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SAFETY

ASSESSMENT

According to EC Regulation 1223/2009

PURE LUXURY SOAP 40G

Formula Ref.: SFO1043

MING FAI INDUSTRIAL CO., LTD.

SAFETY EVALUATION OF FINISHED COSMETIC PRODUCT

ACCORDING TO

ANNEX I OF (EC) REGULATION 1223/2009

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PURE LUXURY SOAP 40G
(SFO1043)
MING FAI INDUSTRIAL CO., LTD.

PART A- COSMETIC PRODUCT SAFETY INFORMATION

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

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

Manufacturer Ming Fai Enterprise International Co., Ltd.
STUDY PERIOD January 2018
QACS LAB ID 17 06 01072
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	67.8000000	CLEANSING, EMULSIFYING, SURFACTANT, VISCOSITY CONTROLLING
	SODIUM PALM KERNELATE	61789-89-7	16.9500000	CLEANSING, EMULSIFYING, SURFACTANT, VISCOSITY CONTROLLING
	AQUA	7732-18-5	12.0000000	SOLVENT
	GLYCERIN	56-81-5	0.5000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
	PALMITIC ACID	57-10-3	0.5000000	EMOLLIENT, EMULSIFYING
	SODIUM CHLORIDE	7647-14-5	0.5000000	BULKING, MASKING, ORAL CARE, VISCOSITY CONTROLLING
	SODIUM GLUCONATE	527-07-1	0.3000000	CHELATING, SKIN CONDITIONING
PALMERA REFFINED GLYCERINE USP 99.5% LIQUID (PALMERA G995U)	GLYCERIN	56-81-5	1.0000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
TITANIUM DIOXIDE	TITANIUM DIOXIDE (CI 77891)	13463-67-7	0.2000000	COSMETIC COLORANT, OPACIFYING
SYMRISE / 881676 RELAX IN STYLE	PARFUM	N/A	0.23750000	DEODORANT, MASKING, PERFUMING

BONTOUX / EO BLEND - FIRE 1SQ 00107/ 1VC 07003	CITRUS AURANTIUM AMARA (BITTER ORANGE) PEEL OIL	68916-04-1	0.01250000	SKIN CONDITIONING
	CANANGA ODORATA FLOWER OIL	8006-81-3		MASKING, PERFUMING
	EUGENIA CARYOPHYLLUS (CLOVE) BUD OIL	8000-34-8** [84961-50-2]		MASKING, PERFUMING
	CORIANDRUM SATIVUM (CORIANDER) FRUIT OIL	8008-52-4		MASKING, PERFUMING
	GERANIUM MACULATUM OIL	84650-10-2		MASKING, TONIC
	ORIGANUM MAJORANA LEAF OIL	84082-58-6		MASKING, REFRESHING
	ELETTARIA CARDAMOMUM SEED OIL	8000-66-6		MASKING, PERFUMING, TONIC

Note: * The CAS No. mentioned in the provided formula and the documents of the raw materials were entered in the table above. The marked CAS No. (**) do not correspond with the CAS No. assigned to the specific ingredients in CosIng. For the cases that the CAS No. are not mentioned in the provided formula/documents or they do not match with the ones assigned to those ingredients in CosIng, the latter - where available - have been entered in the table above (CAS No. in brackets).

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: Dec 11, 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.

- 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.

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

- It may contain Methyl Salicylate (*Cananga Odorata, Eugenia Caryophyllus*). Taking into account data on hepatotoxicity, the toxic effect on reproduction, the ability to cause severe malformation in the unborn, the ability to irritate skin and mucous membranes and the skin penetration, the concentration of methyl salicylate in plant extract should be limited in order to not to exceed 2% in finished cosmetic products. Due to irritation potential when combined with ethanol the maximum authorised concentration in products high in that vehicle should not exceed 0.4%. Methyl salicylate should be forbidden in products near the eyes. Further data on mutagenicity (in vivo) and photo toxicity should be provided. (Plants in cosmetics - Potentially harmful components - Volume III - prepared by the Committee of Experts on Cosmetic Products).

- It may contain Eucalyptol (*Elettaria Cardamomum*). 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).

- 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
PARFUM	0.2375	N/A	N/A	-
TITANIUM DIOXIDE (CI 77891)	0.2	ANNEX IV (COLORANT USE), 375	15319	SCCNFP/0005/98
CITRUS AURANTIUM AMARA (BITTER ORANGE) PEEL OIL	<0.0125	N/A	N/A	http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR666.pdf . Cosmetic Ingredient Review Expert Panel - Safety Assessment of Citrus-Derived Peel Oils as Used in Cosmetics - Final Report - September 2014. Conclusion: The CIR Expert Panel concluded the citrus-derived peel oils are safe for use in cosmetic products, excluding rinse-off products, if they do not contain more than 0.0015% (15 ppm) 5-methoxypsoralen (5-MOP), and when formulated to be non-sensitizing and non-irritating. Citrus Aurantium Amara (Bitter Orange) Peel Oil: Maximun concentration in dermal contact leave-on products: 2%
CANANGA ODORATA FLOWER OIL	<0.0125	N/A	N/A	Food Ingredient http://www.aseanfood.info/Articles/11022798.pdf
EUGENIA CARYOPHYLLUS (CLOVE) BUD OIL	<0.0125	N/A	N/A	https://www.nlm.nih.gov/medlineplus/druginfo/natural/251.html http://article.sciencepublishinggroup.com/pdf/10.11648.j.sjc.20150306.13.pdf. www.pjoes.com/pdf/20.2/Pol.J.Environ.Stud.Vol.20.No.2.429-434.pdf EUGENIA CARYOPHYLLUS BUD OIL TOXICOLOGY LD 50 3,597.5 mg/kw bw clove flower oil http://www.academicjournals.org/article/article1380126568_Bhuiyan%20et%20al.pdf. Essential oil obtained by hydrodistillation from fresh leaves and dry buds of Syzigium caryophyllatum were analyzed by Gas Chromatography Mass Spectrometry (GC-MS). Thirty eight components were identified in the leaf oil. The main components were eugenol (74.3%), eucalyptol (5.8%), caryophyllene (3.85%) and a-cadinol (2.43%). Thirty one components were identified in bud oil with the

				main components being eugenol (49.7%), caryophyllene (18.9%), benzene,1-ethyl-3-nitro (11.1%) and benzoic acid,3-(1-methylethyl) (8.9%). The clove oil from Bangladesh was found to be comparable in terms of its eugenol content.
CORIANDRUM SATIVUM (CORIANDER) FRUIT OIL	<0.0125	160	>104575	http://www.ncbi.nlm.nih.gov/pubmed/19032971
GERANIUM MACULATUM OIL	<0.0125	N/A	N/A	http://www.webmd.com/vitamins-supplements/ingredientmono-1244-spotted%20geranium.aspx?activeingredientid=1244&activeingredientname=spotted%20geranium
ORIGANUM MAJORANA LEAF OIL	<0.0125	N/A	N/A	http://www.webmd.com/vitamins-supplements/ingredientmono-563-marjoram.aspx?activeingredientid=563&activeingredientname=marjoram Marjoram is LIKELY SAFE in food amounts and POSSIBLY SAFE for most adults when taken by mouth in medicinal amounts for short periods of time. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116495/ The present study aimed to investigate the *in vitro* mutagenic activity of *Origanum majorana* essential oil. The most abundant compounds identified by GC-MS were *γ*-terpinene (25.73%), *α*-terpinene (17.35%), terpinen-4-ol (17.24%), and sabinene (10.8%). Mutagenicity was evaluated by the *Salmonella*/microsome test using the preincubation procedure on TA98, TA97a, TA100, TA102, and TA1535 *Salmonella typhimurium* strains, in the absence or in the presence of metabolic activation. Cytotoxicity was detected at concentrations higher than 0.04 μL/plate in the absence of S9 mix and higher than 0.08 μL/plate in the presence of S9 mix and no gene mutation increase was observed. For the *in vitro* mammalian cell micronucleus test, V79 Chinese hamster lung fibroblasts were used. Cytotoxicity was only observed at concentrations higher than or equal to 0.05 μg/mL. Moreover, when tested in noncytotoxic concentrations, *O. majorana* essential oil was not able to induce chromosome mutation. The results from this study therefore suggest that *O. majorana* essential oil is not mutagenic at the concentrations tested in the *Salmonella*/microsome and micronucleus assays. *Sue Clarke BSc (Hons) PhD, in Essential Chemistry for Aromatherapy (Second Edition), 2008* Sweet marjoram is a pale yellow oil with a warm, camphoraceous and spicy odour. Its main components are alcohols terpinen-1-ol-4 (14–20%), thujan-4-ol (4–13%), linalool (2–10%), α-terpineol (7–27%), hydrocarbon monoterpenes sabinene (2–10%) ß-myrcene (1–9%), ß-terpinolene (1–7%), α-pinene (1–5%), α-terpinene (6–8%), ester geranyl acetate (1–7%) and aldehyde citral (4–6%). Box 7.2 shows a GC analysis report. A versatile oil with many claimed therapeutic properties. Often called a comforting oil. Applied to the mind in

				situations of stress and grief where it calms and relaxes. For the body it is considered warming, analgesic, and antispasmodic suitable for muscle and joint pains. Also acting on the respiratory system for asthma and bronchitis, on the digestive system as a carmative relieving cholics and constipation and in skincare for bruising and chilblains. Considered a safe nontoxic, nonirritating and nonsensitizing essential oil but should be avoided during pregnancy. https://www.researchgate.net/publication/319135048_Study_of_the_toxicity_of_essential_oils_of_Origanum_majorana_on_Tribolium_castaneum_and_Plodia_interpunctella_stored_product_insects http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2016/02/WC500201949.pdf. Results from relevant experimental studies on *O. majorana* to support the proposed indications are very limited. However, documented effects are not considered contradictory to the traditional use for the symptomatic relief of mild spasmodic gastro-intestinal complaints such as bloating and flatulence. There are no pharmacological data to support the indication, "for relief of irritated skin around the nostrils". Specific data on pharmacokinetics of *O. majorana* preparations and interactions are not available. Non-clinical information on the safety is scarce. The use of *O. majorana* herba during pregnancy and lactation cannot be recommended since there no tests on reproductive and developmental toxicity have been performed. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1514/pdf op.niscair.res.in/index.php/IJNPR/article/view/6800/590
ELETTARIA CARDAMOMUM SEED OIL	<0.0125	N/A	N/A	I)Aromatic herb, used as a spice and flavoring in food Essential Oils in Food Preservation Flavor and Safety, V. R. Preedy, Academic Press (Elsevier) 2016 II)http://www.webmd.com/vitamins-supplements/ingredientmono-614-cardamom.aspx?activeingredientid=614& III)as ess. oil data http://essentialoils.co.za/essential-oils/cardamom.htm IV)http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler/elettaria-cardamomum.html V)www.wjpps.com/download/article/1391272760.pdf

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 (SYMRISE / 881676 RELAX IN STYLE) and the raw material BONTOUX / EO BLEND - FIRE 1SQ 00107/ 1VC 07003:

Allergens > 0.01% - to be declared on the labelling - they comply	% w/w
Limonene	*0.012845*

  Allergens >0.1%:

  None

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 (for this product: **Limonene**).

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

- The corrections regarding allergens must be performed as soon as the perfume and 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	**PURE LUXURY SOAP 40G**
Product Category	BATH SOAP (BATHING, SHOWERING)

Name and Address of Responsible Person*

Company Name	**Alliance National**
Address	Alliance House, Marshfield Bank, Crewe, Cheshire CW2 8UY
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 presence of 'Eucalyptol' & other contra indicated phyto-constituents from ess. oil use 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, although the expected concentrations would be expected to be low.

  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

NAME:	**DIMITRIOS A. MELISSOS**
EDUCATION:	**CHEMIST MSc,**
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DATE:	**19/01/2018**

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www. qacs.gr

ERPA Member

EC, Scientific Advisor on Risk Assessment

PURE LUXURY SOAP 40G
(SFO1043)

MING FAI INDUSTRIAL CO., LTD.

FORMULA PROVIDED

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

Ingredients of Pure Luxury Soap

Sample No:ST-10199
Formula No:SFO1043

Item	INCI Name	Dosage(%) w/w as active	CAS.NO		
1	Sodium Palmate	67,80000000	61790-79-2		
2	Sodium Palm Kernelate	16,95000000	61789-89-7		
3	Aqua	12,00000000	7732-18-5		
4	Glycerin	1,50000000	56-81-5		
5	Palmitic Acid	0,50000000	57-10-3		
6	Sodium Chloride	0,50000000	7647-14-5		
7	Sodium Gluconate	0,30000000	527-07-1		
8	Titanium Dioxide	0,20000000	13463-67-7		
9	Parfum	0,23715525	—	881676 Relax In Style	0,2375
	Citrus Aurantium Amara (Bitter Orange) Peel Oil		68916-04-1	FIRE EO BLEND (1VC 07003)	0,0125
	Cananga Odorata Flower Oil		8006-81-3		
	Eugenia Caryophyllus (Clove) Bud Oil		8000-34-8		
	Coriandrum Sativum (Coriander) Fruit Oil		8008-52-4		
	Geranium Maculatum Oil		84650-10-2		
	Origanum Majorana Leaf Oil		84082-58-6		
	Elettaria Cardamomum Seed Oil		8000-66-6		
	Limonene	0,01284475	5989-27-5		

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

date:2016/7/12

Manufacturing Process of Pure Luxury Soap

Formula No:SFO1043

Item	INCI Name	Dosage(%) w/w as active
1	Sodium Palmate	67,8000000
	Sodium Palm Kernelate	16,9500000
	Aqua (Water)	12,0000000
	Glycerin	0,5000000
	Palmitic Acid	0,5000000
	Sodium Chloride	0,5000000
	Sodium Gluconate	0,3000000
2	Glycerin	1,0000000
3	Titanium Dioxide	0,2000000
4	Parfum	0,2500000
	Citrus Aurantium Amara (Bitter Orange) Peel Oil	
	Cananga Odorata Flower Oil	
	Eugenia Caryophyllus (Clove) Bud Oil	
	Coriandrum Sativum (Coriander) Fruit Oil	
	Geranium Maculatum Oil	
	Origanum Majorana Leaf Oil	
	Elettaria Cardamomum Seed Oil	

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.

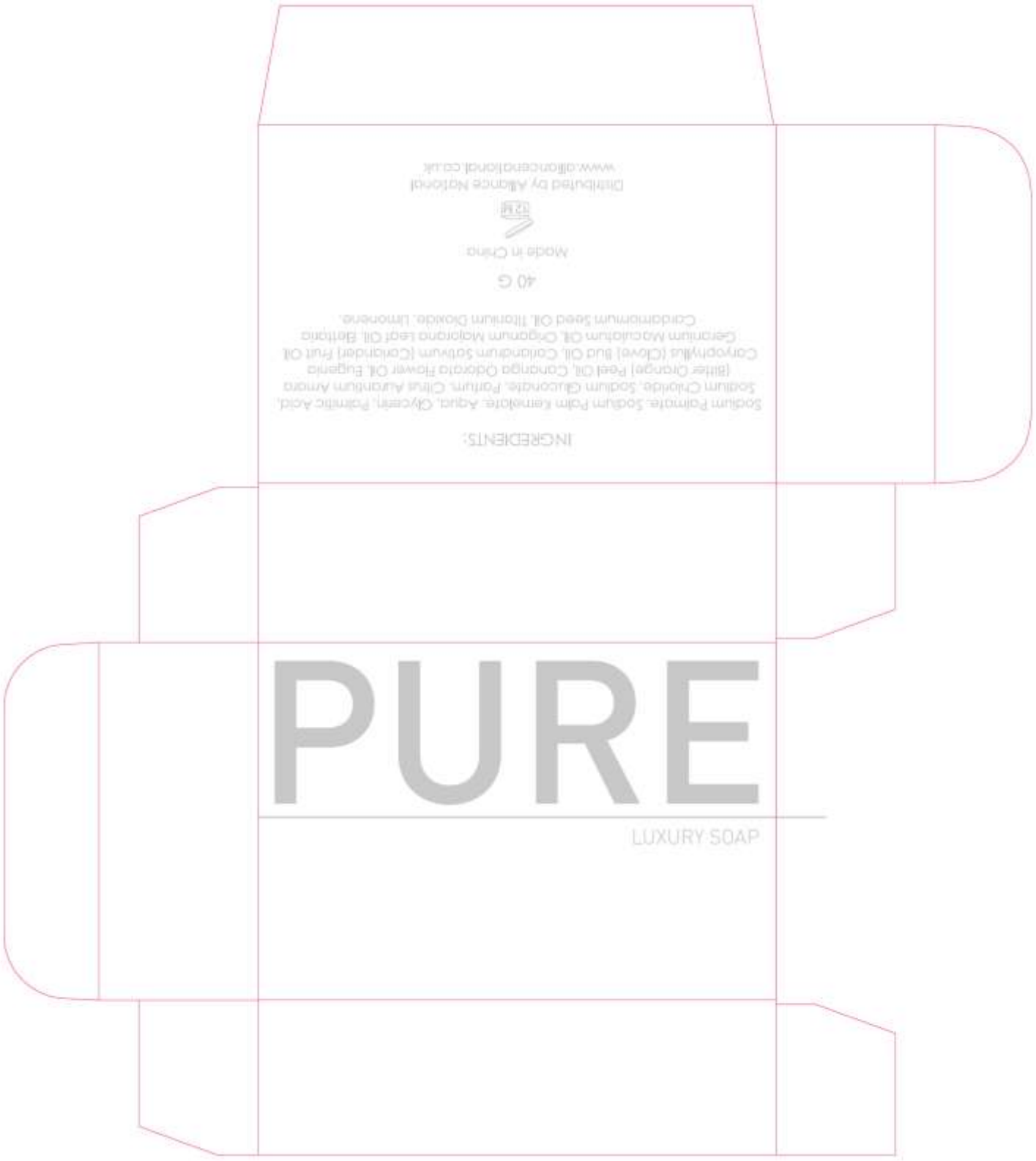
3 Add ingredient Parfum with stiring completely.

4 Add the rest of the water with stiring make it uniform,the whole process at least 8 min.

PURE LUXURY SOAP 40G
(SFO1043)

MING FAI INDUSTRIAL CO., LTD.

PRODUCT LABELLING



PURE LUXURY SOAP 40G

(SFO1043)

MING FAI INDUSTRIAL CO., LTD.

INGREDIENTS:

Sodium Palmate, Sodium Palm Kernelate, Aqua, Glycerin, Palmitic Acid, Sodium Chloride, Sodium Gluconate, Parfum, Citrus Aurantium Amara (Bitter Orange) Peel Oil, Cananga Odorata Flower Oil, Eugenia Caryophyllus (Clove) Bud Oil, Coriandrum Sativum (Coriander) Fruit Oil, Geranium Maculatum Oil, Origanum Majorana Leaf Oil, Elettaria Cardamomum Seed Oil, Titanium Dioxide, Limonene.

40 G

Made in China

Distributed by Alliance National
www.alliancenational.co.uk

PURE LUXURY SOAP 40G
(SFO1043)

MING FAI INDUSTRIAL CO., LTD.

ALLERGENS CERTIFICATE OF THE FRAGRANCE

symrise
always inspiring more...

Special Ingredients
Substances considered as fragrance allergens according to Cosmetic Regulation (EC) No. 1223/2009, Annex III, No. 67-92

Shanghai 201206 P.R.China,
12-May-2016

Product number: 881676
Product name: RELAX IN STYLE

CAS	Substance chemical name / INCI - Name (as such, from essential oils and as carry over)	Concentration (%)
80-54-6	2-(4-tert-Butylbenzyl) propionaldehyde / Butylphenyl Methylpropional	n.d.
127-51-5	3-Methyl-4-(2,6,6-tri-methyl-2-cyclohexen-1-yl)-3-buten-2-one / Alpha - Isomethyl Ionone	n.d.
122-40-7	Amylcinnamal / Amyl Cinnamal	n.d.
101-85-9	Amylcinnamylalcohol / Amylcinnamyl Alcohol	n.d.
105-13-5	Anisylalcohol / Anise Alcohol	n.d.
100-51-6	Benzyl alcohol / Benzyl Alcohol	n.d.
120-51-4	Benzyl benzoate / Benzyl Benzoate	n.d.
103-41-3	Benzyl cinnamate / Benzyl Cinnamate	n.d.
118-58-1	Benzyl salicylate / Benzyl Salicylate	n.d.
104-55-2	Cinnamal / Cinnamal	n.d.
104-54-1	Cinnamic alcohol / Cinnamyl Alcohol	n.d.
5392-40-5	Citral / Citral	0,016
106-22-9	Citronellol / Citronellol	1,703
91-64-5	Coumarin / Coumarin	n.d.
97-53-0	Eugenol / Eugenol	0,001
4602-84-0	Farnesol / Farnesol	n.d.
106-24-1	Geraniol / Geraniol	0,048
101-86-0	Hexyl cinnamaldehyde / Hexyl Cinnamal	n.d.
31906-04-4 51414-25-6	Hydroxy-methylpentylcyclohexenecarboxaldehyde / Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde	n.d.
107-75-5	Hydroxycitronellal / Hydroxycitronellal	n.d.
97-54-1	Isoeugenol / Isoeugenol	n.d.
	Limonene (d-and l-Limonene) / Limonene	4,882
78-70-6	Linalool / Linalool	2,902
111-12-6	Methyl heptine carbonate / Methyl 2-Octynoate	n.d.
90028-68-5	Oak moss extract / Evernia Prunastri (Oakmoss) Extract	n.d.
90028-67-4	Treemoss extract / Evernia Furfuracea (Treemoss) Extract	n.d.

(Declaration limit 10ppm / n.d. = not detectable)

The declaration is a result of a calculatory analysis of the formula.

Symrise Ltd.

This is a computer printout and has therefore not been signed by hand.

ALLERGENS CERTIFICATE OF THE RAW MATERIAL
EO BLEND - FIRE 1SQ 00107/ 1VC 07003

BONTOUX S.A.S.
26170 St Auban sur l'Ouvèze
France

26/09/2017

CLIENT	BONTOUX ASIA PACIFIC LTD

Produit/Product	EO BLEND - FIRE 1SQ 00107/ 1VC 07003

Ingredient	CAS #	%
Anisyl alcohol	1331-81-3/105-13-5	ND
Benzyl Alcohol	100-51-6	ND
Benzyl benzoate	120-51-4	< 2
Benzyl cinnamate	103-41-3	ND
Benzyl salicylate	118-58-1	< 1
Cinnamic alcohol	104-54-1	ND
Cinnamic aldéhyde	104-55-2	ND
Citral (neral + geranial)	5392-40-5 (106-26-3+141-27-5)	< 2
Citronellol	106-22-9	< 6
Coumarin	91-64-5	ND
Eugenol	97-53-0	< 5
Farnesol	4602-84-0	< 0,6
Geraniol	106-24-1	< 3,5
Isoeugenol	97-54-1	< 1
Limonene (D&L and DL)	589-27-5/5989-54-8/1338-86-3	< 10
Linalool	78-70-6	< 20
Oakmoss	68917-10-2/90028-68-5	ND
Treemoss	68648-41-9/900028-67-4	ND
Amyl cinnamic alcohol	*101-85-9*	*These components are*
Amyl cinnamic aldehyde	*122-40-7*	*not known to be present*
Hexyl cinnamic aldehyde	*101-86-0*	*in essential oils.*
Hydroxycitronellal	*107-75-5*	
Lilial	*80-54-6*	
Lyral	*31906-04-4*	
Methyl heptin carbonate	*111-12-6*	
Methyl octin carbonate	*111-80-8*	
Methyl ionone iso/alpha	*127-51-5*	
Phenyl acetaldehyde	*122-78-1*	

ND : not detected / non détecté

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, Sunscreen Lotion, Deodorant, Shower Gel and Soap

Authorized by

Helen Xue
General Manager
Chemicals & Pharmaceuticals

Certification Administration Centre
Intertek Testing Services

Date of Issue: Dec 11, 2015
Date of Renewal: Jul 26, 2018
Certification Number: SZ1507C2

ISO 22716

Stuck Logo 1st year

Stuck Logo 2nd year

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.

Intertek

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.