Test Report

No [redacted] Date :Nov 29, 2018 Page 1 of 12

[redacted]

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

Net Weight	:	15 mL per consumer product
AN Code	:	[redacted]
SGS Report No.	:	
SGS Case No.	:	
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jul 11 – Nov 28, 2018
Test Period	:	Jul 11 – Nov 29, 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.

Lee Chun Ngai, Gerald
MSc, CBiol, MRSB, MBTS
Cosmetic Safety Assessor

[redacted]

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 of 3 years old or above.

However, the product name implies an antibacterial action that can entitle it as a biocidal product, which shall comply with the Biocidal Products Regulation (EU) No. 528/2012, and specific labeling requirements, as well as claim substantiation in additional to cosmetic regulation. This product is assessed based on the EU Cosmetic Regulation only, while the efficacy and claim (if any) of the product are not assessed.

The net weight of this product (The formulation under assessment) is 15 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
Alcohol	64-17-5	200-578-6	62.0000	Antifoaming / antimicrobial / astringent / masking / solvent / viscosity controlling
Aqua	7732-18-5	231-791-2	27.9500	Solvent
Glycerin	56-81-5	200-289-5	5.0000	Denaturant / hair conditioning / humectant / masking / oral care / perfuming / skin protecting / viscosity controlling
Propylene Glycol	57-55-6	200-338-0	3.0000	Humectant / skin conditioning / solvent / viscosity controlling
Aloe Barbadensis Leaf Extract	85507-69-3	287-390-8	1.0000	Skin conditioning / emollient / masking
Carbomer	54182-57-9	N/A	0.3000	Emulsion stabilising / gel forming / viscosity controlling
Parfum (MY15-G099 Lemon)	N/A (Mixture)	N/A (Mixture)	0.3000	Deodorant / masking / perfuming
Triethanolamine	102-71-6	203-049-8	0.2500	Buffering / emulsifying / masking / surfactant
Tocopheryl Acetate	7695-91-2	231-710-0	0.2000	Antioxidant / skin conditioning

FRAGRANCE ALLERGENS

Fragrance allergens **BENZYL BENZOATE, CITRAL, CITRONELLOL, GERANIOL, LIMONENE,** and **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 colourless liquid, with the pH value of 5.9, and the fragrance MY15-G099 Lemon.

2.2 The stability test results on formulation, by in house method of Yuao Jessie Commodity Co., Ltd., with the product name Hand Sanitizer, with 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 : 5℃, 20℃, 30℃, 40℃, 50℃ 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, and TVC bacteria
Conclusion: The stability of the formulation is acceptable for this application.

3 Microbiological quality

3.1 The microbiological test result on formulation is not required because the product is a low microbiological risk product with high percentage of alcohol.

3.2 The preservation efficacy test result on the formulation is not required because the product is a low microbiological risk product with high percentage of alcohol.

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. XMCPCH180901099), with testing period Oct 09 – 12, 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 client has supplied the following list of packaging parts for this product as the immediate container.

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

4.3 For packaging material, test results of lead, cadmium, mercury, chromium (VI), PAHs, DBP, BBP, DEHP, DNOP, DINP, and DIDP of immediate container by third party laboratory (AGC report no. AGC03899180701-001), with a testing period Jul 03 – Jul 06, indicate none of them is detected, with detection limit 5 ppm for lead, cadmium, and mercury, 1 ppm for hexavalent chromium, 0.1 ppm for PAHs, and 0.01% for phthalates.
Conclusion: The chemical purity of the packaging material is acceptable.

4.4 Packaging compatibility test results on packaging material, indicated to be tested with the formulation, by in house method of Yuao Jessie Commodity Co., Ltd., with the product name Hand Sanitizer, with testing period Mar 04 – Jun 04, 2018, were submitted and reviewed.
Testing conditions : 5℃, 20℃, 30℃, 40℃, 50℃ 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 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 by children of 3 years old or above. Application of the product to other part of the body is unlikely. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Miscellaneous 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: 2 g
The duration of exposure: 720 minutes
The frequency of use: 1825 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact and potential inhalation of volatiles
The targeted (or exposed) population(s): Adults
The body weight: 60 kg
Estimated daily amount applied: 10000 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 Yuyao Jessie Commodity Co., Ltd. in a manufacturing setting according to ISO 22716:2007 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.
In addition, this product can be considered as biocidal product and hence it should also comply with the Biocidal Product Regulation (EU) No. 528/2012 in order to be put on the market.
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

Flammable. Keep away from heat, fire or flame.
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 significant irritation, but it 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 and stability, while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP.
The microbiological and preservative efficacy test results on formulation are not required because the product is a low microbiological risk product with high percentage of alcohol.
The product is assessed based on EU Cosmetic Regulation only. The efficacy of the product has not been assessed. In addition, the client is drawn to the attention that this product can be considered as a biocidal product and hence it should also comply with the Biocidal Product Regulation (EU) No. 528/2012 in order to be put on the market.

4. Assessor's credentials and approval of Part B

Date: Nov 29, 2018

Chun-Ngai Lee, Gerald MSc, CBiol, MRSB, MBTS

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.

 The Company's consulting services, including compilations(s) of data and any review of cosmetic label and formulation, are based upon the Company's know-how and on publicly available sources available at the time the services were provided. The Company disclaims any and all liability for the accuracy of any such publicly available information or any legal interpretation of such information. The Company provides its services in a consulting capacity only and offers no legal opinion(s) 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 ********