The following sample was submitted and identified by the client as FACE PAINT (1 formulation and 6 additional styles).

Net Weight	:	4g per consumer product
SGS Report No.	:	HKHC2201000094HC
SGS Case No.	:	HKHC220100000068-101 (SHCPCH220100028)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jan 04 – 18, 2022
Test Period	:	Jan 04 – 18, 2022

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 the areas 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 FACE PAINT in 7 assorted styles for consumer health and no other part of the product. The product is for EU market and intended for application on face for changing appearance by adults. The net weight of this product (The formula under assessment) is 4g 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. % (Max.)	Intended Function
Paraffinum Liquidum	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	27.8000000000	Emollient / Skin Protecting / Solvent
Cera Microcristallina	63231-60-7	264-038-1	26.0000000000	Emulsion Stabilising / Viscosity Controlling
Beeswax	8006-40-4 / 8012-89-3	232-383-7	15.0000000000	Emollient / Emulsifying / Film Forming
Mica	12001-26-2	N/A	12.0000000000	Opacifying
Ceresin	8001-75-0	232-290-1	10.0000000000	Antistatic / Opacifying / Viscosity Controlling
Isooctyl Palmitate	1341-38-4	215-675-9	5.0000000000	Emollient / Perfuming
Methylparaben	99-76-3	202-785-7	0.1000000000	Preservative
Propylparaben	94-13-3	202-307-7	0.1000000000	Preservative
Colouring Agent (May Contain)				
CI 73385	5462-29-3	226-750-0	4.0000000000	Cosmetic Colorant
CI 77266	1333-86-4	215-609-9	4.0000000000	Cosmetic Colorant
CI 15850	5858-81-1	227-497-9	4.0000000000	Cosmetic Colorant
CI 77891	13463-67-7	236-675-5	4.0000000000	Cosmetic Colorant
CI 74260	1328-53-6	215-524-7	4.0000000000	Cosmetic Colorant
CI 19140	12225-21-7	235-428-9	4.0000000000	Cosmetic Colorant
CI 42090	3844-45-9	223-339-8	4.0000000000	Cosmetic Colorant

FRAGRANCE ALLERGENS

No parfum is present in the formulation.

2. Physical/chemical characteristics and stability of the formulation

2.1 The product is red, green, black, white, blue, purple or yellow colored solid with pH value (at 20°C, 10g/100ml) of 5.77.

2.2. The stability test result on formulation, by third party laboratory NIINGBO PRODUCT TEST CENTER CO., LTD (Report no. PTC210913355-6), on product name Face paint, with a testing period of Sep 20 – Dec 29, 2021, 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 : -5°C±1, Room condition and 40±2°C, 60±5% humidity for 3 months

Testing parameters : Appearance, odour, colour and pH
Conclusion: The stability of the formulation is acceptable for this application.

3. Microbiological quality

3.1. The microbiological test results on formulation, with reference to European Pharmacopeia 10.0 2.6.12 and 10.0 2.6.13, by third party laboratory NIINGBO PRODUCT TEST CENTER CO., LTD (Report no. PTC210913355-5), on product name Face paint, with a testing period of Sep 20 – Sep 30, 2021, 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 on formulation, with reference to European Pharmacopeia 10.0 5.1.3, by third party laboratory NIINGBO PRODUCT TEST CENTER CO., LTD (Report No.: PTC210913355-4S), on product name Face paint, with a testing period of Sep 20 – Nov 06, 2021, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
		Log reduction			
Criteria A	*E.coli, P.aeruginosa*, *S.aureus*	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	*E.coli, P.aeruginosa*, *S.aureus*	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase
Conclusion: The preservative efficacy of the formulation achieved Criteria A and 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 NIINGBO PRODUCT TEST CENTER CO., LTD (Report no. PTC210913355-2), on product name Face paint, with a testing period of Sep 20 – Sep 30, 2021, was submitted and reviewed based on following criteria.

	The maximum permissible limit quoted from Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (Published online:06 Oct 2016)					The maximum permissible limit is quoted from German Health No. 7/1992, Session 45 from Nov 14, 1991
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit in cosmetic products in general (mg/kg)	≤0.5[b]	≤ 0.1	≤2.0[a]	≤0.5	≤0.1	≤10

[a] For the products make-up powder, rough, eye shadow, eyeliner, kajal, as well as theater, fan or carnival make-up: 5 mg/kg
[b] For theater, fan or carnival make-up: 2.5 mg/kg
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 packaging.

No.	Immediate Packaging	Material

1.	Box	PP

4.3. For packaging material, test result of lead, cadmium, mercury, chromium (VI) on immediate packaging, by third party laboratory NIINGBO PRODUCT TEST CENTER CO., LTD (Report no.: PTC210913355-1), on product name Face paint, with a testing period of Sep 20 – Sep 30, 2021, indicate the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.4. Packaging compatibility test result on packaging material, indicated to be tested together with the product, by third party laboratory NIINGBO PRODUCT TEST CENTER CO., LTD (Report no. PTC210913355-6), on product name Face paint, with a testing period of Sep 20 – Dec 29, 2021, was submitted and reviewed.
Testing conditions : -5°C±1, Room condition and 40±2°C, 60±5% humidity for 3 months
Testing parameters : Appearance and appearance 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 face by adults. Application of this product to any other parts of the body is foreseeable. Ingestion of this product would be a misuse.

6. Exposure to cosmetic product
Product type: Miscellaneous cosmetics
Use category: Face paint
Physical form: Solid
The site(s) of application: Face
The surface area(s) of application: 580 cm^2
The amount per application: 1.7 g
The duration of exposure: 480 minutes
The frequency of use: 365 times per year (indicated by client)
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: 1700 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 lipstick, lip gloss, face paint, lip oil, etc., by third party laboratory (DEKRA Certificate Number DW2020GMP(B)0081 which is valid until Mar 08, 2024).

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.

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 eye, 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 may cause slight irritation, but 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, stability, microbiological quality, and preservative efficacy while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP.

4. Assessor's credentials and approval of Part B

Date: Jan 18, 2022

Mei-Yin CHIU, Sondy MSc, FRSB, CBiol, DABT, EUROTOX Registered Toxicologist

The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

******** End of Report ********

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. 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 (only high viscosity MHC applied)
SED: 3.9383333333 mg/kg bw/day
MOS: 152
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 Product Data Sheet of this ingredient, on product name Ervol, as supplied by Sonneborn, indicated that the result of Polycyclic Aromatic Hydrocarbons is pass with specification. And stated it met the requirements of FDA § 172.878. It is the manufacturer's responsibility to ensure each batch of the ingredient used in the formulations are of acceptable grade to substantiate the safety of the product and to comply with the EU Cosmetic Regulation. If it is not the case, it will void this assessment.

2. 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: 3.6833333333 mg/kg bw/day
MOS: 149
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.

3. 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: 2.1250000000 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.

4. Mica
CAS No.: 12001-26-2
EINECS/ELINCS: N/A
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: 1.7000000000 mg/kg bw/day
MOS: --
Mica (CI 77019) is a series of silicate minerals of varying chemical composition but with similar physical properties (predominantly of potassium and aluminum silicate). Mica has well-defined cleavage and splits into very thin sheets. It is used as opacifying in cosmetics. CIR has reviewed the safety of a variety of silicates including Aluminum, Calcium, Lithium Magnesium, Lithium Magnesium Sodium, Magnesium Aluminum, Magnesium, Sodium Magnesium, and Zirconium Silicates, Magnesium Trisilicate, Attapulgite, Bentonite, Fuller's Earth, Hectorite, Kaolin, Montmorillonite, Pyrophyllite, and Zeolite. It is concluded that these ingredients are not significantly toxic in oral acute or short-term oral or parenteral toxicity studies in animals. The ingredients are also non- or minimal irritating to skin and eye (with a wash-out). Inhalation toxicity, however, is readily demonstrated in animals. Occupational exposure to mineral dusts has also studied extensively. Fibrosis and pneumoconiosis have been documented in workers involved in the mining and processing of Aluminum Silicate, Calcium Silicate, Zirconium Silicate, Fuller's Earth, Kaolin, Montmorillonite, Pyrophyllite, and Zeolite. The Panel concluded that the extensive pulmonary damage in humans was the result of direct occupational inhalation of the dusts and noted that lesions seen in animals were affected by particle size, fiber length and concentration. The Panel considered that most of the formulations are not respirable and of the preparations that are respirable, the concentration of the ingredient is very low. Even so, the Panel considered that any spray containing these solids should be formulated to minimize their inhalation. With this admonition to the cosmetics industry, the CIR Expert Panel concluded that these ingredients are safe as currently used in cosmetic formulations.

5. Ceresin
CAS No.: 8001-75-0

EINECS/ELINCS: 232-290-1
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 20%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 1.4166666667 mg/kg bw/day
MOS: --
Ceresin is a complex combination of hydrocarbons produced by the purification of ozocerite with sulfuric acid and filtration through bone black to form waxy cakes. It is used as antistatic, binding, emulsion stabilising, hair conditioning, opacifying and viscosity controlling in cosmetic. No death in rats given 80ml/kg orally of a cosmetic formulation containing 6% beeswax and 6% ceresin and the formulation were neither cause irritation nor sensitization as indicated by CIR.

6. Isooctyl Palmitate
CAS No.: 1341-38-4
EINECS/ELINCS: 215-675-9
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 46%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.7083333333 mg/kg bw/day
MOS: --
Isooctyl 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 g/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.

7. Methylparaben
CAS No.: 99-76-3
EINECS/ELINCS: 202-785-7
CLP Classification: None
EU Cosmetic Regulation: Annex V: Maximum authorized concentration is 0.4% (as 4-hydroxybenzoic acid) for single ester (equivalent to 0.44% methylparaben), 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used up to 0.4% if used alone; parabens mixture up to 0.8%
Food additive recommendation: Yes, the ADI is 0 to 10 mg/kg bw
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.0141666667 mg/kg bw/day
MOS: 35294
Methylparaben is the ester of Methyl Alcohol and p-Hydroxybenzoic acid that is used as preservative in cosmetics. Parabens are rarely irritating or sensitizing to normal human skin at concentration used in cosmetics. With regard to their general toxicological profile, acute, sub-acute and chronic toxicity studies in

rats, dogs and mice, have proven parabens to be practically non-toxic, non-carcinogenic, non- genotoxic or co-carcinogenic, and non-teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolyzed. Until a properly conducted dermal absorption and toxicokinetic study in humans will allow the assignment of a more scientifically solid value, the SCCS uses a dermal absorption value of 3.7% in its MOS safety calculations. The major concern on parabens is the endocrine disrupting property. In a number of in vitro studies, such as the recombinant yeast estrogen screen, parabens have proven to be able to bind to the estrogen receptor, to activate genes controlled by these receptors, and to stimulate cell growth and increase the level of immune reactive estrogen receptor protein. The estrogenic potency increases with increasing length and branching of the alkyl side chains (methyl <ethyl <propyl <butyl <isobutyl). The potency, however, remained at all times 1,000 to 1,000,000 times below the potency of 17ß- estradiol. p-Hydroxybenzoic acid, the common metabolite of all parabens, was inactive in the in vitro assays. The in vivo estrogenic activities of parabens have been tested in uterotrophic assays employing female rodents. Butylparaben appeared to be more potent than propyl-, ethyl- and methylparaben, and again the values remained several magnitudes of order below the potency of 17ß-estradiol. Conflicting results, however, were reported for p-Hydroxybenzoic acid tested in vivo. One study claimed that it had no estrogenic effect, whereas another study gave potency values 1000-fold below the 17ß-estradiol level. Taking into account all the available data, the EU Cosmetic regulation continue to limit Methylparaben at 0.4% (as 4-hydroxybenzoic acid) for single ester; 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters.

8. Propylparaben
CAS No.: 94-13-3
EINECS/ELINCS: 202-307-7
CLP Classification: N/A
EU Cosmetic Regulation: Annex V: Maximum authorized concentration in ready for use preparation is 0.14% (as 4-hydroxybenzoic acid) for single ester (equivalent to 0.18% propylparaben), 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters, where the sum of the individual concen
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used up to 0.4% if used alone; parabens mixture up to 0.8%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (NOEL)
SED: 0.0141666667 mg/kg bw/day
MOS: 35294
Propylparaben is the ester of n-propyl alcohol and p-hydroxybenzoic acid that is used as masking and preservative in cosmetics. Parabens are rarely irritating or sensitizing to normal human skin at concentration used in cosmetics. With regard to their general toxicological profile, acute, sub-acute and chronic toxicity studies in rats, dogs and mice, have proven parabens to be practically non-toxic, non-carcinogenic, non-genotoxic or co-carcinogenic, and non-teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolyzed. Until a properly conducted dermal absorption and toxicokinetic study in humans will allow the assignment of a more scientifically solid value, the SCCS uses a dermal absorption value of 3.7% in its MOS safety calculations. The major concern on parabens is the endocrine disrupting property. In a number of in vitro studies, such as the recombinant yeast estrogen screen, parabens have proven to be able to bind to the estrogen receptor, to activate genes controlled by these receptors, and to stimulate cell growth and increase the level of immune reactive estrogen receptor protein. The estrogenic potency increases with increasing length and branching of the alkyl side chains (methyl <ethyl <propyl <butyl <isobutyl). The potency, however, remained at all times 1,000 to 1,000,000 times below the potency of 17ß- estradiol. p-Hydroxybenzoic acid, the common metabolite of all parabens, was inactive in the in vitro assays. The in vivo estrogenic activities of parabens have been tested in uterotrophic assays employing female rodents. Butylparaben appeared to be more potent than propyl-,

ethyl- and methylparaben, and again the values remained several magnitudes of order below the potency of 17ß-estradiol. Conflicting results, however, were reported for p-Hydroxybenzoic acid tested in vivo. One study claimed that it had no estrogenic effect, whereas another study gave potency values 1000-fold below the 17ß-estradiol level. The EU Cosmetic regulation limits propylparaben at 0.14% (as 4-hydroxybenzoic acid) for single ester; 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters, and it is not to be used in leave-on products designed for application on the nappy area of children under three years of age.

9. CI 73385
CAS No.: 5462-29-3
EINECS/ELINCS: 226-750-0
CLP Classification: None
EU Cosmetic Regulation: Annex IV/101
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.5666666667 mg/kg bw/day
MOS: --
CI 73385 is classed chemically as a thioindigoid color. It is generally used as violet colorant and allowed in cosmetic products according to EU Cosmetic Regulation.

10. CI 77266
CAS No.: 7440-44-0 / 1333-86-4
EINECS/ELINCS: 215-609-9 / 231-153-3 / 931-328-0 / 931-334-3
CLP Classification: None
EU Cosmetic Regulation: Annex IV
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.5666666667 mg/kg bw/day
MOS: --
CI 77266 is a colorant composed of finely divided particles of elemental carbon obtained by the incomplete combustion of hydrocarbons. Its purity >97%, with the following impurity profile: Ash content less than or equal to 0.15 %, total sulphur less than or equal to 0.65 %, total PAH less than or equal to 500 ppb and benzo(a)pyrene less than or equal to 5 ppb, dibenz(a,h)anthracene less than or equal to 5 ppb, total As less than or equal to 3 ppm, total Pb less than or equal to 10 ppm, total Hg less than or equal to 1 ppm. It should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E 153).
The submitted TECHNICAL DATA SHEET of this ingredient, on product name C47-2222 SunCROMA® D&C Black 2, as supplied by Sun Chemical Corporation, indicated that the purity was controlled at minimum 97.0%, with the following impurity profile: Ash content at maximum 0,15 %, total sulphur at maximum 0,65 %, total PAH at maximum 500 ppb and benzo(a)pyrene at maximum 5 ppb, dibenz(a,h)anthracene at maximum 5 ppb, total As at maximum 3 ppm, total Pb at maximum 10 ppm and total Hg at maximum 1 ppm. It is the manufacturer's responsibility to ensure each batch of the ingredient used in the formulations are of acceptable grade to substantiate the safety of the product and to comply with the EU Cosmetic Regulation. If it is not the case, it will void this assessment.

11. CI 15850
CAS No.: 5281-04-9 / 5858-81-1 / 17852-98-1 / 29092-56-6
EINECS/ELINCS: 226-109-5 / 227-497-9 / 241-806-4 / -
CLP Classification: N/A
EU Cosmetic Regulation: Annex IV
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 150 mg/kg bw/day
SED: 0.5666666667 mg/kg bw/day
MOS: 132
CI 15850 (Disodium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate and its insoluble barium, strontium and zirconium lakes, salts and pigments) is generally used as red colorant and allowed in cosmetic products according to EU Cosmetic Regulation. However, It should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E 180).

12. CI 77891
CAS No.: 13463-67-7 / 1317-70-0 / 1317-80-2
EINECS/ELINCS: 236-675-5 / 215-280-1 / 215-282-2
CLP Classification: N/A
EU Cosmetic Regulation: Annex IV; Annex VI: Maximum concentration in ready for use preparation is 25% as UV filter (sum of Titanium Dioxide and Titanium Dioxide (nano))
SCCS opinion: No
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.5666666667 mg/kg bw/day
MOS: --
CI 77891 (Titanium dioxide) is the inorganic oxide with an empirical formula O2Ti. It functions as opacifier, UV absorber, UV filter and colorant in cosmetics. INCI name CI 77891 should be used when it functions as colorant. CI 77891 is generally used as white colorant and allowed in cosmetic products according to EU Cosmetic Regulation and should fulfill the purity criteria as set out in Commission Directive 2008/128/EC (E171). IARC concluded that there is inadequate evidence in humans for the carcinogenicity of titanium dioxide but sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. Both nano and non nano size Titanium dioxide was classified as a Group 2B carcinogen (Possibly carcinogenic to humans). Titanium dioxide particles have shown to lead to carcinogenic effects after inhalation. Therefore the SCCS does not recommend the use of nano titanium dioxide in applications that might lead to inhalation exposure to the nanoparticles (such as powders or sprayable products). However, due to the lack of penetration of titanium dioxide nanoparticles through human skin, systemic exposure of the titanium dioxide to reach viable cells of the epidermis, dermis, or other organs is unlikely. Therefore, the SCCS considers that the use of nano titanium dioxide in dermally applied cosmetic products should not pose any significant risk to the consumer. The EU Cosmetic Regulation currently allows the safe use of titanium dioxide as a UV-filter at a maximum concentration of 25% in cosmetic products. In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorised for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end-user's lungs by inhalation.
On Jun 9, 2017, the ECHA's Committee for Risk Assessment (RAC) assessed the carcinogenic potential of titanium dioxide against the criteria in the Classification, Labelling and Packaging (CLP) Regulation and,

having considered the available scientific data, concluded that it meets the criteria to be classified as suspected of causing cancer (category 2, through the inhalation route) (ECHA/PR/17/10). The committee also concluded that there was insufficient evidence to classify titanium dioxide in the more severe category for carcinogenicity (category 1B) as was originally proposed by the French Agency for Food, Environmental and Occupational Health and Safety (Anses). The proposed opinion will be formally adopted later by written procedure.

13. CI 74260
CAS No.: 1328-53-6
EINECS/ELINCS: 215-524-7
CLP Classification: N/A
EU Cosmetic Regulation: Annex II: Prohibited when used as a substance in hair dye products; Annex IV: Not to be used in eye products
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.5666666667 mg/kg bw/day
MOS: --
CI 74260 is classed chemically as a phthalocyanine colour which is generally used as green colorant, and allowed in cosmetic products according to EU Cosmetic Regulation. However, it should not be used in eye products.

14. 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: 0.5666666667 mg/kg bw/day
MOS: 2329
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).

15. 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: 0.5666666667 mg/kg bw/day
MOS: 556
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).

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