



Cosmetic Product Safety Report

Henna
Pavandeep Kaur Dhanjal
11584



This document addresses the requirements of EU Regulation (EC) No. 1223/2009 Article 10 in accordance with Annex I and is a statement on the safety of the cosmetic product taking into account the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in the final formulation.

Advanced Development & Safety Laboratories Ltd

Unit 18 Yalberton Tor Industrial Estate
Alders Way, Paignton, Devon TQ4 7QN, UK

Product name Henna

Product Code

Company (Customer) Name Pavandeep Kaur Dhanjal

Company (Customer) Address 12 Airthrie Road, Goodmayes, Ilford, Essex, IG3 9QU

Company (Customer) Phone

Company (Customer) Fax

Company (Customer) Responsible Contact

Other Contact Details

ADSL Reference 11584

CPSR Completion Date 16-09-2019 15:19:04

The product is safe for use in the stated application, and complies with EC Regulation 1223/2009. This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

Date and signature of safety assessor.

Signed: _____



Date: _____

September 16, 2019

PART A

Quantitative & Qualitative Composition of the Cosmetic Product

INCI	Chemical name	CAS	EINECS	Concentration in Formulation % (w/w)
AQUA	Water	7732-18-5	231-791-2	70.000000%
	Function SOLVENT			
HENNA	2-Hydroxy-1,4-naphthoquinone	83-72-7 / 84988-66-9	201-496-3 / 284-854-1	25.000000%
	Function BULKING HAIR DYEING SKIN CONDITIONING			
EUCALYPTUS GLOBULUS LEAF OIL	Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucalyptus, Eucalyptus globulus and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese)	8000-48-4 / 84625-32-1	- / 283-406-2	2.500000%
	Function PERFUMING SKIN CONDITIONING			
EUGENIA CARYOPHYLLUS FLOWER OIL	N/A	8000-34-8	- / 284-638-7	2.500000%
	Function MASKING, PERFUMING, SKIN CONDITIONING, TONIC			

Fragrance / Parfum Information

Name of Fragrance None present

Code of Fragrance

Fragrance Manufacturer

Physical/Chemical Characteristics & Stability of the Cosmetic Product

Physical Description of the Product	Paste
Aroma	Characteristic
Colour	Brown/Green
Taste	N/A
pH of Product	4.7
Viscosity	N/A
Specific Gravity	N/A
Stability	The product has passed a stability test. Test report attached.

INCI	Physical Description	Chemical description
AQUA	Clear, odourless, tasteless liquid	H ₂ O
HENNA	Greenish-grey powder	The natural constituents of Lawsonia inermis are essential oils, 1,4-naphthoquinone, tannins, gallic acid, flavonoids, lipids, sugars, triacontyl tridecanoate, mannitol, xanthonones, coumarins (5-alkyloxy 7-hydroxycoumarin), 2-3% resins, 5-10% tannic ingredients and up to 2% Lawsonia (2-hydroxy-1,4-naphthoquinone). Lawsonia inermis is partially soluble in water with varying degree of solubility, depending upon the composition of the sample.
EUCALYPTUS GLOBULUS LEAF OIL	Colourless to pale yellow liquid	<p>main chemical components of eucalyptus oil: 1,8-cineole (>70% pharmaceutical grade), pinene, b-pinene, a-phellandrene, limonene, terpinen-4-ol, aromadendrene, epiglobulol, piperitone and globulol</p> <p>Molecular formula of cineole (eucalyptol): C₁₀H₁₈O</p> <p>Molecular weight: 154.25</p> <p>Boiling point of cineole (eucalyptol): 176°C to 177°C.</p> <p>Density of cineole (eucalyptol) 0.921 to 0.923</p> <p>Solubility: Insoluble in water Soluble 1 in 5 of alcohol 70%, Miscible with alcohol (90%), dehydrated alcohol, oils, fats and paraffins Miscible with ether, chloroform, glacial acetic acid</p> <p>Angular Rotation: -5 Deg to +10 Deg Refractive Index @ 20°C: 1.458 - 1.470 Specific Gravity @ 25°C: 0.905 - 0.925</p>

INCI	Physical Description	Chemical description
EUGENIA CARYOPHYLLUS FLOWER OIL	Yellow liquid with a characteristic odour of cloves.	75-92% eugenol, 2-17% caryophyllene and 0.2-15% eugenyl acetate. SG 1.040g/ml, Refractive Index 1.478, Insoluble in water.

Microbiological Quality

Preservative Efficacy Preservative Efficacy Test (PET) report not supplied. Preservative Efficacy Test (PET) reports must be submitted prior to a full CPSR being produced.

Plate Count

Impurities, Traces & Packaging

Description of the Packaging & Suitability for Use The product is packaged in cellophane. All materials are suitable for the application and comply with the Cosmetic Regulations 1223/2009.

Notes of Impurities, Traces in the INCI No impurities of concern have been identified in the raw material data supplied.

Normal & Reasonably Foreseeable Use

Description of Intended Application & Directions for Use The product is applied to the skin. It is a leave-on product.

Exposure to the Cosmetic Product

Site of Application area hands

Surface Area of Application (cm²) 860

Amount Applied (g) per day 1.34 g

Duration Leave-on

Frequency 1/day

Retention Factor 1

Exposure Routes Dermal (incidental ocular and oral)

Target Population Adult 60kg

Calculated relative daily exposure (mg/kg bw/day) 22.34

Typical consumer use of the product is taken from the SCCS's Notes of Guidance and the EPA Exposure Factors Handbook

Exposure to the Substances

INCI	Calculated Relative Daily Exposure	Concentration % (w/w)	Dermal Absorption	Systemic Exposure Dosage
AQUA	22.34	70.000000%	100.000000%	15.638000
HENNA	22.34	25.000000%	5.300000%	0.296005
EUCALYPTUS GLOBULUS LEAF OIL	22.34	2.500000%	100.000000%	0.558500
EUGENIA CARYOPHYLLUS FLOWER OIL	22.34	2.500000%	100.000000%	0.558500

Exposure data and method of calculation taken from the SCCS's Notes of Guidance. The conventional conservative approach of assuming a dermal absorption of 100% is taken where appropriate

Toxicological Profile of the Substances

Local Toxicity

INCI	Eye Irritant	Skin Irritant Skin Irritant	Skin Sensitizer	Photo Sensitizer
AQUA	No	No	No	No
HENNA	Slight	No	No	No
EUCALYPTUS GLOBULUS LEAF OIL	Yes	Moderate	No	No
EUGENIA CARYOPHYLLUS FLOWER OIL	Yes	Yes	Yes	No

Margin of Safety and Comments

INCI	Margin of Safety (MOS)	NOAEL	SED
AQUA	No Data		15.638000
HENNA	135	40	0.296005
EUCALYPTUS GLOBULUS LEAF OIL	537	300	0.558500
EUGENIA CARYOPHYLLUS FLOWER OIL	537	300	0.558500

INCI	General Safety Comments	Data Reference
AQUA	The quality of water used in the production of cosmetics and personal care products, called process water, is monitored according to international guidelines on Good Manufacturing Practices known as ISO 22716.	-
HENNA	Henna is an extract of the plant Lawsonia inermis. In cosmetics and personal care products it is used as a skin conditioner and hair dye. It has minimal acute oral and dermal toxicity and is well tolerated in long-term use with some spleen and kidney effects being reported at higher doses. It is a slight ocular irritant, but is not a dermal irritant or sensitiser. It has little ability to penetrate the skin. It is not considered a carcinogen, mutagen, or reproductive toxin	SCCP (Scientific Committee on Consumer Products), Opinion on Lawsonia inermis (Henna), 13 December 2005, SCCP/0943/05 SCCS (Scientific Committee on Consumer Safety), Opinion on Lawsonia inermis (henna), 19 September 2013
EUCALYPTUS GLOBULUS LEAF OIL	Eucalyptus Globulus Leaf Oil is a volatile oil obtained from the fresh leaves of Eucalyptus globulus. It has a long history of use as a medicine and a flavouring. In cosmetics and personal care products it is used as a skin conditioner and fragrance. It is of low toxicity but excessive doses can cause CNS, gastrointestinal, and respiratory effects. It is an irritant to mucous membrane and a moderate irritant to skin undiluted. It is not classed as a carcinogen, mutagen, or reproductive toxin.	Eucalyptus oil, International Programme on Chemical Safety, Poisons Information Monograph 031, Peer review: INTOX Meeting, London UK, March 1998 RTECS Number LE2530000 Who Food Additives Series: 52, Annex 6 ECHA dossier for Eucalyptus globulus, ext.

INCI	General Safety Comments	Data Reference
EUGENIA CARYOPHYLLUS FLOWER OIL	The content of clove bud, clove leaf and clove stem oil has, with little variation, been determined by GC as 75-92% eugenol, 2-17% caryophyllene and 0.2-15% eugenyl acetate – the latter compound found in particularly caryophyllene and 0.2-15% eugenyl acetate – the latter compound found in particularly high concentration in bud oil (34). According to another source, the following maximum content (%) has been observed regarding the constituents listed: eugenol (92,0).	SCCS/1459/11 Opinion on fragrance allergens in cosmetic products caryophyllene (17); eugenyl acetate (15); isoeugenol (0.5) (30). NOAEL - The EFSA Journal (2009) ON-965, 1-53

Undesirable Effects & Serious Undesirable Effects

None reported

Information on the Cosmetic Product

No further information submitted.

PART B

Assessment conclusion

*** PROVISIONAL ***

No preservation challenge information has been provided for this product. The following assessment is contingent on this information being supplied and found to be satisfactory.

The evaluation of the data available on the product and the information about the ingredients for the claimed use do not indicate a significant risk to users that outweighs any benefits of use. The clinical data indicate very low incidence of adverse events

The product is safe for use in the stated application, and complies with EC Regulation 1223/2009. This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

Labelled warnings and instructions of use

Warning - 'If tingling sensation occurs, please rinse with cold water'

Reasoning

The toxicological data given in Part A section 8 indicate that the ingredients are safe for their intended use.

In general, the final product would not be considered an irritant or potential skin sensitiser if the total concentration of irritant ingredients is less than 10% and the total concentration of skin sensitisers is less than 1%. These levels are not exceeded in the product. The product does not contain any known photosensitising ingredients.

Assessor's credentials and approval of part B

Mark Richard Bowes-Cavanagh BSc (Hons) App. Chem CSci CChem MRSC
Address: Green Pastures, Totnes Road, Collaton St. Mary, Paignton, Devon,U.K.

Further Education 1991 - 1994 University Of Plymouth. Drake Circus, Plymouth.
2nd Class BSc (HONS) - Degree in Applied Chemistry.

Specially Qualified In Qualitative & quantitative analysis of Material, Bio-organic, Analytical, Environmental, Physical, Organic and Inorganic chemistry.
Close liaison with industrial processes and particular attention was given on GLP and all inferences recorded.
Synthetic work and analysis using FTIR, IP, GC-MS, GC, HPLC, H-NMR, ICP-MS and bioassay preparations.
Final year dissertation entitled "Isothiocyanates of the Larval Cabbage Root Fly (D.Radicum) Attractants"

Career History 2000-Present Advanced Development & Safety Laboratories Ltd Paignton, Devon. TQ4 7PW.

Technical Director

Analysis and Signing-Off of Safety Assessments in accordance to Cosmetics Directives, EU, ASEAN, Canada and FDA and to 2013 regulations.
Presentation of new products or raw materials to customers including point of sale, including new actives from In-Cosmetics and other trade shows.
Negotiation of price points and order details with both internal departments and customers through procurement or sales.
Research & Development of new products, including sourcing of new ingredients, componentry and fragrance.
Sourcing of all packaging connected to new products, enabling product to arrive on time at third party manufacturers.
Management of bank accounts and supplier credit accounts.
Legal paperwork to enable smooth transfer of product to Far East and FDA in USA through their internal governing bodies.
Creation of website and update including ePDQ selling facility.
Collation of orders with manufacturers including Quality Control and adherence to specifications.
Organizing Trade Shows including NEC Fairs, Regional shows and Oversea Trade shows e.g. Hong Kong Beauty Show.
Consultancy with manufacturers to establish new ranges for both them and feasibility to be successful on the market.
Preparation of stability testing on all products including product compatibility.
Strategy planning for both ECL and with consultancy to clients on better systems within their organizations including training.

1999 - 2000 The Bodyline Group Plc, Paignton, Devon. TQ4 7QZ.

Technical Manager

2010-2012 LF Beauty

To manage the team to ensure products are developed to specified standards to meet customer and company requirements ensuring that all relevant technical standards are applied.

Lead the R&D team and ensure close working relationships between R&D and key internal departments: NPD, Process, Commercial, Purchasing

Manage workload to ensure product developments are in line with critical paths.

To keep abreast of new technology with a view to:

- introduction into existing products
- introduction into new products
- use in innovation presentations
- use in technical bulletins

Ensure that products developed by R&D are:

- Market focused
- Legal (according to claim and composition)
- Safe to use
- Stable (will not separate, discolour etc.)
- Can be manufactured consistently to specification

Assess external testing product development requirements. Ensure testing is focused, best value and accurately costed.

To liaise with customers in order to provide them with required levels of technical support, backed by the supply of all data, samples and specifications.

To liaise with outside suppliers in order to:

- find new sources of innovation
- find equivalent raw materials at competitive costs
- tested externally, where internal facilities are inadequate for the purpose
- at minimum cost

Assist as necessary in the development of the R&D budget.

Ensure R&D spending is in line with agreed budgets and that external testing is properly targeted.

Undertake succession planning within the department and ensure that sufficient developmental training takes place.

To reduce failure rate in process through managing pilot production programme and troubleshooting bulk production issues.

The management, leadership, performance management, development, recruitment and training of all staff within the function to ensure that department performance and customer service are optimised.

Technical Manager

1999 - 2000 The Bodyline Group Plc, Paignton, Devon. TQ4 7QZ

Direct involvement with sales in initiating new projects and servicing the account.

Upgrading the company's capabilities in order to achieve ISO 9001 by March 2000.

Appearance on The Shopping Channel to promote Bodyline Products because of my technical sales skills.

Organized trade shows for Bodyline Group including, NEC Cosmetic Fair, Frankfurt show.

Operating and maintaining a discipline factory environment with close control of logistical planning.

Close liaison with technical departments of all customers to ensure product quality and safety is paramount.

Develop customer accounts to enable maximum potential for both the customer and the company.

Drive the dynamic creative engine of the company to achieve franchise Bodyline shops in Europe and Oceania.

Increase bottom line profit by efficiently programming in projects and maximizing the workforce to achieve manufacturing wages lower ever before.

Maximize output due to cash flow considerations enabling Bodyline to invest in other project ventures.

Evaluate customer requirements to measure Bodylines to achieve maximum profit margin and to enable projects capability of achieving product goal or sub-contracting to other contacts.

Close liaison with suppliers to accomplish cost saving initiatives to complete within the critical path.

Organizing meetings between departments and collaborating with managers to ensure a smooth project path.

Research & Development Chemist

1999 - 1995 The Bodyline Group Plc, Paignton, Devon. TQ4 7QZ.

Formulated a more comprehensive range of products to promote the Bodyline range within the cost parameters and our animal testing declaration (1985).

Achieved suspensions for sophisticated skin care and innovative designs.

Produced varied emulsified systems according to customer requirements and production facilities.

Introduced new systems into the Research & Development arena to achieve high standards in conjunction with EEC directives on stability and safety of products.

Researched into most commercially used preservatives within cosmetic sector according to product, cost and customers needs.

Initiate point of sale and manufacturing information for customers on recommended applications and benefits of product.

Oversee Quality Assurance to answer customer enquiries and required contingency measures.

Evaluation of all additives in product to achieve maximum stability and safety, to prolong shelf-life.

Zeneca Environmental Laboratory, Brixham, Devon.

Work Experience in Vertebrae Laboratory monitoring temperature, pH and other environmental parameters.

Achievements

Member of the Royal Society Of Chemistry and a "Chartered" Chemist and Scientist.

Member of The Society Of Cosmetic Scientists.

Member of the British Toxicology Society

Date and signature of safety assessor.

Signed:  _____

Date: _____ September 16, 2019 _____

This assessment is based on information supplied by the client, raw material manufacturers and published information in recognised authoritative sources. Whilst best endeavours have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied and used for preparing this assessment.



Customer:	Pavan	Appearance:	Paste
Test Date:	28/06/2016	Colour:	Dark Brown
End Date:	20/09/2016	Odour:	Typical
Product:	Henna	KEY 1=No Change 2=Mild Change (acceptable) 3=Concern (failed)	
Technician:	C.Priestman		
Chemist:	Mark Bowes-Cavanagh		
Lab Ref:	0460		

TEMP	4°C	20°C	40°C
	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 1	Comment	Comment	Comment
05/07/2016			

	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 2	Comment	Comment	Comment
12/07/2016			

	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 3	Comment	Comment	Comment
19/07/2016			

	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 4	Comment	Comment	Comment
26/07/2016			Slightly Darker

	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 8	Comment	Comment	Comment
23/08/2016	Distinctive henna	Smell gone, more of a	perfum smell

	Appearance, Colour, Odour	Appearance, Colour, Odour	Appearance, Colour, Odour
Week 12	Comment	Comment	Comment
20/09/2016		Same as week 8	



Provisional Specification		Viscometer	Brookfield
Viscosity:	n/a	Settings	T Bar:
pH:	4.7		Spindle:
S.G	n/a		Speed:
			Time:

20 Sample	20°C	Viscosity	pH
Initial			
Week 1	05/07/2016	n/a	4.7
Week 2	12/07/2016	n/a	4.5
Week 3	19/07/2016	n/a	4.3
Week 4	26/07/2016	n/a	4.3
Week 8	23/08/2016	n/a	4.2
Week 12	20/09/2016	n/a	4.1

Result	Pass ✓	Fail
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Chemist: J. DEAN
 Signature: *J. Dean*
 Date: 20th September, 2016

Comments: