MID OCEAN BRANDS B.V.
ADDRESS 7/F., KINGS TOWER, 111 KING LAM STREET, CHEUNG SHA WAN, KOWLOON, HONG KONG

The following sample was submitted and identified by the client as WET WIPES (1 formulation).

Net Weight	:	42g (10 wipes) per consumer product
Style/Item no.	:	MO3863
SGS Report No.	:	HKHC2207005286HC
SGS Case No.	:	HKHC220700002289-101 (XMCPCH220500938)
Buyer	:	Mid Ocean Brands B.V.
Manufacturer	:	
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jul 22 – Sep 26, 2022
Test Period	:	Jul 22 – Oct 07, 2022

Test Requested
This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.

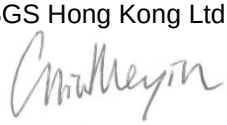
Test Results
Please refer to the following pages.

Summary
It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.
This assessment takes account of:

a) The general toxicological profile of each ingredient used.
b) The chemical structure of each ingredient.
c) The level of exposure of each ingredient.
d) The specific exposure characteristics of each ingredient on the areas on which the cosmetic product will be applied.
e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

If there is an adverse reaction from using this formulation then the undersigned should be informed so that the formulation can be further reviewed.

Signed for and on behalf of
SGS Hong Kong Ltd.



Mei-Yin CHIU, Sondy
MSc, FRSB, CBiol, ERT, DABT
Cosmetic Safety Assessor

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula WET WIPES (Style/Item no.: MO3863) for consumer health and no other part of the product. The product is for EU market and intended for application on hands and body skin for cleansing by children of age 3 years or above. The net weight of this product (The formula under assessment) is 42g (10 wipes) per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

1. Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ELINCS	Conc. %	Intended Function
Aqua	7732-18-5	231-791-2	93.9000000000	Solvent
Glycerin	56-81-5	200-289-5	2.0000000000	Humectant
Propylene Glycol	57-55-6	200-338-0	2.0000000000	Humectant
Aloe Barbadensis Leaf Extract	85507-69-3	287-390-8	1.0000000000	Emollient / Humectant / Skin Conditioning
Phenoxyethanol	122-99-6	204-589-7	0.5000000000	Preservative
Tocopheryl Acetate	58-95-7	200-405-4	0.2000000000	Antioxidant
Polysorbate 20	9005-64-5	500-018-3	0.1000000000	Emulsifying / Surfactant
Benzalkonium Chloride	8001-54-5	264-151-6	0.1000000000	Antimicrobial
Ethylhexylglycerin	70445-33-9	408-080-2	0.1000000000	Skin Conditioning
Parfum (LEMON FRAGRANCE PC-356A(DPG))	N/A (Mixture)	N/A (Mixture)	0.1000000000	Perfuming

FRAGRANCE ALLERGENS

Fragrance allergens **LIMONENE, LINALOOL** must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

2. Physical/chemical characteristics and stability of the formulation

2.1 The product is a liquid impregnated in fabric, with pH value of 6.95, with the fragrance (LEMON FRAGRANCE PC-356A(DPG)).

2.2 The stability test result on formulation, by in house method of on product name Wet Wipes, with a testing period of Feb 19 – Aug 19, 2022, was submitted and reviewed. It is the responsibility of manufacturer or responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : -5°C, -15°C, 25°C, 40°C, light exposure for 24 weeks; cycle test (45°C/24h, -10°C/24h, room temperature/4h) for 3 cycles

Testing parameters : Appearance, Colour, Odour, pH value and TVC bacteria (cfu/g)

Conclusion: The stability of the formulation is acceptable for this application.

3. Microbiological quality

3.1 The microbiological test results on formulation, with reference to European Pharmacopoeia 9.0 2.6.12 and 2.6.13, by in house method of on product name Wet Wipes,

with a testing date of Sep 01, 2022, was submitted and reviewed based on following criteria as required by SCCS Notes of Guidance.
Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*E. Coli, P.aeruginosa*, *S.aureus* and *C.albicans*
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 1g or 1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopeia 10.0, 5.1.3, by in house method of on product name Wet Wipes, with a testing period of Aug 06 – Sep 05, 2022, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
		Log reduction			
Criteria A	*E.coli, P.aeruginosa*, *S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa*, *S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase
Conclusion: The preservative efficacy of the formulation achieved criteria B and is acceptable for this application.

4. Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test results on formulation, by in house method of Lan on product name Wet Wipes, with a testing period of Sep 02 – 09, 2022, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	bag	PET /PE
2.	seal film	PP

4.3 For the packaging materials, the test results of total Lead (Pb), Cadmium (Cd), Mercury (Hg), Chromium VI (Cr (VI)), by third party laboratory (SGS report no. XMCPCH220901546-2), with a testing period of Sep 14 – 19, 2022, indicate the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.4 Packaging compatibility test results on packaging material, tested together with the formulation, by in house method of on product name Wet Wipes, with a testing period of

Feb 19 – Aug 19, 2022, was submitted and reviewed. It is the responsibility of manufacturer or responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : -5°C, -15°C, 25°C, 40°C, light exposure for 24 weeks; cycle test (45°C/24h, -10°C/24h, room temperature/4h) for 3 cycles

Testing parameters : Appearance and appearance of package

Conclusion: The stability of the packaging material is acceptable.

5. Normal and reasonably foreseeable use

The normal use of this product is for application on hands and body skin by children of age 3 years or above. Application of this product to any other parts of the body is foreseeable. Ingestion of this product would be a misuse.

6. Exposure to cosmetic product

Product type: Miscellaneous cosmetics
Use category: Wet Wipes
Physical form: Liquid impregnated in fabric
The site(s) of application: hands and body
The surface area(s) of application: depends on applied area
The amount per application: approximately 4.2 g
The duration of exposure: 720 minutes
The frequency of use: 832 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): Children of age 3 years or above
The body weight: 15.1 kg
Estimated daily amount applied: 9574 mg/day

7. Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.
For toxicological profile of ingredients, refer to Annex 1.
Systemic Exposure Dose(SED) is derived for each substance, taking into account of 50 % bioavailability as a default value for oral and dermal absorption, and 100 % bioavailability for inhalation, unless otherwise specified.Margins of safety(MoS) is calculated by dividing systemic NO(A)ELsys by the SED, when NO(A)EL or relevant Point of Departure(POD) is available in the present stage of knowledge.

8. Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

9. Information on the cosmetic product

The product is indicated to be manufactured by , in a manufacturing setting according to Cosmetic Good Manufacturing Practice Guidelines (2008) Issued by US FDA, with scope of compliance on Production of Wax-based Unit (Wax-based), General Liquid Unit (Hair Care Cleansing) and Cream Lotion Unit (Skin Care Cleansing) Products (within the Scope of Production License), by third party laboratory (TOTAL QUALITY CERTIFICATION SERVICES INTERNATIONAL (CHINA) CO., LTD Certificate SHZH-2-0164 which is valid until Dec 16, 2022).

PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments.
Provided the manufacturer's instructions are followed, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

2. Recommended labelled warnings and instructions of use

Avoid contact with eyes. (Mandatory)
Rinse eyes immediately should the product comes into contact with them.
Stop using the product if it disagrees with you.

3. Reasoning

All the ingredients in the formulation are either reported to be used in cosmetic or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR). No CMR substance is indicated to be intentionally added to the formulation.
Margin of Safety (MoS) was derived for all ingredients except those which No Observed (Adverse) Effect Levels (NO(A)ELs) or other Point of Departure (POD) were not available. For ingredients that MoS cannot be derived, their safety is substantiated by history of safe use at similar levels in related cosmetic products, reference doses, TTC approach, etc. Detailed explanation is given in the individual ingredient toxicological summary in annex 1.
The formulation is not expected to be irritating to the skin and respiratory tract, phototoxic, and is unlikely to cause damage to internal organs through skin in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause slight irritation but is expected to be minimal after rinsing. There are substances of allergenic potential but at low level that is not expected to induce an allergenic reaction in most of the users under normal and reasonably foreseeable conditions of use. However, sensitized people can react to allergen present at extremely low concentrations.
The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability, microbiological quality, and preservative efficacy while the product was manufactured in accordance with Cosmetic Good Manufacturing Practice Guidelines (2008) Issued by US FDA.

4. Assessor's credentials and approval of Part B

Date: Oct 07, 2022

Mei-Yin CHIU, Sondy MSc, FRSB, CBiol, DABT, EUROTOX Registered Toxicologist

The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

herein. The opinions provided by the Company are not a substitute for professional legal advice and Client should seek legal review to ensure compliance with any applicable laws and regulations.

******** End of Report ********

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. Aqua
CAS No.: 7732-18-5
EINECS/ELINCS: 231-791-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 74.9165500000 mg/kg bw/day
MOS: --
Aqua is a ubiquitous liquid that is normally used as solvent in cosmetic products and is not expected to result in any acute or chronic toxicity following typical exposures.

2. Glycerin
CAS No.: 56-81-5
EINECS/ELINCS: 200-289-5
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at up to 79.2% in leave-on products and 99.4% in rinse-off products
Food additive recommendation: Yes, but no given ADI
Toxicological profile by chemical supplier: None
NOAEL: ≥ 2200 mg/kg bw/day
SED: 1.5956666667 mg/kg bw/day
MOS: 689
Glycerin is the polyhydric alcohol that is naturally occurring and abundant in animal and human tissues, including the skin and blood. Glycerin is reported to function in cosmetics as a denaturant, fragrance ingredient, hair conditioning agent, humectants, oral care agent, oral health care drug, skin protectant, skin-conditioning agent and viscosity decreasing agent. Glycerin is absorbed following ingestion and metabolised by glycerokinase in the liver to carbon dioxide and water or incorporated in the standard metabolic pathways to form glucose and glycogen. The weight of evidence indicates that glycerin is of low toxicity when ingested, inhaled or in contact with the skin. Glycerin is of a low order of acute oral and dermal toxicity with LD50 values in excess of 4000 mg/kg bw. At very high dose levels, the signs of toxicity include tremor and hyperaemia of the gastro-intestinal -tract. Skin and eye irritation studies indicate that glycerin has low potential to irritate the skin and the eye. The available human and animal data, together with the very widespread potential for exposure and the absence of case reports of sensitisation, indicate that glycerin is not a skin sensitiser. Repeated oral exposure to glycerin does not induce adverse effects other than local irritation of the gastro-intestinal tract. The 2-year study of Hine (1953) was chosen to establish the overall NOEL after prolonged treatment with glycerin of 10,000 mg/kg bw/day (20% in diet), which is in agreement with the findings in other studies. At this dose level no systemic or local effects were observed. For inhalation exposure to aerosols, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/m3 and 662 mg/m3 for systemic effects. Glycerin is not considered to possess genotoxic potential. There were no reproductive or developmental effects observed in oral studies using rats, mice, and rabbits. Glycerin was not genotoxic in multiple in vitro tests and was not carcinogenetic to rats in a long-term feeding study. There were no signs of toxicity or effects on blood or on urine production when human subjects were orally administered approximately 1300-2200 g/kg/d glycerin for 50 days. The NOAEL was >=2200 mg/kg/d.

3. Propylene Glycol
CAS No.: 57-55-6
EINECS/ELINCS: 200-338-0
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 70% for leave-on products; 40% for rinse-off products; 99% for diluted use products, when formulated to be nonirritating
Food additive recommendation: GRAS as a direct food additive with ADI of 25 mg/kg bw/day
Toxicological profile by chemical supplier: None
NOAEL: 1230 mg/kg bw/day
SED: 1.5956666667 mg/kg bw/day
MOS: 385
Propylene glycol does not present an acute, chronic, reproductive, or developmental hazard. Acute toxicity is very low, with LD50 values exceeding 19000 mg/kg after ingestion or skin contact. It is not a skin or eye irritant, and does not cause sensitization. The weight of the evidence indicates that it is not genotoxic in vitro or in vivo. Adequate long-term feeding studies are available which indicate that it does not represent a cancer hazard. Propylene glycol is generally recognized as safe (GRAS) as a direct food additive when used in accordance with GMP, and it is approved as a direct and indirect food additive. According to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the acceptable daily intake (ADI) of propylene glycol is 25 mg/kg bw/day.

4. Aloe Barbadensis Leaf Extract
CAS No.: 85507-69-3 / 94349-62-9
EINECS/ELINCS: 287-390-8 / 305-181-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at up to around 1%, but only when anthraquinone levels in the ingredients do not exceed 50 ppm
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1500 mg/kg bw/day (oral, dog, 90-day study)
SED: 0.7978333333 mg/kg bw/day
MOS: 940
Aloe Barbadensis Leaf Extract is an extract of the leaves of the aloe, Aloe barbadensis, Liliaceae. The extract functions primarily as emollient, humectants, oral care and skin conditioning agent, and is included in cosmetics only at low concentrations. The Aloe leaf consists of the pericyclic cells, found just below the plant's skin, and the inner central area of the leaf i.e. the gel, which is used for cosmetic products, The pericyclic cells produce a bitter yellow latex containing a number phototoxic anthraquinones which are also gastrointestinal irritants responsible for cathartic effects. An industry established limit for anthraquinones in aloe-derived material for non-medicinal use is 50 ppm or lower. Aloe barbadensis derived ingredients were not toxic in acute oral studies using mice and rats. However, in sub-chronic study using mice, Aloe vera extract at 100 mg/kg resulted in reproductive toxicity, inflammation and elevated mortality. Both negative and positive results were found in bacterial and mammalian cell genotoxicity assays, but animal data suggested that components of Aloe inhibit tumor growth and improved survival. Diarrhea was the only adverse effect of note with the use of Aloe-derived ingredients to treat asthma, ischemic heart disease, diabetes, ulcers, skin disease, and cancer. Case reports include acute eczema, contact urticaria, and dermatitis in individuals who applied Aloe-derived ingredients topically. Although the phototoxicity anthraquinone components of Aloe

plants has been demonstrated, several clinical studies of preparations derived from Aloe barbadensis plants demonstrated no phototoxicity, confirming that the concentrations of anthraquinones in such preparations are too low to induce phototoxicity. The CIR Expert Panel concluded that Aloe Barbadensis Leaf Extract is safe as cosmetic ingredient in the practices of use and concentrations, if anthraquinone levels in the ingredients do not exceed 50 ppm. The Panel advised the industry that the total PCB/pesticide contamination of any plant-derived cosmetic ingredient should be limited to not more than 40 ppm, with not more than 10 ppm for any specific residue. The Panel also advised that limits were appropriate for the following impurities: arsenic (3 mg/kg max), heavy metals (20 mg/kg max), and lead (5 mg/kg max).
The submitted certificate of analysis (COA) of the ingredient, in the product name ALOE BARBADENSIS LEAF EXTRACT (batch no. 20220510), as supplied by
Company, indicated the anthraquinone content is 12ppm. It is the manufacturer's responsibility to ensure each batch of the ingredient used in the formulations are of acceptable grade to substantiate the safety of the product and to comply with the EU Cosmetic Regulation. If it is not the case, it will void this assessment.

5. Phenoxyethanol
CAS No.: 122-99-6
EINECS/ELINCS: 204-589-7
CLP Classification: Acute Tox. 4 H302; Eye Dam. 1 H318
EU Cosmetic Regulation: Annex V/29: Maximum authorized concentration is 1.0%
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used up to 1%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 357 mg/kg bw/day (dermal, rabbit, 90-day)
SED: 0.3989166667 mg/kg bw/day
MOS: 447
Phenoxyethanol is generally used as a preservative in cosmetic formulations at a maximum concentration of 1.0% and also used as a fixative for perfumes and soaps. Undiluted 2-phenoxyethanol is considered as a mild irritant to the rabbit skin, and an irritant to the rabbit eye. Contact sensitisation in humans has been documented, but from the available studies it can be concluded that this is rare. The risk of becoming sensitised is very low. Phenoxyacetic acid is the main metabolite of phenoxyethanol in humans, data on background levels of 2-phenoxyacetic acid in human urine samples suggest that cosmetic products are a major source of phenoxyethanol exposure to consumers. Haematotoxicity is a predominant toxicological feature of phenoxyethanol in vivo and in vitro. Systemic availability of phenoxyethanol after oral exposure of rats is very low due to a strong first pass effect in rat liver and the rapid formation of the main metabolite 2-phenoxyacetic acid, which may accumulate in the kidney and may be responsible for kidney toxicity in rats after oral exposure. In contrast, dermal exposure of rats to phenoxyethanol revealed much higher concentrations of the parent compound in blood than after oral exposure. This may also be true for other species such as humans. In dermal treatment studies, Phenoxyethanol was neither teratogenic, embryotoxic, nor fetotoxic at doses which were maternally toxic. Phenoxyethanol was non-mutagenic in the Ames test, with and without metabolic activation, and in the mouse micronucleus test. The SCCS concludes that phenoxyethanol is safe for use as a preservative with a maximum concentration of 1.0%, even for infants and children.

6. Tocopheryl Acetate
CAS No.: 52225-20-4 / 58-95-7 / 7695-91-2
EINECS/ELINCS: 200-405-4 / 231-710-0
CLP Classification: N/A
EU Cosmetic Regulation: None

SCCS opinion: alpha-tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed
CIR recommendation: Safe to be used up to 36% for leave-on products; 10% for rinse-off products; 0.1% for diluted use products
Food additive recommendation: Yes, but no given ADI
Toxicological profile by chemical supplier: None
NOAEL: 500 mg/kg bw/day
SED: 0.1595666667 mg/kg bw/day
MOS: 1566
Tocopheryl Acetate functions as antioxidant or skin-conditioning agent in cosmetic formulations. Tocopheryl Acetate can be hydrolyzed to Tocopherol which is a natural component of cell membranes protecting against oxidative damage. It has been reported that Tocopheryl Acetate and Tocopherol protected against ultraviolet radiation induced skin damage. Tocopheryl Acetate is generally not toxic in animal feeding studies, although very high doses (2 g/kg/day) have hemorrhagic activity. It is generally not irritating or sensitizing to skin or irritating to eyes, but it was shown in one animal test that Tocopheryl Acetate produced sensitization. Reproductive and developmental toxicity tests in animals were all negative or showed some effects of reducing toxicity. It was almost uniformly negative in genotoxicity, exhibited anti-mutagenic activity and was not carcinogenic. Based on current knowledge, the Scientific Committee on Cosmetic Products and Non-Food Products Intended For Consumers (SCCNFP) concluded that alpha-tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed. The CIR Expert Panel also concluded that Tocopheryl Acetate is safe as used in cosmetic formulations, but the purity of the Tocopherol should be of similar grade to that used in food.

7. Polysorbate 20
CAS No.: 9005-64-5
EINECS/ELINCS: 500-018-3
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe as used in rinse off product up to 19.6% and safe at concentration up to 9.1% in leave on products, when formulated to be non-irritating
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 500 mg/kg bw/day
SED: 0.0797833333 mg/kg bw/day
MOS: 3133
Polysorbate 20 is a mixture of laurate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide. It is used as hydrophilic, nonionic surfactants in a variety of cosmetic products. It is approved as diluents in color additives for drug use, permitted as a secondary direct food additive for human consumption, and approved for indirect addition to all food types as components of adhesives, emulsifiers and/or surfactants. There is lack of systemic toxicity at low and moderate doses in several acute and repeated-dose oral exposure studies, and low toxicity at high doses; little or no irritation or sensitization in multiple tests of dermal and ocular exposure; the absence of genotoxicity in multiple Ames tests and chromosome aberration tests, and minimal irritation and lack of sensitization in tests of dermal exposure at concentration of use. Some studies showed minimal irritation at concentrations that are used in cosmetics, the CIR Panel advised that products containing these ingredients should be formulated to be non-irritating.
The submitted certificate of analysis (COA) of the ingredient, in the product trade name RaysonCare T20 (batch no. F1627EL111), as supplied by indicated the 1,4-dioxane

content is not detected with standard value of ≤10ppm. It is the manufacturer's responsibility to ensure each batch of the ingredient used in the formulations are of acceptable grade to substantiate the safety of the product and to comply with the EU Cosmetic Regulation. If it is not the case, it will void this assessment.

8. Benzalkonium Chloride
CAS No.: 8001-54-5/ 63449-41-2 / 91080-29-4 / 68989-01-5 / 68424-85-1 / 68391-01-5 / 61789-71-7 / 85409-22-9
EINECS/ELINCS: 264-151-6 / 293-522-5 / 273-545-7 / 270-325-2 / 269-919-4 / 263-080-8 / 287-089-1
CLP Classification: Acute Tox. 4, H312; Acute Tox. 4, H302; Skin Corr. 1B, H314; Aquatic Acute 1, H400
EU Cosmetic Regulation: Annex III/65: Maximum at 3% (as benzalkonium chloride) in rinse-off (head) products; maximum at 0.1% (as benzalkonium chloride) in other products; Annex V/54: Maximum at 0.1% (as benzalkonium chloride) as preservative. Wording of conditions of use and warnings: Avoid contact with the eyes.
SCCS opinion: None
CIR recommendation: Safe to be used at 0.1% as free active ingredient
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 30 mg/kg bw/day
SED: 0.0797833333 mg/kg bw/day
MOS: 188
Benzalkonium Chloride is a mixture of alkylbenzyldimethylammonium chlorides. In the United States, Benzalkonium Chloride may be used as an active ingredient in OTC drug products. The compound was non-mutagenic in several different cell assays. Concentrations of 0.01 % and above caused eye irritation in guinea pigs when applied repeatedly on the same day. Single treatment of human eyes with 0.1 %, or daily treatment with 0.03 - 0.04 % caused irritation. Skin irritation tests in rabbits with 0.1 % solutions, and in humans with 1.0 % solutions were negative. With extended contact period in the rabbit, or repeated application in humans, these concentrations produce distinct irritation. In rabbits, repeated application of 0.3 % induced only mild erythema. A sensitization test in 100 male and 100 female volunteers with 0.l %, applied daily for 5 days, followed by a challenge treatment with 1 % after 3 weeks, was negative. In the literature only a few cases of sensitization in humans have been reported. For cosmetics in EU, in the final products the concentration of benzalkonium chloride, bromide and saccharinate with an alkyl chain of C14, or less must not exceed 0.1% (as benzalkonium chloride). For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. Some of the products tested contained concentrations of Benzalkonium Chloride greater than 0.1%. If these products contain proteins or other agents that bind Benzalkonium Chloride, then Benzalkonium Chloride concentrations greater than 0.1% would have to be added to yield 0.1% free Benzalkonium Chloride. It is important to note that only free Benzalkonium Chloride is effective as an antimicrobial agent and, also, that the free agent induces dermal toxicity.

9. Ethylhexylglycerin
CAS No.: 70445-33-9
EINECS/ELINCS: 408-080-2
CLP Classification: Eye Dam. 1, H318; Aquatic Chronic 3, H412
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe as used in rinse off product up to 8% and safe at concentration up to 2% in leave on products
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 50 mg/kg bw/day

SED: 0.0797833333 mg/kg bw/day
MOS: 313
Ethylhexylglycerin is the organic compound that is used for skin conditioning in cosmetic up to 8% in rinse off product according to the FDA. It was indicated to be highly soluble in organic solvents and with an estimated Log Pow of 2.4. The oral LD50 and dermal LD50 in rats were reported to be greater than 2000 mg/kg. Both of the NOAEL and LOAEL were indicated to be 50 mg/kg/day by different studies. It was not a sensitizer in a LLNA up to 50%. There was absence of reproductive and developmental toxicity in oral studies, and was negative in skin irritation, sensitization, phototoxicity and photoallergenicity. Taking into account the available animal toxicity and clinical data, including the low dermal absorption, the CIR Expert Panel concluded that the ingredient is safe in the present practices of use and concentration.

10. Parfum (LEMON FRAGRANCE PC-356A(DPG))
CAS No.: N/A (Mixture)
EINECS/ELINCS: N/A (Mixture)
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: H226, H304, H315, H317, H400, H410
NOAEL: --
SED: 0.0797833333 mg/kg bw/day
MOS: --
Parfum (LEMON FRAGRANCE PC-356A(DPG)) as supplied by and the corresponding IFRA certificate of 50th amendment, SDS and allergen declaration were provided, was used at 0.1% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 18.17% of this parfum can be used in leave on wet wipes product (Class 3 product).

******** End of Annex ********