MID OCEAN BRANDS B.V.
WELLENSIEKSTRAAT 2，6718 XZ EDE，THE NETHERLANDS

 # This report supersedes testing report HKHC1811010830HC #

The following sample was submitted and identified by the client as HAND SANITIZER (1 formulation)

Net Weight	:	10 mL per consumer product
Style/Item No.	:	MO8743
SGS Report No.	:	HKHC1811010830HC-01
SGS Case No.	:	HKHC181100004120-101 (XMCPCH181101291)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Nov 20 – Dec 5, 2018
Test Period	:	Nov 20 – Dec 21, 2018

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 HAND SANITIZER for consumer health and no other part of the product. The product is for EU market and intended for application on hands for cleansing by children above three years old. Although the product is named as hand sanitizer, it is assessed according to EU cosmetic regulation.
The net weight of this product (The formulation under assessment) is 10 mL 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	89.7000	Solvent
Propylene Glycol	57-55-6	200-338-0	3.0000	Humectant / skin conditioning / solvent / viscosity controlling
Glycerin	56-81-5	200-289-5	2.0000	Denaturant / hair conditioning / humectant / masking / oral care / perfuming / skin protecting / viscosity controlling
Dimethicone	63148-62-9	N/A	2.0000	Antifoaming / emollient / skin conditioning / skin protecting
Aloe Barbadensis Leaf Extract	85507-69-3	287-390-8	2.0000	Emollient / humectant / oral care / skin conditioning
Tocopherol	59-02-9	200-412-2	0.5000	Antioxidant / masking / skin conditioning
DMDM Hydantoin	6440-58-0	229-222-8	0.3000	Preservative
Parfum (MY18-S088 Citrus)	N/A (Mixture)	N/A (Mixture)	0.3000	Deodorant / masking / perfuming
Disodium EDTA	6381-92-6	205-358-3	0.1000	Chelating / viscosity controlling
Benzalkonium Chloride	8001-54-5	N/A	0.1000	Antimicrobial / antistatic / deodorant/ preservative / surfactant

FRAGRANCE ALLERGENS

Fragrance allergens **BUTYLPHENYL METHYLPROPIONAL, CITRAL, CITRONELLOL, GERANIOL, 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 transparent liquid, with the pH value of 5.90 and the fragrance MY18-S088 Citrus.

2.2 The stability test results on formulation, by in house method with the product name HAND SANITZER, and testing period Mar 04 – Jun 04, 2018, were 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 : -15℃, -5℃, 25℃, 40℃ and light exposure for 12 weeks; cycle test (40℃ to 4℃ to 40℃ to 4℃ to room temperature in 36 hours) for 3 cycles

Testing parameters : Appearance, colour, odour, pH value, TVC bacteria and appearance of liquid

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 & 2.6.13, by third party laboratory (SGS report no. XMCPCH180901036.1), with the product name Hand Sanitizer and testing period Sep 13 – Sep 21, 2018, were submitted and reviewed based on following criteria as required by the 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 results on the formulation, with reference European Pharmacopoeia 9.0 5.1.3, by third party laboratory (SGS report no. XMCPCH180901036.3), with sample name hand sanitizer, and testing period Sep 13 – Oct 24, 2018, were 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 B criteria 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 third party laboratory (SGS report no. XMCPCH180901036.2), all with sample name hand sanitizer, and a testing period of Sep 14 – 19, 2018, were 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 determination of Formaldehyde test result on the formulation is not submitted by the time of assessment. The client is required to provide the information to substantiate the safety and fulfil the labelling requirement of the product.

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

No.	Immediate Container	Material
1.	Bottle	PP
2.	Cap	PP

4.4 For packaging material PP, test results of lead, cadmium, mercury and chromium (VI) of immediate container, by third party laboratory (AGC report no. AGC03899181101-001S1), both with testing period Nov 06 to Nov 09, 2018 indicate the total amount is less than 100 ppm
Conclusion: The heavy metal content of the packaging material is acceptable.

4.5 Packaging compatibility test results on packaging material, indicated to be tested with the formulation, by in house method with the product name HAND SANITZER, and testing period Mar 04 – Jun 04, 2018, were submitted and reviewed.
Testing conditions : -15℃, -5℃, 25℃, 40℃ and light exposure for 12 weeks; cycle test (40℃ to 4℃ to 40℃ to 4℃ to room temperature in 36 hours) for 3 cycles
Testing parameters : 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 by children above age 3. Application of this product to face and other parts of body is possible. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Skin care cosmetics
Use category: Hand sanitizer
Physical form: Liquid
The site(s) of application: Hands
The surface area(s) of application: 860 square centimeter
The amount per application: 1.08 g
The duration of exposure: 720 minutes
The frequency of use: 730 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): children of 3 years old or above
The body weight: 15.1 kg
Estimated daily amount applied: 2160 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 a manufacturer in a manufacturing setting according to ISO 22716:2007(E) with scope of compliance on manufacturing of general liquid unit, including hair care & cleansing products, manufacturing of cream & lotion unit, including skin care & cleansing products, manufacturing of wax base unit, including lipstick and lip balm, by third party laboratory (Intertek Certificate SZ1705B1 which is valid until May 11, 2020).

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

For external use only.
Discontinue use if irritation or redness develops.
Avoid contact with the eye. Rinse eyes immediately should the product come into contact with them.

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, be sensitizing, 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 will cause 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, especially the product is expected to be rinsed off and the contact time is short. 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 ISO 22716:2007 Cosmetic GMP.
It should be drawn to the attention that all finished products containing formaldehyde releaser which release formaldehyde must be labelled with the warning 'contains formaldehyde' when the concentration of formaldehyde in the finished product exceeds 0.05% according to the EU Cosmetic Regulation. Although the concentration used for the formaldehyde releaser, DMDM Hydantoin, is below the EU regulatory limits, the client is highly recommended to determine the formaldehyde content in the final product and label the product accordingly if the product contains more than 0.05% formaldehyde.

4. Assessor's credentials and approval of Part B

Date: Dec 21, 2018

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.

******** 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: 16.1460000 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. 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 as cosmetic ingredients in the present practices of use and concentrations (up to 50%) 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: 0.5400000 mg/kg bw/day
MOS: 1139
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.

3. 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: 0.3600000 mg/kg bw/day
MOS: 3056
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.

4. Dimethicone
CAS No.: 63148-62-9 / 9006-65-9 / 9016-00-6 / 107-52-8 / 141-62-8 / 141-63-9
EINECS/ELINCS: - / - / - / - / - / 205-491-7 / 205-492-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 80% in hair preparation; up to 24% in make up
Food additive recommendation: Yes, the ADI is 0-1.5 mg/kg bw (applied only to compounds with a relative molecular mass in the range of 200-300
Toxicological profile by chemical supplier: None
NOAEL: 1500 mg/kg bw/day
SED: 0.3600000 mg/kg bw/day
MOS: 2083
Dimethicone is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. It is used as conditioning agents in cosmetic formulations at concentrations of use of 80% in hair preparation and up to 24% in make-up products, Clinical and animal absorption studies reported that dimethicone was not absorbed following oral or dermal exposure due to their large molecular weight. 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. It also did not produce adverse effects in acute and short-term inhalation-route studies. The dermal LD50 for dimethicone

was greater than 2 g/kg in rats and rabbits. Most dermal irritation studies using rabbits classified dimethicone as a minimal irritant. Dimethicone was not a sensitizer in four assays using mice and guinea pigs. It was not a sensitizer at 5% in a clinical repeated insult patch test using 83 panelists. Most ocular irritation studies using rabbits classified dimethicone as a mild to minimal irritant. Dimethicone was negative in all mutagenicity assays. It was negative in both an oral and dermal dose carcinogenicity assay using mice. Dimethicone was found to cause no treatment-related adverse effects in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits and monkeys) reproductive and developmental toxicity studies. Adverse effects were noted in one inhalation study with small aerosol particles. Although there were only limited inhalation toxicity findings, dimethicone is only used in aerosol formulations at a very low concentration. The CIR Panel indicated that particles from cosmetic formulation containing dimethicone would not likely be inhaled. In particular, it was stated that expected particle sizes would primarily be in the range of 60-80 µm, and less than 1% would be under 10 µm, which is an upper limit for respirable particles. The CIR Panel expects that the manufacture process for cosmetic formulations in which dimethicone is found and which may be inhaled would continue to produce particle size distribution that are not significantly respirable. The CIR Expert Panel concluded that Dimethicone is safe as used in cosmetic formulations at concentrated known to be used.

5. 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 as cosmetic ingredients in the practices of use and concentrations as described in the CIR safety assessment, if anthraquinone levels in the ingredients do not exceed 50 ppm

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 0.3600000 mg/kg bw/day

MOS: --

Aloe Barbadensis Leaf Extract is an extract of the leaves of the aloe, Aloe barbadensis, Liliaceae. It functions as skin-conditioning agents, emollient, masking and miscellaneous use. An industry established limit for anthraquinones in aloe-derived material for non-medicinal use is 50 ppm or lower. Aloe-derived ingredients are used in a wide variety of cosmetic product types at concentrations of raw material that are 0.1% or less, although can be as high as 20%. The concentration of Aloe in the raw material also may vary from 100% to a low of 0.0005%. Aloe-derived material has fungicidal, antimicrobial, and antiviral activity, and has been effective in wound healing and infection treatment in animals. 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 have been demonstrated, several clinical studies of preparations derived from Aloe barbadensis plants demonstrated no phototoxicity. In Aloe-derived ingredients used in cosmetics, regardless of species, anthraquinone levels should 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 and 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 Botanical Safety Handbook classified dried juice of aloe species as 2B: Not to be used during pregnancy. The Natural Medicines comprehensive Database concluded the aloe product possibly safe when used orally or topically and appropriately.

The submitted Certificate of Analysis (COA) of the ingredient did not mentioned the anthraquinone content.

The ingredient shall be of acceptable purity and free from/contain technically unavoidable amount of residue/contaminants as a cosmetic ingredient. If it is not the case, it will void this assessment.

6. Tocopherol

CAS No.: 54-28-4 / 16698-35-4 / 10191-41-0 / 119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 / 59-02-9 /7616-22-0

EINECS/ELINCS: 200-201-5 / 240-747-1 / 233-466-0 / 204-299-0 /215-798-8 / - / 218-197-9 / 200-412-2 / -

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 5%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 500 mg/kg bw/day (Read across to Tocopheryl Acetate)

SED: 0.0900000 mg/kg bw/day

MOS: 2778

Tocopherol (Vitamin E) consists of alpha-tocopherol, beta-tocopherol, delta-tocopherol and/or gamma-tocopherol. It generally functions as antioxidant, masking and skin conditioning in cosmetics. It is a natural component of cell membranes thought to protect against oxidative damage, and was reported to protect against ultraviolet radiation induced skin damage. Tocopherol is generally not toxic in animal feeding studies, although very high doses (2 g/kg/day) have hemorrhagic activity. It is not irritating or sensitizing to skin or irritating to eyes. Reproductive and developmental toxicity tests in animals using Tocopherol were all negative or showed some effect of reducing toxicity. It was also uniformly negative in genotoxicity tests, exhibited anti-mutagenic activity consistent with its antioxidant properties, not carcinogenic and inhibited tumor promotion. Because methylhydroquinone is used in the chemical synthesis of Tocopherol, there was concern that hydroquinone may be present as an impurity. However, residual levels of hydroquinone would be expected to be limited to those achieved by good manufacturing practices. The CIR Expert Panel concluded up to 5% of this ingredient can be used in cosmetics.

7. DMDM Hydantoin

CAS No.: 6440-58-0

EINECS/ELINCS: 229-222-8

CLP Classification: N/A

EU Cosmetic Regulation: Annex V: Maximum authorized concentration is 0.6%

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: 440 mg/kg bw/day

SED: 0.0540000 mg/kg bw/day

MOS: 4074

DMDM Hydantoin is a preservative, which is used in cosmetic products at concentrations up to 1%. It is a formaldehyde donor containing up to 2% of the free aldehyde in equilibrium with the hydantoin. The LD50 dermal and oral toxicity of DMDM hydantoin was greater than 2 g/kg. No significant toxic effects were noted in a subchronic oral toxicity study. In skin irritation studies using product formulations, results ranged from non-irritating to moderate skin irritation. At most, transient minimal irritation was noted in albino rabbits treated with DMDM hydantoin formulations. In clinical studies, skin irritation ranged from none to

observations of intense erythema and edema when various formulations containing DMDM hydantoin were applied. DMDM hydantoin formulations did not induce sensitization in some clinical studies. DMDM hydantoin formulations were neither phototoxic nor photoallergenic. Use of DMDM hydantoin at its current concentration of use in cosmetic products would not expose the consumer to levels of formaldehyde above the limit previously considered as acceptable in cosmetic products. Based on the available data, it is concluded that DMDM hydantoin is safe as a cosmetic ingredient in the present practices of use. However, all finished products containing formaldehyde releaser which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05 % according to the EU Cosmetic Regulation.

8. Parfum (MY18-S088 Citrus)
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: None
NOAEL: --
SED: 0.0540000 mg/kg bw/day
MOS: --
Parfum MY18-S088 Citrus as supplied by Meiyi Flavor Fragrance Co., Ltd and the corresponding IFRA certificate of 48th amendment, allergen declaration and MSDS, was used at 0.3% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 15.67% of this parfum can be used in leave on hand sanitizer product (Class 5 product).

9. Disodium EDTA
CAS No.: 139-33-3 / 6381-92-6
EINECS/ELINCS: 205-358-3
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at less than 1%
Food additive recommendation: Yes, with the ADI of 0-2.5 mg/kg bw
Toxicological profile by chemical supplier: None
NOAEL: 250 mg/kg bw/day
SED: 0.0180000 mg/kg bw/day
MOS: 6944
Disodium EDTA usually functions as chelating agent in cosmetic. It can also be used as preservative, sequestrant, and stabilizer in foods. It is classified as a nonirritant in a primary skin irritation test and a primary mucous membrane irritation test in rabbits. In addition it caused no signs of allergic reactions in skin-sensitization test towards guinea pigs. For humans, it caused no signs of irritation during a 4-hour patch test with 0.2 g of the powder applying on the skin of upper outer arm of volunteers using a 25-mm Plain Hill Top Chamber containing a moistened Webril pad. EDTA is cytotoxic and weakly genotoxic, but not carcinogenic. Oral exposures to EDTA produced adverse reproductive and developmental effects in animals. However, clinical tests reported no absorption of an EDTA salt through the skin. These ingredients

are likely, however, to affect the passage of other chemicals into the skin because they will chelate calcium. Exposure to EDTA in most cosmetic formulations, therefore, would produce systemic exposure levels well below those seen to be toxic in oral dosing studies. Exposure to EDTA in cosmetic formulations that may be inhaled, however, was a concern. An exposure assessment done using conservative assumptions predicted that the maximum EDTA dose via inhalation of an aerosolized cosmetic formulation is below that which has been shown to produce reproductive or developmental toxicity. The CIR Expert Panel concluded that EDTA is safe as used in cosmetic formulations. Because of the potential to increase the penetration of other chemicals, formulators should continue to be aware of this when combining EDTA with ingredients that previously have been determined to be safe primarily because they were not significantly absorbed.

10. 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

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: 0.0180000 mg/kg bw/day

MOS: 833

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.

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