

# Safety Assessment Report (SAR)

## according to EU/1223/2009 Annex 1

### PART A - Cosmetic product safety information

#### 1. Quantitative and qualitative composition

Product composition for product „Dyotics Brow Henna - Ash Brown”, is provided in the following table:

Product: DYOTICS BROW HENNA - Ash Brown	
INCI name ingredient	CAS nr.
Aqua	7732-18-5
Sodium Carbonate Peroxide	15630-89-4
Cellulose Gum	9004-32-4
P-Phenylenediamine	106-50-3
Lawsonia Inermis Extract	83-72-7
Citric Acid	77-92-9
Magnesium Sulfate	7487-88-9
Silica	7631-86-9
p-Aminophenol	123-30-8
Sodium Lauryl Sulfate	151-21-3
1-Naphthol	90-15-3
4-Amino-2-Hydroxytoluene	2835-95-2
4-Chlororesorcinol	95-88-5
Simmondsia Chinensis Oil	61789-91-1
Aloe Barbadosensis Leaf Extract	85507-69-3

*Exposure scenario: 0,12g powder + 15 drops of water (0,75ml)*

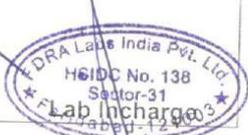
#### 2. Physical/chemical characteristics and product stability

The product physico-chemical and microbiological parameters are described in table below.

SAMPLE DESCRIPTION: A sample in Sealed pouch.

TEST SPECIFICATION				
S.NO.	PARAMETERS	RESULTS	LIMIT OF REPORTING	UNIT
01.	Description	Brownish Grey Powder	Brownish Grey powder	-
02.	Odour	Odourless	Odourless	-
03.	Solubility	soluble in water	Soluble	-
04.	pH (5% soln)	7.40	7.0 to 8.5	-
05.	Heavy metal	<0.05	0.05	mg/kg
06.	Salmonella typhi	Absent	Absent	CFU
07.	Escherichia coli count	Absent	Absent	CFU
08.	Pseudomonas aeruginosa	Absent	Absent	CFU
09.	Candida albicans	Absent	Absent	CFU

Chemist/Microbiologist



The product stability has been evaluated in RT (25C-30C) study for 36 months.

The performed real life room temperature stability study results indicate that the product was found to be stable for 36 months and that all specified parameters fall within the acceptable deviation at all measurement points. Based on the stability study results there is no indication of product deterioration and the expected product shelf is 3 years.

### 3. Microbiological quality

The product is a dry powder with high content of oxidising substances, which is considered a microbiologically low risk product.

Due to the fact that the product is intended for single-use (one sachet per treatment, consumed completely after opening) there is no need for challenge test which is required for products intended for multiple use after opening.

The stability report and the manufacturing batch control ensure the required microbiological purity for this product category.

### 4. Impurities, traces, information about packaging material

Due to the fact that the product is in powder form, with very limited surface-contact between the product and the packaging and very low migration potential (absence of solution required for substance migration), the potential for migration of unintentional and/or unwanted contaminants from packaging into the product can be regarded as negligible.

### 5. Normal and reasonably foreseeable use

The product is an oxidative hair (eyebrows) dye. The product is applied on eyebrows after mixing with water ( $\pm 0,1$ g of product in 1,1 ml water). The product is intended for colouring eyebrows only and is not suitable for dyeing eye-lashes or any other body-hair. The product is intended for professional use only.

### 6. Exposure to cosmetic product

Exposure to the cosmetic product is calculated based on the following parameters.

Exposure scenario: eyebrows dye		
Amount applied	1,10	g
Application frequency	0,02	per day
Skin surface area	10,00	cm <sup>2</sup>
Skin retention	1,00	%
Percutaneous absorption	100,00	%
Average body weight (adult)	64,00	kg
Total systemic exposure	0,003	mg/kgBW/d

### 7. Exposure to the substances

See chapter 8.

### 8. Toxicological profile of individual substances

The data about the toxicological profiles of and exposure to individual substances in formulation is summarised in the attached table. The calculation based on the available toxicity data and the respective systemic exposure and dermal loads indicate that the MoS for all toxicologically relevant components is within the acceptable margins. For some of the substances other toxicologically relevant end-point data is used in stead of NOAEL values when relevant or if NOAEL values are

not established (e.g. DNEL, GRAS status, ADI or TDI values from food ingredients assessments, CIR assessments, sub chronic toxicity, etc.).

## **9. Undesirable effects (Cosmetovigilance)**

At present no cosmetovigilance data is available yet.

## **10. Other relevant information for safety assessment**

Oxidative hair dyes contain strongly sensitising substances. All regulated substances are formulated and used within the limits as defined in Annex III of the Eu regulation 1223/2009.

Since the product is not a standard two-component hair (eyebrows) dye, to confirm the correct interpretation of the Annex III requirements applying to product ingredients (e.g. PPD), we have inquired advise from the Dutch authorities. The Dutch authority (VWA) confirmed in writing that the assessed product (permanent powder color) can be considered as oxidative hair dye as ment in Annex III requirements and that the Annex III requirements apply to the product as applied on the hair, after mixing with water.

To verify the skin compatibility and the irritation potential of the product, the product has been clinically tested on human volunteers in a patch test to test for primary skin irritation and hypersensitivity. No evidence of any skin disorder is observed up to 48h contact time. Test report concluded that no hypersensitivity was observed on 32 persons.

## PART B - Cosmetic product safety assessment

### 1. Assessment conclusions

This assessment has been conducted according to the requirements laid down in the cosmetic regulation No 1223/2009 as amended at the date of this assessment, and in line with the Cosmetics Europe (former COLIPA) technical guidance document for the safety assessment of cosmetic products. The undersigned consider that in the present state of knowledge and considering the general toxicological profile of the single ingredients used, their chemical structure, their reactivity and interaction with other ingredients, their level of exposure and the experimental conditions adopted, the product put on the market can be regarded as safe to human health when applied under conditions of use as instructed on the product label.

### 2. Mandatory labelling information and warnings related to product safety

Mandatory ingredients listing for product labelling:

Product ingredients list (INCI): DYOTICS BROW HENNA - Ash Brown - for professional use
Sodium Carbonate Peroxide, Cellulose Gum, P-Phenylenediamine, Henna (Lawsonia Inermis Extract), Citric Acid, Magnesium Sulfate, Silica, p-Aminophenol, Sodium Lauryl Sulfate, 1-Naphthol, 4-Amino-2-Hydroxytoluene, 4-Chlororesorcinol, Simmondsia Chinensis Oil, Aloe Barbadensis Leaf Extract

Mandatory warnings:

Wear suitable gloves. Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them. Indication of the mixing ratio.

For professional use only. This product is not intended for use on persons under the age of 16.

Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary black henna tattoos may increase your risk of allergy. Do not colour your hair if:

- you have a rash on your face or sensitive, irritated and damaged scalp,
- you have ever experienced any reaction after colouring your hair,
- you have experienced a reaction to a temporary black henna tattoo in the past.

Contains phenylenediamines.

### 3. Reasoning of the assessment conclusions

The assessed product, oxidative hair dye, falls under the product category which is extensively studied and evaluated for safety by SCCP. Based on the opinions published by SCCP on ingredients used in this formulation and corresponding conditions of safe use, it can be concluded that this product as formulated and as used by professional users can be regarded as safe.

The use instructions and conditions/warning for safe use are clearly indicated on the product label and included leaflets.

### 4. Assessor's credentials and approval of part B

Name of the qualified assessor: Drs. Zoran Gavrić

Qualifications: M.Sc. BioPharmaceutical Sciences, Leiden University, The Netherlands; Post-graduate Course in Dermato-Cosmetic Sciences, University of Brussels, Belgium; Post-graduate Course in Safety Assessment of Cosmetics in the EU, University of Brussels, Belgium.

Address and contact details: Boomsluiterskade 216, 2511 VJ The Hague, The Netherlands; tel: +31-643828286, e-mail: z.gavric@regcom.nl

Date of the assessment: 19 Nov 2018



Safety Assessment - Substances with relevant/significant systemic exposure >0,0001 mg/kgBW/day

29/10/2018

Product name	Dyoticks Brow Henna - Ash Brown
Product type - LEVEL 1	HAIR AND SCALP PRODUCTS
Product type - LEVEL 2	HAIR COLOURING PRODUCTS
Product type - LEVEL 3	Oxidative hair colour products
Product type - LEVEL 4 (TRC)	eyebrow dye (1 % availability for skin contact)

Body Weight (baby/child/adult)	64,00 kg	Woman
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Exposure scenario	
Amount applied	1,10 g
Application frequency	0,02 per day
Skin surface area	10,00 cm <sup>2</sup>
Skin retention	1,00 %
Per cutaneous absorption	100,00 %
Average body weight (adult)	64,00 kg
Total systemic exposure	0,003 mg/kgBW/d

Customer: Mrs. Highbrown  
 Safety assessor: drs. Z. Gavric MSc, Bio-Pharmaceutical Sciences, regulatory toxicologist

Comments: The product is an oxidative hair dye intended for coloring the eyebrows. Eyebrows are considered as general hair contrary to eyelashes where the exposure scenario and related restrictions consider the proximity of the eye. The product should be based on the content of specifically Annex III regulated ingredients include following warnings:  
 Wear suitable gloves. Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them. The mixing ratio.  
 For professional use only. This product is not intended for use on persons under the age of 16.  
 Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary black henna tattoos may increase your risk of allergy. Do not colour your hair if:  
 - you have a rash on your face or sensitive, irritated and damaged scalp,  
 - you have ever experienced any reaction after colouring your hair,  
 - you have experienced a reaction to a temporary black henna tattoo in the past.  
 Contains phenylenediamines.

#	Ingredient name (customer) >> verified into INCI name by TRC	Ingredient CAS code (customer)	Ingredient % of total (customer)	Ingredient name (INCI)	SED mg/kgBW/d	Reg Annex	CIR / GRASS / IFRA	NOAEL mg/kgBW/d	MoS or other conformity	Reference to scientific tox data / comment
1	Aqua	7732-18-5	83,3333	AQUA	0,002500	n.a.	n.a.	n.a.	n.a.	n.a.
2	Sodium Carbonate Peroxide	15630-89-4	4,1667	SODIUM CARBONATE PEROXIDE	0,000125	Annex III: Hydrogen peroxide, and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide; (a) Hair products - 12% of H2O2 (40 volumes), present or released (f) Products intended for eyelashes - 2 % of H2O2, present or released - For professional use only! Warnings for a) and f); Wear suitable gloves. Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them. f) To be printed on the label: "For professional use only. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them. Contains hydrogen peroxide."	REACH registered, CLP classified: Acute Tox. 4 H302 Eye Dam. 1 H318	Local dermal effect (corrosion) is the most significant toxicological effect. DNEL (skin irritation / corrosion): 6,4 mg/cm2	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	Regulation 1223/2009 Annex III REACH registration data
3	Cellulose Gum	9004-32-4	3,3333	CELLULOSE GUM	0,000100	n.a.	CIR safe up to 20% GRAS Food additive	ADI 25 mg/kg/day, NEL 5% food 2 year; NOAEL: 3000 mg/kgbw/d	MoS = 3000/0,0001 = 3000000 Considered safe at this level of use and exposure	Amended safety assessment 03/09 - Available from CIR IACT 5(3):1-59, 1986 (original report) WHO Food additive series 50
4	p-Phenylenediamine	106-50-3	2,0000	P-PHENYLENEDIAMINE	0,000060	Annex III: Hair dye substance in oxidative hair dye products (b) Professional use For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % calculated as free base (b) To be printed on the label: The mixing ratio. For professional use only. Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary black henna tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary black henna tattoo in the past. Contains phenylenediamines. Wear suitable gloves.	PPD is Annex IV listed colorant or use in hair dyes. p-Phenylenediamine is used as an ingredient of oxidative hair colouring products at a maximal concentration of 4,0%, which after mixing in a 1:1 ratio with hydrogen peroxide prior to use, corresponds to a maximal concentration of 2,0% at application to the hair. REACH registered skin CLP classified. According to the harmonised classification and labelling (CLP09) approved by the European Union, this substance is toxic if swallowed, is toxic in contact with skin, is toxic if inhaled, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, causes serious eye irritation and may cause an allergic skin reaction.	Dermal Long-term: (DNEL) 160 µg/kg bw/day repeated dose toxicity Dermal Acute /short term: (DNEL) 30 mg/cm <sup>2</sup> sensitisation (skin) Oral Long-term: (DNEL) 160 µg/kg bw/day repeated dose toxicity Oral repeated dose NOAEL (rat): 16 mg/kg bw/day NESL: 17 µg/cm <sup>2</sup> AEL: 0,58 µg/cm <sup>2</sup>	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	REACH registration dossier SCCP/0989/06 RHM Letter report 050012001 Reg 1223/2009 Annex III
5	Henna	83-72-7	1,3333	HENNA	0,000040	n.a.	The plant Henna (Lawsonia inermis, family Lythraceae) is a shrub that is naturally grown or cultivated from north-east Africa to India. Marketed Henna represents a natural material derived from dried and powdered leaves of the plant. Powdered leaves of Lawsonia inermis plant is marketed as Henna. Lawsonia inermis (Henna) is used as a hair dye based on the staining properties of one of its constituents, e.g. Lawsone. Modified Henna products, such as Black Henna are also available to consumers. The content of Lawsone among various modified Henna products may vary significantly, but these products contain some other substances for modifying the intensity of the colour provided by Henna alone. According to the information provided to SCCS, a representative hair dye formulation will be prepared by mixing 100 g Lawsonia inermis as dried plant powder with 300 ml of boiling water. After cooling the mixture (mud) the pulp will be applied on the hair for a period of 15 min to 2h. Thereafter, the mud is rinsed off with water and the hair will be washed with a mild shampoo to eliminate any residues. The SCCS is of the opinion that the information provided is sufficient to assess the safe use of Henna as a hair dye. The assessment is based on the Henna batches 1271 and Opinion on Lawsonia Inermis (Henna) C169 and relates to a Lawsone content of max. 1.4%. When formulated and applied as indicated under functions and uses, e.g. 100 g Henna powder mixed with 300 ml boiling water Henna is considered safe for the consumer. Other kinds of extracts of Henna that may have different compositions are not covered by this assessment.	Not irritating and not sensitizing to skin. Dermal penetration ratio (as Lawsone): 5,3% (most cases) The calculated median lethal dose was > 2000 mg/kg bw (acute oral and dermal). The NOAEL (No-Observed-Adverse-Effect-Level) of Henna Rot was 40 mg/kg bw/day (13 week day rat study); the NOAEL was 200 mg/kg bw/day for the pregnant female rats and 40 mg/kg bw/day for the rat foetuses (teratogenicity study).	MoS = 40/0,00004 = 100000 Considered safe at this level of use and exposure	SCCS/1511/13, SCCS Opinion on Lawsonia inermis (Henna) C169
6	Citric Acid	77-92-9	1,3333	CITRIC ACID	0,000040	n.a.	REACH registered CLP not classified CIR Safe issued <10% if the formulation pH is >3,5	not irritating, not sensitizing ADI unlimited, NEL 1,2 % food 2 year. NOAEL 241 mg/kgBW/day (SCCP)	MoS = 241/0,00004 = 6.025.000 Considered safe at this level of use and exposure	REACH registration data UT 17(S):1-242, 1998
7	Magnesium Sulfate	7487-88-9	1,1667	MAGNESIUM SULFATE	0,000035	n.a.	Evaluated by CIR as safe for use in cosmetics Magnesium sulfate functions as a bulking agent in cosmetic products and is being used at concentrations up to 11% and 25% in leave-on and rinse-off products, respectively. The CIR Expert Panel noted that the history of safe medical use of magnesium sulfate indicates no significant toxicity concerns relating to systemic exposure to these ingredients. Furthermore, the extensive clinical experience of the Panel, including the results of numerous patch tests, indicates that magnesium salts do not have the potential to induce sensitization. The Panel noted that salts of sulfuric acid, such as sodium sulfate, can be irritating to the skin, so cosmetic products containing magnesium sulfate should be formulated to be non-irritating. The Panel concluded that magnesium sulfate is safe in the present practices of use and concentration in cosmetics, when formulated to be non-irritating. OECD SIDS report evaluated that Magnesium sulfate does not present a hazard for human health due to its low hazard profile.	The oral LD50 values were > 2,000 mg/kg NOAEL for reproductive and developmental toxicity was considered to be 450 mg/kg bw/day	MoS = 450/0,00004 = 11.250.000 Considered safe at this level of use and exposure	Safety Assessment of Magnesium Sulfate as Used in Cosmetics, 2014 OECD SIDS INITIAL ASSESSMENT PROFILE SIAM 31, Magnesium Sulfate October 2010
8	Silica	7631-86-9	1,0000	SILICA	0,000030	n.a.	REACH registered CLP not classified CIR assessed as safe when formulated to be non-respirable.	Non toxic, no DNEL thresholds defined (no hazards identified) Oral NOAEL rat > 5000 mg/kgbw/d	MoS calculation not relevant for non-hazardous substances without established upper adverse effect level. Considered safe at this level of use and exposure	REACH registration data CIR Safety Assessment of Silica and Related Cosmetic Ingredients, 2009
9	p-Aminophenol	123-30-8	0,8333	P-AMINOPHENOL	0,000025	Annex III: Hair dye substance in oxidative hair dye products After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,9 % To be printed on the label: The mixing ratio. Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary black henna tattoos may increase your risk of allergy. Do not colour your hair if: - you have a rash on your face or sensitive, irritated and damaged scalp, - you have ever experienced any reaction after colouring your hair, - you have experienced a reaction to a temporary black henna tattoo in the past.	p-Aminophenol is an oxidative hair dye precursor. It is incorporated in oxidative hair dye formulations and in the bottle on the market at a maximum concentration of 1.8% and is typically mixed in a 1:1 ratio with an oxidative agent thereby reaching a concentration of 0.9% for in use application. p-Aminophenol is also used as an agent in the production of dyes and medicines, notably paracetamol. Based on the data provided, the SCCS is of the opinion that the use of p-aminophenol with a maximum on-head concentration of 0.9% in oxidative hair dye formulations does not pose a risk to the health of the consumer, apart from its sensitising potential.	Absorption through the skin: 6,9 µg/cm <sup>2</sup> (7.84% of applied dose) Dermal absorption per treatment (as hair dye in max allowed conc.): 4.00 mg NOAEL (90-d, oral, rat): 10 mg/kg bw/d Irritating, strong sensitiser	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	SCCS/1409/11, SCCS OPINION ON p-Aminophenol

#	Ingredient name (customer) -> verified into INCI name by TRC	Ingredient CAS code (customer)	Ingredient % of total (customer)	Ingredient name (INCI)	SED mg/kgBW/d	Reg Annex	CIR / GRASS / IFRA	NOAEL mg/kgBW/d	MoS or other conformity	Reference to scientific tox data / comment
10	Sodium Lauryl Sulfate	151-21-3	0,8333	SODIUM LAURYL SULFATE	0,000025	n.a.	REACH registered CLP classified H302 Harmful if swallowed H315 Causes skin irritation H318 Causes serious eye damage H412 Harmful to aquatic life with long lasting effects	DNEL dermal 2440 mg/kgbw/d DNEL oral 24 mg/kgbw/d DNEL inhalation 85 mg/m3 Irritating to skin and eyes, not sensitizing NOAEL systemic (HERA) 50 mg/kgbw/d	MoS = 60/0,00002 = 3.000.000 Considered safe at this level of use and exposure	REACH registration data JOURNAL OF THE AMERICAN COLLEGE OF TOXICOLOGY volume 2, Number 7, 1983 HERA assessment of Alcohol sulphates, 2002 CIR Final Report on the Safety Assessment of Sodium Lauryl Sulfate and Ammonium Lauryl Sulfate, 1983 re-assessed 20115
11	1-Naphthol	90-15-3	0,1667	1-NAPHTHOL	0,000005	Annex III: Hair dye substance in oxidative hair dye products After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0%. To be printed on the label: Hair colorants can cause severe allergic reactions.	1-Naphthol is used in oxidative hair dye formulations at a maximum concentration of 4,0%, which after mixing typically in 1:1 ratio with hydrogen peroxide prior to use, corresponds to a concentration of 2,0% upon application. The SCCP is of the opinion that, apart from the risks associated with the use of a strong sensitizer, the use of 1-naphthol itself in oxidative hair dye formulations at a maximum concentration of 2,0% on the head, does not pose any other risk to the health of the consumer. 1-Naphthol itself has no mutagenic potential.	LD50: > 1000 mg/kgbw 2,5% aqueous suspension of 1-naphthol was considered not to be irritant to rabbit skin. Irritant effects on eyes with an increasing degree of eye irritation with increasing dose. 1-naphthol is a 'strong' sensitizer. Repeated dose oral (mice) NOAEL: 100 mg/kg bw/day Maternal toxicity (oral, rat) NOEL: 20 mg/kg bw Maximum absorption through the skin: 5,46 µg/cm2 (absorption rate ±1%)	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	SCCP/1123/07, SCCP Opinion on 1-naphthol
12	4-Amino-2-Hydroxytoluene	2835-95-2	0,1667	4-AMINO-2-HYDROXYTOLUENE	0,000005	Annex III: Hair dye substance in oxidative hair dye products For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair or eyelashes must not exceed 1,5% (b) For professional use only. (b) To be printed on the label: The mixing ratio: For professional use only. This product can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary black henna tattoos may increase the risk of allergy. Eyelashes shall not be coloured if the consumer: - has a rash on the face or sensitive, irritated and damaged scalp, - has experienced any reaction after colouring hair or eyelashes, - has experienced a reaction to a temporary black henna tattoo in the past. Rinse eyes immediately if product comes into contact with them.	4-Amino-2-hydroxytoluene is used in oxidative hair dye formulations at a final concentration of 1,5%, after mixing with peroxide developer. Based on the information provided, the SCCP is of the opinion that the use of 4-amino-2-hydroxytoluene itself as an oxidative hair dye substance at a maximum concentration of 1,5% in the finished cosmetic product (after mixing with hydrogen peroxide) does not pose a risk to the health of the consumer, apart from its sensitising potential.	NOAEL (90d oral): 180 mg/kg bw maximum dermal absorption of 3,48 µg/cm2 no relevant mutagenic potential in vivo	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	SCCP/1001/06, SCCP Opinion on 4-Amino-2-hydroxytoluene
13	4-Chlororesorcinol	95-88-5	0,1667	4-CHLORORESORCINOL	0,000005	Annex III: Hair dye substance in oxidative hair dye products After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,5%. To be printed on the label: Hair colorants can cause severe allergic reactions.	4-Chlororesorcinol is used as a coupler in oxidative hair dye formulations. It reacts with primary intermediates to form the final dye-stuff. The coupling reaction can be accelerated by addition of an oxidizing agent (e.g. hydrogen peroxide), but can also be achieved by air oxidation. The final concentration of 4-chlororesorcinol on head can be up to 2,5%.	NOAEL: 50 mg/kgbw/d	Reg conform Considered safe at this level of use and exposure (within Annex III limits)	SCCS opinion (SCCS/1224/09) on 4-chlororesorcinol
14	Simmondsia Chinensis Seed Oil	90045-98-0	0,0833	SIMMONDSIA CHINENSIS SEED OIL	0,000003	n.a.	Simmondsia Chinensis Oil is the fixed oil expressed or extracted from seeds of the jojoba, Simmondsia chinensis. Simmondsia chinensis (jojoba) Seed Oil is composed almost completely (97%) of wax esters of monounsaturated, straight-chain fatty acids and alcohols with high molecular weights (C16-C26). These wax esters exist principally (83%) as combinations of C20 and C22 unsaturated acids and alcohols. Simmondsia chinensis (jojoba) Seed Oil is stable and resists oxidation. The amount and composition of the oil expressed from S. chinensis seeds varies with maturity of the seeds and somewhat with location and climate conditions surrounding the plant. CIR evaluated Simmondsia chinensis (jojoba) Seed Oil, Wax, Hydrogenated Jojoba Oil, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Esters, Simmondsia chinensis (jojoba) Butter, Jojoba Alcohol, and Synthetic Jojoba Oil as safe as used in cosmetics.	The CIR expert panel recognized that jojoba oil can enhance the penetration of other ingredients through the skin (e.g. fluconazole and aminophylline). The Panel cautioned that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption data, or when dermal absorption was a concern. There are no reports of serious acute or chronic toxicity. There are no indications of mutagenicity (Ames test).	MoS calculation not relevant for non-hazardous substances without established upper adverse effect level. Considered safe at this level of use and exposure	CIR Safety Assessment of Simmondsia chinensis (jojoba) Seed Oil, Simmondsia chinensis (jojoba) Seed Wax, Hydrogenated Jojoba Oil, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Esters, Simmondsia chinensis (jojoba) Butter, Jojoba Alcohol, and Synthetic Jojoba Oil; 2008
15	Aloe Barbadensis Leaf Extract	85507-69-3	0,0833	ALOE BARBADENSIS LEAF EXTRACT	0,000003	n.a.	CIR evaluated as safe cosmetic ingredients, if anthraquinone levels in the ingredients do not exceed 50 ppm. Has long history of safe use as food supplement (sold in health food shops) with recommended daily intake on average 25-50 ml/day.	NOAEL 88 mg/kgbw/d (Based on rat studies using whole leaf powder by Matsuda et al. referenced in Herbal Medicine: Biomolecular and Clinical Aspects (CRC Press, Benzie et al). This reference also reported that no signs of carcinogenicity were found in a 2 year rat study carried out in 2009 by Nomohira et al. NOAEL for anthraquinone free juice/gel is > 1000 mg/kgbw/d	MoS = 88/0,000003 = 29.333.000 Considered safe at this level of use and exposure	IT 26(52)1-50, 2007, Final assessment of Aloe Barbadensis Leaf Juice Herbal Medicine: Biomolecular and Clinical Aspects (CRC Press, Benzie et al)