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COSMETIC PRODUCT SAFETY REPORT

Sample Name: Blue Hair Serum

Sample Reference: -

The following Safety Assessment is carried out according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) which replaces all other regulations and directives.

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 which the cosmetic product will be applied.
e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

Signed for and on behalf of
SGS United Kingdom Ltd

R. W. Pengilly

Roger Pengilly
BSc, PhD, MRSC, CChem
Cosmetic Safety Assessor

Part A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

Blue Hair Serum

INCI	CAS Number	EC Number	Conc. %	Function
Aqua	7732-18-5	231-791-2	<80.00	Solvent
Glycerin	56-81-5	200-289-5	<10.00	Denaturant Hair Conditioning Humectant Perfuming Solvent Viscosity Controlling
Propylene Glycol	57-55-6	200-338-0	<10.00	Humectant Solvent Viscosity Controlling
Panthenol	81-13-0	201-327-3	<1.50	Antistatic Hair Conditioning
Keratin	68238-35-7	269-409-1	<1.50	Hair Conditioning
Phenoxyethanol	122-99-6	204-589-7	<0.75	Preservative
Caffeine	58-08-2	200-362-1	<0.50	Perfuming Skin Conditioning
Chamomilla Recutita (Matricaria) Flower Extract	84082-60-0	282-006-5	<0.50	Masking Skin Conditioning
Equisetum Arvense Extract	71011-23-9	275-123-8	<0.50	Astringent Emollient Soothing Tonic
Urtica Dioica Leaf Extract	84012-40-8	281-685-5	<0.50	Skin Conditioning
Echinacea Purpurea Extract	90028-20-9	289-808-4	<0.50	Moisturising Skin Conditioning Tonic
Aloe Barbadensis Leaf Extract	85507-69-3 / 94349-62-9	287-390-8 / 305-181-2	<0.50	Emollient Humectant Skin Conditioning
Tocopheryl Acetate	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	<0.50	Antioxidant Skin Conditioning
Alcohol	64-17-5	200-578-6	<0.50	Antifoaming Antimicrobial Astringent Masking Solvent Viscosity Controlling
PEG-35 Castor Oil	61791-12-6	N/A	<0.50	Emulsifying Surfactant

Polysorbate 20	9005-64-5	N/A	<0.50	Emulsifying Surfactant
Aesculus Hippocastanum (Horse Chestnut) Seed Extract	8053-39-2	232-497-7	<0.50	Skin Conditioning
Retinyl Palmitate	79-81-2	201-228-5	<0.50	Skin Conditioning
Tocopherol	1406-66-2 / 10191-41-0 / 2074-53-5 / 59-02-9 / 148	- / 233-466-0 / 218-197-9 / 200-412-2 / 205-708-5	<0.50	Antioxidant Masking Skin Conditioning
Inositol	87-89-8	201-781-2	<0.50	Antistatic Hair Conditioning Humectant
Calcium Pantothenate	137-08-6	205-278-9	<0.50	Antistatic Hair Conditioning
Allantoin	97-59-6	202-592-8	<0.50	Skin Conditioning Skin Protecting Soothing
Linoleic Acid	60-33-3	200-470-9	<0.50	Antistatic Cleansing Emollient Hair Conditioning Skin Conditioning Surfactant
Biotin	58-85-5	200-399-3	<0.50	Antiseborrhoeic•Hair Conditioning Skin Conditioning
CI 42090	3844-45-9	223-339-8	<0.50	Cosmetic Colorant
Caprylyl Glycol	1117-86-8	214-254-7	<0.10	Deodorant Emollient Hair Conditioning Skin Conditioning

Ingredient Listing

INGREDIENTS:
Aqua, Glycerin, Propylene Glycol, Panthenol, Keratin, Phenoxyethanol, Caffeine, Chamomilla Recutita (Matricaria) Flower Extract, Equisetum Arvense Extract, Urtica Dioica Leaf Extract, Echinacea Purpurea Extract, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate, Alcohol, PEG-35 Castor Oil, Polysorbate 20, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Retinyl Palmitate, Tocopherol, Inositol, Calcium Pantothenate, Allantoin, Linoleic Acid, Biotin, CI 42090, Caprylyl Glycol*

*The ingredients are recorded for the purposes of safety assessment and do not necessarily represent the Ingredient List that must be included on the product label.

The hair serum does not contain a fragrance.

2 Physical/chemical characteristics and stability of the cosmetic product

Blue Hair Serum is a blue liquid. The following specification applies to this product:

Parameter	Specification
Appearance	Liquid
Odour	Characteristic
Colour	Blue
pH (20°C)	5.0-6.5
Density	1.00-1.10

Samples of the hair serum were tested to assess the product's stability (reference: 916/0/20.08.2019). Samples of the product were tested in daylight at room temperature and at 45°C for a 90-day period. Observations of the samples' colour and odour were made and recorded. At the end of the 90-day test period samples were reported to be within the specification for colour and odour that has been set for this product. Samples of the product were also stored in daylight for 90 days to observe and record changes in pH and density. At the end of the 90-day test period samples were reported to be within the specification for pH that has been set for this product. The results from the stability test are considered to be acceptable.

3 Microbiological Quality

The hair serum is a water based product which contains the preservative phenoxyethanol.

According to the SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation 9th Revision (SCCS/1564/15) it is generally accepted that for cosmetics not intended for children under 3 years, or products that are not used in the eye area and on mucous membranes that the total viable count for aerobic mesophyllic microorganisms should not exceed 1000 cfu/g or 1000 cfu/ml when tested in 1.0 g or 1.0 ml of the product. *Pseudomonas aeruginosa, Staphylococcus aureus* and *Candida albicans* must not be detectable in 0.1 g or 0.1 ml of the product.

Samples of the product were compared with the manufacturer's microbiological specification with the following results (reference: 916/0/20.08.2019):

Parameter	Specification	Results
Aerobic mesophilic microorganisms	<0.1 g or ml Max 10^2 CFU/g or 10^3 CFU/g	<10
Yeast/Mold	<0.1 g or ml Max 102 CFU/g or 103 CFU/g	<10
Pseudomonas aeruginosa	0	0
Staphylococcus aureus	0	0
Candida albicans	0	0
Eschericia coli	0	0

Samples of the product underwent a further microbiological test (reference 915/0/20.08.2019). Samples of the product were stored in daylight at room temperature and at 45°C for 90 days. After 90 days, the samples were tested for aerobic colony count, mold and yeast, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Candida albicans* and *Eschericia coli*. After the 90-day period, all of the samples were in accordance with the specification set out by the manufacturer. The results from the microbiological test are considered to be acceptable.

Samples of the serum also underwent a Preservative Efficacy Test according to European Pharmacopoeia 5.1.3. The samples passed the test in line with the criteria set out in European Pharmacopoeia 5.1.3 (reference 19031424, dated 7th October 2019).

4 Impurities, traces, information about the packaging

The cosmetic regulation 1223/2009 prohibits the use of heavy metals such as lead, arsenic, cadmium, mercury and antimony unless they are present at trace levels and their presence is inevitable from correct manufacturing processes. The product must be safe. Best practice has been sort and it is my opinion that the most relevant study is that by Health Canada that has proposed the following levels for heavy metals:
Lead 10 ppm, Arsenic 3ppm, Cadmium 3 ppm, Mercury 3 ppm, and Antimony 5 ppm.

Results from a heavy metal analysis of this product have not been submitted for consideration. Following a review of the ingredients used in making the product, it would be expected that the residual heavy metal content of the product are within the limits recommended above. The manufacturer must ensure that measures to reduce the levels of heavy metals remain in place.

Packaging details have not been submitted for consideration.
Packaging must be appropriate to the product type and meet the requirements of the Packaging (Essential Requirements) Regulations 2015. According regulation 5 of the regulation a responsible person must not place any packaging on the European market if the sum of the regulated metals in the packaging or any of its components exceeds 100ppm.

5 Normal and reasonably foreseeable use

The normal use of this product is as a hair styling product. Ingestion of this product would be considered as misuse and is not considered in this report. Inhalation of the product is not expected due to the product format (viscous liquid).

6 Exposure to the ingredients and the cosmetic formulation

As a hair styling product it is anticipated that the serum will be used at a frequency of once or twice per day.

IFRA category 4C
Site of application: Head and hands
Surface area of application: 1010 cm^2
The duration and frequency of use: 1.14 / day
Estimated daily amount applied: 4.00 g / day
Exposure to product: 4000 / 1010 = 3.96 mg/ cm^2 / day
Weight of adult: 60 kg
Retention Factor: 0.1
Calculated daily exposure: 0.40 g/day
Calculated relative daily exposure: 5.74 mg/kg bw/day

(Exposure calculation based on SCCS 1602/18)

7 Exposure and toxicological profile of the substances

There are no nanoparticles in this formulation.

All of the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation 1223 / 2009.

The Responsible Person must ensure that all ingredients are of appropriate cosmetic grade.

Glycerin

CAS 56-81-5 EC No. 200-289-5

Glycerin is a humectant. The Food and Drug Administration (FDA) includes glycerin on its list of direct food additives considered Generally Recognized as Safe (GRAS - 21CFR182.1320), and on its list of approved indirect food additives (21CFR178.3500). According to Hine C. in Arch. Ind. Hyg. Occup. Med. 7 (1953): 282-291 the no observable adverse effect level (NOAEL) was found to be 8000 – 10000 mg/kg bw for Long-Evans rats fed glycerin for up to 2 years. In a study report that was submitted to ECHA (https://echa.europa.eu/registration-dossier/-/registered-dossier/14481) as part of the REACH registration for glycerin it was found that 5% glycerin in the diet of rats did not produce any adverse effects when administered for 90 days. This corresponds to a no observable adverse effect level (NOAEL) of 4580 mg/kg bw/day for male rats and 6450 mg/kg bw/day for female rats. In a repeated

dose toxicity test glycerin was applied to the skin of rabbits for 4 hours/day, 5 days/week for 45 weeks (ECHA database). There were no effects noted in rabbits dosed 8 hours/day, 5 days/week for 45 weeks with dose levels as high as 4.0 ml/kg. Using a density of 1.2611 g/cm3 at 20 °C, a dose of 4.0 ml/kg corresponds to a no observed effect level (NOEL) of 5040 mg/kg/day. The use of glycerin is not restricted by the cosmetic regulation 1223 / 2009 and its use is acceptable in this application.

NOAEL	4580 mg/kg bw/day
Dermal absorption	100% (Default value)
Systemic exposure dose:	5.74 x 10/100 x 100/100 = 0.57
Margin of safety:	4580 /0.57 = 8035

Propylene Glycol

CAS 57-55-6 EC No. 200-338-0

Propylene glycol is a humectant and solvent with skin conditioning properties. The Food and Drug Administration (FDA) in USA includes propylene glycol on its list of substances Generally Recognised as Safe (GRAS) for direct addition to food (reference: 21CFR184.1666). Propylene glycol is also permitted as an indirect food additive for use as a coating agent/adhesive (reference: 21CFR175.300).
In an earlier review the Cosmetic Ingredient Review Expert Panel (reference: JACT 13(6):437-491, 1994) established a concentration limit of 50% for propylene glycol based on the results of human irritation and skin sensitisation tests. New data provided to the Cosmetic Ingredient Review expert panel suggested when carefully formulated to avoid skin irritation, propylene glycol can be safely used at higher concentrations. Therefore the Cosmetic Ingredient Review expert panel revised their previous limitation and concluded that polypropylene glycol is safe for use in cosmetic products when formulated to be non-irritating (reference: IJT 31(Suppl 2):245-260, 2012). Additional data reviewed by the Cosmetic Ingredient Review expert panel indicated that propylene glycol is not genotoxic, nor carcinogenic, nor a reproductive or development toxicant. The National Toxicology Programs Center for the Evaluation of Risk to Human Reproduction Expert Panel in 2003 reviewed the reproductive and development effects of propylene glycol and concluded that there is “negligible concern for reproductive or developmental toxicity to humans”. According to OECD SIDS report (SIDS INITIAL ASSESSMENT PROFILE, 2001) the NOAEL for rats fed 5%w/w propylene glycol for 2 years was 1700 mg/kg bw/day. For dogs fed 8% propylene glycol as part of their diet the NOAEL was found to be 2000 mg/kg bw/day. For cats fed propylene glycol for 94 days the NOAEL was found to be 443 mg/kg bw/day. According to Fasano WJ et al in Toxicol in Vitro 2011 Dec;25(8): 1664-70 the dermal absorption of propylene glycol was found to be 23%. The use of propylene glycol is not restricted by cosmetic regulation 1223 / 2009 and its use is acceptable in this application.

NOAEL	443 mg/kg bw/day
Dermal absorption	23%
Systemic exposure dose:	5.74 x 10/100 x 23/100 = 0.13
Margin of safety:	443/0.13 = 3408

Panthenol

CAS 81-13-0 EC No. 201-327-3

Panthenol is an alcohol that has antistatic properties and is used as a hair and skin conditioner in both leave-on and rinse off products.
The US Food and Drug Administration have approved Panthenol is Generally Regarded as Safe (GRAS) when used in animal feeds and dietary supplements (reference: 21CFR582.5580).
The Cosmetic Ingredient Review Expert Panel have declared that Panthenol safe in the present practices of use up to a maximum concentration of 25% (reference: IJT 25(Suppl. 2): 1-89, 2006). In their Final Report (reference: CIR Final Report dated 12th May 2017) the panel noted that Panthenol may contain residual and potentially *N*-nitrosatable amines as impurities and thus, cautioned that Panthenol should not be used in cosmetic products which *N*-nitroso compounds may be formed.
A NOAEL of 1000 mg/kg bw/day (oral, rat) has been identified for Panthenol (reference: REACH Registration Dossier available at https://echa.europa.eu/brief-profile/-/briefprofile/100.001.208). A dermal absorption rate has not been identified for Panthenol, as such a 'worst case' default value of 100% shall be considered in this assessment.
The cosmetic regulation 1223 / 2009 does not restrict it use and it is considered acceptable for use in this application.

NOAEL	1000 mg/kg bw/day
Dermal absorption	100% (Default value)
Systemic exposure dose:	5.74 x 1.5/100 x 100/100 = 0.086
Margin of safety:	1000 / 0.086 = 11628

Keratin

CAS 68238-35-7 EC No. 269-409-1

Keratin is a protein skin conditioner and hair conditioner commonly used in cosmetics such as body and hand creams, hair conditioners, mascara and shampoo. Keratin also has non-cosmetic applications such as wound dressings, drug delivery, tissue engineering and other medical devices. Keratin occurs naturally in epithelial cells and is essential for normal tissue structure and function. The main sources of keratin are sheep wool, and bovine hoof and horn, goat wool and chicken feathers. Human hair was also once used as a source of keratin but its use is now limited due to the European ban on human-sourced materials for cosmetics. The Cosmetic Ingredient Review (CIR) Panel assessed the use of keratin and 7 other keratin-derived ingredients in their report "Safety Assessment of Keratin and Keratin-derived Ingredients as Used in Cosmetics" dated 6th July 2016. They concluded that keratin and the keratin-derived ingredients reviewed are safe for use in cosmetics in the present practices of use and concentration. A NOAEL has not been identified for keratin. Formulators should be aware that pesticide and heavy metal residues may be present in keratin sourced materials, it is strongly recommended that any necessary steps to reduce or limit the presence of these impurities must be taken before using them in cosmetic formulations. The cosmetic regulation 1223 / 2009 does not restrict the use of keratin and it is considered acceptable to use it in this application.

Phenoxyethanol

CAS 122-99-6 EC No. 204-589-7

Phenoxyethanol is a preservative listed in annex V of cosmetic regulation 1223/2009, the maximum usage level is 1.0% in both leave-on and wash-off products.
Agence nationale de sécurité du medicament et des produits de santé (ansm) in their paper “Evaluation du risque lié à l’utilisation du phénoxyéthanol dans les produits cosmétiques”, May 2012 have proposed a maximum level for phenoxyethanol of 0.40% for products aimed at children under the age of 3 years and that it is not used in products that are applied to babies’ bottoms. They have proposed a no observable adverse effect level of 164 mg/ kg bw/day.
http://www.ansm.sante.fr/var/ansm_site/storage/original/application/0b46fedc079e8bb174a40b7b6f16d04c.pdf .
In a study report submitted to ECHA the LD_{50} for Wistar rats fed phenoxyethanol is 1850 mg/ kg bw. In skin irritation tests following OECD guideline 404 (acute dermal irritation / corrosion) phenoxyethanol was applied to the shaved skin of Russian white (Chbb-SPF) rabbits for 4 hours. Out of 6 rabbits tested 2 showed very slight erythema after 24 hours. None of the rabbits showed signs of oedema. The conclusion reached from this testing on rabbits was that phenoxyethanol was not irritating to the skin.
According to a repeated dose toxicity study similar to OECD guideline 411 (subchronic dermal toxicity 90 day study) reported by Breslin W.J et al in Fundamental and Applied Toxicology 17, 466 – 481, the NOAEL for phenoxyethanol applied to the skin of New Zealand white rabbits for 6 hours per day, 5 days per week for 13 weeks was 500 mg/kg bw/day. Ref.: ECHA database for phenoxyethanol.
In a recent SCCS report on phenoxyethanol the NOAEL was adjusted to account for the study dosing design (out of practical considerations) to dose the animals 5/7 days. The NOAEL is considered to be 357 mg/kg bw/day.

NOAEL	357 mg/kg bw/day
Dermal absorption	100% (Default value)
Systemic exposure dose:	5.74 x 0.75/100 x 100/100 = 0.043
Margin of safety:	357 / 0.043 = 8302

Caffeine

CAS 58-08-2 EC No. 200-362-1

Caffeine is a bitter white crystalline xanthine alkaloid and a stimulant drug. It is used in cosmetics for its skin conditioning properties. Caffeine is found in coffee, cola, chocolate, guarana, kola nuts and tea. It is most commonly consumed by humans in infusions extracted from the seeds of the coffee plant and the leaves of the tree bush. The Food and Drug Administration (FDA) in USA lists caffeine as generally recognised as safe (GRAS) when used in cola type beverages at a concentration of 0.02% (21CFR182.1180). Caffeine is also approved for use as an active ingredient in Over-the-Counter (OTC) drug products (21CFR310.545 and 21CFR340.10). LD50 orally in mice, hamsters, rats, and rabbits (mg/ kg bw) 127, 230, 355, 246 in males; 137, 249, 247, 224 females (Ref. Merck Index 12th Edition).
Cosmetic Regulation 1223/2009 does not restrict its use and it is acceptable for use in this application.

Chamomilla Recutita (Matricaria) Flower Extract

CAS 84082-60-0 EC No. 282-006-5

Chamomilla Recutita (Matricaria) Flower Extract is an extract of the flower heads of the matricaria, Chamomilla recutita (L.), Compositae. It has skin conditioning properties. The Food and Drug Administration (FDA) in USA lists camomile flowers on its list of essential oils, oleoresins, and natural extractives that are generally recognised as safe (GRAS) in food for human consumption (21CFR182.20). The cosmetic regulation 1223 / 2009 does not restrict its use. It is considered acceptable for use in this application.

Equisetum Arvense Extract

CAS 71011-23-9 EC No. 275-123-8

Equisetum Arvense Extract is an extract of the sterile caules of the Horsetail, *Equisetum arvense L., Equisetaceae*. It is a skin conditioning agent and has been used in bath preparations, body and hand preparations, aftershave lotions eye lotions; eye makeup preparations, hair preparations (non-colouring), moisturizing preparations, permanent waves, personal cleanliness products and fragrance preparations.

In the “Botanical Safety Handbook” Equisetum Arvense Extract herb is classified as category 2d (other specific use restrictions as noted) and is contra-indicated for consumption in those with cardiac or renal dysfunction (M McGuffin, 1997) and Van Hellemont states that daily use of the powdered extract of the herb should not exceed 2.0 grams and that doses in excess of 5.0 grams a day of the herb powder should be taken during meals (Van Hellemont, 1986).

Adulteration of E. arvense with E. palustre, which contains the potentially toxic alkaloid palustrine, is widely reported although it has not yet been established whether palustrine-containing drugs are indeed toxic to man (British Herbal Compendium, 1992).

Echinacea Purpurea Extract

CAS 90028-20-9 EC No. 289-808-4

Echinacea Purpurea Extract is the extract of the whole plant, *Echinacea purpurea*.
It has been used in cosmetics as a skin-conditioning agent in products such as bath preparations, cleansing products, face and neck preparations, eye lotions, eye makeup and lipsticks. It is listed in American Herbal Products Association's Botanical Safety Handbook (M McGuffin et al. 1997) as Class: 1: Herbs that can be safely consumed when used appropriately. A NOAEL was not identified for this ingredient. Cosmetic regulation EC 1223/2009 does not restrict its use and it is considered acceptable for this application.

Urtica Dioica Leaf Extract

CAS 84012-40-8 EC No.281-685-5

Urtica Dioica (Nettle) Leaf Extract is the extract of the leaves of *Urtica dioica.* It has been used in cosmetics as a skin-conditioning agent in products such as blushers, foundations, hair conditioners, lipsticks, mascaras and shampoos. It is listed in American Herbal Products Association's Botanical

Safety Handbook (M McGuffin et al. 1997) as Class: 1: Herbs that can be safely consumed when used appropriately. A NOAEL was not identified for this ingredient. Cosmetic regulation EC 1223/2009 does not restrict its use and it is considered acceptable for this application.

Aloe Barbadensis Leaf Extract

CAS 85507-69-3 / 94349-62-9 EC No. 287-390-8 / 305-181-2

Aloe Barbadensis Leaf Extract is an extract of the leaves of the aloe, *Aloe barbadensis, Liliaceae*. It is used as an emollient, humectant and has skin conditioning properties. The Cosmetic Ingredient Review Expert Panel have declared that aloe barbadensis leaf extract is safe in the present practices of use if the anthraquinone level does not exceed 50 ppm (reference: IJT-26(SUPPL. 2)2007). The cosmetic regulation 1223 / 2009 does not restrict its use. It is considered acceptable for use in this application.

Tocopheryl Acetate

CAS 7695-91-2 / 58-95-7 EC No. 231-710-0 / 200-405-4

Tocopheryl acetate is an antioxidant and skin conditioning agent used in many cosmetic applications including after shaves, baby lotions, bath products, eye make-up, feminine hygiene deodorants, mascaras and dentifrices. The Cosmetic Ingredients Review Expert Panel have concluded that tocopheryl acetate is safe as used in concentrations up to 36% (Final report dated 18th March 2014). There are no restrictions on its use in cosmetic regulation 1223 / 2009 it is considered acceptable for this application.
The following no observable adverse effect level (NOAEL) from short term repeated dose toxicity study (28 days) have been reported: Rat NOAEL 1111 mg/kg bw; Dog NOAEL > 360 mg/kg bw. From sub chronic toxicity study (90 day) the NOAEL are as follows: Rat NOAEL
2000 mg/kg bw/d; and for minipig no observed effect (NOEL) level is 2000 mg/kg bw/d. (Reference: Review of Annex IV of regulation (EC) No. 1907/2006 (REACH) Evaluation of Existing Entries in Annex IV).

Dermal absorption	100% (default value)
NOAEL	360 mg/kg bw/day
Systemic exposure dose:	5.74 x 0.5/100 x 100/100 = 0.029
Margin of safety:	360/0.029 = 12414

Alcohol

CAS 64-17-5 EC No. 200-578-6

Alcohol is a synthetic, undenatured ethyl alcohol. It is used in cosmetic products including aftershave lotions, baby lotions, shampoos, nail base coat and undercoats, bath products, toothpastes, deodorants (underarm), eye lotions, depilatories, fragrance preparations, hair sprays, skin tonics and eye make-up as an antifoaming agent, cosmetic astringent, antimicrobial agent, and solvent.
The US Food and Drugs Administration approve the use of alcohol as a direct and indirect food additive (references: 21CFR73.1, 21CFR73.1001, 21CFR175.105, 21CFR176.200, 21CFR176.210,

21CFR178.1010, 21CFR184.1293, 21CFR310.545, 21CFR328.3, 21CFR328.10, 21CFR330.12, 21CFR584.200, 27CFR20.11, 27CFR21.11, 27CFR21.21 and 27CFR21.31).
In a study to assess the skin penetration potential of Alcohol, an in vitro study was carried out using excised pig skin and radiolabelled Alcohol. Alcohol penetration was greater under occlusion conditions than non-occlusive conditions, as might be expected. Absorption rates were around 21% and 1% of applied doses respectively (reference: Pendlington RU, *et al*. Food Chem Toxicol, 39, 169-74, 2001).
A repeated dose 90-day oral toxicity in Sprague-Dawley rats suggests a NOAEL of 10 mg/kg bw/day (reference: REACH Registration Dossier available at https://echa.europa.eu/registration-dossier/-/registered-dossier/16105/7/6/2/?documentUUID=ce06b336-f26d-4cd2-8240-e9662afdce14).
The cosmetic regulation 1223 / 2009 does not restrict the use of alcohol in cosmetics and it is considered acceptable for this application.

NOAEL	10 mg/kg bw/day
Dermal absorption	21% (conservative value)
Systemic exposure dose:	5.74 x 0.5/100 x 21/100 = 0.0060
Margin of safety:	10 / 0.0060 = 1667

PEG-35 Castor Oil

CAS 61791-12-6 EC No. N/A

PEG-35 castor oil is a polyethylene glycol derivative of castor oil. It is used in cosmetics as an emulsifier. The Cosmetic Ingredient Review expert panel have declared that PEG-35 castor oil is safe in the present practices of use and concentrations in cosmetics when formulated to be non-irritating. They considered the use of PEG-35 castor oil at 1 % in leave-on products and 1 % in rinse – off products. The Cosmetic Ingredient Review expert panel expressed concern regarding the possible presence of ethylene oxide and trace amounts of 1,4-dioxane as impurities in any cosmetic ingredient containing a PEG moiety. They stressed that the cosmetic industry should continue to use the necessary purification procedures to remove these impurities from the ingredients before blending it into cosmetic formulations. The cosmetic regulation 1223 / 2009 does not restrict the use of PEG-35 castor oil and its use is acceptable in this application.

Polysorbate 20

CAS 9005-64-5 EC No. N/A

Polysorbate 20 is a mixture of laurate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide. The ingredient can be derived from plant material or produced synthetically. Polysorbate-20 is used as a surfactant and emulsifier in cosmetic products including aftershave lotions, baby products, bath additives, eye make-up, oral care products, aerosolised hair spray, moisturisers and haircare products. The US Food and Drug Administration have approved the use of Polysorbate-20 as a direct and indirect food additive in foods and drugs for human consumption (references: 21CFR73.1001, 21CFR172.515, 21CFR173.310, 21CFR175.105, 21CFR178.3400 and 21CFR310.527). The Cosmetic Ingredient Review Expert Panel have declared that polysorbate 20 is safe as used in concentrations greater than 50 % (reference: JACT 3(5) 1984).
According to a QSAR study described in the REACH Registration Dossier for Polysorbate-20 the dermal

absorption of the test substance was predicted to be very low with an estimated dermal permeability coefficient (Kp) of 0.000826 (1 EO) and 2.18 e-006 (7 EO) cm/hr and a dermal absoprtion rate of 0.00034 mg/cm²/h (=0.0000861 mg/cm²/event, 1 EO) and 0.0000024 mg/cm²/h (=0.00000064 mg/cm²/event, 7 EO) (reference: https://echa.europa.eu/registration-dossier/-/registered-dossier/13525/7/2/3). A NOAEL of >2000 mg/kg bw/day was established for the ingredient in a chronic oral toxicity study on rats (reference: https://echa.europa.eu/registration-dossier/-/registered-dossier/13525/7/6/2).
The cosmetic regulation 1223 / 2009 does not restrict the use of Polysorbate-20 in cosmetics and it is considered acceptable for this application.

NOAEL	2000 mg/kg bw/day
Dermal absorption	10% (conservative estimate)
Systemic exposure dose:	5.74 x 0.5/100 x 10/100 = 0.0029
Margin of safety:	2000/ 0.0029 = 689655

Retinyl Palmitate

CAS 79-81-2 EC No. 201-228-5

Retinyl Palmitate is the ester of Retinol. It is used in cosmetic products including aftershave lotions, baby products, mascara, powders, eye make-up removers, bath products, face masks, hair care products and shaving creams and has skin conditioning properties. It is generally used at concentrations ≤ 1%.
In their published report in 1987 the Cosmetic Ingredient Review Expert Panel concluded that retinyl palmitate is safe as used in the present practices of use and concentration (reference: JACT 6(3): 279-320, 1987). The panel re-reviewed the safety of the ingredient as there were newly available data and reported uses of the ingredient. The safety assessment was not re-opened and the panel confirmed that Retinyl Palmitate is safe in present practices of use and concentration, they also recommended monitoring progress of the new, ongoing National Toxicology Program photococacinogenesis study on Retinyl Palmitate and Retinoic Acid.
A NOAEL has not been identified for this ingredient.
The use of Retinyl Palmitate in cosmetic products is not restricted by the cosmetic regulation 1223 / 2009. It is considered acceptable for use in this application.

Aesculus Hippocastanum (Horse Chestnut) Seed Extract

CAS 8503-39-2 EC No. 232-497-7

Aesculus Hippocastanum (Horse Chestnut) Extract is the extract of the nut of the Horse Chestnut. It is used as a skin conditioner in products such as shampoos, moisturisers, eye makeup preparations, mascara and indoor tanning preparations. The Cosmetic Regulation (1223/ 2009) does not restrict it use. It is considered acceptable for use in this application.

Tocopherol

CAS 1406-66-2 / 10191-41-0 / 2074-53-5 / 59-02-9 / 148-03-8 / 119-13-1 / 54-28-4
EC No. - / 233-466-0 / 218-197-9 / 200-412-2 / 205-708-5 / 204-299-0 / 200-201-5
Tocopherol is an antioxidant used in many cosmetic applications including aftershave lotions, baby

products, bath preparations, talcum powders, oral hygiene products, hair care products and colour cosmetics (including lipsticks, nail polishes and eyeshadows).
The United States Food and Drug Administration (FDA) have approved Tocopherol as Generally Regarded as Safe (GRAS) as a food preservative and as a direct and indirect food additive (references: 21CFR182.3890, 21CFR182.8890, 21CFR184.1890, 21CFR310.545, 21CFR582.3890 and 21CFR582.5890).
The Cosmetic Ingredients Review Expert Panel have concluded that Tocopherol is safe as used in concentrations up to 5% (references: IJT 21 (Suppl. 3): 51-116, 2002 and Final Report dated 18th March 2014).
A sub-chronic oral toxicity study in male and female Fischer rats concluded a NOAEL of 500 mg/kg bw/day (reference: Fd Chem Toxic. 24 (10/11): 1043-1050).
A dermal absorption rate for Tocopherol has not been identified.
There are no restrictions on its use in cosmetics regulation 1223 / 2009and it is considered acceptable for this application.

NOAEL	500 mg/kg bw/day.
Dermal absorption	100% (Default value)
Systemic exposure dose:	5.74 x 0.5/100 x 100/100 = 0.029
Margin of safety:	500/0.029 = 17241

Inositol

CAS 87-89-8 EC No. 201-781-2

Inositol is a humectant and has hair conditioning properties. The Food and Drug Administration (FDA) in USA includes inositol on its list of direct food substances affirmed as generally recognised as safe (GRAS) in food for human consumption (21CFR184.1370). Cosmetic regulation 1223 / 2009 does not restrict its use and it is acceptable for use in this application.

Calcium Pantothenate

CAS 137-08-6 EC No. 205-278-9

Calcium pantothenate has hair conditioning properties. The Food and Drug Administration (FDA) in USA includes calcium pantothenate on its list of direct food substances affirmed as generally recognised as safe (GRAS) in food for human consumption (21CFR184.1212). Cosmetic regulation 1223 / 2009 does not restrict its use and it is acceptable for use in this application.

Allantoin

CAS 97-59-6 EC No. 202-592-8

Allantoin is a skin conditioner, and protectant widely used in cosmetic formulations. The Cosmetic Ingredient Review expert panel have reviewed the safety of allantoin and have concluded that it is safe as a cosmetic ingredient in the practices of use and concentrations as described in their 2010 report. They considered its use at up to 2% in leave – on baby products; 0.3% in bath products; 0.2% in eye makeup products; 0.3% in non colouring hair products; 0.8% in lipsticks; 0.5% in makeup; 0.1% in nail

care products; 0.2% in oral hygiene products; 0.1% in personal hygiene products; 0.5% in shaving products; 0.2% in skin cleansing creams, lotions, liquids and pads; 0.5% in face and neck creams, lotions, powders and sprays; 0.5% in moisturisers; and 0.5% in sun tan products. Allantoin is found in the blood or serum of humans in the range of 7.2 to 48.2 µmol/L. The acute oral toxicity (LD_{50}) for wistar rats administered a single dose of allantoin is greater than 5000 mg/kg. The acute dermal toxicity for allantoin on abraded rabbit skin is LD50 > 5000 mg/kg. Allantoin was found to be not irritating to the eyes of rabbits when a Draize test was performed. Allantoin was found not to be a primary irritant when 0.5% in water was applied to the abraded skin of rabbits. The cumulative irritation score was found to be 0.2 for 10% allantoin in water applied to the clipped and shaved flanks of guinea pigs. Allantoin was not mutagenic in an Ames test. There are no restrictions on its use in cosmetic regulation 1223 / 2009 and it is considered acceptable for this application.

Linoleic Acid

CAS 60-33-3 EC No. 200-470-9

Linoleic acid is a fatty acid. It is used as an emollient and has conditioning properties. The Food and Drug Administration (FDA) in USA includes linoleic acid on its list of direct food substances affirmed as generally recognised as safe (GRAS) in food for human consumption (21CFR184.1065). Cosmetic regulation 1223 / 2009 does not restrict its use and it is acceptable for use in this application.

Biotin

CAS 58-85-5 EC No. 200-399-3

Biotin is a water soluble vitamin which has hair and skin conditioning properties. The Cosmetic Ingredient Review expert panel have reviewed the safety of biotin and have declared that it is safe as used in cosmetic formulations. They considered its use at up to 0.6 % in face and neck preparations. Cosmetic regulation 1223 / 2009 does not restrict its use and it is acceptable for use in this application.

CI 42090

CAS 3844-45-9 EC No. 223-339-8

CI 42090 is equivalent to FD & C Blue No.1 or D & C Blue No. 4 in USA. Both of these colours are regulated by the Food and Drug Administration (FDA) in the USA. The Food and Drug Administration (FDA) in the USA have stated that FD & C Blue No. 1 may be safely used in colouring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice. The Food and Drug Administration (FDA) have also stated that D & C Blue No.4 may be safely used for colouring externally applied cosmetics consistent with good manufacturing practice. Cosmetic regulation 1223/2009 permits the use CI 42090 providing its purity conforms to that of E133 as specified in Commission Directive 95/45/EC. It is considered acceptable for this application.

Caprylyl Glycol

CAS 1117-86-8 EC No. 214-254-7

Caprylyl glycol is a diol. It is used as an emollient and has skin and hair conditioning properties. Products that commonly contain this ingredient include after shave lotions, baby lotions, bath additives, eye lotions, cleansers, eye make-up hair care products, mascaras, powder cosmetics and sunscreens.
Caprylyl glycol also has antimicrobial properties but is not listed as a preservative in annex V of the cosmetic regulation 1223 / 2009.
The Cosmetic Ingredient Review Expert Panel declared caprylyl glycol as safe as used in concentrations up to 5% (reference: IJT 31 (Suppl. 2): 147-168, 2012).
A NOAEL of 300 mg/kg bw/day has been established for caprylyl glycol following oral gavage feeding studies on male and female Wistar rats (reference: ECHA Registration document available at https://echa.europa.eu/registration-dossier/-/registered-dossier/14120/7/6/2).
There are no restrictions on the use of caprylyl glycol in cosmetic regulation 1223 / 2009 and it is considered acceptable for this application.

NOAEL	3000 mg/kg bw/day.
Dermal absorption	100% (Default value – no dermal absorption data identified)
Systemic exposure dose:	5.74 x 0.1/100 x 100/100 = 0.0057
Margin of safety:	3000/0.0057 = 526316

8 Undesirable effects and serious undesirable effects

No data on undesirable effects was submitted for consideration.

9 Information on the cosmetic product

No further information was submitted for consideration.

Part B – Cosmetic product safety assessment

1. Assessment conclusion

The product is safe for use under normal or reasonably foreseeable use. It complies with EC regulation 1223/2009. The assessment is conditional on the responsible person complying with any conditions raised in this report.

2. Labelled warnings and instructions of use

There are no extra labelling requirements for this product. Labelling must comply with the requirements of cosmetic regulation 1223/2009 as amended.

3. Reasoning

The toxicological profile of substances in the baby shampoo has been assessed. The formulation has been reviewed for the potential to be a skin irritant, sensitiser or photo-sensitiser.

All significant toxicological routes of absorption have been considered as well as the systemic effects. Margins of safety have been calculated where applicable.

Each ingredient has been assessed and the toxicological impact of any impurities present considered. Also any interactions between substances have been considered. Stability data has been assessed for this product.

4. Assessor's credentials and approval of part B

Date: 20th January 2020

Roger Pengilly
BSc, PhD, MRSC, CChem

End of Report