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SAFETY ASSESSMENT

According to EC Regulation 1223/2009

FRESH CONDITIONING SHAMPOO 30ML

Formula Ref.: SH1-2395

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:	**FRESH CONDITIONING SHAMPOO 30ML**
Manufacturer	Ming Fai Enterprise International Co., Ltd.
STUDY PERIOD	January 2018
QACS LAB ID	17 06 00999-i
Product Category	SHAMPOO (HAIR CARE)

TABLE I. FORMULA PROVIDED

RAW MATERIAL TRADE NAME	INCI	CAS No. *	%	FUNCTION
-	AQUA	7732-18-5	80.927981000	SOLVENT
AES 270N	SODIUM LAURETH SULFATE	68891-38-3	9.000000000	CLEANSING, EMULSIFYING, FOAMING, SURFACTANT
	AQUA	7732-18-5		SOLVENT
TC-CAB 35	COCAMIDOPROPYL BETAINE	61789-40-0	5.000000000	ANTISTATIC, CLEANSING, FOAM BOOSTING, HAIR CONDITIONING, SURFACTANT, VISCOSITY CONTROLLING
	AQUA	7732-18-5		SOLVENT
SODIUM CHLORIDE	SODIUM CHLORIDE	7647-14-5	2.320000000	BULKING, MASKING, VISCOSITY CONTROLLING
PALMERA REFINED GLYCERINE USP 99.5% LIQUID	GLYCERIN	56-81-5	1.000000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
HI-FOAM 850	COCAMIDE MEA	68140-00-1	1.000000000	EMULSIFYING, EMULSION STABILISING, FOAM BOOSTING, SURFACTANT, VISCOSITY CONTROLLING
RHEOSOL Q7P	POLYQUATERNIUM-7	26590-05-06	0.250000000	ANTISTATIC, FILM FORMING
	AQUA	7732-18-5		SOLVENT
CPL AROMAS (FAR EAST) LIMITED / HK311653 WHITE JASMINE LYRAL FREE AP	PARFUM	N/A	0.400000000	DEODORANT, MASKING, PERFUMING
VERSENE™ 220 CRYSTALS CHELATING AGENT	TETRASODIUM EDTA	64-02-8	0.050000000	CHELATING

CITRIC ACID	CITRIC ACID	5949-29-1	0.030000000	BUFFERING, CHELATING, MASKING
BIOEXTENDER SPE	HYDROLYZED RHODOPHYCEA EXTRACT	92128-82-0**	0.010000000	SKIN PROTECTING
	PHENOXYETHANOL	[122-99-6]		PRESERVATIVE
BIORESTORER PF	HYPNEA MUSCIFORMIS EXTRACT	223751-71-1	0.010000000	SKIN PROTECTING
	AQUA	7732-18-5		SOLVENT
	BUTYLENE GLYCOL	[107-88-0]		HUMECTANT, MASKING, SKIN CONDITIONING, SOLVENT, VISCOSITY CONTROLLING
MICROCARE IT	AQUA	7732-18-5	-	SOLVENT
	METHYLCHLORO ISOTHIAZOLINONE	26172-55-4	0.001012500	PRESERVATIVE
	METHYL ISOTHIAZOLINONE	2682-20-4	0.000337500	PRESERVATIVE
FD&C BLUE 1	CI 42090	3844-45-9	0.000470000	COSMETIC COLORANT
FD&C YELLOW No. 5 POWDER	CI 19140	1934-21-0	0.000165000	COSMETIC COLORANT
FD&C RED 4	CI 14700	4548-53-2	0.000034000	COSMETIC COLORANT

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:	Transparent Viscous Liquid
Color:	Green
Odor:	Characteristic
pH:	5.50 - 6.50 (25 °C)
Viscosity:	3000 - 5000 mPa·s (25 °C, LVT#4@30RPM)

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

3. MICROBIOLOGICAL QUALITY

Microbiological Quality: The product, due to the presence of preservatives in the formula (e.g. Methylchloroisothiazolinone and Methylisothiazolinone) is unlikely to present, under normal production conditions, any kind of bio burden.

Challenge Test: The test has been performed (QACS Ltd.) according to the current EUROPEAN PHARMACOPOEIA.
Each strain mentioned below, has been studied separately: Ps. Aeruginosa ATCC 9027, St. Aureus ATCC 6538, E. Coli ATCC 8739, C. Albicans ATCC 10231, A. Brasiliensis ATCC 16404.
Results are satisfactory.

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: Tube: PE. Cap: PP.
- 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 hair and it is rinsed off. External use only.

6. EXPOSURE TO THE COSMETIC PRODUCT

The product is applied on the hair and it is rinsed off so taking under consideration the SCCS/1564/15 opinion it can be studied toxicologically as a shampoo (hair care) with an estimated daily amount applied 10.46 g and a calculated relative daily exposure 1.51 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 colorants **CI 42090, CI 19140** and **CI 14700** which are allowed for use in cosmetics in the EU according to the REGULATION (EC) No 1223/2009. The producer must ensure that every batch of those colorants 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), where applicable.

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

- The product contains **polyacrylamides** (**Polyquaternium-7**) and, according to the Regulation (EC) No 1223/2009 and the SCCP opinion 0011/98, the maximum residual acrylamide content in the final product must be 0.5mg/kg. The manufacturer of the raw material suggests/guarantees that the maximum residual acrylamide content in the raw material is such so that the final product fulfils this restriction.

- 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 (**1.51**).

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site (here **Parfum 0.4%**),

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= 1.51 x 0.4/100 x 1= 0.006 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 * 0.006 / 2 = **0.3 extrapolated to 1 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	% (max)	NOAEL (mg/Kg bw/day)	MoS (min)	NOAEL/SAFETY REFERENCE
AQUA	Q.S. TO 100%	NON TOXIC	N/A	-
SODIUM LAURETH SULFATE	6.3	225	1183	www.epa.gov/hpv/pubs/.../c16316tp.pd... The CIR (http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR533.PDF) assessed the presence of Sodium Laureth Sulfate as: up to 24% for bubble baths and up to 47% for bath soaps as long as its use can be formulated to be nonirritating
SODIUM CHLORIDE (Total - added as is and from the raw materials)	2.62	56400	712805	http://www.epa.gov/dfe/pubs/pwb/ctsa/ch3/ch3-3.pdf
COCAMIDOPROPYL BETAINE	1.5	1000	22075	http://www.heraproject.com/files/45-HH-E101023F-D12F-6A30-DEB0770E9BF8E4D0.pdf
COCAMIDE MEA	1	>750	>24834	http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR605.pdf
GLYCERIN	1	2000	66225	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%
PARFUM	0.4	N/A	N/A	-
POLYQUATERNIUM-7	0.1	N/A	N/A	SCCP opinion 0011/98: the maximum residual acrylamide content must be <0.1 ppm in body care leave-on products and <0.5 ppm in other cosmetic products. The manufacturer of the raw material must guarantee that the raw material fulfils this restriction.
TETRASODIUM EDTA	0.05	500	331126	http://ec.europa.eu/food/fs/sc/sct/out191_en.pdf
CITRIC ACID	0.03	1200	1324503	www.inchem.org/documents/sids/sids/77929.pdf
HYDROLYZED RHODOPHYCEA EXTRACT	<0.01	N/A	N/A	CosIng Description: Hydrolyzed Rhodophycea Extract is a hydrolysate of an extract of the Red Alga, Rhodophycea derived by acid, enzyme or other method of hydrolysis - Functions: SKIN PROTECTING https://www.drugs.com/npc/seaweed.html

				Carrageenan is a high-molecular-weight sulfated polygalactan derived from several species of red seaweeds of the class Rhodophyceae. http://www.cir-safety.org/sites/default/files/plpogu092014slr.pdf https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/MicroorganismsMicrobialDerivedIngredients/default.htm Table 2. Substances Derived from Microorganisms Affirmed by FDA as Generally Recognized as Safe in 21 CFR184 §184.1115 Agar-agar, extracted from a number of related species of red algae class Rhodophyceae
BUTYLENE GLYCOL	0.0027	6000	73583517	www.epa.gov/hpv/pubs/summaries/13butane/c14133rr.pdf, http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr193.pdf up to 5% for mascara
METHYLCHLORO ISOTHIAZOLINONE (AND) METHYL ISOTHIAZOLINONE	0.00135	ANNEX V (2.8) 3:1 MIX ONLY IN RINSED OFF PRODUCTS	>100 (ANNEX V)	SCCS/1238/09 - Reg (EU) No 1003/2014 (amend Annex V to Regulation (EC) No 1223/2009): Max. concentration in ready for use preparation 0,0015 %. RINSE-OFF The two entries are mutually exclusive: the use of the mixture of Methylchloroisothiazolinone (and) Methylisothiazolinone is incompatible with the use of Methylisothiazolinone alone in the same product.
CI 42090	0.00047	REF I) 630 II) 2000	44384951	COSING: Colour Blue / Field of application 1 / Annex/Ref: IV/63 & III/190 Restrictions: Purity criteria as set out in Commission Directive 95/45/EC (E 133). Maximum concentration in ready for use preparation: 0.5% (as hair dye substance i) Opinion SCCNFP/0787/04 http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out261_en.pdf. ii)http://www.mst.dk/NR/rdonlyres/1C99CFFB-6C34-4009-8FFB-F0D02729FD54/0/40.pdf
HYPNEA MUSCIFORMIS EXTRACT	0.0003	N/A	N/A	Hypnea Musciformis Extract is an extract of the Red Alga, Hypnea musciformis, Hypneaceae SKIN PROTECTING Pharmaceutical and Bioactive Natural Products www.bioline.org.br/pdf?md10011 http://uses.plantnet-project.org/en/Hypnea_(PROSEA) 5http://www.ccsenet.org/journal/index.php/jfr/article/viewFile/62731/34724

CI 19140	0.000165	2640	529801325	REF: SCCNFP/0786/04 Cosing: Colour Yellow / Field of application 1 / Other limitations and requirements E 102 (2)
PHENOXYETHANOL	0.00012	80 / 500 (DERMAL) - ANNEX V	>100 (ANNEX V)	Opinion 0125/99 and Danish Ministry of the Environment Survey of Chemical Substances in Consumer Products, No. 88, 2007 Safe for use max.1% as a preservative / http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf
CI 14700	0.000034	N/A	N/A	http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=74 Food additive RESTRICTED however in many countries/uses as E125 ANNEX IV/18 Colour Red Field of application 1 #note: when used as a substance in hair dye products it remains under ANNEX II/1341 Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate (Ponceaux SX; CI 14700) (CAS No 4548-53-2; EINECS 224-909-9)

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 [CPL AROMAS (FAR EAST) LIMITED / HK311653 WHITE JASMINE LYRAL FREE AP]:

Allergens > 0.01% - to be declared on the labelling - they comply	% w/w
Hexyl Cinnamal	*0.019968*
Linalool	*0.018018*

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

  No data presented for the plant-derived raw materials (i.e. Hydrolyzed Rhodophycea Extract, Hypnea Musciformis Extract). However, allergens at concentration >0.01% in the final preparation are not expected from the specific plant-derived raw materials considering their low concentrations.

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: **Linalool**).

- 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.

- The product contains mixture of **"Methylchloroisothiazolinone - Methylisothiazolinone"**. Those substances are a subject of extensive discussion during past years, while SCCS has recently expressed very skeptical on its use:

- Opinion SCCS/1521/13 & Revision of 27 March 2014, in terms of Sensitisation: «Current clinical data indicate that 100 ppm MI in cosmetic products is not safe for the consumer. For leave-on cosmetic products (including 'wet wipes'), no safe concentrations of MI for induction of contact allergy or elicitation have been adequately demonstrated. For rinse-off cosmetic products, a concentration of 15 ppm (0.0015%) MI is considered safe for the consumer from the view of induction of contact allergy. However, no information is available on elicitation»; «There is no harmonised classification of MI as a skin sensitizer. The risk for skin sensitisation by MI is at least equivalent to that of other substances which have received a harmonised classification according to the CLP Regulation.»
- EU REG. 1003/2014 of 18 September 2014, ANNEX V/39: mixture MCl:MI in the ratio 3:1 only allowed in rinse-off products max.0.0015%.
- EU REG. 2017/1224 of 6 July 2017, ANNEX V/57: MI allowed max 0.0015% only in rinse-off products *(from 27 January 2018 only cosmetic products which comply with this Regulation shall be placed on the Union market - from 27 April 2018 only cosmetic products which comply with this Regulation shall be made available on the Union market).*

Subnote: The two entries (39, 57) are "mutually exclusive" – simultaneous use not allowed.

N.B.: As far as it concerns **Butylphenyl Methylpropional**, acknowledged here <0.01%, according to SCCS/1540/14 which has been finalized with the Revision issued on 16 March 2016: "The SCCS is of the opinion that BMHCA is not safe for use as fragrance ingredient in cosmetic leave-on and rinse-off type products, neither at concentration limits according to the ones set up by IFRA in 2013 (MoS = 3.6) nor at concentration limits as set up by IFRA in the revised proposal that has been submitted in 2015 belatedly (MoS = 53). In addition, no firm conclusion could be drawn on mutagenicity. BMHCA poses a risk of inducing skin sensitisation in humans. During the commenting period the applicant commented on the maximum use levels of BMHCA in the finished cosmetic product types. Also further information on genotoxicity was provided. It was also proposed to initiate an in vitro study on dermal penetration of 14CBMHCA through human skin (according OECD TG 428). A reassessment of 2-(4-tert-butylbenzyl) propionaldehyde (BMHCA) based on the new data is foreseen."

SCCS/1540/14 opinion: Revision of opinion on Butylphenyl Methylpropional, 16 March 2016 pages 41-45: (second IFRA submission data) 19000 MoS for 0.05% in SHAMPOO/CONDITIONER individually assessed; hence here at the given limit it

remains possibly within "safety region" individually. As further considerations or outcome of the opinion for the aggregate exposure might raise leading to industry & regulation restrictions, the matter must be closely followed while a reformulation is recommended to be in place to avoid the allergen presence.

N.B.: Currently, Cocamide DEA is regulated in ANNEX III/60:

Maximum concentration in ready for use preparation	Maximum secondary amine content: 0.5%
Other	- Do not use with nitrosating systems - Maximum secondary amine content: 5% (applies to raw materials) - Maximum nitrosamine content: 50 microgram/kg - Keep in nitrite-free containers

Despite the fact that here Cocamide MEA is being used, similar considerations and producer data with reference to the above specs, is advised to apply.

Data on absence of nitrosamines on final product is advised to be in place.

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	**FRESH CONDITIONING SHAMPOO 30ML**
Product Category	SHAMPOO (HAIR CARE)

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 with restrictions** for human health when used under normal or reasonably foreseeable conditions of use.

In order the product to be characterized as safe all the suggestions (regarding safety) within the assessment should be met.

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.

SUGGESTIONS:

- 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.
- *The ingredients Butylene Glycol and Phenoxyethanol are suggested to be added in the ingredient listing on the labelling of the product, *especially if their concentrations in the final preparation are above the detection limit*.
- 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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ERPA Member

EC, Scientific Advisor on Risk Assessment

FORMULA PROVIDED

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

Ingredients of Fresh Conditioning Shampoo

Sample No: MFS-10391
Formula No: SH1-2395

Item	INCI Name	%W/W	CAS.NO
1	Aqua	80,927981000	7732-18-5
2	Sodium Laureth Sulfate	9,000000000	68891-38-3
3	Cocamidopropyl Betaine	5,000000000	61789-40-0
4	Sodium Chloride	2,320000000	7647-14-5
5	Glycerin	1,000000000	56-81-5
6	Cocamide MEA	1,000000000	68140-00-1
7	Polyquaternium-7	0,250000000	26590-05-06
	Parfum	0,362013600	—
8	Hexyl Cinnamal	0,019968000	101-86-0
	Linalool	0,018018400	78-70-6
9	Tetrasodium EDTA	0,050000000	64-02-8
10	Citric Acid	0,030000000	5949-29-1
11	Hydrolyzed Rhodophycea Extract	0,010000000	92128-82-0
12	Hypnea Musciformis Extract	0,010000000	223751-71-1
13	Methylchloroisothiazolinone	0,001012500	26172-55-4
	Methylisothiazolinone	0,000337500	2682-20-4
14	CI 42090	0,000470000	3844-45-9
15	CI 19140	0,000165000	1934-21-0
16	CI 14700	0,000034000	4548-53-2

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

Date:2016/7/11

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

Manufacturing Process of Fresh Conditioning Shampoo

Formula No:SH1-2395

Item	INCI Name	%W/W
1	Aqua	80,927981000
2	Tetrasodium EDTA	0,050000000
3	Sodium Laureth Sulfate	9,000000000
4	Glycerin	1,000000000
5	Cocamide MEA	1,000000000
6	Cocamidopropyl Betaine	5,000000000
7	Polyquaternium-7	0,250000000
8	Citric Acid	0,030000000
9	Methylchloroisothiazolinone	0,001012500
	Methylisothiazolinone	0,000337500
10	Hydrolyzed Rhodophycea Extract	0,010000000
11	Hypnea Musciformis Extract	0,010000000
12	CI 14700	0,000034000
13	CI 42090	0,000470000
14	CI 19140	0,000165000
15	Parfum	0,400000000
16	Sodium Chloride	2,320000000

1 Put ingredient 1 into the water tank, heat the batch to 80-85°C.
2 Add ingredient 2~7 with stiring until completely dissolved.
3 Slow down the mixing speed,cool down the batch to 42~38°C, add ingredient 8 to adjust pH value.
4 Add ingredient 9~15 with stiring until completely dissolved.
5 Add ingredients 16 to adjust the viscosity,and stiring more 3min,take the sample for QC check.
6 After QC passed, then discharge into storage tank through filter for next step.

FRESH CONDITIONING SHAMPOO 30ML
(SH1-2395)

MING FAI INDUSTRIAL CO., LTD.

PRODUCT LABELLING

FRESH CONDITIONING SHAMPOO 30ML
(SH1-2395)

MING FAI INDUSTRIAL CO., LTD.

ALLERGENS CERTIFICATE FOR THE FRAGRANCE

CPL AROMAS

Allergen Analysis

INFORMATION SUPPLIED IN LINE WITH THE COSMETIC PRODUCTS REGULATION (EC) 1223/2009 AND DETERGENTS REGULATION (EC) 648/2004

Fragrance Name: WHITE JASMINE LYRAL FREE AP
Fragrance Code: HK311653

Perfume Ingredient given as listed in legislation (Common Name)	Cas Number	% Concentration Present		
		Added as such	From natural & other sources	Total
Amyl cinnamal	122-40-7	Absent	0.0025	0.0025
Amylcinnamyl alcohol	101-85-9	Absent	Absent	Absent
Anise alcohol	105-13-5	Absent	Absent	Absent
Benzyl alcohol	100-51-6	Absent	0.0012	0.0012
Benzyl benzoate	120-51-4	Absent	0.0050	0.0050
Benzyl cinnamate	103-41-3	Absent	Trace	Trace
Benzyl salicylate	118-58-1	Absent	Trace	Trace
Cinnamal	104-55-2	Absent	Trace	Trace
Cinnamyl alcohol	104-54-1	Absent	Absent	Absent
Citral	5392-40-5	Absent	0.0062	0.0062
Citronellol	106-22-9	Absent	0.0065	0.0065
Coumarin	91-64-5	Absent	Absent	Absent
Eugenol	97-53-0	Absent	0.0003	0.0003
Farnesol	4602-84-0	Absent	0.0019	0.0019
Geraniol	106-24-1	0.6937	0.0284	0.7221
Hexyl cinnamal	101-86-0	4.9920	Absent	4.9920
Hydroxycitronellal	107-75-5	Absent	Trace	Trace
Isoeugenol	97-54-1	Absent	0.0005	0.0005
Butylphenyl methylpropional	80-54-6	2.3000	0.0061	2.3060
Limonene	5989-27-5	Absent	0.1936	0.1936
Linalool	78-70-6	4.5000	0.0046	4.5046
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	31906-04-4	Absent	Absent	Absent
Methyl 2-octynoate	111-12-6	Absent	Absent	Absent
alpha-Isomethyl ionone	127-51-5	Absent	Absent	Absent
Evernia prunastri extract	90028-68-5	Absent	Absent	Absent
Evernia furfuracea extract	90028-67-4	Absent	Absent	Absent

This information is generated by calculation and is given to the best of our knowledge based upon the formulation and information on its components received from our ingredient suppliers and therefore may be subject to change.

"Trace" reflects the presence of a component at a level of <0.0001% in the fragrance oil.

Evaluated on: 09 November 2017

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

Helen Xue
General Manager
Chemicals & Pharmaceuticals

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

Authorized by

ISO 22716

Intertek

Certification Administration Centre
Intertek Testing Services

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.

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.