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COSMETIC PRODUCT

SAFETY REPORT

According to EC Regulation 1223/2009

AQUEOUS HAIR & BODY WASH 300ML

SH1-1905

MING FAI INDUSTRIAL CO. LTD.

SAFETY EVALUATION OF FINISHED PRODUCT (1223/2009 ANNEX I-PART B.1-4)

INDEX:

1. INFORMATION FOR THE EVALUATION OF THE INGREDIENTS AND FINAL PRODUCT

1.1 IDENTIFICATION OF THE PRODUCT

A. COMMERCIAL NAME:

AQUEOUS HAIR & BODY WASH 300 ML SH1-1905

B. INGREDIENTS

Have been reviewed. Raw materials known, not forbidden and listed.

C. SPECIFICATIONS OF INGREDIENTS

Supplier's specifications for each raw material have been reviewed.

D. INCI NAMES OF INGREDIENTS

Have been reviewed. Are referred in detail in supplier's raw material MSDS.

E. CAS NUMBERS OF INGREDIENTS

Are referred in detail in supplier's raw material MSDS.

1.2 SAFETY DATA SHEETS OF INGREDIENTS (MSDS)

Have been reviewed especially for the toxicological data.

1.3 PRODUCTION METHOD AND SPECIFICATIONS OF FINAL PRODUCT–

GMP COMPLIANCE – STABILITY OF THE PRODUCT

- PRODUCTION METHOD: Has been reviewed.
- SPECIFICATIONS OF FINAL PRODUCT: Have been reviewed.
- G.M.P. COMPLIANCE: Exists and the company is supervised under Intertek GMPC (July 14, 2010).
- STABILITY OF THE PRODUCT: Has been reviewed and it is acceptable.

1.4 MICROBIOLOGICAL QUALITY – PRESERVATION EFFICACY TEST

- MICROBIOLOGICAL QUALITY: The product, due to the presence of preservatives in the formula(Benzyl alcohol, Methylisothiazolinone, Methylchloroisothiazolinone), is unlikely to present, under normal production conditions, any kind of bio burden.
- CHALLENGE TEST: The test has been performed (QACS) according to the current EUROPEAN PHARMACOPOEIA.

Each strain mentioned below, has been studied at least with: St. Aureus ATCC 6538, Ps. Aeruginosa ATCC 9027, E.Coli ATCC 8739, C. Albicans ATCC 10231, A. Brasiliensis ATCC 16404.
Results are satisfactory.

1.5 IMPURITIES - TRACES IN THE FINAL PRODUCT OR SUBSTANCES – PROPERTIES OF PACKAGING MATERIAL

- IMPURITIES: There are no data reported in MSDS.

- TRACES: There are no data reported in MSDS.

- PROPERTIES OF PACKAGING MATERIAL:

Type of Packaging Material: PP.

According to the presentation and the formula of the product, package is considered unlikely to affect its purity and stability. (See stability report)

1.6 WAY OF USE-EXPOSURE TO THE PRODUCT - EXPOSURE TO THE SUBSTANCES (1223/2009 ANNEX I-PART A.5-6-7)

- WAY OF USE: The product is applied on the body and it is rinsed off. External use only.

- WAY OF EXPOSURE:

The product is applied on the hair so taking also under consideration guidelines from SCCS/1501/12 opinion it can be foreseen to be studied as a shower gel with an estimated daily amount applied 18.67 g and a calculated relative daily exposure 2.79 mg/Kg bw/day.

1.7 INFORMATION ON THE PRODUCT (STUDIES ON HUMAN VOLUNTEERS / RELEVANT LITERATURE) (1223/2009 ANNEX I-PART A.10)

- PATCH TEST: Satisfactory. (Non irritant-QACS)

- OTHER TESTS: Not Applicable

- LITERATURE DATA: Not Applicable

2 LABELLED WARNINGS & 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.

3 TOXICOLOGICAL PROFILE OF THE SUBSTANCES(1223/2009AnnexI-PartA.8)

- 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.

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 (Chapter IV, Article 14, i.e. preservatives,) there are already limits in legislation (Annex V) and they comply.
- There are no nanomaterials in the product or substances.
- 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.
- CI 19140: Colouring agents whose numbers is preceded by the letter "E" in accordance with the EEC Directives of 1962 concerning foodstuffs and colouring matters must fulfil the purity requirements laid down in those Directives. They continue to be subject to the general criteria set out in Annex III to the 1962 Directive concerning colouring matter, where the "E" number has been deleted therefrom.

The insoluble barium, strontium and zirconium lakes, salts and pigments of these colouring agents shall also be permitted. They must pass the test for insolubility which will be determined by the procedure laid down in Article 8.

- 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 (**ora**l) 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 **(2.79)**.

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site (**here Polyquaternium-7 0.5 %**),

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= 2.79 x 0.5/100 x 1= **0.014** mg/kg bw/day

- The minimum NO(A)EL, according to the above suggested calculations (SCCS/1416/11) for the pure maximum concentrated ingredient should be:

Minimum NO(A)EL= MoS x SED = 100 * 0.014=1.4 extrapolated at **2 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 (TABLE I) includes the relevant available NOAEL and MoS calculated for each ingredient of the formula.

TABLE I:

INCI	MAX %	NOAEL (mg/Kg/ bw/day)	MoS (> 100)	REFERENCE
AQUA	QS to 100	Non Toxic	N/A	-
SODIUM LAURETH SULFATE	12	225	672	www.epa.gov/hpv/pubs/.../c16316tp.pd...Παρόμοιες
COCAMIDE DEA	3.0	1000	11947	toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs
SODIUM CHLORIDE	1.25	56400	1617204	http://www.epa.gov/dfe/pubs/pwb/ctsa/ch3/ch3-3.pdf

GLYCERIN	1.0	2000	71684	www.inchem.org/documents /sids/sids/56815.pdf
COCAMIDOPROPYL BETAINE	3.0	1000	11948	www.heraproject.com/.../45-HH-05-Fin...Παρόμοιες
POLYQUATERNIUM-7	0,50	N/A	N/A	SCCP opinion 0011/98: the maximum residual acrylamide content must be 0.5mg/kg. The manufacturer of the raw material must guarantee that the raw material fulfils this restriction
BENZYL ALCOHOL	0.4	188	16846	Danish Ministry of the Environment, Danish surveys on chemicals in consumer products, No.88, 2007 Max. 1%
PARFUM	0,30	N/A	N/A	-
CITRIC ACID	0,1	1200	430107	www.inchem.org/documents/sids/sids/77929.pdf
TETRASODIUM EDTA	0,1	500	179211	http://ec.europa.eu/food/fs/sc/sct/out191_en.pdf
METHYLISOTHIAZOLINONE/ METHYLCHLOROISOTHIAZOLINONE	0.0012	2.8	83632	SCCNFP/0805/04 (Max 0.0015%)
CI 19140	0.000065	2640	1455748552	SCCNFP/0786/04
CI 42090	0.000005	2000	1433691756	http://www.mst.dk/NR/rdonlyres/1C99CFFB-6C34-4009-8FFB-F0D02729FD54/0/40.pdf

ALLERGEN FACTORS :

Allergens on the final product: ***(Allergens declared >0.01%)***

No data presented.

Parfum (86311473 - Drom):

LIMONENE: 0.084%, HEXYL CINNAMAL: 0.036%, other allergens <0.01%

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 fragrance (opinion 1459/11, Conclusions-question 1). The corrections must be performed as soon as the perfume and plant extracts manufacturers will supply the relevant data as well as the EC gives final guidelines on the subject .

SUGGESTION:

- It contains **Polyquaternium-7** and according to SCCP opinion 0011/98, the maximum residual **acrylamide** content must be 0.5mg/kg. The manufacturer of the raw material must guarantee that the raw material fulfils this restriction.

4 UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS (1223/2009 Annex I-Part A.9)

NOT KNOWN OR REPORTED

5 CLAIM SUPPORT

There is no need for special claims and the already existing are satisfactory.

6 SAFETY ASSESSMENT REPORT-REASONING

6.1 PRODUCT NAME

AQUEOUS HAIR & BODY WASH 300 ML SH1-1905

6.2 PRODUCT CATEGORY

SHAMPOO (HAIR CARE)

6.3 NAME AND ADDRESS OF RESPONSIBLE PERSON

Alliance National
www.alliancenational.co.uk

6.4 NAME AND ADDRESS OF PRODUCT MANUFACTURER

MING FAI INDUSTRIAL (SHENZHEN) CO. LTD.
Address :Ming Fai Industrial Estate, Bainikeng, Pinghu, Longgang,
Shenzhen, PRC.
Phone : 86-755-28802888
Fax : 86-755-84662992

6.5 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.

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, this should be also taken into the consideration of the signatory of this certificate.

7 ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

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