MID OCEAN BRANDS B.V.
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 BATH BOMB (1 formulation).

Net Weight	:	40g per consumer product
Style/Item No.	:	MO6211
SGS Report No.	:	HKHC2011008662HC
SGS Case No.	:	HKHC201100003729 – 101 (XMCPCH201101750)
Manufacturer	:	107961
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Nov 04 – Nov 30, 2020
Test Period	:	Nov 04 – Nov 30, 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.

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 BATH BOMB for consumer health and no other part of the product. The product is for EU market and intended for application on body skin after dissolving in water for bathing and cleansing by adults.
The net weight of this product (The formulation under assessment) is 40g 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
Sodium Bicarbonate	144-55-8	205-633-8	48.3490	Buffering
Sodium Sulfate	7757-82-6	231-820-9	25.0000	Bulking
Citric Acid	77-92-9	201-069-1	25.0000	Buffering
PEG-8	25322-68-3	225-856-4	1.2500	Humectant
Parfum (The ocean scent E11420)	N/A (Mixture)	N/A (Mixture)	0.3000	Perfuming
Colouring Agent				
CI 16035	25956-17-6	247-368-0	0.0420	Cosmetic colorant
CI 17200	3567-66-6	222-656-9	0.0360	Cosmetic colorant
CI 42090	3844-45-9	223-339-8	0.0200	Cosmetic colorant
CI 19140	1934-21-0	217-699-5	0.0030	Cosmetic colorant

FRAGRANCE ALLERGENS

Fragrance allergens **BUTYLPHENYL METHYLPROPIONAL** 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 multi-colored compressed powder solid with the fragrance (The ocean scent E11420) with pH 7.

2.2 The stability test result on formulation, by in house method of manufacturer on product name Bath Bomb, with a testing period Aug 16 – Nov 20, 2020, 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 : -4°C, 40°C, light, 25°C for 12 weeks
Testing parameters : Appearance, color, odor, and pH

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

3 Microbiological quality

3.1 The microbiological test results on formulation, by third party laboratory (SGS report no. XMCPCH201101753), on product name Bath Bomb, with a testing period of Nov 11 – 19, 2020, 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 of formulation is not required because the product is a one-off product.

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. XMCPCH201101754), on product name Bath Bomb, with testing period Nov 12 – 18, 2020, 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.	Shrink film	POF

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container by third party laboratory (SGS report no. XMCPCH201101751 for shrink plastic film and XMCPCH201101752 for cotton drawstring pouch), both with a testing period of Nov 04 – 09, 2020, 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, by in house method of manufacturer , on product name Bath Bomb, with a testing period of Aug 16 – Nov 20, 2020, was submitted and reviewed.

Testing conditions : -4°C, 40°C, light, 25°C for 12 weeks

Testing parameters : Appearance, color

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 body skin after dissolving in water for bathing and cleansing by adults. Application of this diluted product to face is foreseeable. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Bath- shower products
Use category: Bath bomb
Physical form: Solid
The site(s) of application: Body skin
The surface area(s) of application: 16340 square centimeter
The amount per application: 40 g (Assumed to be diluted in 100L water)
The duration of exposure: 30 minutes
The frequency of use: 365 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): adults
The body weight: 60 kg
Estimated daily amount applied: 40000 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 ISO 22716: 2007, with scope of compliance on manufacturing of bath fizzer, by third party laboratory (Intertek Certificate SZ2011E5 which is valid until Nov 24, 2023).

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. Rinse eyes immediately should the product comes into contact with them.
Keep out of reach of children.

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 and inhalation in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause significant 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 and microbiological quality while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP. The preservation efficacy test result of formulation is not required because the product is a one-off product.

4. Assessor's credentials and approval of Part B

Date: Nov 30, 2020

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.

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 ********

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. Sodium Bicarbonate
CAS No.: 144-55-8
EINECS/ELINCS: 205-633-8
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 50%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 1.6116333 mg/kg bw/day
MOS: --
Sodium bicarbonate is the inorganic salt with a function in cosmetic as abrasive, buffering, deodorant, oral care and skin protection. For bath fizzer product, it is used to react with acid to generate carbon dioxide by neutralization. It is used in cosmetic products at concentration up to 50%. Past studies in experimental animal indicated it was neither an ocular irritant nor teratogen. Based on the available data, CIR Expert Panel concluded that Sodium Bicarbonate is safe as presently used in cosmetics. There are no directly relevant studies on repeated dose exposure, however, knowledge of prior use and available literature does not indicate any adverse effects of long-term use of exposure via any route. In vitro bacterial and mammalian cell tests showed no evidence of genotoxic activity. As with other sodium salts, high doses of sodium bicarbonate promote carcinoma formation in rat urinary bladder after pre-exposure to initiator or BBN. However, when rats were only exposed to sodium bicarbonate no carcinogenic effect on the urinary bladder was found. Based on the available information there are no indications that sodium bicarbonate has carcinogenic effects. Sodium bicarbonate has a long history of use in foodstuff, feed and industrial processes. The bicarbonate ion is a normal constituent in vertebrates, as the principal extracellular buffer in the blood and interstitial fluid is the bicarbonate buffer system. Excess sodium and bicarbonate ions are readily excreted in the urine. It is therefore assumed that normal handling and use will not have any adverse effects. The consequences of accidental or excessive oral ingestion have been described in a number of publications. Acute oral ingestion by the patients may result in a ruptured stomach due to excessive gas development. Acute or chronic excessive oral ingestion may cause metabolic alkalosis, cyanosis and hypernatraemia. These conditions are usually reversible, and will not cause adverse effects. Adequate repeated dose toxicity studies are not available and therefore a NOAEL or LOAEL has not been determined. However, in humans there is a long history of sodium bicarbonate use as an antacid in doses up to 4 g without adverse effects of long-term use.

2. Sodium Sulfate
CAS No.: 7727-73-3 / 7757-82-6
EINECS/ELINCS: - / 231-820-9
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used in rinse-off formulations and up to 1% in leave-on formulations
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: >320mg/kg bw/day

SED: 0.8333333 mg/kg bw/day
MOS: 192
Sodium Sulfate is the inorganic salt with the chemical formula Na2SO4. It is a GRAS ingredient that is used in cosmetic formulations as a viscosity increasing and bulking agent. CIR indicated that the clinical studies reported no significant adverse effects following oral or inhalation exposure to Sodium Sulfate. Mild-to-no irritation and no sensitization were noted in dermal studies that tested Sodium Sulfate-containing bath formulations at exaggerated-use concentrations and conditions. However, the Panel restricted the use of Sodium Sulfate in leave-on products as a clinical sensitization study resulted one isolated incidence of mild erythema in 1 of 61 panelists when tested on patches containing 1.01% sodium sulfate. Therefore, the CIR Expert panel concludes Sodium Sulfate to be safe as used in rinse-off formulations, and safe up to 1% in leave-on formulations.

3. Citric Acid
CAS No.: 77-92-9 / 5949-29-1
EINECS/ELINCS: 201-069-1 / -
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 4% for leave-on products; 10% for rise-off products; 39% for diluted use products
Food additive recommendation: Yes, but no given ADI
Toxicological profile by chemical supplier: None
NOAEL: 1200 mg/kg bw/day
SED: 0.8333333 mg/kg bw/day
MOS: 720
Citric acid is an α-hydroxytricarboxylic acid which functions as chelating agents, fragrance ingredients and pH adjusters. It is used in almost every category of cosmetic product. Citric acid is GRAS direct food additives and therefore oral toxicity was not a concern. Based on many experimental data in animals and on human experience, citric acid is of low acute toxicity. The NOAEL for repeated dose toxicity for rats is 1200 mg/kg bw/day. The major, reversible subchronic and chronic toxic effects seem to be limited to changes in blood chemistry and metal absorption/excretion kinetics. Citric acid is not suspected of being a carcinogen nor a reprotoxic or teratogenic agent. The NOAEL for reproductive toxicity for rats is 2500 mg/kg bw/day. Further, it is not mutagenic in vitro and in vivo. Also, the sensitising potential is seen as low. In contrast, irritation, in particular of the eyes but also of the respiratory pathways and the skin, is the major toxicological hazard presented by citric acid; this is confirmed by a series of reports relating to eye and skin irritation. The irritant effects of citric acid on the skin depend on the pH of the applied solution.

4. PEG-8
CAS No.: 5117-19-1 / 25322-68-3 (generic)
EINECS/ELINCS: 225-856-4 / 500-038-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used from 0.0002 to 85%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1100 mg/kg bw/day

SED: 0.0416667 mg/kg bw/day
MOS: 13200
PEG-8 has been reported to be used in cosmetic as humectants, solvents, binders, emulsion stabilizers, and viscosity increasing agents. According to the CIR, PEGs have low oral and dermal toxicity and are not irritating to the skin of rabbits or guinea pigs. PEG-8 were not dermal irritants in several rabbit studies and caused little to no ocular irritation. It was not mutagenic or genotoxic in a Chinese hamster ovary assay, a sister chromatid exchange assay and in an unscheduled DNA synthesis assay or neither carcinogenic when administered orally, intraperitoneally or subcutaneously in animal studies. It was not a sensitizer in clinical studies on normal skin. Due to the manufacturing processing , there may be a concern of 1,4-dioxane and ethylene oxide as impurities. The CIR considered this ingredient is safe at the current level of use if it is has employed necessary purification procedures to remove the impurities from the ingredient before blending into cosmetic formulations.
The submit test report, on the sample description FTE400-190922B01, supplied by BASF-YPC Company Limited, the 1,4-dioxane content was detected as less than 1 mg/kg which complies to the specification of 20 mg/kg.

5. Parfum (The ocean scent E11420)
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: H317, H305 and H411
NOAEL: --
SED: 0.0100000 mg/kg bw/day
MOS: --
Parfum The ocean scent E11420 as supplied by
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 5% of this parfum can be used in rinse off Bath Bomb product (Class 9 product).

6. CI 16035
CAS No.: 25956-17-6 / 68583-95-9 / 84455-18-5
EINECS/ELINCS: 247-368-0 / 271-524-7 / -
CLP Classification: N/A
EU Cosmetic Regulation: Annex III: Maximum authorized concentration in ready for use preparation is 0.4% in hair dye substance in non-oxidative hair dye products; Annex IV
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 700 mg/kg bw/day
SED: 0.0014000 mg/kg bw/day
MOS: 250000

CI 16035 (Disodium 6-hydroxy-5-[(2-methoxy-4-sulphonato-m-tolyl)azo]naphthalene-2-sulphonate) and its salt is generally used as red colorant and allowed in cosmetic products according to EU Cosmetic Regulation. However, it should fulfill the purity requirement as set out in Commission Directive 2008/128/EC (E 129).

7. CI 17200

CAS No.: 3567-66-6
EINECS/ELINCS: 222-656-9
CLP Classification: None
EU Cosmetic Regulation: Annex III: Maximum at 0.5% in hair dye substance in non-oxidative hair dye products; Annex IV
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 25 mg/kg bw/day
SED: 0.0012000 mg/kg bw/day
MOS: 10417
CI 17200 is generally used as red colorant and allowed in cosmetic products according to EU Cosmetic Regulation. It should fulfill the general purity criteria. The acute oral toxicity (LD50) was > 3 160 mg/kg bw in rats and > 1 000 mg/kg bw in dogs. The NOAEL in a long-term feeding toxicity study in rats was set at 102 mg/kg bw/d. In mice, the LOEL was set at 150 mg/kg bw/day. In a multi-generation study in rats, the NOAEL was set at 25 mg/kg bw/d. The NOAEL of parental toxicity was set at 102 mg/kg bw for males and at 129 mg/kg bw for females. The NOAEL for developmental toxicity was set at 129 mg/kg bw/d. Acid Red 33 was considered not to be irritant to rabbit skin and eye. It was found not to be a skin sensitiser in a Guinea pig maximisation test. Acid Red 33 did not induce gene mutations in the gene mutation assay neither in bacteria nor in mammalian cells, and did not induce an increase in micronucleated erythrocytes in mice. As it did not induce gene mutations in vitro nor chromosome aberrations or aneuploidy in vivo, Acid Red 33 can be considered to have no relevant mutagenic potential in vivo. Acid Red 33 has also been studied for carcinogenicity after oral administration to mice for 2 years and by an in utero long term rat feeding study (2 years). It was concluded in both studies that under the conditions of the bioassays Acid Red 33 was not carcinogenic.

8. CI 42090

CAS No.: 2650-18-2 / 3844-45-9 / 68921-42-6 / 15792-67-3 / 71701-18-3 / 71701-19-4 / 53026-57-6
EINECS/ELINCS: 220-168-0 / 223-339-8 / 272-939-6 / 239-897-0 / 275-866-8 / 275-867-3
CLP Classification: None
EU Cosmetic Regulation: Annex III: Maximum at 0.5% in hair dye substance in non-oxidative hair dye products; Annex IV
SCCS opinion: Same as EU regulation
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 630 mg/kg bw/day
SED: 0.0006667 mg/kg bw/day
MOS: 472476

CI 42090 (Benzene-methanaminium, N-ethyl-N-(4-((4-(ethyl((3-sulfophenyl)methyl)amino) phenyl)(2-sulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-3-sulfo-, hydroxide, inner salt, disodium salt) is generally used as blue colorant and allowed in cosmetic products according to EU Cosmetic Regulation. It should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E 133).

9. CI 19140

CAS No.: 1934-21-0 / 12225-21-7
EINECS/ELINCS: 217-699-5 / 235-428-9
CLP Classification: None
EU Cosmetic Regulation: Annex III: Maximum at 0.5% in hair dye substance in non-oxidative hair dye products; Annex IV
SCCS opinion: Same as EU regulation
CIR recommendation: None
Food additive recommendation: Yes, but No given ADI.
Toxicological profile by chemical supplier: None
NOAEL: 2640 mg/kg bw/day
SED: 0.0001000 mg/kg bw/day
MOS: 13200000
CI 19140 (Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-((4-sulphophenyl)azo)pyrazole-3-carboxylate and its insoluble barium, strontium and zirconium lakes, salts and pigments) is generally used as yellow colorant and allowed in cosmetic products according to EU Cosmetic Regulation. It should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E 102).

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