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SAFETY

ASSESSMENT

According to EC Regulation 1223/2009

ENERGIZE LUXURY SOAP 40G

Formula Ref.: SFO1122

MING FAI INDUSTRIAL CO., LTD.

SAFETY EVALUATION OF FINISHED COSMETIC PRODUCT

ACCORDING TO

ANNEX I OF (EC) REGULATION 1223/2009

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PART A- COSMETIC PRODUCT SAFETY INFORMATION

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

Product Name: **ENERGIZE LUXURY SOAP 40G**

Manufacturer Ming Fai Enterprise International Co., Ltd.
STUDY PERIOD January 2018
QACS LAB ID 17 06 01073
Product Category BATH SOAP (BATHING, SHOWERING)

TABLE I. FORMULA PROVIDED

RAW MATERIAL TRADE NAME	INCI	CAS No.	%	FUNCTION
SOAP NOODLE KSN8800	SODIUM PALMATE	61790-79-2	67.800000	CLEANSING, EMULSIFYING, SURFACTANT, VISCOSITY CONTROLLING
	SODIUM PALM KERNELATE	61789-89-7	16.950000	CLEANSING, EMULSIFYING, SURFACTANT, VISCOSITY CONTROLLING
	AQUA	7732-18-5	12.000000	SOLVENT
	GLYCERIN	56-81-5	0.500000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
	PALMITIC ACID	57-10-3	0.500000	EMOLLIENT, EMULSIFYING
	SODIUM CHLORIDE	7647-14-5	0.500000	BULKING, MASKING, ORAL CARE, VISCOSITY CONTROLLING
	SODIUM GLUCONATE	527-07-1	0.300000	CHELATING, SKIN CONDITIONING
PALMERA REFFINED GLYCERINE USP 99.5% LIQUID (PALMERA G995U)	GLYCERIN	56-81-5	1.000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
TITANIUM DIOXIDE	TITANIUM DIOXIDE (CI 77891)	13463-67-7	0.200000	COSMETIC COLORANT, OPACIFYING
PATCHOULI OIL MD 1SQ 00181 / 1VC 06213	POGOSTEMON CABLIN OIL	8014-09-3	0.250000	MASKING

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

- Supplier's specifications for each raw material have been reviewed (Safety and Technical Data Sheets, MSDS and TDS).
- Specifications of Final Product: Have been reviewed.

Appearance:	Opaque solid
Color:	White
Odor:	Characteristic
pH:	N/A (solid soap)
Viscosity:	N/A (solid soap)

- Stability of The Product: Has been reviewed (manufacturer).

3. MICROBIOLOGICAL QUALITY

Microbiological Quality: The product, due to its type (solid soap bar) and the low water activity / certain pH values, is unlikely to present, under normal production conditions, any kind of bio burden.

Challenge Test: As described above (MICROBIOLOGICAL QUALITY), microbial growth is prevented in this type of product, thus a challenge-test is not required (ISO 29621:2010).

4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

- Regarding any traces and impurities from the raw materials please refer to Table I of section 1 Quantitative and qualitative composition of the cosmetic product and section 8. Toxicological Profile of the Substances.
- Properties of Packaging Material: According to the presentation and the formula of the product, package is considered unlikely to affect its purity and stability.
  Type of packaging materials: Paper.
- Production Method: Has been reviewed.
- G.M.P. Compliance:
  Certification Body: INTERTEK. Certification Number: SZ1507C2 – Date of Issue: Jul 27, 2015. Date of Renewal: July 26, 2018.

5. NORMAL AND REASONABLY FORESEEABLE USE

The product is applied on the hands and body and it is rinsed off. External use only.

6. EXPOSURE TO THE COSMETIC PRODUCT

The product is applied on the hands and body, it is rinsed off and it can be considered taking into account guidelines from SCCS/1564/15 opinion as a soap similar in use with a hand wash soap and shower gel (combined) with an estimated daily amount applied 38.67 g and a calculated relative daily exposure 6.12 mg/Kg bw/day.

Target Group for Use: Adults

7. EXPOSURE TO THE SUBSTANCES

Please refer to Table I of section 1. 1. Quantitative and qualitative composition of the cosmetic product

8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

- The product itself has not been tested on animals (Article 18).

MSDS TOXICOLOGICAL REVIEW:

Respiratory : Not required for consumer use of this product. Inhalation exposure is not applicable for this type of product.

Skin : This product is unlikely to be sensitizing to human skin. It is not expected to produce allergy by skin contact, except the cases of people with known allergic reaction in the specific allergens referred on the label. The absorption through the skin is considered limited.

Eye : As with any material contacting the eye its accidental exposure may result in slight eye irritation.

Ingestion : Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous, under foreseeable use.

All information available refers to the relevant MSDS of each raw material that takes part in the formula of the product. The specific ingredients that have been chosen for the production of this product have been used for years, for same products, without any known toxicity problems, under foreseeable conditions of use.

- Especially for ‘hazardous’ raw materials (substances under restrictions listed in the Annexes i.e. Annex II-Substances Prohibited in Cosmetic Products, Annex III-Substances Which Cosmetic Products Must Not Contain Except Subject to the

Restrictions, Annex IV-Colorants Allowed, Annex V-Preservatives Allowed and Annex VI-UV Filters Allowed) there are already limits in legislation.

- There are no data for evaluation in the product of any impurities of the substances and raw material used.

- There is no evidence from the formula of the product for interaction of substances.

- There are known plant-derived raw materials (e.g. extracts, oils, waxes, etc.) in the formula.

- It may contain Eucalyptol (*Pogostemon Cablin*). The Council of Europe Committee of experts on flavouring substances was of the opinion that the toxicological data on eucalyptol were too limited and not of an optimal quality, in order to set a TDI. For a more precise risk characterisation, further data on metabolism, skin toxicity, skin penetration, effects on mucous membranes and a 28-day oral study would be needed. A limited and harmonised concentration of eucalyptol in cosmetic products has to be set. A ban of the use of eucalyptol in cosmetic products for children below the age of 3 years is recommended. (Plants in cosmetics - Potentially harmful components - Volume III - prepared by the Committee of Experts on Cosmetic Products).

- It contains the permissible colorant / opacifying agent **Titanium Dioxide (CI 77891)*** which is allowed for use in cosmetics in the EU according to the REGULATION (EC) No 1223/2009. The producer must ensure that every batch of that colorant used for the production of this product is in conformity with EU legislation. Cosmetic colorants must pass purity criteria as set out in Commission Directive 95/45/EC (and its subsequent legislative replacements) or specific purity criteria as set by REGULATION (EC) No 1223/2009 (see ANNEX IV - LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS).

* According to the recently presented declaration of the raw material manufacturer (KRONOS INTERNATIONAL, Inc.), the ingredient **Titanium Dioxide (CI 77891)** shouldn't be considered as nanomaterial.

- Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NOAEL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a **'worst case approach'**, where, taking under consideration the pure maximum concentrated material of the formula, the minimum NO(A)EL (**oral**) is calculated, according to the Estimated daily exposure (A) of the product (§ 1.6).

In this way 'dangerous' ingredients are considered only those with 'hypothetical' NO(A)EL values lower than the minimum NO(A)EL calculated value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS<100.

The combination above is statistically difficult to yield in MoS<100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NOAEL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value),

2. In this approach the calculation of the minimum NO(A)EL, is usually lower than 1000 mg/Kg bw/day, depending on the type of the product. The minimum NO(A)EL values at these levels can be found only in ingredients like biocides/preservatives (i.e. Phenoxyethanol 500 mg/Kg bw/day or Methyl Paraben 1000 mg/Kg bw/day (SCCP/0125/99 & SCCP/0873/05 respectively).

3. Ingredients with low NO(A)EL values (<1000 mg/Kg bw/day) are very well defined in toxicological literature and there are exact data that have already been taken into consideration for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS= NO(A)EL / SED > 100, With:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (**6.12**).

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site (here **Sodium Palmate 67.8%**),

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (**100%**).

SED = **A** (mg/kg bw/day) x **C** (%)/100 x **DAp** (%)/100= 6.12 x 67.8/100 x 1= 4.1494 mg/kg bw/day

- The minimum NO(A)EL, according to the above suggested calculations (SCCS/1564/15) for the pure maximum concentrated ingredient should be:

All MoS calculations of Table II take into account an oral bioavailability of 50% of an orally administered dose (systemically available).

Minimum NO(A)EL= MoS x SED / 2 = 100 * 4.1494 / 2 = **207.47 extrapolated to 208 mg/Kg bw/day** and is satisfactory. (Acceptable minimum NO(A)EL <1000 mg/Kg bw/day)

Conclusion: It is unlike for the ingredients of the specific formula, without NO(A)EL values and total lack of safety reference, to present NO(A)EL values lower than the minimum NOA(E)L calculated according to the *'Worst Case Approach'* and consequently, with present concentrations, to yield in MoS<100.

The 'worst case approach' is in compliance with Annex I, point 8: "All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated. The absence of these considerations shall be duly justified."

The following table includes the relevant available NOAEL and MoS calculated for each ingredient of the formula.

TABLE II.

INCI	%	NOAEL (mg/Kg bw/day)	MoS	NOAEL/SAFETY REFERENCE
SODIUM PALMATE	67.8	RECOGNIZED AS SAFE	N/A	The 2011 Cosmetic Ingredient Review Expert Panel concluded that the 244 plant-derived fatty acid oils included in this review are safe in the present practices of use and concentration described in this safety assessment: Final Report on "Plant-Derived Fatty Acid Oils as Used in Cosmetics", March 4, 2011online.personalcarecouncil.org/ctfa-static/online/lists/cir.../FR577.pdf UP TO 68%
SODIUM PALM KERNELATE	16.95	RECOGNIZED AS SAFE	N/A	The 2011 Cosmetic Ingredient Review Expert Panel concluded that the 244 plant-derived fatty acid oils included in this review are safe in the present practices of use and concentration described in this safety assessment: Final Report on "Plant-Derived Fatty Acid Oils as Used in Cosmetics", March 4, 2011online.personalcarecouncil.org/ctfa-static/online/lists/cir.../FR577.pdf UP TO 44%
AQUA	12	NON TOXIC	N/A	-
GLYCERIN	1.5	2000	10893	http://www.inchem.org/documents/sids/sids/56815.pdf, http://www.cir-safety.org/sites/default/files/glycer_092014_Tent.pdf baby products 2-21% Incidental ingestion 2-68.6%
PALMITIC ACID	0.5	750 (SEE ACROSS DATA)	12255	"The available toxicological data demonstrates that fatty acid salts are neither genotoxic, mutagenic or carcinogenic, nor was there any evidence of reproductive toxicity (except at very high exposure levels) or developmental or teratogenic effects in animals. In addition, the fatty acids and their salts have a long history of safe use in foods. Further evidence of their safe use in foods is the GRAS status of several of the fatty acids. The WHO also set an unlimited ADI for the salts of myristic, palmitic and stearic acids and stated that myristic, palmitic and stearic acid and their salts are normal products of the metabolism of fats. Their metabolic fate after absorption is well established. Provided the contribution of the cations does not add excessively to the normal body load, which would not be the case following exposure to fatty acid salts in household cleaning products, then there is no reason to consider these substances more hazardous than dietary fatty acids." www.heraproject.com/.../5-HH-04-

				HERA%20Fatty%20acid%20salts% 20HH%20web% (Fatty Acid Salts Human Health Risk Assessment , par 5.3.1.6 & 5.4), up to 10% for eyeshadow http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr161.pd up to 25%, JACT 6(3):321-401, 1987 confirmed 06/05
SODIUM CHLORIDE	0.5	56400	921569	http://www.epa.gov/dfe/pubs/pwb/ctsa/ch3/ch3-3.pdf
SODIUM GLUCONATE	0.3	>500	>13617	http://www.inchem.org/documents/sids/sids/gluconates.pdf
POGOSTEMON CABLIN OIL	0.25	N/A	N/A	Long use in perfumery, cosmetics, flavor ingredient in food products, food supplements etc Essential Oils in Food Preservation Flavor and Safey, V. Preedy, 2016 globalresearchonline.net/journalcontents/v21-2/02.pdf www.achs.edu/mediabank/files/achs_patchouli_monograph.pdf may contain eugenol.
TITANIUM DIOXIDE (CI 77891)	0.2	ANNEX IV (COLORANT USE), 375	15319	SCCNFP/0005/98

ALLERGEN FACTORS:

- Allergens in the final product (determined by analysis): (An allergen is declared on the label when its concentration in the final preparation is >0.01%)

  No data available

- Allergens from the perfume:

  According to the provided formula the product does not contain perfume.

  None

- Allergens from plant-derived raw materials (extracts, oils, waxes, etc.) at concentration >0.01% in the final preparation:

  None (according to the documentation provided for the plant-derived raw materials).

The SCCS is of the opinion that for substances identified as posing a high risk to the consumer and for which no individual thresholds could be derived (Table 13-5), the general threshold of 0.01% would limit the problem of fragrance allergy in the consumer significantly.

- There are no detailed data for **all** allergens existing in the plant-derived raw materials (opinion 1459/11, Conclusions-question 1).

- The corrections regarding allergens must be performed as soon as the plant-derived raw materials manufacturers will supply the relevant data as well as the EC gives final guidelines on the subject.

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

Not known or reported.

10. INFORMATION ON THE COSMETIC PRODUCT

- Patch Test: Satisfactory (Non irritant – QACS Ltd).
- Other Tests: Four Heavy Metals test (QACS Ltd).
- Literature Data: Not Applicable.

PART B- COSMETIC PRODUCT SAFETY ASSESSMENT

Product Name	**ENERGIZE LUXURY SOAP 40G**
Product Category	BATH SOAP (BATHING, SHOWERING)

Name and Address of Responsible Person*

Company Name	**Alliance National**
Address	-
Tel	-
Fax	-
URL	www.alliancenational.co.uk
e-mail	-

***note:** (unique EU organization declared as distributor on label)

Name and Address of Product Manufacturer

Company Name	**Ming Fai Enterprise International Co., Ltd.**
Address	Bainikeng, Pinghu, Longgang, Shenzhen, China
Tel	-
Fax	-
URL	-
e-mail	-

Name and Address of Product Producer

Company Name	**Ming Fai Industrial (Shenzhen) Co., Ltd.**
Address	Bainikeng, Pinghu, Longgang, Shenzhen, China
Tel	-
Fax	-
URL	-
e-mail	-

1. ASSESSMENT CONCLUSION

The product is considered **safe** for human health when used under normal or reasonably foreseeable conditions of use.

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE

- Producer's data have been reviewed. There is no need for further instructions of the use as this is clear to the consumer from its presentation.
- The container and packaging of the cosmetic product must bear all the necessary information in indelible, easily legible and visible lettering according to Article 19 of the Regulation (EC) No 1223/2009 (e.g. date of minimum durability).
- The presentation of the cosmetic product and in particular its form, odour, colour, appearance, packaging, labelling, volume or size does not endanger health and safety of consumers due to confusion with foodstuffs, in accordance with Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers.
- All ingredients referred in the formula and the MSDS of the raw materials should be written on the label with their correct INCI names in descending order (see Table II). Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %. The labelling must follow Article 19 of regulation 1223/2009.

  N.B.: Because of the possible presence of Eucalyptol in the product, the addition of the warning phrase 'Not to be used for children under 3 years of age' on the labelling is recommended.

  SUGGESTION: According to the Regulation (EC) No 1223/2009 only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market. For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation. Cosmetic products shall be made available on the EU market only where the container and packaging of cosmetic products bear **the name or registered name and the address of the responsible person** in indelible, easily legible and visible lettering. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted.

Claim support:

- All claims on the label should be in compliance with Regulation (EU) 655/2013 and the guidelines to this Regulation.
- A Dermatological in vivo test (cutaneous irritancy test-patch test) has been performed with satisfactory results (Non Irritant - QACS Ltd). Based on these results the claim 'Dermatologically tested' can be referred on the label, even though the number of volunteers is not statistically significant.

3. REASONING

Taking under consideration

- The composition of the product
- The physicochemical properties of the raw material contained in the final product
- The manufacturing process of the product
- The microbial purity of the raw materials and final product.
- Impurities –Traces in the final product or substances
- Properties of packaging material
- The preservation efficacy of the final product.
- The chemical structure and toxicological properties of the raw materials
- Studies on human volunteers / relevant literature.
- The level of exposure of the consumer to the final product
- Data on documented undesirable effects to the product (no such data reported/available)
- Labelled warnings & instructions of use

Additionally the Product Manufacturer / Responsible person is aware of the following:

- All necessary measurements have been followed for the product to comply with the article 18 (Animal testing) of Regulation 1223/2009.
- All colouring agents whose number is preceded by the letter 'E' in accordance with the EEC Directive of 1962 concerning foodstuffs and purity criteria as set out in Commission Directive 95/45/EC (ANNEX IV)
- The Responsible person / Product manufacturer is responsible for the accuracy of primary information contained in the product dossier.
- For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in the Articles 4 and 5 of Regulation 1223/2009.
- This safety assessment relates to the information received up until the date the assessment was performed.

All information provided by the technical dossier may be used, for any legal purpose within the EU, and according to the best current scientific knowledge, the product fulfils the requirements for safety for the consumers, under conditions of normal use, as long as data contained will be updated in accordance with the **SUGGESTIONS** (regarding safety) mentioned above and the guidelines of the current Regulation 1223/2009.

In the case that any complaint is communicated to the Responsible person and/or Product manufacturer or there are any alterations in the information regarding the product these should be also taken into the consideration of the signatory of this certificate.

4. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

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DATE:	**10/01/2018**

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ERPA Member

EC, Scientific Advisor on Risk Assessment

FORMULA PROVIDED

Ingredients of Energize Luxury Soap

Sample No:ST-10202

Formula No:SFO1122

Item	INCI Name	Dosage(%) w/w as active	CAS.NO
1	Sodium Palmate	67,800000	61790-79-2
2	Sodium Palm Kernelate	16,950000	61789-89-7
3	Aqua	12,000000	7732-18-5
4	Glycerin	1,500000	56-81-5
5	Palmitic Acid	0,500000	57-10-3
6	Sodium Chloride	0,500000	7647-14-5
7	Sodium Gluconate	0,300000	527-07-1
8	Pogostemon Cablin Oil	0,250000	8014-09-3
9	Titanium Dioxide	0,200000	13463-67-7

Remark: This ingredient list is issued by Ming Fai R&D department and is a property of Ming Fai.

Date: 2016/04/27

明輝實業國際有限公司
Ming Fai Enterprise International Co. Ltd.

Manufacturing Process of Energize Luxury Soap

Formula No:SFO1122

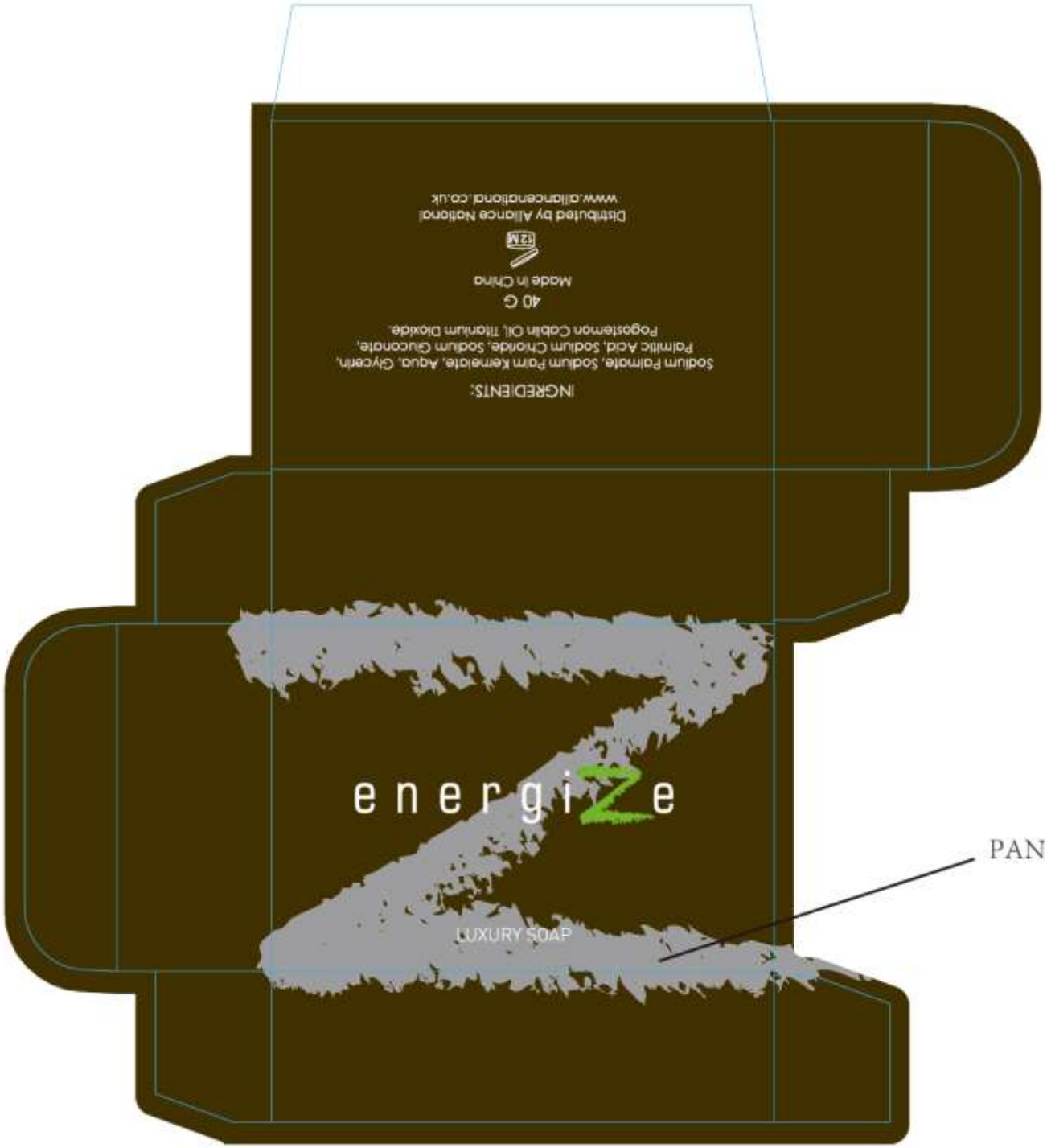
Item	INCI Name	Dosage(%) w/w as active
1	Sodium Palmate	67,800000
	Sodium Palm Kernelate	16,950000
	Aqua (Water)	12,000000
	Glycerin	0,500000
	Palmitic Acid	0,500000
	Sodium Chloride	0,500000
	Sodium Gluconate	0,300000
2	Glycerin	1,000000
3	Titanium Dioxide	0,200000
4	Pogostemon Cablin Oil	0,250000

1 Add the soap base 1 into the mixing pot with stiring until grain is uniform.
2 Add ingredient 2,3 orderly with stiring completely.
3 Add ingredient Parfum with stiring completely.
4 Add the rest of the water with stiring make it uniform,the whole process at least 8 min.

ENERGIZE LUXURY SOAP 40G
(SFO1122)

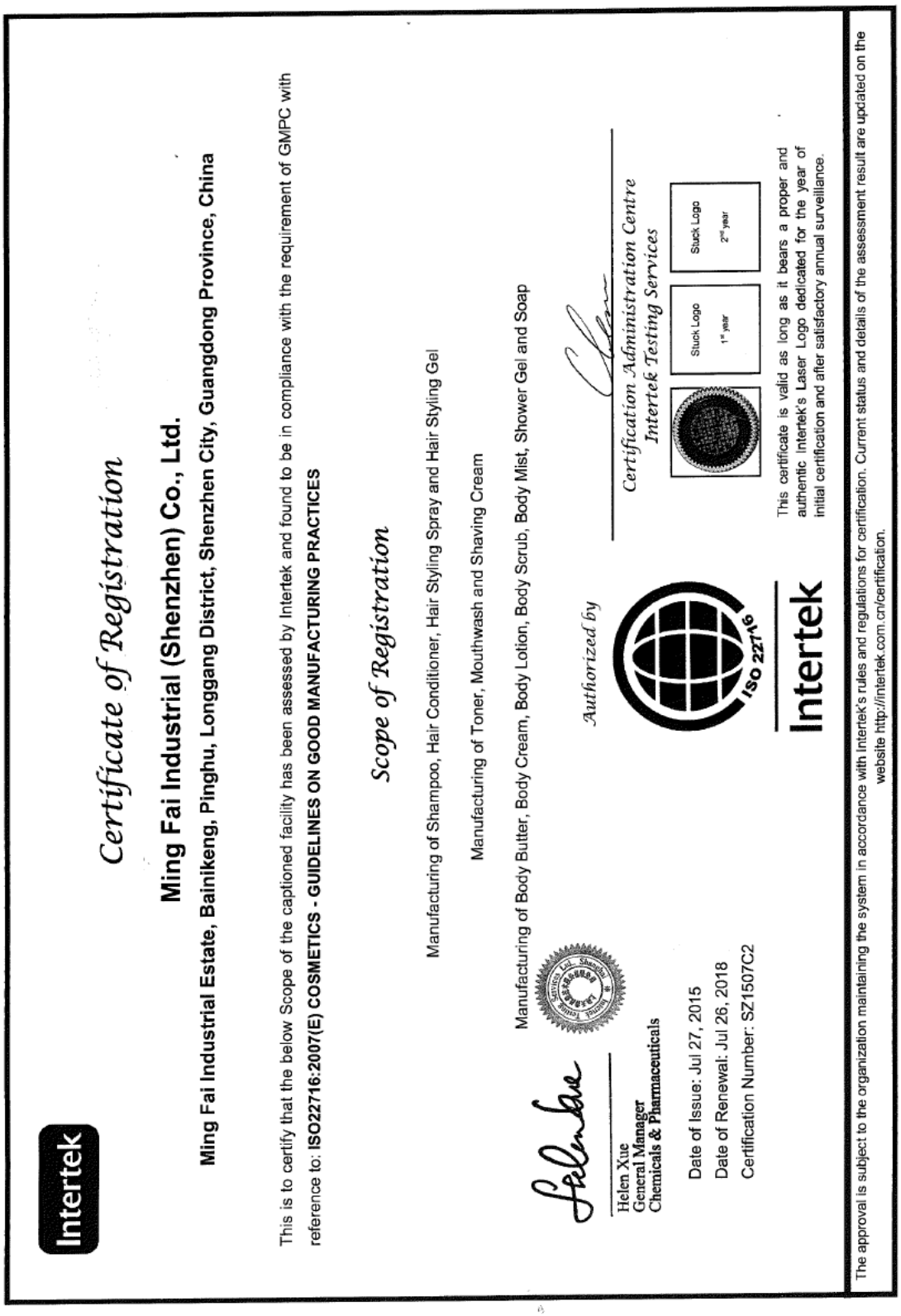
MING FAI INDUSTRIAL CO., LTD.

PRODUCT LABELLING




INGREDIENTS:
Sodium Palmate, Sodium Palm Kernelate, Aqua, Glycerin,
Palmitic Acid, Sodium Chloride, Sodium Gluconate,
Pogostemon Cablin Oil, Titanium Dioxide.
40 G
Made in China
12M
Distributed by Alliance National
www.alliancenational.co.uk

PRODUCER'S GMP ISO 22716:2007 CERTIFICATE



Intertek

Certificate of Registration

Ming Fai Industrial (Shenzhen) Co., Ltd.

Ming Fai Industrial Estate, Bainikeng, Pinghu, Longgang District, Shenzhen City, Guangdong Province, China

This is to certify that the below Scope of the captioned facility has been assessed by Intertek and found to be in compliance with the requirement of GMPC with reference to: **ISO22716:2007(E) COSMETICS - GUIDELINES ON GOOD MANUFACTURING PRACTICES**

Scope of Registration

Manufacturing of Shampoo, Hair Conditioner, Hair Styling Spray and Hair Styling Gel

Manufacturing of Toner, Mouthwash and Shaving Cream

Manufacturing of Body Butter, Body Cream, Body Lotion, Body Scrub, Body Mist, Shower Gel and Soap

Authorized by

Helen Xue
General Manager
Chemicals & Pharmaceuticals

Date of Issue: Jul 27, 2015
Date of Renewal: Jul 26, 2018
Certification Number: SZ1507C2

Certification Administration Centre
Intertek Testing Services

Stuck Logo
1st year

Stuck Logo
2nd year

ISO 22716

Intertek

This certificate is valid as long as it bears a proper and authentic Intertek's Laser Logo dedicated for the year of initial certification and after satisfactory annual surveillance.

The approval is subject to the organization maintaining the system in accordance with Intertek's rules and regulations for certification. Current status and details of the assessment result are updated on the website http://intertek.com.cn/certification.