QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

SAFETY

ASSESSMENT

According to EC Regulation 1223/2009

FRESH BODY LOTION 30ML

Formula Ref.: LT1-2678

MING FAI INDUSTRIAL CO., LTD.

SAFETY EVALUATION OF FINISHED COSMETIC PRODUCT

ACCORDING TO

ANNEX I OF (EC) REGULATION 1223/2009

INDEX

FRESH BODY LOTION 30ML
(LT1-2678)
MING FAI INDUSTRIAL CO., LTD.

PART A- COSMETIC PRODUCT SAFETY INFORMATION

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

Product Name:	**FRESH BODY LOTION 30ML**
Manufacturer	Ming Fai Enterprise International Co., Ltd.
STUDY PERIOD	January 2018
QACS LAB ID	17 06 01000-i
Product Category	BODY LOTION (SKIN CARE)

TABLE I. FORMULA PROVIDED

RAW MATERIAL TRADE NAME	INCI	CAS No. *	%	FUNCTION
-	AQUA	7732-18-5	90.51914000	SOLVENT
CARNATION WHITE MINERAL OIL	PARAFFINUM LIQUIDUM	8042-47-5	3.00000000	ANTISTATIC, EMOLLIENT, SKIN PROTECTING, SOLVENT
PALMERA REFINED GLYCERINE USP 99.5% LIQUID	GLYCERIN	56-81-5	1.00000000	DENATURANT, HAIR CONDITIONING, HUMECTANT, PERFUMING, SKIN PROTECTING, VISCOSITY CONTROLLING
TRIPLE PRESSED STEARIC ACID 1660L ***	STEARIC ACID	67701-03-5** [57-11-4]	1.00000000	CLEANSING, EMULSIFYING, EMULSION STABILISING, MASKING, REFATTING, SURFACTANT
GLYCERYL STEARATE	GLYCERYL STEARATE	123-94-4	1.00000000	EMOLLIENT, EMULSIFYING
CETYL STEARYL ALCOHOL 30:70	CETEARYL ALCOHOL	67762-27-0	0.50000000	EMOLLIENT, EMULSIFYING, EMULSION STABILISING, FOAM BOOSTING, OPACIFYING, SURFACTANT, VISCOSITY CONTROLLING
TWEEN 60-SS-(SG)	POLYSORBATE 60	9005-67-8	0.50000000	EMULSIFYING, SURFACTANT
CPL AROMAS (FAR EAST) LIMITED / HK311653 WHITE JASMINE LYRAL FREE AP	PARFUM	N/A	0.40000000	DEODORANT, MASKING, PERFUMING

XIAMETER(R) PMX-200 SILICONE FLUID 350CS	DIMETHICONE	63148-62-9	0.30000000	ANTIFOAMING, EMOLLIENT, SKIN CONDITIONING, SKIN PROTECTING
ARLACEL™ 170-PA-(SG)	GLYCERYL STEARATE	123-94-4	0.30000000	EMOLLIENT, EMULSIFYING
	PEG-100 STEARATE	9004-99-3		SURFACTANT
TRIETHANOLAMINE 99	TRIETHANOLAMINE	102-71-6	0.18000000	BUFFERING, EMULSIFYING, MASKING, SURFACTANT
POLYGEL CA / POLYGEL CB	CARBOMER	9003-01-4	0.20000000	EMULSION STABILISING, GEL FORMING, VISCOSITY CONTROLLING
VERSENE™ 220 CRYSTALS CHELATING AGENT	TETRASODIUM EDTA	64-02-8	0.10000000	CHELATING
MICROCARE® EMOLLIENT EHG	ETHYLHEXYLGLYCERIN	70445-33-9	0.10000000	SKIN CONDITIONING
MICROCARE PE	PHENOXYETHANOL	122-99-6	0.90000000	PRESERVATIVE
FD&C YELLOW No. 5 POWDER	CI 19140	1934-21-0	0.00080000	COSMETIC COLORANT
FD&C RED 4	CI 14700	4548-53-2	0.00006000	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).

*** INCI Formula (see attached to this repost) was related to submitted safety data sheets to investigate purity of materials; The Responsible Person/Manufacturer must ensure that clarified pure ingredients are denoted in descending order till 1% and in any order after that. If stearic acid / palmitic acid mixture is employed, it is recommended to indicate both substances.

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 Viscous Emulsion
Color:	Yellow
Odor:	Characteristic
pH:	5.50 - 6.50 (25 °C)
Viscosity:	4000 - 8000 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. Phenoxyethanol) 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 body and it is not rinsed off. External use only.

6. EXPOSURE TO THE COSMETIC PRODUCT

The product is applied on the body and it is not rinsed off, so taking under consideration the SCCS/1564/15 opinion it can be studied toxicologically as a body lotion (skin care product) with an estimated daily amount applied 7.82 g and a calculated relative daily exposure 123.20 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 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 no plant-derived raw materials (e.g. extracts, oils, waxes, etc.) directly added in the formula.

- It contains **Paraffinum Liquidum**. According to the provided specification sheet of the raw material "CARNATION® WHITE MINERAL OIL", that raw material conforms to the requirements of USP.

- It contains **Triethanolamine** within limits**.** According to the Regulation (EC) No 1223/2009 (ANNEX/Ref: III/62) the maximum permitted concentration of that substance in ready for use preparations is 2.5%.

- According to the Regulation (EC) No 1223/2009, as the product contains Trialkylamines, trialkanolamines (**triethanolamine**) and their salts, the producer declares that the following limitations and requirements are fulfilled for that raw material:

- Minimum purity: 99%
- Maximum secondary amine content: 0.5% (applies to raw materials)
- Maximum nitrosamine content: 50 microgram/kg*

*** Note:** According to the presented declaration of the manufacturer of the raw material "TRIETHANOLAMINE, 99%", analysis of that raw material for N-nitrosodiethanolamine (NDELA) has not revealed its presence at the detection limit of the test (10 ppb).

- 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 (**123.20**).

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= 123.20 x 0.4/100 x 1= 0.4928 6 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 * 0.4928 / 2 = **24.64 extrapolated to 25 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	-
PARAFFINUM LIQUIDUM	3	1200 ORAL DERMAL 12000	1623	i) http://www.efsa.europa.eu/en/efsajournal/doc/1387.pdf (MW>500, Log Kow 6, 10% dermal absorption) The Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion on the safety of high viscosity white mineral oils (HVMO) (CAS Registry Number 8042-47-5) when used as food additives. HVMO have previously been evaluated by the EC Scientific Committee for Food (SCF) (1995) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (1995, 2002). The SCF allocated a Temporary Group ADI of 0-4 mg/kg bw/day for white paraffinic oils which included white mineral oils with a viscosity higher than 8.5 cSt at 100°C. In 2002, JECFA recommended an ADI of 0 – 20 mg/kg bw/day for HVMO. Dietary exposure to HVMO did not produce adverse effects in subchronic toxicity and chronic toxicity/carcinogenicity studies in rats. Infiltration of histiocytes (granulomas) in mesenteric lymph nodes and oil deposition in the liver were considered to be an indication of exposure to white mineral oils rather than an adverse effect. The NOAEL for HVMO was considered to be 1200 mg/kg bw/day, the highest dose tested. Using this NOAEL and applying an uncertainty factor of 100 the Panel established an ADI of 12 mg/kg bw/day for HVMO (kinematic viscosity ≥ 11 mm^2/s (cSt) at 100 °C, a carbon number > 28 at 5 % distillation point and an average molecular weight > 500 g/mol). The Panel considered the dietary exposure to HVMO from current uses as well as proposed uses, and estimated that the potential dietary exposures for high level consumers (95th/97.5th) would reach up to approximately 13 mg/kg bw/day for adults and 19 mg/kg bw/day for children. The Panel considers these estimates to be very conservative since high levels of exposure from different sources, in consumers only, have been added up. ii)http://www.ncbi.nlm.nih.gov/pubmed/23283704 The safety of isoparaffins as used in cosmetic products is reviewed in this safety assessment. These ingredients function mostly as solvents and also function as emollients in the 0001% to 90% concentration range. The Cosmetic Ingredient Review (CIR) Expert Panel has reviewed relevant animal and clinical data and concluded that these ingredients are safe in the present practices of use

				and concentration described in this safety assessment. iii)http://www.bfr.bund.de/cm/349/determination-of-hydrocarbons-from-mineral-oil-or-plastics.pdf. Mineral oils in cosmetics: Considering all available scientific evidence, no health risks are to be expected from absorption via the skin BfR Opinion No 014/2015 of 26 May 2015 Considering all available scientific evidence, health risks for consumers caused by the uptake of the mineral oils in cosmetics through the skin are unlikely from the BfR`s point of view. No effects on health attributable to the mineral oil components of cosmetic products have been reported up to now despite the fact that they have been in widespread use for many years. In the opinion of the BfR, state-of-the-art technology should nevertheless be used to reduce the MOAH content in cosmetic products to the trace amounts which are unavoidable. A final risk assessment of the absorption of mineral oil through the skin can only be carried out by the BfR when more data becomes available. http://www.bfr.bund.de/en/questions_and_answers_on_mineral_oil_in_cosmetic_products-194384.html * The question of the health risk assessment of MOSH and MOAH in cosmetic products - in particular regarding the development of skin cancer - was discussed intensively at the 15th meeting of the BfR committee for cosmetic products. The dermatologists in attendance emphasised that there are no indications for dermal health-damaging effects which can be attributed to cosmetic products. There is, for example, no data indicating that the use of lipstick would increase the rate of skin cancer in the area around the mouth. Although baby oils and creams, some of which contain high concentrations of mineral oils due in part to the low sensitisation potential, are used in the nappy area, no increase in skin diseases or even skin tumours has been observed in this body area among children or adults. In the treatment of psoriasis, Vaseline, which consists of petroleum jelly, is applied over the entire body and covered with cloths. To date, no increase in the incidence of skin lesions has been reported in connection with this treatment either. http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf
GLYCERYL STEARATE	<1.3	7500	>2341	http://ec.europa.eu/environment/chemicals/reach/pdf/6b_appendix_2.pdf
GLYCERIN	1	2000	812	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%

STEARIC ACID / PALMITIC ACID also present in the mixture "TRIPLE PRESSED STEARIC ACID 1660L", if employed as such	1	750	304	"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) Baby products up to 3.0% >50% JACT 6(3):321-401, 1987 confirmed 06/05 IJT 25(S2), 2006, http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr161.pdf mascara up to 10.0%
PHENOXYETHANOL	0.9	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
CETEARYL ALCOHOL	0.5	>750 REF. I	>609	i)www.aciscience.org/docs/Draft_SIDS_Long_Chain_Alcohols_1.pdf, ii) Referenced in CIR quick Ref. Guide Feb 2017 safe as used up to 25% (generic) JACT 7(3):359-413,1988 confirmed 12/05 : see specific categories date on http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/prn547.PDF Face and neck creams, lotions, powder, and sprays: up to 6%. Baby products up to 5.0%. # Body and hand creams, lotions, powder, and sprays: up to 13% iii)https://www.ncbi.nlm.nih.gov/pubmed/3987517 iv) https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+2643 & ref. therein (cetyl alcohol data):

				TOXICOKINETICS: As with other alcohols, absorption from the gastrointestinal tract appears to be rapid and efficient. Dermal penetration of higher alcohols does not occur as readily as with smaller molecular weight alcohols. Absorption from inhalation is limited and higher chain alcohols are less likely to be inhaled.
POLYSORBATE 60	0.5	>5000	>4058	www.epa.gov/opprd001/inerts/sorbitan5-20-05.pdf see also: www.cir-safety.org/sites/default/files/polysorbates.pdf 0.0021-3.8 % for eye area / 0.2-0.4% for Incidental ingestion / 0.00009-6.0% for dermal contact
PARFUM	0.4	N/A	N/A	-
DIMETHICONE	0.3	I) NON TOXIC II) READ ACROSS 1000	1353	i) ec.europa.eu/enterprise/sectors /.../rpa_non_surf_organ_zeolites ii) http://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+1808, http://www.ncbi.nlm.nih.gov/pubmed/14555417 <15%, Clinical and animal absorption studies reported that Dimethicone was not absorbed following oral or dermal exposure. Dimethicone, Methicone, and Vinyldimethicone were not acutely toxic following oral exposure. No adverse reactions were found in rabbits following short-term dermal dosing with 6% to 79% Dimethicone iii) Dimethicone is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. Methicone is a linear monomethyl polysiloxane. Most of these ingredients function as conditioning agents in cosmetic formulations at current concentrations of use of < or =15%. Clinical and animal absorption studies reported that Dimethicone was not absorbed following oral or dermal exposure. Dimethicone, Methicone, and Vinyldimethicone were not acutely toxic following oral exposure. No adverse reactions were found in rabbits following short-term dermal dosing with 6% to 79% Dimethicone. Mice and rats were dosed for 90 days with up to 10% Dimethicone without adverse effect. Dimethicone did not produce adverse effects in acute and short-term inhalation-route studies. Dimethicone (tested undiluted and at 79%) was not a sensitizer in four assays using mice and guinea pigs. The Cosmetic Ingredient Review (CIR) Expert Panel considered it unlikely that any of these polymers would be significantly absorbed into the skin due to their large molecular weight. Although adverse effects were noted in one inhalation study with small aerosol particles, the expected particle sizes for cosmetic products would primarily be in the range of 60 to 80 micro, and less than 1%

				would be under 10 micro, which is an upper limit for respirable particles. Overall, the safety test data support the safety of these ingredients at the concentrations they are known to be used in cosmetic formulations http://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr307.pdf 0.3-4.0% for mascara
PEG-100 STEARATE	<0.3	NO SAFETY CONCERN	N/A	Safety assessment on polyethylene glycols (PEGs) and their derivatives as used in cosmetic products, Claudia Fruijtier-Polloth, Toxicology 214 (2005) 1-38
CARBOMER	0.2	1512	3068	www.lubrizol.com/WorkArea/ linkit.aspx?LinkIdentifier=id&ItemID…U - polymerisation solvent residues must be evaluated as possible CMR
TRIETHANOLAMINE	0.18	1000 (Also see ANNEX III - within limits, must comply with restrictions)	2255	www.epa.gov/hpv/pubs/summaries/plyacdts/c14950rr.pdf, CosIng max. 2.5% (also see ANNEX iii - within limits, must comply with restrictions)
ETHYLHEXYLGLYCERIN	0.1	N/A	N/A	www.quetzalquimica.com/images/Sensiva_SC10_e20-08-2010.pdf (Safe at a concentation 2%), http://www.cir-safety.org/sites/default/files/ethylh122011finalx.pdf up 0.02-1.0 % for eye area/ 0.08-0.5 % for Incidental ingestion / 0.000001-8.0% for dermal contact
TETRASODIUM EDTA	0.1	500	2029	http://ec.europa.eu/food/fs/sc/sct/out191_en.pdf
CI 19140	0.0008	2640	1339286	REF: SCCNFP/0786/04 Cosing: Colour Yellow / Field of application 1 / Other limitations and requirements E 102 (2)
CI 14700	0.00006	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 >0.001%)

  No data available

- Allergens from the perfume [CPL AROMAS (FAR EAST) LIMITED / HK311653 WHITE JASMINE LYRAL FREE AP]:

Allergens > 0.001% - to be declared on the labelling - they comply	% w/w
Hexyl Cinnamal	*0.019968*
Linalool	*0.018018*
Butylphenyl Methylpropional	*0.009224*
Geraniol	*0.002888*

  Allergens >0.1%:

  None

- Allergens from plant-derived raw materials (extracts, oils, waxes etc) at concentration >0.001% in the final preparation:

  According to the provided formula the product does not contain directly added plant-derived raw materials.

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

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

- The corrections regarding allergens must be performed as soon as the perfume manufacturer will supply the relevant data as well as the EC gives final guidelines on the subject.

N.B.: Analytical solvent traces data of Carbomer would be advised to be in place (possible CMR).

N.B.: According to the Regulation (EC) No 1223/2009, as the product contains Trialkylamines, trialkanolamines (**triethanolamine**) and their salts, the producer must ensure that the following limitations and requirements are fulfilled for that raw material in every one of its batches that are used for the production of the assessed product:

- Not to be used with nitrosating systems
- Keep in nitrite-free containers

N.B.: As far as it concerns **Butylphenyl Methylpropional** 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) 160 MoS for 0.1% in BODY LOTION 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.

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 BODY LOTION 30ML**
Product Category	BODY LOTION (SKIN 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** 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.

  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,**
ADDRESS / TEL-FAX:	**ANTIGONIS 1, METAMORFOSSI 14451, ATHENS,**
	GREECE / +30 210 2934745 - +30 210 2934606
DATE:	**22/01/2018**

QACS Laboratories
1 Antigonis str 144 51 Metamorfossi Greece
VAT no EL [illegible] email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

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 Body Lotion

Sample No: MFL-10566A
Formula No: LT1-2678

Item	INCI Name	%W/W	CAS.NO
1	Aqua	90,51914000	7732-18-5
2	Paraffinum Liquidum	3,00000000	8042-47-5
3	Glycerin	1,00000000	56-81-5
4	Stearic Acid	1,00000000	67701-03-5
5	Glyceryl Stearate	1,00000000	123-94-4
6	Cetearyl Alcohol	0,50000000	67762-27-0
7	Polysorbate 60	0,50000000	9005-67-8
	Parfum	0,34990120	—
	Geraniol	0,00288840	106-24-1
8	Hexyl Cinnamal	0,01996800	101-86-0
	Butylphenyl Methylpropional	0,00922400	80-54-6
	Linalool	0,01801840	78-70-6
9	Dimethicone	0,30000000	63148-62-9
10	Glyceryl Stearate PEG-100 Stearate	0,30000000	123-94-4 9004-99-3
11	Triethanolamine	0,18000000	102-71-6
12	Carbomer	0,20000000	9003-1-4
13	Tetrasodium EDTA	0,10000000	64-02-8
14	Ethylhexylglycerin	0,10000000	70445-33-9
15	Phenoxyethanol	0,90000000	122-99-6
16	CI 19140	0,00080000	1934-21-0
17	CI 14700	0,00006000	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 Body Lotion

Formula No:LT1-2678

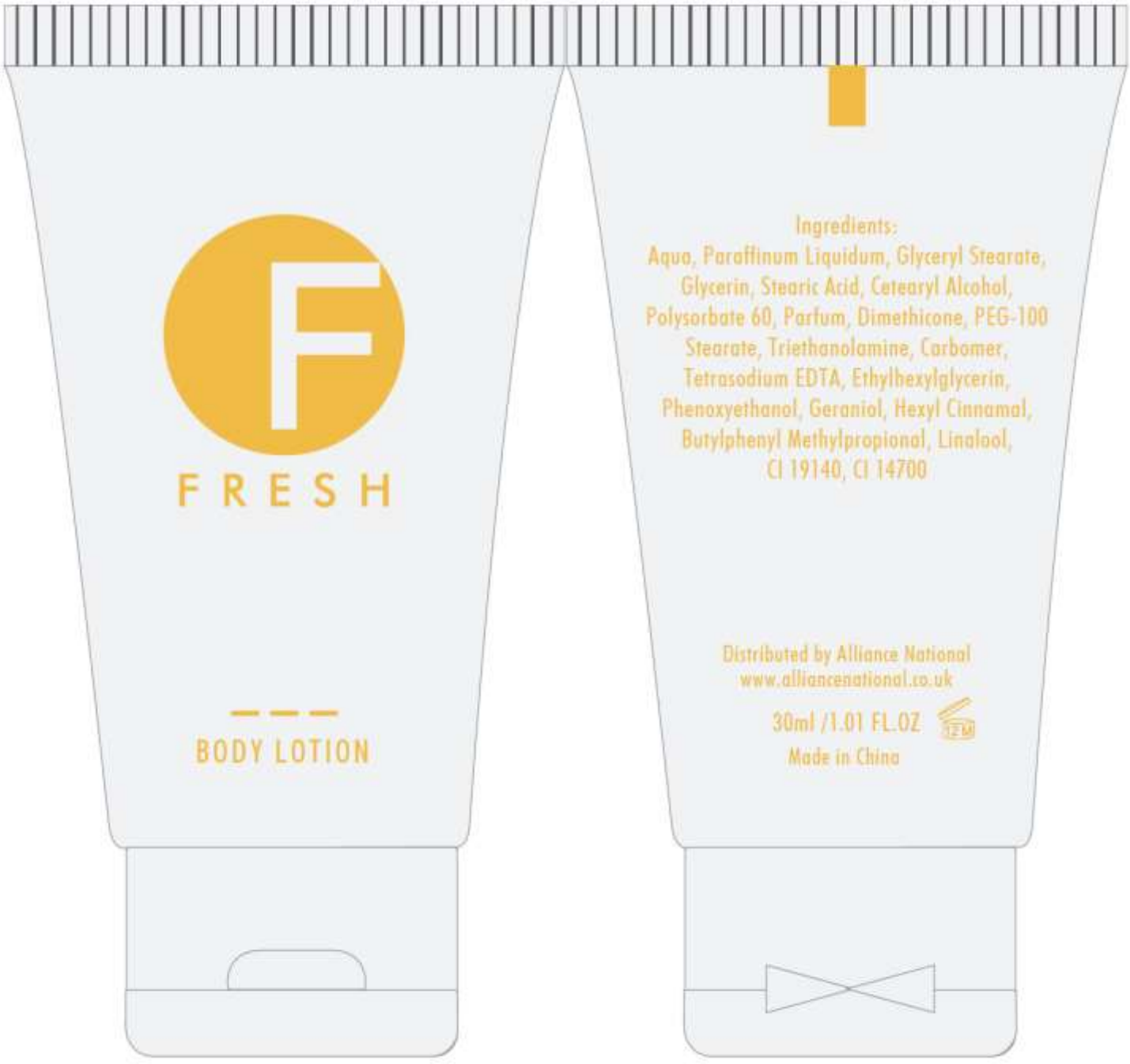
Item	INCI Name	%W/W
Part A		
1	**Aqua**	**90,51914000**
2	**Tetrasodium EDTA**	**0,10000000**
3	**Carbomer**	**0,10000000**
4	**Carbomer**	**0,10000000**
5	**Glycerin**	**1,00000000**
6	**Triethanolamine**	**0,18000000**
Part B		
14	**Phenoxyethanol**	**0,90000000**
15	**Ethylhexylglycerin**	**0,10000000**
16	**CI 14700**	**0,00006000**
17	**CI 19140**	**0,00080000**
18	**Parfum**	**0,40000000**
Part C		
7	**Cetearyl Alcohol**	**0,50000000**
8	**Stearic Acid**	**1,00000000**
9	**Paraffinum Liquidum**	**3,00000000**
10	**Dimethicone**	**0,30000000**
11	**Glyceryl Stearate**	**0,30000000**
	PEG-100 Stearate	
12	**Glyceryl Stearate**	**1,00000000**
13	**Polysorbate 60**	**0,50000000**

1 Put ingredient 1 into the emulsifying tank,add ingredient 2 with stiring until completely dissolved.
2 add ingredient 3,4 with stiring until completely dissolved. heat the batch to 80~85℃
3 Add ingredient 5,6 with stiring until completely dissolved.
4 Combine Part B into oil tank, heat the batch to 80-85℃.
5 Put the oil tank matreial into the another tank, heat the batch to 80-85℃.
6 Open the homogenizer for require,until the batch looks smooth and uniform.
7 Turn off the homogenizer,and record.
8 Slow down the mixing speed,cool down the batch to 42~38℃, Add ingredient 14~17 with stiring until completely dissolved.
9 Add ingredient 18 with stiring until completely dissolved,Open the homogenizer.
10 Turn off the homogenizer, and stiring more 3min. Take the sample for QC check, After QC passed, then discharge into storage tank through filter for next step.

FRESH BODY LOTION 30ML
(LT1-2678)

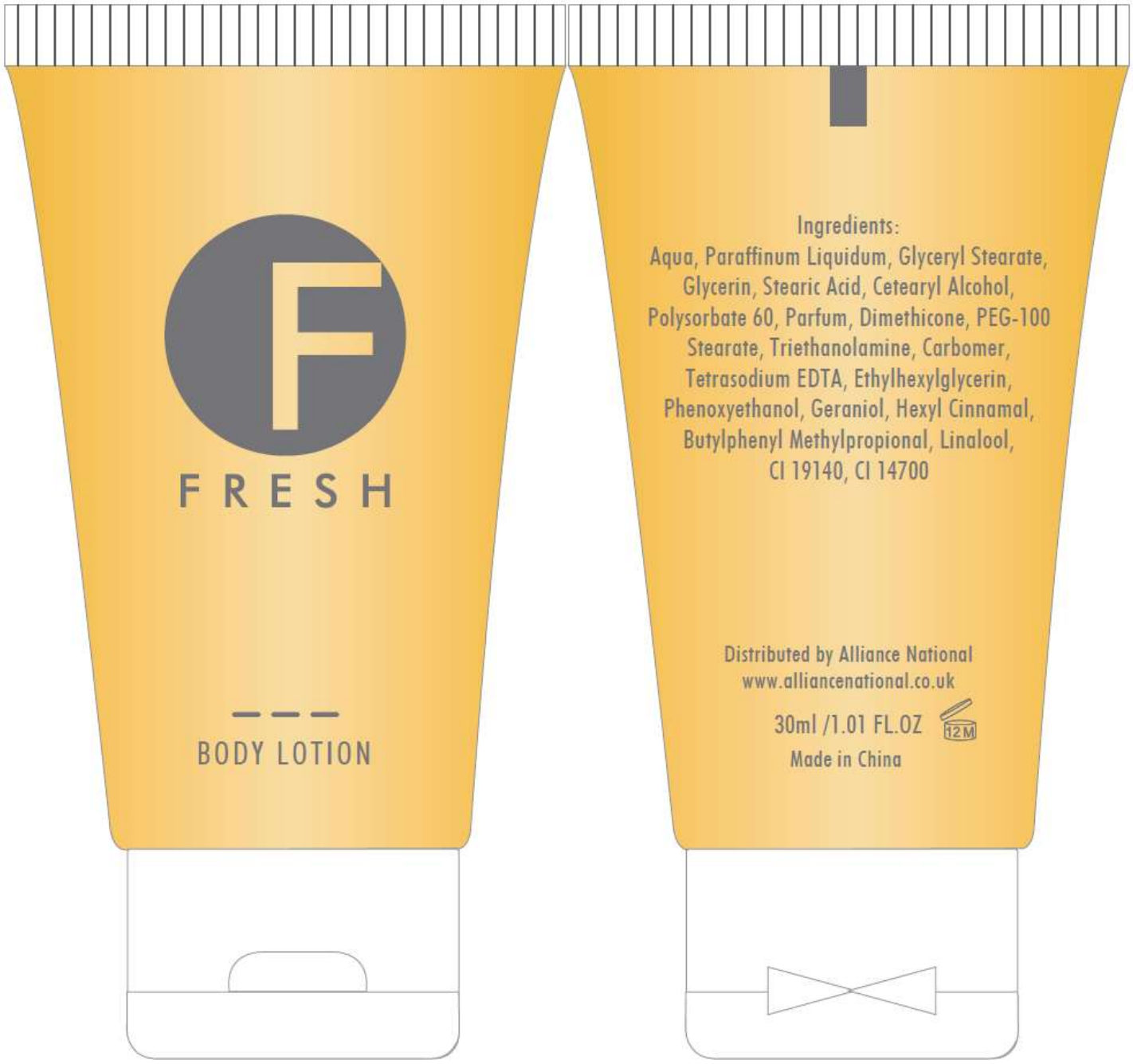
MING FAI INDUSTRIAL CO., LTD.

PRODUCT LABELLING



FRESH BODY LOTION 30ML
(LT1-2678)

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

Authorized by

Helen Xue
General Manager
Chemicals & Pharmaceuticals

Certification Administration Centre
Intertek Testing Services

Stuck Logo
1st year

Stuck Logo
2nd year

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

ISO 22716

Intertek

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

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