STORY OF LOVE COSMETICS CO.,LTD
NO.358,SHENGSHOU ROAD,CHENGXI SPECIAL INDUSTRIAL ZONE,YIWU CITY,CHINA
 # This report supersedes testing report HKHC2004003149HC-01 #

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

Net Weight	:	20 mL / 30 mL / 50 mL / 60 mL / 100 mL / 237mL / 240 mL / 250 mL / 500 mL / 1000 mL per consumer product
SGS Report No.	:	HKHC2004003149HC-02
SGS Case No.	:	HKHC200400001537 – 101 (SHCPCH200403792)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Apr 28 – May 06, 2020
Test Period	:	Apr 28 – May 12, 2020

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.

Shuping Yu, Cecilia
MSc (Food Safety and Toxicology), MSc (Bioscience), MRSB
Cosmetic Safety Assessor

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula HAND CLEANSING GEL 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 20 mL / 30 mL / 50 mL / 60 mL / 100 mL / 237mL / 240 mL / 250 mL / 500 mL / 1000 mL per consumer product 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	75.0000	Antifoaming / antimicrobial
Aqua	7732-18-5	231-791-2	20.3500	Solvent
Glycerin	56-81-5	200-289-5	3.0000	Denaturant / humectant / skin protecting / viscosity controlling
PEG-7 Glyceryl Cocoate	66105-29-1 / 68201-46-7	N/A	1.0000	Skin conditioning / surfactants
Carbomer	9007-20-9	N/A	0.4000	Emulsion stabilising / gel forming / viscosity controlling
Triethanolamine	102-71-6	203-049-8	0.2500	Buffering / emulsifying

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is translucent light white uniform gel with pH 6.65 – 6.67.

2.2 The stability test results on formulation, by in house method of Story of Love Cosmetics Co., Ltd., with the product name HAND CLEANSING GEL, with testing start date Jan 10 – Apr 26, 2020, 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 : Room conditions, 40±2°C with 60±5% humidity, 0±1°C for 3 months

Testing parameters : Colour, odour. pH, TPC (CFU/g) and alcohol content (%)

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

3 Microbiological quality

3.1 The microbiological test result on formulation of HAND CLEANSING GEL, with reference to ISO 21149:2017 for Aerobic mesophilic bacteria, ISO 16212:2017 for Mould & Yeast, ISO 22717:2015 for *Pseudomonas aeruginosa*, ISO 22718:2015 for *Staphylococcus aureus*, ISO 21150:2015 for *Escherichia coli* and ISO 18416:2015 for *Candida albicans*, by in house method of Story of Love Cosmetics Co., Ltd., with a

testing period of Jan 10 – Jan 21, 2020, was 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 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 of HAND CLEANSING GEL, by in house method of STORY OF LOVE COSMETICS CO., LTD., with testing period Jan 10 – Jan 21, 2020, 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.	Pump	PP
3.	Straw	PP

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container by in house method of STORY OF LOVE COSMETICS CO., LTD, with a testing period of Jan 10 – Jan 21, 2020, indicate the total amount is less than 100ppm.
Conclusion: The chemical purity test result of the packaging materials is acceptable.

4.4 Packaging compatibility test results on packaging material of HAND CLEANSING GEL, indicated to be tested with the formulation, by in house method of Story of Love Cosmetics Co., Ltd., with the product name HAND CLEANSING GEL, with testing start date Jan 10 – Apr 26, 2020, were submitted and reviewed.
Testing conditions : Room conditions, 40±2°C with 60±5% humidity, 0±1°C for 3 months
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 cleansing gel

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): Children of 3 years old or above
The body weight: 15.1 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

No valid GMP certificate on manufacturing setting covering the scope of hand cleansing gel has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.

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.
Keep it out of reach of children, unless use under adult supervision.

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.
The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, microbiological quality and stability. No valid GMP certificate on manufacturing setting covering the scope of hand cleansing gel has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.
The preservative efficacy test result on formulation is 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: May 12, 2020

Shuping Yu, Cecilia MSc (Food Safety and Toxicology), MSc (Bioscience), MRSB

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. Alcohol

CAS No.: 64-17-5
EINECS/ELINCS: 200-578-6
CLP Classification: Flam. Liq. 2, H225
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 2400 mg/kg bw/day
SED: 4.47 mg/kg bw/day (absorption through inhalation)
MOS: 268

Alcohol is undenatured ethyl alcohol that can function as antifoaming, antimicrobial, astringent, masking, solvent, and viscosity controlling agent in cosmetic.

Alcohol is frequently applied to skin as a biocidal surgical wipe (70–80 % concentration) and as a component of cosmetics, personal care, and household cleaning products. Alcohol has a low order of acute toxicity by all routes of exposure. Lowest robust reported values are an inhalation LC50 of >60,000ppm (114,000 mg/m3), 1 hour, mouse), and an oral LD50 of 8300mg/kg.bw (mouse). Ethanol is a moderate eye irritant but is neither a skin irritant nor a sensitizer. Evidence of the carcinogenicity of ethanol is confined to epidemiological studies assessing the impact of alcoholic beverage consumption. These do not indicate such hazard exists from potential exposure to ethanol in the work place or from the use of ethanol in consumer products. Alcohol has a very low octanol: water partition coefficient and this is seen as contributing to the poor dermal uptake of ethanol in intact human skin. It suggests that a systemic dose of ethanol is likely to be very low after the use of formulations delivering ethanol to the skin. The volatility of ethanol would suggest that inhalation exposure would be a more relevant route of exposure.

Due to the very low dermal absorption and fast evaporation of alcohol, the systemic exposure of alcohol in the product would be expected solely due to inhalation. According to an exposure study of alcohol vapor from alcohol-based hand rubs [(1)], the total amount of alcohol absorbed for one use of hand rub containing 65% alcohol is 46.5mg. As the hand cleansing gel assessed herein contains 75% of alcohol, the calculated inhaled dose of alcohol will be ~53.65 mg. Assuming the product is used 5 times a day, the total amount of alcohol inhaled will be 268.3 mg/day. Corrected SED, calculated based on these values, will be 4.47 mg/kg bw/day, and hence a MoS of 268 is resulted. Moreover, a few studies [(2,3)] have also conducted assessment on the ethanol absorption during hand disinfection where they reported that the blood ethanol concentration was below the toxic level for humans (50mg/L) after successive application of hand rubs containing ethanol concentration varying from 55% to 95% by weight. Another study [(4)] also found that, as with ethanol-based hand rubs, the amount absorbed via inhalation and/or dermal contact were very low and probably unlikely to induce adverse health effects. These further support the fact that inhaling alcohol from the hand cleansing gel will not pose a significant risk to consumers under normal and reasonably foreseeable condition of use.

(1) Bessonneau V., Thomas O. Assessment of Exposure to Alcohol Vapor from Alcohol-Based Hand Rubs, Int J Environ Res Public Health. 2012 Mar; 9(3): 868–879.
(2) Kramer A., Below H., Bieber N., Kampf G., Toma C.D., Huebner N.O., Assadian O. Quantity of ethanol absorption after excessive hand disinfection using three commercially available hand rubs is minimal and below toxic levels in humans. BMC Infect. Dis.2007;7 doi: 10.1186/1471-2334-7-117.
(3) Miller M.A., Rosin A., Levsky M.E., Patel M.M., Gregory T.J.D., Crystal C.S. Does the clinical use of ethanol-based hand sanitizer elevate blood alcohols levels? A prospective study. Am. J. Emerg. Med. 2006;24:815–817.

(4) Below H., Partecke I., Huebner N.O., Bieber N., Nicolai T., Usche A., Assadian O., Below E., Kampf G., Parzefall W., et al. Dermal and pulmonary absorption of propan-1-ol and propan-2-ol from hand rubs. Am. J. Infect. Control. 2012 Apr;40(3):250-7. doi: 10.1016/j.ajic.2011.03.009. Epub 2011 Jul 8.

2. 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: 16.9583333 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.

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: 2.5000000 mg/kg bw/day
MOS: 440
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. PEG-7 Glyceryl Cocoate

CAS No.: 66105-29-1 / 68201-46-7
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: safe as used in rinse off product and safe at concentration up to 10% in leave on products
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.8333333 mg/kg bw/day
MOS: --
PEG-7 Glyceryl Cocoate is the polyethylene glycol ether of Glyceryl Cocoate, with 7 mole ethylene oxide average molar ratio. It is used as skin-conditioning agents and surfactants in cosmetic. The CIR indicated Intracutaneous injection of PEG-7 Glyceryl Cocoate at a concentration of 10% did not produce sensitization. This same concentration was not an ocular irritant in animal tests. PEG-7 Glyceryl Cocoate was not phototoxic at a concentration of SO% and concluded that it is safe as used in rinse off product and safe at concentration up to 10% in leave on products.
The Technical Data Sheet (TDS) of this ingredient with product name PEG 7 GLYCERYL COCOATE provided by Haj Exports states that the Dioxane content is 10 ppm maximum.

5. Carbomer

CAS No.: 9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4
EINECS/ELINCS: N/A
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 2%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL:
SED: 0.3333333 mg/kg bw/day
MOS: --
Carbomers are synthetic, high molecular weight, nonlinear polymers of acrylic acid cross-linked with a polyalkenyl polyether. It is widely used as thickening, suspending, dispersing, and emulsifying agents. These polymers are hygroscopic and, when exposed to sunlight, they undergo oxidative degradation. Acute oral animal studies showed that Carbomers-910, -934, -934P, -940, and -941 have low toxicities when ingested. Subchronic feeding of rats and dogs with Carbomer-934 in the diet resulted in lower than normal body weights, but no pathological changes were observed. Dogs chronically fed Carbomer-934P manifested gastrointestinal irritation and marked pigment deposition within Kupffer cells of the liver. Clinical studies with carbomer-934 and its various salts showed that these polymers have low potential for skin irritation and sensitization at concentrations up to 100 percent. When tested on humans at 1.0%

concentration, carbomers-940, -941, and their various salts also demonstrate low potential for skin irritation and sensitization. Carbomer-934 also demonstrated low potential for phototoxicity and photo-contact allergenicity. The CIR Expert Panel concluded that Carbomers are safe as cosmetic ingredients.
The Certificate of Analysis (COA) of this ingredient with product name PEMULEN (TM) TR-2 POLYMER, BOX provided by Lubrizol had indicated that the residual solvents are ethyl acetate and cyclohexane with a total residual concentration 0.23%.

6. Triethanolamine
CAS No.: 102-71-6
EINECS/ELINCS: 203-049-8
CLP Classification: None
EU Cosmetic Regulation: Annex III: Maximum authorized concentration is 2.5% for non-rinse-off products; do not use with nitrosating systems; minimum purity of 99%; maximum secondary amine content of 0.5% (applies to raw materials); maximum nitrosamine content of 50 µg/kg; keep in nitrite-free containers
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used for rinse-off products but up to 5% for leave-on products; safe for use in cosmetic formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin; should not be used with products containing N-nitrosating agents
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.2083333 mg/kg bw/day
MOS: 2400
Triethanolamine (TEA) is clear, colourless, viscous liquid with ammoniacal odor. It is widely used in cosmetic formulations as emulsifier, thickener, wetting agent, detergent and alkalizing agent. The LD50 value for rats of TEA is 4.19 g/kg. Long-term oral ingestion of TEA by rats and guinea pigs produced lesions limited mainly to the liver and kidney. Long-term cutaneous applications to animals of the ethanolamines also produced evidence of hepatic and renal damage. TEA showed little potential for rabbit skin irritation in acute and subchronic skin irritation tests. A lotion containing 1% TEA was not phototoxic to guinea pigs, and TEA was not a guinea pig skin sensitizer. TEA did not cause DNA-damage inducible repair in an unscheduled DNA synthesis test. TEA had no carcinogenic or cocarcinogenic activity when dermally applied to mice for 18 months. 10% of TEA produced essentially no eye irritation with or without rinsing in rabbits. Clinical skin testing of TEA and cosmetic products containing TEA showed mild skin irritation in concentration above 5%. There was very little skin sensitization. TEA does not react with N-nitrosating agents to directly from nitrosamines. However, it can act as precursors in nitrosamine formation by undergoing nitrosative cleavage. The resultant secondary amine, diethanolamine, can then be N-nitrosated to products that may be carcinogenic. Therefore, TEA or TEA-containing ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed.
The statement of this ingredient with product name Triethanolamine 99% provided by Dow Chemical Pacific Limited no NEDLEA is detected with detection limit 10 ppb and the secondary amine is less than 0.5%.

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