISTRATION**

Annex to Cert. No.: 2006US943518

D359127	EIE	DAM, RUBBER (Dental Dam; Dental Gum Dam; Gum Protector Gel; Gingival Protection Gel)
D359128	BYP	MOUTHPIECE, BREATHING (Anti Snore Kit; Stop Snoring Device; Anti Snore Mouth Piece; Snoring Stopper; Anti Snore Mouth Tray; Stop Snoring Solution)
D359129	EFW	TOOTHBRUSH, MANUAL (Finger Brush; Oral Brush Ups; Teeth Wipes; Brush Ups;; Toothbrush, Bamboo Toothbrush)

END OF THE ANNEX



Fiscal Year 2020 CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US943518

Listing No	Code	Device Name
D359106	KXF	APPLICATOR, ABSORBENT TIPPED, NON-STERILE (Vitamin E Swab)
D359107	EEG	HEAT SOURCE FOR BLEACHING TEETH (Wireless Mouthpiece Led Light, Wireless Teeth Whitening Device; Teeth Whitening Light; Teeth Whitening Led Light; Portable Teeth Whitening Light; Smart Teeth Whitening Device; ProLite LED Teeth Whitening Device; Smart Teeth Whitening Light; Teeth Whitening Lamp; SNOW Teeth Whitening Light; Teeth Whitening Accelerator; Teeth Whitening Mini Light; Teeth Whitening Mouth Tray Led Light; Teeth Whitening Mouth Tray Light; Mini Light 1led/5led;Teeth Whitening Light 8led/16led/32led;Teeth Whitening Led Light 8led/16led/32led; Plusma Light)
D359108	LWF	DILATOR, NASAL (Stop Snoring Chin Strap; Anti Snore Jaw Supporter; Stop Snoring Solution; Anti Snore Belt; Chin Strap Belt)
D359109	MAU	ERASER, DENTAL STAIN (Premium Teeth Whitening System - LED Light; Teeth Whitening System; Teeth Bleaching System; SNOW Teeth Whitening Kit; SNOW Maximum Strength Serum; SNOW Teeth Whitening Wands; Tetyana Naturals Teeth Whitening Pen (2 Pack); Teeth Whitening Foam; Charcoal Teeth Whitening Strips; Teeth Whitening Gel 2ml/3ml/4ml/5ml/10ml; SNOW Desensitizing Serum; Teeth Bleaching Kit; Teeth Whitening Strips; Double Elastic Gel Strips; AsaVea Premium Teeth Whitening Kit, LED Light; Dry Strips; Dissolving Strip; Teeth Whitening Pen; Bleaching Pen; Coconut Oil Sachet; Remineralization Gel; Desensitizing Gel; Teeth Whitening Kit; Teeth Whitening Home Kit; Teeth Whitener; Dual Barrel Syringe Gel; Double Barrel Syringe Gel; Teeth Whitening Powder; Coconut Oil Pulling; Aroamas Teeth Whitening Pen, 3 Pack;Aroamas TEETH WHITENING KIT; AsaVea Teeth Whitening Pen (2 Pack); Professional Whitening Gel; Dual Barrel Gel; Double Barrel Gel; Teeth Whitening Pen [3 Pens])
D359123	EHY	TRAY, IMPRESSION, PREFORMED (Foam Strip Mouth Tray; Gel Prefilled Mouth Tray; Thermoplastic Mouth Tray; Mouth Piece; Teeth Whitening Mouth Tray)
D359124	EIG	RETRACTOR, ALL TYPES (Cheek Retractor; Mouth Opener; Lip Retractor)
D359125	EFT	CLEANSER, DENTURE, OVER THE COUNTER (Denture Cleansing Tablet)
D359126	JEQ	TOOTHBRUSH, POWERED (Electric Toothbrush, Sonic Toothbrush, Electric Led Toothbrush, Sonic Led Toothbrush)



INTRODUCTION

SGS is requested to review the safety of the product formula CHARCOAL TEETH WHITENING STRIPS for consumer health and no other part of the product. The product is for EU market and intended for application on teeth and then rinse off for cleansing by adults. Only the safety of the formulation is assessed while the claim and efficacy (if there is any) of the product, whether it is presented in product label, on website as well as other labeling and promotional materials, has not been evaluated or verified in this assessment.

The net weight of this product (The formulation under assessment) is 3g per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

1 Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ELINCS	Conc. %	Intended Function
Glycerin	56-81-5	200-299-5	38.0000	Solvent
Aqua	7732-18-5	231-791-2	37.9320	Solvent
Propylene Glycol	57-55-6	200-338-0	12.0000	Solvent
Cellulose Gum	9004-32-4	N/A	6.0000	Binding
Phthalimidoperoxyacaproic Acid	128275-31-0	410-850-8	1.3680	Oxidising
Carbomer	9007-17-4	N/A	1.0000	Increase Consistency
Cocos Nucifera Oil	8001-31-8	232-262-8	1.0000	Perfuming
Charcoal Powder	7440-44-0	231-153-3	1.0000	Abrasive
PVP	9003-39-8	N/A	0.5000	Binding
Sea salt	7647-14-5	231-598-3	0.5000	Abrasive / Humectant / Skin Conditioning
Chamomilla Recutita Flower Extract	84082-60-0	282-006-5	0.5000	Masking / Skin Conditioning
Menthol	89-78-1	201-939-0	0.1000	Denaturant / Masking / Refreshing / Soothing
Sodium Hydroxide	1310-73-2	215-185-5	0.1000	Buffering

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is a black colored solid.

2.2 The stability test result on formulation, by in house method of Nanchang Smile Technology Co., Ltd, on product name CHARCOAL TEETH WHITENING STRIPS, with a testing period of Apr 08 - Jun 29, 2020, was submitted and reviewed. It is the responsibility of the manufacturer and responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : -8 \pm 2C and 45 \pm 2 \circ C for 12 weeks

Testing parameters : Appearance, odor, total bacterial count, pH (10% suspension)

Conclusion: The stability of the formulation is acceptable for this application.

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Test Report

No. HKHC2009007396HC

Date : Oct 29, 2020

Page 3 of 14

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopeia 10.0 2.6.12 and 2.6.13, by third party laboratory (SGS report no. GZCPCH200704088-2.2), on product name Charcoal teeth whitening strips, with a testing period of Jul 22 - 31, 2020, was submitted and reviewed based on following criteria as required by the SCCS Notes of Guidance.

Product Category of this product: 1

Micro-organisms	Total viable count and Total yeast and mold	<i>E. Coli</i> , <i>P.aeruginosa</i> , <i>S.aureus</i> and <i>C.albicans</i>
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 1g or 1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result of formulation is not required because the product is a single use and low microbiological risk product.

4 Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. GZCPCH200704088-2.1), on product name Charcoal teeth whitening strips, with a testing period of Jul 22 - 29, 2020, was submitted and reviewed based on following criteria.

Test items	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	Bag	PET+PE+aluminum
2.	Plastic	PO

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratory (SGS report no. GZCPCH200704088-3) with a testing period of Jul 22 - 29, 2020 indicate the total amount is less than 100ppm.

Conclusion: The heavy metal content of the packaging material is acceptable.

4.4 Packaging compatibility test result on packaging material, indicated to be tested together with the product, by in house method of Nanchang Smile Technology Co., Ltd, on product name CHARCOAL TEETH WHITENING STRIPS, with a testing period of Apr 08 - Jun 29, 2020, was submitted and reviewed.

Testing conditions : -8°±2C and 45±2°C for 12 weeks

Testing parameters : Appearance

Conclusion: The stability of the packaging material is acceptable.

5 Normal and reasonably foreseeable use

The normal use of this product is for application on teeth by adults. Application of this product to any other parts of the body is unlikely. Ingestion of this product would be a reasonably foreseeable use.

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1. Assessment conclusion

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments. Provided the manufacturer's instructions are followed, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

2. Recommended labelled warnings and instructions of use

Use only as directed.
Do not swallow.
Keep out of reach of children.
Avoid contact with eyes. Rinse eyes immediately should the product comes into contact with them.

3. Reasoning

All the ingredients in the formulation are either reported to be used in cosmetic or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR). No CMR substance is indicated to be intentionally added to the formulation.

Margin of Safety (MoS) was derived for all ingredients except those which No Observed (Adverse) Effect Levels (NO(A)ELs) or other Point of Departure (POD) were not available. For ingredients that MoS cannot be derived, their safety is substantiated by history of safe use at similar levels in related cosmetic products, reference doses, TTC approach, etc. Detailed explanation is given in the individual ingredient toxicological summary in annex 1.

As there is a chance of ingestion of this oral product with customary use, the ingredients used should be of food grade or any appropriate grade.

The pH value of the formulation is determined to be around 8.52 at 10% suspension. The formulation is not expected to be irritating to the skin and respiratory tract, be sensitizing, phototoxic, and is unlikely to cause damage to internal organs through ingestion, skin and inhalation in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes will cause significant irritation, but is expected to be minimal after rinsing.

The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability and microbiological quality.

The preservation efficacy test result of formulation is not required because the product is a single use and low microbiological risk product.

However, no valid GMP certificate on manufacturing setting covering the scope of tooth strip product has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.

4. Assessor's credentials and approval of Part B

Date: Oct 29, 2020

Mei-Yin CHIU, Sonly MSc, FRSB, CBiol, DABT, EUROTOX Registered Toxicologist

The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

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SGS

Test Report

No. HKHC2009007396HC

Date : Oct 29, 2020

Page 4 of 14

6 Exposure to the cosmetic product

Product type: Oral care cosmetics

Use category: Tooth strip

Physical form: Solid

The site(s) of application: Teeth

The surface area(s) of application: 200 square centimeter

The amount per application: 3 g (indicated by client)

The duration of exposure: 30 minutes (indicated by client)

The frequency of use: 730 times per year

The normal and reasonably foreseeable exposure route(s): Primary via dermal contact with potential ingestion

The targeted (or exposed) population(s): adults

The body weight: 60 kg

Estimated daily amount applied: 6000 mg/day

7 Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.

For toxicological profile of ingredients, refer to Annex 1.

Systemic Exposure Dose (SED) is derived for each substance, taking into account of 50% bioavailability as a default value for oral and dermal absorption, and 100% bioavailability for inhalation, unless otherwise specified. Margins of safety (MoS) is calculated by dividing systemic NO(A)EL_{sys} by the SED, when NO(A)EL or relevant Point of Departure (POD) is available in the present stage of knowledge.

8 Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

9 Information on the cosmetic product

No valid GMP certificate on manufacturing setting covering the scope of tooth strip product has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.



SGS

Test Report

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Page 4 of 14

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Product Name	Type
Teeth Whitening Strips	FST-01, FST-02
Teeth Wipe	FSW-01
Teeth Whitening Gel	Syringe: 1.2ml, 3ml, 5ml, 10ml Pen: 2ml/4ml
Desensitizing Gel	Syringe: 1.2ml, 3ml, 5ml Pen: 2ml/4ml
Dental Gum Dam	Syringe: 1.2ml/1.5ml/2.2ml
Dual Barrel Syringe Teeth Whitening Gel	2.5m (FSD-2.5), 5ml (FSD-5)
Anti-snoring mouth tray	FSAS-01
Anti-snoring band	FSASD-01
Mouth Spray	2ml (FSMS-2), 5ml (FSMS-5), 8ml (FSMS-8)
Teeth Whitening LED Light	1led, 5leds
Teeth Whitening Foam	FSF-01
Vitamin E Swab	FSVE-01
Cheek Retractor	Type C, Type O, Type W
Dental Brace	FSDB-4
Teeth Whitening Mouth Tray	FSMT-01, FSMT-02, FSMT-03, FTPT-01, FTPT-02, FTPT-03, FTPT-04
Dental impression material (Si-Impression Material)	FSDM-01
Denture Adhesive	FSDA-01
Mouth Tray Case	MTC-01, MTC-02, MTC-03, MTC-04
Teeth Whitening Powder	FSTP-01, FSTP-02
Charcoal Teeth Whitening Powder	FSCTP-01, FSCTP-02
Coconut oil pulling, Coconut oil sachet	FSCOP-01
Teeth Whitening Kit (Smart Teeth Whitening Kit, Smart Teeth Whitening Device Kit, Teeth Whitening Light Kit, The Professional Whitening Kit, Teeth Whitening Home Kit)	FSWK-01, FSWK-02, custom-made

This annex is only valid if attached to the report mentioned above.

PRODUCT TEST RAPPORT

December 2020



Net Weight : 3g per consumer product
SGS Report No. : HKHC2009007396HC
SGS Case No. : HKHC200800002752-102 (GZCPCH200704088)
Region of Origin : China
Region of Destination : EU
Sample Receiving Date : Aug 07 – Oct 14, 2020
Test Period : Aug 07 – Oct 29, 2020

Test Requested

This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.

Test Results

Please refer to the following pages.

Summary

It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.

This assessment takes account of:

- a) The general toxicological profile of each ingredient used.
- b) The chemical structure of each ingredient.
- c) The level of exposure of each ingredient.
- d) The specific exposure characteristics of each ingredient on the areas on which the cosmetic product will be applied.
- e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

If there is an adverse reaction from using this formulation then the undersigned should be informed so that the formulation can be further reviewed.

Signed for and on behalf of
SGS Hong Kong Ltd.

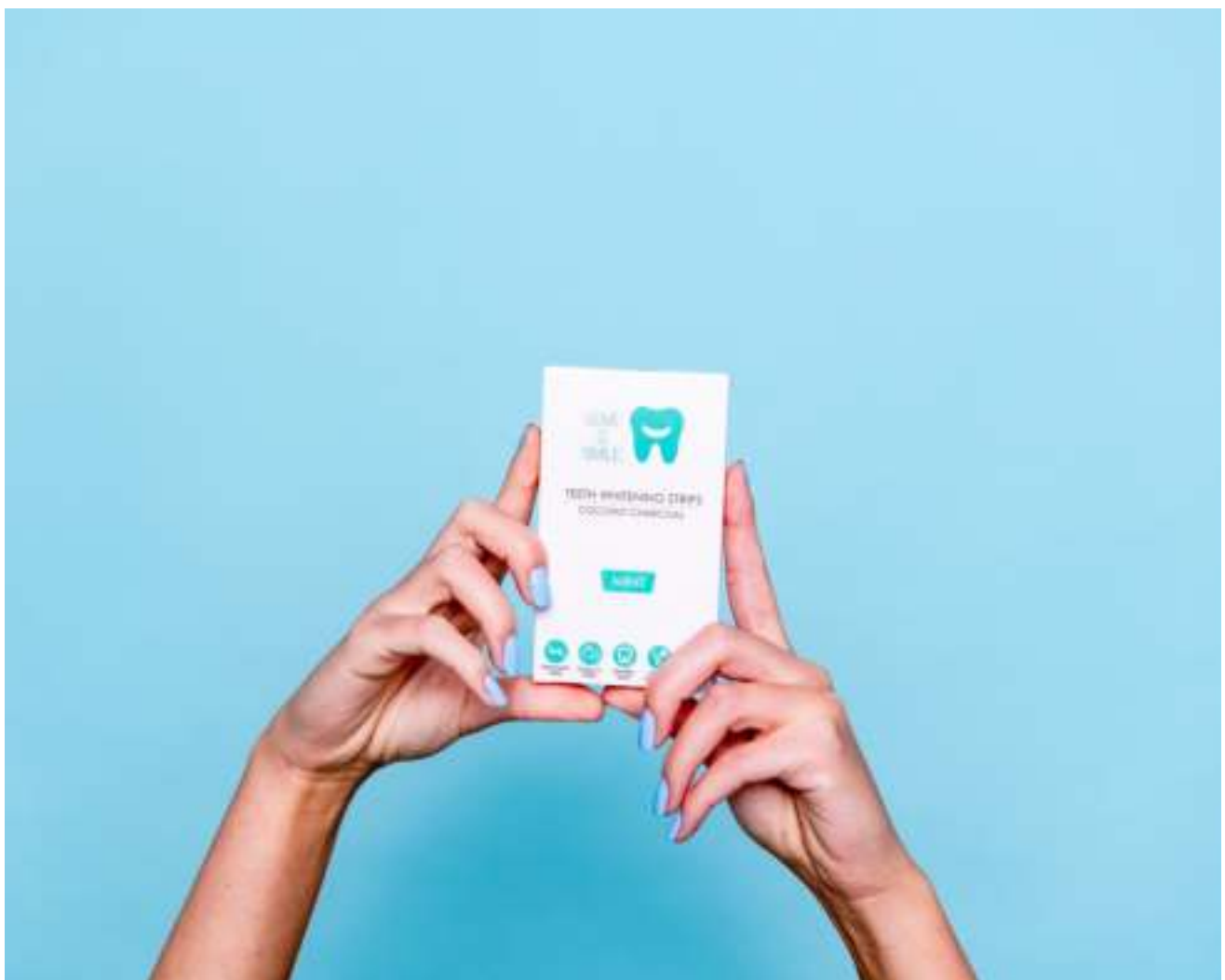
A handwritten signature in black ink, appearing to read "Mei-Yin Chiu".

Mei-Yin CHIU, SONDY
MSc, FRSB, CBiol, ERT, DABT
Cosmetic Safety Assessor

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