

SAFETY ASSESSMENT

According to EC Regulation 1223/2009

PURE SHAMPOO 45ML

Formula Ref.: SH1-2394

MING FAI INDUSTRIAL CO., LTD.

PURE SHAMPOO 45ML
(SH1-2394)
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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: PURE SHAMPOO 45ML
Manufacturer Ming Fai Enterprise International Co., Ltd.
STUDY PERIOD January 2018
QACS LAB ID 17 06 00994
Product Category SHAMPOO (HAIR CARE)

TABLE I. FORMULA PROVIDED

RAW MATERIAL TRADE NAME	INCI	CAS No. *	%	FUNCTION
-	AQUA	7732-18-5	81.07791500	SOLVENT
AES 270N	SODIUM LAURETH SULFATE	68891-38-3	9.00000000	CLEANSING, EMULSIFYING, FOAMING, SURFACTANT
	AQUA	7732-18-5		SOLVENT
TC-CAB 35	COCAMIDOPROPYL BETAINE	61789-40-0	5.00000000	ANTISTATIC, CLEANSING, FOAM BOOSTING, HAIR CONDITIONING, SURFACTANT, VISCOSITY CONTROLLING
	AQUA	7732-18-5		SOLVENT
SODIUM CHLORIDE	SODIUM CHLORIDE	7647-14-5	2.32000000	BULKING, MASKING, VISCOSITY CONTROLLING
PALMERA REFINED GLYCERINE USP 99.5% LIQUID	GLYCERIN	56-81-5	1.00000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
HI-FOAM 850	COCAMIDE MEA	68140-00-1	1.00000000	EMULSIFYING, EMULSION STABILISING, FOAM BOOSTING, SURFACTANT, VISCOSITY CONTROLLING
RHEOSOL Q7P	POLYQUATERNIUM-7	26590-05-06	0.25000000	ANTISTATIC, FILM FORMING
	AQUA	7732-18-5		SOLVENT
SYMRISE / 881676 RELAX IN STYLE	PARFUM	N/A	0.23750000	DEODORANT, MASKING, PERFUMING

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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
VERSENE™ 220 CRYSTALS CHELATING AGENT	TETRASODIUM EDTA	64-02-8	0.05000000	CHELATING
CITRIC ACID	CITRIC ACID	5949-29-1	0.03000000	BUFFERING, CHELATING, MASKING
BIOEXTENDER SPE	HYDROLYZED RHODOPHYCEA EXTRACT	92128-82-0**	0.01000000	SKIN PROTECTING
	PHENOXYETHANOL	[122-99-6]		PRESERVATIVE
BIORESTORER PF	HYPNEA MUSCIFORMIS EXTRACT	223751-71-1	0.01000000	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	0.00101250	PRESERVATIVE
	METHYL SOTHIAZOLINONE	2682-20-4	0.00033750	PRESERVATIVE
FD&C YELLOW No. 5 POWDER	CI 19140	1934-21-0	0.00062500	COSMETIC COLORANT
FD&C RED 4	CI 14700	4548-53-2	0.00011000	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).

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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:	Yellow
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 PHARMACOPUEIA.

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: Bottle: PET (EastPET™ A12)*. Cap: PP.

* The manufacturer of the PET material declares that that material is suitable for food contact applications.

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- 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

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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 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.

- 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).

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- 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.

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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 0.2375%**),

D_{Ap} (%) = 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 **D_{Ap}** (%) / 100 = 1.51 x 0.2375 / 100 x 1 = 0.0036 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 * 0.0036 / 2 = **0.18 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."

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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/c h3/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/si ds/56815.pdf, http://www.cir- safety.org/sites/default/files/glycer_092014 _Tent.pdf baby products 2-21% Incidental ingestion 2-68.6%
PARFUM	0.2375	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/7792 9.pdf

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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: Maximum 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.Envir.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 α-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	>423841	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

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ORIGANUM MAJORANA LEAF OIL	<0.0125	N/A	N/A	<p>http://www.webmd.com/vitamins-supplements/ingredientmono-563-marjoram.aspx?activeingredientid=563&activeingredientname=marjoram</p> <p>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.</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116495/ The present study aimed to investigate the <i>in vitro</i> mutagenic activity of <i>Origanum majorana</i> 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 <i>Salmonella</i>/microsome test using the preincubation procedure on TA98, TA97a, TA100, TA102, and TA1535 <i>Salmonella typhimurium</i> 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 <i>in vitro</i> 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, <i>O. majorana</i> essential oil was not able to induce chromosome mutation. The results from this study therefore suggest that <i>O. majorana</i> essential oil is not mutagenic at the concentrations tested in the <i>Salmonella</i>/microsome and micronucleus assays.</p> <p><u>Sue Clarke BSc (Hons) PhD, in <i>Essential Chemistry for Aromatherapy (Second Edition)</i>, 2008</u> 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%) β-myrcene (1-9%), β-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 carminative relieving colics and constipation and in skincare for bruising and chilblains. Considered a safe nontoxic, nonirritating and nonsensitizing essential oil but</p>
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				<p>should be avoided during pregnancy.</p> <p>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</p> <p>http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPc_assessment_report/2016/02/WC500201949.pdf.</p> <p>Results from relevant experimental studies on <i>O. majorana</i> 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 <i>O. majorana</i> preparations and interactions are not available. Non-clinical information on the safety is scarce. The use of <i>O. majorana</i> herba during pregnancy and lactation cannot be recommended since there are no tests on reproductive and developmental toxicity have been performed.</p> <p>http://onlinelibrary.wiley.com/doi/10.2903/j.efs.a.2010.1514/pdf</p> <p>op.niscair.res.in/index.php/IJNPR/article/view/6800/590</p>
ELETTARIA CARDAMOMUM SEED OIL	<0.0125	N/A	N/A	<p>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</p> <p>II)http://www.webmd.com/vitamins-supplements/ingredientmono-614-cardamom.aspx?activeingredientid=614&</p> <p>III)as ess. oil data http://essentialoils.co.za/essential-oils/cardamom.htm</p> <p>IV)http://www.sigmaaldrich.com/life-science/nutrition-research/learning-center/plant-profiler/elettaria-cardamomum.html</p> <p>V)www.wjpps.com/download/article/1391272760.pdf</p>

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HYDROLYZED RHODOPHYCEA EXTRACT	<0.01	N/A	N/A	<p>CosIng Description: Hydrolyzed Rhodophyceae Extract is a hydrolysate of an extract of the Red Alga, Rhodophyceae derived by acid, enzyme or other method of hydrolysis - Functions: SKIN PROTECTING</p> <p>https://www.drugs.com/npc/seaweed.html</p> <p>Carrageenan is a high-molecular-weight sulfated polygalactan derived from several species of red seaweeds of the class <i>Rhodophyceae</i>.²⁶ http://www.cir-safety.org/sites/default/files/plpogu092014slr.pdf</p> <p>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 CFR184.1115Agar-agar, extracted from a number of related species of red algae class <i>Rhodophyceae</i></p>
BUTYLENE GLYCOL	0.0027	6000	73583517	<p>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</p>
METHYLCHLORO ISOTHIAZOLINONE (AND) METHYL ISOTHIAZOLINONE	0.00135	ANNEX V (2.8) 3:1 MIX ONLY IN RINSED OFF PRODUCTS	>100 (ANNEX V)	<p>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.</p>
CI 19140	0.000625	2640	139867550	<p>REF: SCCNFP/0786/04 CosIng: Colour Yellow / Field of application 1 / Other limitations and requirements E 102 (2)</p>
HYPNEA MUSCIFORMIS EXTRACT	0.0003	N/A	N/A	<p>Hypnea Musciformis Extract is an extract of the Red Alga, Hypnea musciformis, Hypneaceae SKIN PROTECTING Pharmaceutical and Bioactive Natural Products</p> <p>www.bioline.org.br/pdf?md10011 http://uses.plantnet-project.org/en/Hypnea_(PROSEA) http://www.ccsenet.org/journal/index.php/jfr/article/viewFile/62731/34724</p>

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(SH1-2394)

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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	0.00011	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 (SYMRISE / 881676 RELAX IN STYLE) and the raw material BONTUUX / EO BLEND - FIRE 1SQ 00107/ 1VC 07003:

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

Allergens >0.1%: *None*

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

No data presented for Hydrolyzed Rhodophyceae Extract and 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: **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).

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- 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 MCI: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.: 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.

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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.

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MING FAI INDUSTRIAL CO., LTD.

PART B- COSMETIC PRODUCT SAFETY ASSESSMENT

Product Name **PURE SHAMPOO 45ML**

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 -

PURE SHAMPOO 45ML
(SH1-2394)
MING FAI INDUSTRIAL CO., LTD.

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.

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.

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 labeling 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

PURE SHAMPOO 45ML

(SH1-2394)

MING FAI INDUSTRIAL CO., LTD.

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.

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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.

PURE SHAMPOO 45ML
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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,**
ADDRESS / TEL-FAX: **ANTIGONIS 1, METAMORFOSSI 14451, ATHENS,
GREECE / +30 210 2934745 - +30 210 2934606**
DATE: **18/01/2018**

QACS Laboratories
1 Antigonis str 144 57 Metamorfossi Greece
VAT no EL 898700211 email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www.qacs.gr

ERPA Member
EC, Scientific Advisor on Risk Assessment

PURE SHAMPOO 45ML
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MING FAI INDUSTRIAL CO., LTD.

FORMULA PROVIDED



Ingredients of Pure Shampoo

Sample No: MFS-10328

Formula No: SH1-2394

Item	INCI Name	%W/W	CAS.NO		
1	Aqua	81,07791500	7732-18-5		
2	Sodium Laureth Sulfate	9,00000000	68891-38-3		
3	Cocamidopropyl Betaine	5,00000000	61789-40-0		
4	Sodium Chloride	2,32000000	7647-14-5		
5	Glycerin	1,00000000	56-81-5		
6	Cocamide MEA	1,00000000	68140-00-1		
7	Polyquaternium-7	0,25000000	26590-05-06		
	Parfum		—	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		
8	Coriandrum Sativum (Coriander) Fruit Oil	0,23715525	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		
9	Tetrasodium EDTA	0,05000000	64-02-8		
10	Citric Acid	0,03000000	5949-29-1		
11	Hydrolyzed Rhodophyceae Extract	0,01000000	92128-82-0		
12	Hypnea Musciformis Extract	0,01000000	223751-71-1		
13	Methylchlorisothiazolinone	0,00101250	26172-55-4		
	Methylisothiazolinone	0,00033750	2682-20-4		
14	CI 19140	0,00062500	1934-21-0		
15	CI 14700	0,00011000	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

PURE SHAMPOO 45ML
(SH1-2394)

MING FAI INDUSTRIAL CO., LTD.



Manufacturing Process of Pure Shampoo

Formula No:SH1-2394

Item	INCI Name	% W/W
1	Aqua	81,07791500
2	Tetrasodium EDTA	0,05000000
3	Sodium Laureth Sulfate	9,00000000
4	Glycerin	1,00000000
5	Cocamide MEA	1,00000000
6	Cocamidopropyl Betaine	5,00000000
7	Polyquaternium-7	0,25000000
8	Citric Acid	0,03000000
9	Methylchloroisothiazolinone	0,00101250
	Methylisothiazolinone	0,00033750
10	Hydrolyzed Rhodophycea Extract	0,01000000
11	Hypnea Musciformis Extract	0,01000000
12	CI 14700	0,00011000
13	CI 19140	0,00062500
14	Parfum	0,25000000
	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	
15	Sodium Chloride	2,32000000

- 1 Put ingredient 1 into the water tank, heat the batch to 80-85°C.
- 2 Add ingredient 2~7 with stirring 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 9~14 with stirring until completely dissolved.
- 5 Add ingredients 15 to adjust the viscosity, and stirring more 3min, take the sample for QC check.
- 6 After QC passed, then discharge into storage tank through filter for next step.

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(SH1-2394)

MING FAI INDUSTRIAL CO., LTD.

PRODUCT LABELLING

Front



Back



PURE SHAMPOO 45ML
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MING FAI INDUSTRIAL CO., LTD.

ALLERGENS CERTIFICATE OF THE FRAGRANCE



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
Page 1 of 1

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	Hydroxy-methylpentylcyclohexenecarboxaldehyde / Hydroxyisoheptyl 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.

PURE SHAMPOO 45ML (SH1-2394) MING FAI INDUSTRIAL CO., LTD.

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
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Produit/Product	EO BLEND - FIRE 1SQ 00107/ 1VC 07003
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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 aldehyde	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 not known to be present in essential oils.
Amyl cinnamic aldehyde	122-40-7	
Hexyl cinnamic aldehyde	101-86-0	
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

BONTOUX SAS. – Le Clôt - Quartier Aguzon - 26170 SAINT-AUBAN-SUR-L'OUVEZE - (France)
Capital : 13 500 060 € - SIRET : 504 506 593 00012 – NAF : 2053Z
Tel. : 33(0)4 75 28 64 64 – Fax : 33(0)4 75 28 60 32 – Email : contact@bontoux.com

PURE SHAMPOO 45ML
(SH1-2394)

MING FAI INDUSTRIAL CO., LTD.

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, Screenshot Lotion, Deodorant, Shower Gel and Soap



Helen Xue

Helen Xue
General Manager
Chemicals & Pharmaceuticals

Authorized by

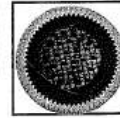


Date of Issue: Dec 11, 2015

Date of Renewal: Jul 26, 2018

Certification Number: SZ1507C2

*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.

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>.