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 - Hazelnut", is provided in the following table:

Product: DYOTICS BROW HENNA - Natural 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 Barbadensis 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)	7.80	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.	Canddida albicans	Absent	Absent	CFU

Chemist/Microbiologist

Lab Incharge

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 (±0,1g of product in 1,1 ml water). The product is intended for colouring eyebrows only and is not suitable for dying 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		
Ammount applied	1,10	g
Application frequency	0,02	per day
Skin surface area	10,00	cm2
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 form 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 - Hazelnut - 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
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