adsl
your product inside out

Cosmetic Product Safety Report

Generic of Olympea by Paco Rabanne
Fine Fragrance Collection Ltd.
56289
Passed

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

UKAS TESTING 9064
ISO 9001

Product name	Generic of Olympea by Paco Rabanne
Product Code	MC587 FFCL-38-MCP
Company (Customer) Name	Fine Fragrance Collection Ltd.
Company (Customer) Address	1st Floor, 124 Cleveland Street, London, W1T 6PH, United Kingdom
Company (Customer) Phone	-
Company (Customer) Fax	-
Company (Customer) Responsible Contact	Head Office
Other Contact Details	
ADSL Reference	56289
CPSR Passed Date	21-07-2024 11:32:25

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: 21-07-2024 11:32:25

PART A

Quantitative & Qualitative Composition of the Cosmetic Product

INCI	Chemical name	CAS	EINECS	Concentration in Formulation % (w/w)
ALCOHOL DENAT.	Ethanol plus denaturant/s	N/A	N/A	72.000000%
Function	ANTIFOAMING ANTIMICROBIAL ASTRINGENT MASKING SOLVENT VISCOSITY CONTROLLING			
EU 2013 Regs	Not Controlled			
Global Regs				
PARFUM	-	-	-	28.000000%
Function	FRAGRANCE			
EU 2013 Regs	-			
Global Regs				

Fragrance / Parfum Information

Allergen	% Percent in fragrance	% frag in product	% allergen in product	Declare for Rinse-off	Declare for leave-on
ALPHA-ISOMETHYL IONONE	0.315000%	28.000000%	0.088200%	Yes	Yes
ANISE ALCOHOL	0.002000%	28.000000%	0.000560%	No	No
Benzyl Alcohol	0.014000%	28.000000%	0.003920%	No	Yes
BENZYL BENZOATE	0.003000%	28.000000%	0.000840%	No	No
BENZYL SALICYLATE	3.486000%	28.000000%	0.976080%	Yes	Yes
CINNAMAL	0.005000%	28.000000%	0.001400%	No	Yes
CINNAMYL ALCOHOL	0.495000%	28.000000%	0.138600%	Yes	Yes
Citral	0.006000%	28.000000%	0.001680%	No	Yes
CITRONELLOL	1.554000%	28.000000%	0.435120%	Yes	Yes

Allergen	% Percent in fragrance	% frag in product	% allergen in product	Declare for Rinse-off	Declare for leave-on
COUMARIN	0.699000%	28.000000%	0.195720%	Yes	Yes
FARNESOL	0.001000%	28.000000%	0.000280%	No	No
GERANIOL	0.149000%	28.000000%	0.041720%	Yes	Yes
LIMONENE	1.395000%	28.000000%	0.390600%	Yes	Yes
LINALOOL	1.205000%	28.000000%	0.337400%	Yes	Yes

Physical/Chemical Characteristics & Stability of the Cosmetic Product

Physical Description of the Product Liquid

Aroma AS STANDARD

Colour AS STANDARD

Taste N/A

pH of Product N/A

Viscosity N/A

Specific Gravity 0.833 - 0.853g/ml

Stability The product has passed a 4 week stability test. Test report attached.

INCI	Physical Description	Chemical Description
ALCOHOL DENAT.	Colourless liquid with a characteristic odour.	Molecular formula: C2H6O Molar mass: 46.07 g mol−1 Density: 0.789 g/cm3 Melting point: −114 °C, 159 K, -173 °F Boiling point: 78.37 °C, 352 K, 173 °F log P: -0.18 includes denaturant such as methanol, isopropyl alcohol, acetone, methyl ethyl ketone, methyl isobutyl ketone, and denatonium.
PARFUM	-	-

Microbiological Quality

Preservative Efficacy This product is hydroalcoholic and inherently hostile to the growth of micro-organisms. Microbial challenge testing is not required.

Plate Count

Impurities, Traces & Packaging

Description of the Packaging & Suitability for Use All materials are suitable for the application and comply with Cosmetic Regulations 1223/2009.

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

Normal & Reasonably Foreseeable Use

Description of Intended Application & Directions for Use EDP - to be applied to the wrists and neck.

Exposure to the Cosmetic Product

Site of Application Wrist & Neck
Surface Area of Application (cm2) 200
Amount Applied (g) per day 0.72g
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) 12.0

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
ALCOHOL DENAT.	12.0	72.0%	100.0%	8.640000
PARFUM	12.0	28.0%	100.0%	3.360000

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 Sensitizer	Photo Sensitizer
ALCOHOL DENAT.	Moderate	No	No	No
PARFUM	-	-	-	-

Margin of Safety and Comments

INCI	Margin of Safety (MOS)	NOAEL	SED
ALCOHOL DENAT.	278	2400	8.640000
PARFUM	No data	No Data	3.360000

General Safety Comments

INCI	General Safety Comments	Data Reference
ALCOHOL DENAT.	Alcohol, also called ethanol or ethyl alcohol, is formed by the fermentation of sugars or can be synthetically produced. It is a 2-carbon alcohol. Alcohol denat. is alcohol which has been made unpotable by a variety of substances. It is used in cosmetics and personal care products primarily to conform to import, tax, and duty requirements. Alcohol is readily absorbed by the oral and inhalation routes and subsequently, metabolized and excreted in humans. At exposures relevant to consumer exposure during use of alcohol containing products, the alcohol dehydrogenase metabolic route in the liver dominates and does not become saturated. Alcohol is not accumulated in the body. Dermal uptake of alcohol is very low. Alcohol has a low order of acute toxicity by all routes of exposure. Alcohol is widely used in topical applications and adverse effects are seldom reported. The Cosmetic Ingredient Review Expert Panel investigated a variety of the most frequently used denaturants. They determined that at the low concentrations at which they were present Alcohol Denat. denatured with t-Butyl Alcohol, Diethyl Phthalate, Methyl Alcohol, Salicylic Acid, Sodium Salicylate, and Methyl Salicylate is safe as used in cosmetic formulations with no qualifications. The available data, however, were not sufficient to support the safety of Quassin, Brucine, and Brucine Sulfate, Alcohol Denat. denatured with those denaturants, or SD Alcohol 39 and SD Alcohol 40. It is considered safe at its current use and concentration.	"Safety evaluation of topical applications of ethanol on the skin and inside the oral cavity", Dirk W Lachenmeier , Journal of Occupational Medicine and Toxicology 2008, 3:26 doi:10.1186/1745-6673-3-26 "OECD SIDS ETHANOL", SIDS Initial Assessment Report For SIAM 19, Berlin, Germany, 19 – 22 October 2004 "Final report of the safety assessment of Alcohol Denat., including SD Alcohol 3-A, SD Alcohol 30, SD Alcohol 39, SD Alcohol 39-B, SD Alcohol 39-C, SD Alcohol 40, SD Alcohol 40-B, and SD Alcohol 40-C, and the denaturants, Quassin, Brucine Sulfate/Brucine, and Denatonium Benzoate.", Cosmetic Ingredient Review Expert Panel, Int J Toxicol. 2008;27 Suppl 1:1-43. Absorption of Alcohol Hand Disinfectants, Prof. Axel Kramer, Institute of Hygiene and Environmental Medicine, University Hospital, Greifswald, Germany ECHA dossier for Ethanol
PARFUM	The safety of perfumes and fragrances is assessed via a valid IFRA Certificate	-

Undesirable Effects & Serious Undesirable Effects

None reported.

Information on the Cosmetic Product

The product has been assessed and found to be compliant with the relevant regulations and standards required by:

EUROPEAN UNION: Regulation 1223/2009

UNITED KINGDOM: Regulation (EC) No 1223/2009 on Cosmetic Products, as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

PART B

Assessment conclusion

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

None

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"
	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 though 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.

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.

Career History

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.

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.

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

Date: 21-07-2024 11:32:25

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.

JARVIS
COSMETIC DEVELOPMENTS

Stability Report

Customer name:	Fine Fragrances	Test Reference (CT):	3585
Product name:	Generic of Olympea by Paco Rabanne	MC number:	587
Start date:	01 May 2024	Project number:	FFCL-38-MCP
Completion Date:	29 May 2024		
Microbiology:	N/A		

Additional Information:
Keep RT for Retain

Sample Distribution

	RT	*F4°C*	*35°C*	*45°C*	*Cycle*	*UV*
100ml glass jar	1	1	1	1	1	1
30ml glass jar						

KEY:

0 = No change
1 = Minor change
2 = Noticeable change
3 = Major change

R = More red
D = Darker
Y = Yellowed
P = Paler
G = More grey
B = More blue

T = Loss of top note
C = Base odour
M = Off odour
S = Separation/Creaming
A = Separation/Seepage
E = Blooming
F = Clarity/Clouding
H = Sedimentation/Precipitation

Test Conclusion			
Result:	Passed	JCD Signed:	Karis Cullum
At week 4 there was some faint yellowing and loss of top note in the 45°C sample and slight paling of the UV sample.			
Date:		Client Signed:	

Fine Fragrances

Generic of Olympea by Paco Rabanne

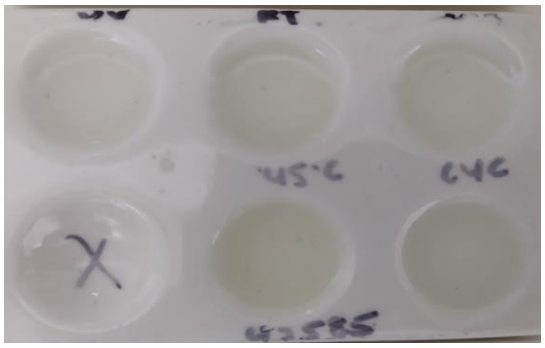
MC587
CT3585

Initial Readings		
	Appearance	Liquid
	Colour	Clear to Slightly Hazy
	Odour	Generic of Olympea by Paco Rabanne
	Temperature	22.6°C
	SG	0.843

Sample	Test	4 Weeks	Notes
		29/05/24	
RT	Appearance	0	
	Colour	0	
	Odour	0	
	Temperature	18.9°C	
4°C	Appearance	0	
	Colour	0	
	Odour	0	
	Temperature	18.8°C	
45°C	Appearance	0	
	Colour	0-Y1	
	Odour	0-T1	
	Temperature	18.8°C	
Cycle	Appearance	0	
	Colour	0	
	Odour	0	
	Temperature	18.8°C	
UV	Appearance	0	
	Colour	0-P1	
	Odour	0	

Initial

4 Weeks after oven.



4 Weeks