POLYCONCEPT TRADING (SHANGHAI) CO., LTD.
5TH FLOOR, HERO BUILDING, NO. 2669, XIETU ROAD, XUHUI DISTRICT, SHANGHAI, CHINA

The following sample was submitted and identified by the client as DEALE LIPBALM STICK (1 formulation).

Net Weight	:	4.5 g per consumer product
Style/Item No.	:	19538480 WH, 19538481 BK, 19538442 SD, 19538443 RR, 19538445 GRN, 19538446 OR, 10303000 PK, 10303001 LBL
SGS Report No.	:	HKHC1901000406HC
SGS Case No.	:	HKHC181200004337 – 101 (SHCPCH181109409)
Manufacturer	:	#10617
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Dec 05, 2018 – Jan 04, 2019
Test Period	:	Dec 05, 2018 – Jan 14, 2019

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

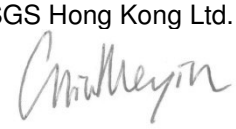
Test Results
Please refer to the following pages.

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 DEALE LIPBALM STICK for consumer health and no other part of the product. The product is for EU market and intended for application on lips for keeping in good condition by children of 6 months old and above.
The net weight of this product (The formulation under assessment) is 4.5 g 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
Paraffinum Liquidum	8042-47-5	232-455-8	36.3500	Emollient
Beeswax	8012-89-3	232-383-7	15.0000	Viscosity controlling
Ozokerite	64742-33-2	265-134-6	10.0000	Binding
Polyisobutene	9003-27-4	N/A	10.0000	Emollient
Ethylhexyl Palmitate	29806-73-3	249-862-1	10.0000	Emollient
Cera Microcristallina	63231-60-7	264-038-1	6.0000	Binding
Cocos Nucifera Oil	8001-31-8	232-282-8	5.0000	Emollient
Polyethylene	9002-88-4	N/A	3.0000	Emollient
Tridecyl Trimellitate	94109-09-8	302-446-4	2.0000	Emollient
Butyrospermum Parkii Butter	91080-23-8	293-515-7	2.0000	Emollient
Parfum (PFB-014 Vanilla)	N/A (Mixture)	N/A (Mixture)	0.5000	Odour
Tocopheryl Acetate	7695-91-2	231-710-0	0.1500	Antioxidant

FRAGRANCE ALLERGENS

None of the 26 fragrance allergens was present in the parfum as indicated by the supplier declaration.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is semi-solid with fragrance (PFB-014 Vanilla).

2.2 The stability test results on formulation, by in house method of manufacturer, on product name LIP BALM, with a testing period of Jul 06 – Sep 28, 2018, were submitted and reviewed. It is the responsibility of the manufacturer and responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : Temperature cycling Test (-18℃ ~ 48℃), Constant temperature -18℃, 50℃, 5℃, 45℃, 37℃ and room temperature for 12 weeks

Testing parameters : Appearance, odour and colour

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

3 Microbiological quality

3.1 The microbiological test result on formulation, with reference to European Pharmacopoeia 9.0 2.6.12 & 2.6.13, by third party laboratory (SGS report no. SHCPCH181109409-2, SHCPCH181109409-3 and SHCPCH181109409-4), on sample name Deale lipbalm stick (White + Black), Deale lipbalm stick (Green + Dark blue + Orange) and Deale lipbalm stick (Red + Light blue + Pink) with testing period Nov 22 – Nov 30, 2018, were submitted and reviewed based on following criteria as required by the SCCS Notes of Guidance.

Product Category of this product: 1

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 to United State Pharmacopoeia XXXVIII (2015) Chapter 5, by third party laboratory (Intertek report no. AGT161100137SH), with product name Lip Balm, with a testing period of Jan 10 – Feb 14, 2017, were submitted and reviewed based on following criteria.

	Day 14	Day 28
	Log reduction	
E.coli, P.aeruginosa, *S.aureus*	≥2	NI from Day 14
C. albicans	NI	NI
A. brasiliensis (niger)	NI	NI

NI: No increase

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

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

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. SHCPCH181109409-1), on sample name Deale lipbalm stick, with a testing period of Nov 22 – Nov 27, 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.	Over Cap	ABS
2.	Button	ABS
3.	Inner Cup	POM
4.	Tube	GPPS
5.	Chute	PP

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) on immediate container by third party laboratories (Intertek report no. SHAH01035476) with testing period Nov 22 – Nov 26, 2018, 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, with a testing period of Jul 06 – Oct 06, 2018, were submitted and reviewed.
Testing conditions : Constant temperature 5℃, 25℃, 45℃, 40℃ with 75%RH and under artificial daylight D65 for 12 weeks
Testing parameters : Fragrance, colour, appearance, leakage of the product and inside and outside surface of the 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 lips by children of 6 months old or above. Application of this product to any other parts of the body is unlikely. Ingestion of small amount of this product would be possible.

6 Exposure to the cosmetic product

Product type: Lip care cosmetics
Use category: Lipbalm
Physical form: Semi-solid
The site(s) of application: Lip
The surface area(s) of application: 4.8 square centimeter
The amount per application: 0.0285 g
The duration of exposure: 360 minutes
The frequency of use: 730 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact and potential oral ingestion
The targeted (or exposed) population(s): Children of 6 months old or above
The body weight: 9.4 kg
Estimated daily amount applied: 57 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 ZHEJIANG AYAN BIOTECH CO.,LTD, in a manufacturing setting according to cosmetic good manufacturing practice guidelines (2008) published by U.S. Food and Drug Administration, with scope of compliance on manufacturing of general liquid unit, including hair care & cleansing products and skin care liquid products; manufacturing of cream & lotion unit, including skin care

& cleansing products and hair care products; manufacturing of wax base unit, including lipstick, lip balm and lip oil, by third party laboratory (Intertek Certificate SZ1604C8 which is valid until Apr 25, 2019).

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

There are no extra labelling requirements for this product. Labelling must comply with the requirements of Regulation (EC) No. 1223/2009 and its subsequent amendments.

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.
As there is a chance of ingestion of this lip product with customary use, the ingredients used should be of food grade or any appropriate grade.
The formulation is not expected to be irritating to the eye, skin, and respiratory tract, be sensitizing, phototoxic, and is unlikely to cause damage to internal organs through skin and ingestion in the majority of consumers under normal and reasonably foreseeable conditions of use. There are substances of allergenic potential but at low level that is not expected to induce an allergenic reaction in most of the users under normal and reasonably foreseeable conditions of use. However, sensitized people can react to allergen present at extremely low concentrations.
The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability, microbiological quality, and preservative efficacy while the product was manufactured in accordance with cosmetic good manufacturing practice guidelines (2008) published by U.S. Food and Drug Administration.

4. Assessor's credentials and approval of Part B

Date: Jan 14, 2019

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.

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 ********

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. Paraffinum Liquidum
CAS No.: 8012-95-1 / 8042-47-5 / 8020-83-5
EINECS/ELINCS: 232-384-2 / 232-455-8
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: 1200 mg/kg bw/day
SED: 0.1726625 mg/kg bw/day
MOS: 3475
Paraffinum Liquidum / Mineral Oil is a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50. In the United States, Mineral Oil may be used as an active ingredient in OTC drug products. The EFSA Panel established an acceptable daily intake (ADI) of 12 mg/kg bw/day for high viscosity white mineral oils based on the NOAEL of 1200 mg/kg bw/day.
The submitted Certificate of Analysis (COA) of this ingredient, in the product trade name C-26-X04, as supplied by Zhejiang Chxin Oil Technology Co., Ltd., indicated that the UV absorbance (260-420nm) corresponding to PAHs was determined to be 0.049, which is below the internal specification 0.1. The solid paraffin and readily carbonisable substances conforms to the internal standard.

2. Beeswax
CAS No.: 8006-40-4 (white) / 8012-89-3
EINECS/ELINCS: 232-383-7
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 56%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0712500 mg/kg bw/day
MOS: --
Beeswax is the wax obtained from the honeycomb of the bee. It consists primarily of myricyl palmitate, cerotic acid and esters and some high-carbon paraffins. It is used as emollient, emulsifying, film forming and perfuming in cosmetics. Beeswax was not phototoxic in hairless mice and swine. It caused minimal irritation in human patch test and was non-sensitizing when tested under open or closed conditions. It was also not mutagenic in Ames test with and without metabolic activation. Beeswax is a GRAS food ingredient and is used in cosmetics at concentration of less than 0.1% to greater than 50%. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.

3. Ozokerite
CAS No.: 12198-93-5 / 64742-33-2
EINECS/ELINCS: - / 265-134-6
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 22%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0475000 mg/kg bw/day
MOS: --
Ozokerite is a naturally occurring fossil wax which consists of aliphatic series of straight-chain, cyclic hydrocarbons, and some oxygenated resinous bodies. It has a delicate needle or short plate microcrystalline structure. Ozokerite is found near soft shale, which acts as a molecular filter and condenser. It has been suggested that the wax was produced into large ones. Wax from different deposits has somewhat different chemical compositions and physical properties. No toxic effects were reported after gastric administration to mice of up to 200 mg/kg of a 0.2% solution of Ozokerite, or to rabbits of up to 200 mg/kg of a 2.0% solution of the wax. Rabbit skin test and ocular irritation test showed that Ozokerite was mild/non-irritating. The available human clinical data indicated mild to minimal reactions. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.

4. Polyisobutene
CAS No.: 9003-27-4
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 40%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0475000 mg/kg bw/day
MOS: --
Polyisobutene is the homopolymer of 2-methyl-1 propene which is used for binding, film forming and viscosity controlling in cosmetic. Polyisobutene is an approved direct food additive for chewing gum bases. The LD50 of undiluted polyisobutene was > 15,400 mg/kg in an oral rat study. In rabbit studies, the dermal LD50 values for polyisobutene was >25,000 mg/kg. No treatment-related gross microscopic changes were observed following exposure to 100% polyisobutene in a 90-day dietary study of rats and 2-year dietary studies in rats or dogs. Polyisobutene at 100% was not carcinogenic in rats (dosed up to 20,000 ppm) or dogs (dosed up to 1000 mg/kg) in oral studies and was not irritating to rabbit skin and eyes in respective irritation studies. The available data indicated polyisobutene has low systemic toxicity at high doses in single-dose and repeated-dose animal studies, no teratogenic effects in animal studies, and no genotoxicity in in vitro and in vivo studies. Although molecular weights are in the range that could be dermally absorbed, the lack of heteroatom functional groups dramatically limits solubility and would prevent significant absorption. The lack of functional groups also limits interactions with other biomolecules and

probably accounts for the apparent biological inertness of these ingredients. The CIR Expert Panel concluded that Polyisobutene is safe in cosmetics in the present practices of use and concentrations.

5. Ethylhexyl Palmitate
CAS No.: 29806-73-3
EINECS/ELINCS: 249-862-1
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 78%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (Read across to 2-ethylhexyl stearate)
SED: 0.0475000 mg/kg bw/day
MOS: 10526
Ethylhexyl Palmitate is the ester of 2-ethylhexyl alcohol and palmitic acid. It is used as emollient and perfuming in cosmetics. The acute oral LD50 in rats is estimated to be greater than 64.0 ml/kg. It was also shown to be nontoxic in sub-chronic dermal studies. Rabbit skin tests with the Palmitates showed that they were non-irritating and non-sensitizing. Also, Draize rabbit eye irritation tests produced either no or only very slight ocular irritation. A body lotion containing 77.9% of Ethylhexyl Palmitate is not an irritant or a sensitizer when applied neat on 104 subjects in a HRIPT test (24-h semi-occlusive). Up to 45% of ethylhexyl palmitate is reported to be used in indoor tanning preparation which could be inhaled. There were no repeated-dose inhalation toxicity data available for the alkyl esters, but the actual exposure in the breathing zone is small and given the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. Also, this ingredient is large molecule and insoluble in water, which supports the view that it is unlikely to be absorbed or cause local effects in the respiratory tract. The CIR states concluded that alkyl esters tend not to produce systemic toxicity at high does in single-dose oral, dermal, or inhalation studies and not to produce significant system toxicity in oral repeated-dose studies. The CIR Expert Panel concluded that Ethylhexyl Palmitate is safe in the present practices of use and concentration when formulated to be non-irritating.

6. Cera Microcristallina
CAS No.: 63231-60-7 / 64742-42-3
EINECS/ELINCS: 264-038-1 / 265-144-0
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: 1100 mg/kg bw/day
SED: 0.0285000 mg/kg bw/day
MOS: 19298
Cera Microcristallina is a complex combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists predominantly of saturated straight and branched chain hydrocarbons predominantly greater than C35. It is used as binders, emulsion stabilizers, opacifying

agents, viscosity increasing agents in cosmetic. Based on the available documented animal and clinical test data, the CIR concluded that it is safe for use as cosmetic ingredients in the present practices of concentration and use.

7. Cocos Nucifera Oil
CAS No.: 8001-31-8
EINECS/ELINCS: 232-282-8
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 80%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0237500 mg/kg bw/day
MOS: --
Cocos Nucifera Oil is fixed oil obtained by expression of the kernels of the seeds of the Coconut, Cocos nucifera L., Palmaceae and is used for emollient, hair conditioning, masking, skin conditioning and solvent in cosmetic in the range of 0.0001-80%. Coconut oil and its derivatives are not restricted for uss in the European Union. Undiluted Cocos Nucifera (Coconut) Oil was non- irritating to rabbit skin. In guinea pigs, undiluted Cocos Nucifera (Coconut) Oil was not a sensitizer in a Magnusson-Kligman maximization study. The CIR Expert Panel considered that the available acute, subchronic, chronic, ocular, dermal and clinical toxicity data are adequate to support the safety of coconut acid, coconut oil, hydrogenated coconut acid and hydrogenated coconut oil. The Panel further concluded that these ingredients are safe for use as cosmetic ingredients.

8. Polyethylene
CAS No.: 9002-88-4
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 24%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0142500 mg/kg bw/day
MOS: --
Polyethylene is an ethylene polymer used for a variety of purposes in cosmetics, including as an abrasive, adhesive, binder or bulking agent, an emulsion stabilizer, a film former, an oral care agent, and as a nonaqueous viscosity-increasing agent. Polyethylene is also used in food packaging materials and medical products, including prosthetic. The CIR Panel considered the available data on polybutene, and noted low systemic toxicity at high doses in single-dose and repeated-dose animal studies, no teratogenic effects in animal studies, and no genotoxicity in in vitro and in vivo studies The Panel also noted that although molecular weights are in the range that could be dermally absorbed, the lack of heteroatom functional groups dramatically limits solubility and would prevent significant absorption. The lack of functional groups also limits interactions with other biomolecules and probably accounts for the apparent biological inertness

of these ingredients. The limited data available from inhalation studies, including acute exposure data, suggest little potential for respiratory effects at relevant doses. The LD50 for polyethylene (average molecular weight of 450) in rats (201 to 223 g) was found to be > 2000 mg/kg, and in polyethylene with an average molecular weight of 655, the LD50 was determined as >5.0 g/kg. Polyethylene causes tumors in rats implanted with squares of the test substance; however, testing involving implanting coverslips and powdered polyethylene suggest that tumors are caused by the physical reaction to imbedded plastic films and not the polyethylene itself. International Agency for Research on Cancer (IARC) lists polyethylene as "not classifiable as to carcinogenicity in humans" based on no adequate human data and inadequate animal data.

9. Tridecyl Trimellitate

CAS No.: 94109-09-8
EINECS/ELINCS: 302-446-4
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 57.1% when formulated to be non-irritating
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 100 mg/kg bw/day (Read across to Triethylhexyl Trimellitate)
SED: 0.0095000 mg/kg bw/day
MOS: 5263

Tridecyl Trimellitate is the triester of Tridecyl Alcohol and trimellitic acid. It is used as emollient and skin conditioning in cosmetics. Tridecyl trimellitate has a molecular weight of 757 Da, low water solubility, and high log P value, it is expected that there is limited absorption capacity through skin and the GI tract, therefore, systemic availability is limited. The acute oral toxicity of Tridecyl Trimellitate was found to be low in a gavage rat study, where an LD50 of 5000 mg/kg bw/day was found in a limit test. 10% tridecyl trimellitate was slightly irritating to rabbit skin following a single occlusive application, but undiluted tridecyl trimellitate was non-irritating to mouse skin. Up to 100% tridecyl trimellitate was negative in a local lymph node assay. In human repeated insult patch tests, tridecyl trimellitate (57.1% in a lipstick formulation and undiluted) was not a sensitizer. A NOAEL of 100 mg/kg bw/day was established for repeated dose toxicity from a reproductive/developmental screening study on the analogue chemical, Triethylhexyl Trimellitate. The CIR Expert Panel concluded that tridecyl trimellitate is safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating. The NICNAS has concluded that the risk to the public from use of the Tridecyl Trimellitate at ≤ 40% in foundation, lipstick, eye shadow and eyeliner, and ≤ 9% in hand and face cream, is not considered to be unreasonable.

10. Butyrospermum Parkii Butter

CAS No.: 91080-23-8 / 194043-92-0 / 68920-03-6
EINECS/ELINCS: 293-515-7 / - / 272-911-3
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used from 0.0005 to 60%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --

SED: 0.0095000 mg/kg bw/day
MOS: --
Butyrospermum Parkii (Shea) Butter is a fat obtained from the fruit of Butyrospermum parkii. It is used as skin conditioning agent ranges from 0.0005 to 60%. The major composition is the stearic and oleic acid. Since it is edible, the systemic toxicity potential is regarded as low. Butyrospermum Parkii (Shea) Butter at 45% and 60% are not a dermal irritant or sensitizer in HRIPT. As supplied, it is not irritating and only produces mild conjunctival reactions in rabbit. The CIR Expert Panel concluded that the plant-derived fatty acid oil is safe in the present practices of use and concentration.

11. Parfum (PFB-014 Vanilla)
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: Irritating to eyes and skin; Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
NOAEL: --
SED: 0.0023750 mg/kg bw/day
MOS: --
Parfum PFB-014 Vanilla as supplied by ELAN(SHANGHAI) FLAVORS & FRAGRANCES CO.LTD. and the corresponding IFRA certificate of 48th amendment, allergen declaration and MSDS, was used at 0.5% in the formulation. The industry recommendations indicate there is no restriction use of this parfum in leave-on lipbalm product (Class 1 product).

12. Tocopheryl Acetate
CAS No.: 52225-20-4 / 58-95-7 / 7695-91-2
EINECS/ELINCS: 200-405-4 / 231-710-0
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: alpha-tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed
CIR recommendation: Safe to be used up to 36% (100% in vitamin E oil)
Food additive recommendation: Yes, but no given ADI
Toxicological profile by chemical supplier: None
NOAEL: 500 mg/kg bw/day
SED: 0.0007125 mg/kg bw/day
MOS: 350877
Tocopheryl Acetate functions as antioxidant or skin-conditioning agent in cosmetic formulations. Tocopheryl Acetate can be hydrolyzed to Tocopherol which is a natural component of cell membranes protecting against oxidative damage. It has been reported that Tocopheryl Acetate and Tocopherol protected against ultraviolet radiation induced skin damage. Tocopheryl Acetate is generally not toxic in animal feeding studies, although very high doses (2 g/kg/day) have hemorrhagic activity. It is generally not irritating or sensitizing to skin or irritating to eyes, but it was shown in one animal test that Tocopheryl

Acetate produced sensitization. Reproductive and developmental toxicity tests in animals were all negative or showed some effects of reducing toxicity. It was almost uniformly negative in genotoxicity, exhibited anti-mutagenic activity and was not carcinogenic. Based on current knowledge, the Scientific Committee on Cosmetic Products and Non-Food Products Intended For Consumers (SCCNFP) concluded that alpha-tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed. The CIR Expert Panel also concluded that Tocopheryl Acetate is safe as used in cosmetic formulations, but the purity of the Tocopherol should be of similar grade to that used in food.

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