The following sample was submitted and identified by the client as FACE PAINT (1 formulation and 3 additional colors).

Net Weight	:	4g per colour; 12 g per consumer product
SGS Report No.	:	HKHC1911009309HC
SGS Case No.	:	HKHC191100003607 – 101 (SHCPCH191110923)
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Nov 05 – Nov 14, 2019
Test Period	:	Nov 05 – Nov 22, 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.

Cc

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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 FACE PAINT 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 formulation under assessment) is 4g per colour; 12 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	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	27.8000	Emollient / skin protecting / solvent
Cera Microcristallina	63231-60-7	264-038-1 / 265-144-0	26.0000	Emulsion stabilising / viscosity controlling
Beeswax	8006-40-4 / 8012-89-3	232-383-7	15.0000	Emollient / emulsifying / film forming
Mica	12001-26-2	N/A	12.0000	Opacifying
Ceresin	8001-75-0	232-290-1	10.0000	Antistatic / viscosity controlling
Isooctyl Palmitate	1341-38-4	215-675-9	5.0000	Emollient
Methylparaben	99-76-3	202-785-7	0.1000	Preservative
Propylparaben	94-13-3	202-307-7	0.1000	Preservative
Colouring Agent (May Contain)				
CI 15850	5858-81-1	227-497-9	4.0000	Cosmetic colorant
CI 77266	1333-86-4	215-609-9	4.0000	Cosmetic colorant
CI 42090	3844-45-9	223-339-8	4.0000	Cosmetic colorant
CI 19140	12225-21-7	235-428-9	4.0000	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, black, blue, yellow colored uniform waxy solid with pH value 5.77.

2.2 The stability test result on formulation, by a third party laboratory (FOCO test cosmetic assessment center report no. HKFC190718993-4), on product name Face paint, with testing period of Jul 22 – Nov 04, 2019, 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±1°C, Room condition, 40±2°C, 60±5% humidity for 3 months

Testing parameters : Appearance, odour, colour, pH, lead, cadmium, mercury, arsenic, total aerobic microbial count

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 and 2.6.13, by third party laboratory (FOCO test cosmetic assessment center report no. HKFC190718993-2S), with testing period Jul 22 – Nov 13, 2019, 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 formulation, with reference to European Pharmacopeia 9.0 5.1.3, on product name Face paint, by third party laboratory (FOCO test cosmetic assessment center report no. HKFC190718993-3), with testing period Jul 22 – Sep 12, 2019, 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 A criteria 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 (FOCO test cosmetic assessment center report no. HKFC190718993-1S), on product name Face paint with testing period Jul 22 – Nov 13, 2019, 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 container.

No.	Immediate Container	Material
1.	Box	PP

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container by third party laboratory (FOCO test cosmetic assessment center report no. HKFC190718993-6), with a testing period of Jul 22 – 31, 2019, indicate the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable

4.4 The stability test result on formulation by a third party laboratory FOCO test cosmetic assessment center (test report no. HKFC190718993-4), on product name Face paint, with testing period of Jul 22 – Nov 04, 2019, 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±1°C, Room condition, 40±2°C, 60±5% humidity for 3 months
Testing parameters : Appearance, crack of the package, color change of the package and the words on 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 possible. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Miscellaneous cosmetics
Use category: Face paint
Physical form: Semi - Solid
The site(s) of application: Face
The surface area(s) of application: 580 square centimeter
The amount per application: 1.7 g
The duration of exposure: 480 minutes
The frequency of use: 6 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: 28 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 COSMETIC GOOD MANUFACTURING PRACTICE GUIDELINES PUBLISHED by U.S. Food and Drug Administration, with scope of compliance on manufacturing of powder unit, including compact powder products; manufacturing of aerosol & organic solvent unit, including nail polish; manufacturing of wax base unit, including lipstick and lip gloss; filling and packaging of wax base unit, including mascara and liquid eyeliner, by third party laboratory (Intertek Certificate SZ1906F4 which is valid until Jun 27, 2022).

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.
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 ingestion, skin and inhalation in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause slight irritation.
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 PUBLISHED by U.S. Food and Drug Administration.

4. Assessor's credentials and approval of Part B

Date: Nov 22, 2019

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. 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: 0.0647397 mg/kg bw/day
MOS: 9268

Paraffinum Liquidum 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.

According to the product data sheet provided by Sonneborn Inc., on the product name ERVOL ® White Mineral Oil, the polycyclic aromatic hydrocarbons pass the specification. It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the 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: 0.0605479 mg/kg bw/day
MOS: 9084

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.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.

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: 0.0349315 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: 0.0279452 mg/kg bw/day
MOS: --
Mica 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: 0.0232877 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.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.

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: 0.0116438 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: 0.0002329 mg/kg bw/day

MOS: 2146844

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 17β- 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 17β-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 17β-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 concentrations of butyl- and propylparaben and their salts does not exceed 0.14%
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: 2 mg/kg/day (NOEL)
SED: 0.0002329 mg/kg bw/day
MOS: 4294
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 17β- 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 17β-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 17β-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 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: 0.0093151 mg/kg bw/day
MOS: 8051
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 requirement as set out in Commission Directive 2008/128/EC (E 180).

10. CI 77266

CAS No.: 1333-86-4 / 7440-44-0
EINECS/ELINCS: 215-609-9 / 231-153-3 / 931-328-0 / 931-334-3
CLP Classification: N/A
EU Cosmetic Regulation: Annex VI/126 & 126a
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.0093151 mg/kg bw/day
MOS: 53676
CI 77266 is authorized as a colorant in cosmetics under entry 126 of Annex IV to Regulation (EC) No 1223/2009. However, it should have a purity >97%, with the following impurity profile: Ash content ≤ 0,15 %, total sulphur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, total Hg ≤ 1 ppm. The SCCS concluded that the use of Carbon Black in its nano-structured form (with a primary particle size of 20 nm or larger) at a concentration up to 10 % w/w as a colorant in cosmetic products does not pose any risk of adverse effects in humans after application on healthy, intact skin. Carbon Black (nano) (according to the SCCS's specifications) is authorized for use as a colorant in cosmetic products at a maximum concentration of 10 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.
According to the technical data sheet of this ingredient, provided by manufacturer Sun Chemical Corporation, on the trade name C47-2222 SunCROMA® D&C Black 2, the purity is 97.0% minimum, ash content is 0.15% maximum, total sulfur is 0.65% maximum, total PAH content is 500ppb maximum, benzo(a)pyrene is 5 ppb maximum, dibenz(a,h)anthracene is 5 ppb maximum, As is less than 3 ppm, Pb is less than 10 ppm and Hg is less than 1 ppm, which all complies to the EU regulation. 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 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: 0.0093151 mg/kg bw/day
MOS: 33816

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).

12. 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: 0.0093151 mg/kg bw/day
MOS: 141705
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 ********