

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021
Information on the product (P.I.F.)			
Containing the report on the safety (part A and part B)			

PRODUCT INFORMATION FILE AND SAFETY REPORT

REGULATION (CE) n.1223/09 OF THE EUROPEAN PARLIAMENT AND 30/11/09 COUNCIL ABOUT COSMETIC PRODUCTS, RELATED TO ARTICLES 10 AND 11.

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Introduction			

THE REGULATION (CE) n. 1223/2009 OF THE EUROPEAN PARLIAMENT AND COUNCIL OF 30/11/09 ABOUT COSMETIC PRODUCT ESTABLISHES THE RULES THAT EACH COMMERCIALIZED COSMETIC PRODUCT MUST RESPECT, IN ORDER TO GUARANTEE THE CORRECT OPERATIONS OF INTERNAL MARKET AND AN HIGH LEVEL OF HUMAN HEALTH SAFEGUARD.

THE RESPONSIBLE PERSON GUARANTEES THAT FOR EACH LAUNCHED COSMETIC PRODUCT HAS BEEN DRAWN UP A SAFETY REPORT AND A PRODUCT INFORMATION FILE.

THE COSMETIC PRODUCT SAFETY REPORT HAS TO BE UPDATED TAKING INTO ACCOUNT ALL THE ADDITIONAL INFORMATIONS AVAILABLE AFTER THE COMMERCIALIZATION.]

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Cosmetic product description			
Ref. art. 11/a			

THIS DOCUMENT ASSESSES THE COSMETIC PRODUCT LAUNCHED WITH THE NAME "FANM EAU DE PARFUM", OF THE COMPANY ISLAND SCENT PTY LTD.
 THE PRODUCT HAS BEEN DEVELOPED BY ISLAND SCENT PTY LTD THAT IS THE RESPONSIBLE PERSON, ACCORDING TO ART.4 REGULATION 1223/09.
 THIS FILE SATISFIES ART.10 AND 11 OF REGULATION 1223/09: IT MUST BE DRAWN UP A SAFETY REPORT, TAKING INTO CONSIDERATION THE ORIGIN OF THE FORMULATION, THE INGREDIENTS, THE PACKAGING, THE INTENDED USE, THROUGH A QUALIFIED AND SKILLED SECURITY ASSESSOR.
 THE DRAFT TO FOLLOW IN ORDER TO DRAW UP THIS FILE IS CONTAINED IN ATTACHMENT I OF REGULATION 1223/09.
 THE COMPANY COCODEMERCOSMETICS ISLAND SCENT PTY LTD , ENSURED THE CORRECT APPLICATION OF QUALITY SYSTEM ISO22716, RECOMMENDED IN THE COSMETIC INDUSTRY.

RESPONSIBLE PERSON FOR EUROPE IS KOSMELAB SRL SU.

Product Name : **FANM EAU DE PARFUM**

Cosmetic Category : **422** [Profumo alcolico]

Product Id : **SEY002**

Responsible person

Name : **KOSMELAB SRL**

Address : **VIA EINSTEIN, 27**

Zip : **20832**

City : **[DESIO]**

Dossier location

Name : **KOSMELAB SRL**

Address : **via Einstein, 27**

Zip : **20832**

City : **[DESIO]**

CPNP Registration N. : **3631860**

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Qualitative and quantitative composition	
Report on the safety of cosmetic products	
Ref. art. 11/b-section 1 part A-Information on the safety of cosmetic products	

THE QUALITATIVE AND QUANTITATIVE COMPOSITION INCLUDES: CHEMICAL NAME, INCI, CAS, EINECS, ELINCS AND FUNCTIONS.
 IN CASE OF FRAGRANCES: NAME, COMPOSITION CODE AND SUPPLIER'S IDENTITY.
 THIS FORMULATION IS A SIMPLE HYDROALCOHOLIC SYSTEM (PARFUM).

Step	Ingredients	Spcf	Function	%	INCI Name	CAS number	Einecs/Elincs
10	[FRAGRANZA FLEUR]	1		12,0000000	BENZYL ALCOHOL	100-51-6	202-859-9
					BENZYL BENZOATE	120-51-4	204-402-9
					BENZYL SALICYLATE	118-58-1	204-262-9
					CITRAL	5392-40-5	226-394-6
					COUMARIN	91-64-5	202-086-7
					EUGENOL	97-53-0	202-589-1
					FARNESOL	4602-84-0	225-004-1
					GERANIOL	106-24-1	203-377-1
					HYDROXYCITRONELLAL	107-75-5	203-518-7
					LIMONENE	138-86-3	205-341-0/931-8 93-3
					LINALOOL	78-70-6	201-134-4
			FRAGRANCE		PARFUM		
10	[ALCOOL BUONGUSTO]	4	SOLVENT	84,5000000	ALCOHOL	64-17-5	200-578-6
10	[COCO DE MER]	1	PLANT DERIVATIVE	0,5000000	LODOICEA MALDIVICA EXTRACT		
			SOLVENT		ALCOHOL	64-17-5	200-578-6
10	WATER	1	SOLVENT	3,0000000	AQUA	7732-18-5	231-791-2

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Physical/chemical characteristics and stability	
Report on the safety of cosmetic products	
Ref. art. 11/b-part 2-section Information on the safety of cosmetic products	

CHEMICAL, PHYSICAL AND MICROBIOLOGICAL STABILITY EXECUTED AT ISLAND SCENT PTY LTD, PROTOCOLS AVAILABLE.

THE FIRST PACKAGING, THAT GETS IN CONTACT DIRECTLY WITH THE FINISHED PRODUCT IS COMPLETELY CONSISTENT WITH THE CURRENT REGULATION ABOUT CONTAINERS FOR COSMETIC USE.

THE ASSESSMENT OF POSSIBLE INTERACTIONS BETWEEN THE PRODUCT AND ITS PACKAGING OCCURS THROUGH THE FOLLOWING TESTS:

- FRAGILITY AND WEAKNESS
- FISSURES
- DEFORMATIONS
- DAMAGES
- COLOUR VARIATIONS AND TRANSPARENCY LOSS
- PERMEABILITY VARIATIONS
- SEAL LOSS
- SUPPLY PROBLEMS
- LABEL FADING
- COLOURANT TRANSFER FROM PRODUCT TO PACKAGE

IT HAS NOT BEEN OBSERVED ANY ANOMALY AND THE PACKAGING RESULTED SUITABLE. SEE ALSO ATTACHED CERTIFICATES.

IN ORDER TO DETERMINE THE PAO (PERIOD AFTER OPENING) IT HAS BEEN CONSIDERED THE CHEMICAL AND PHYSICAL STABILITY, SUSCEPTIBILITY TO MICROBIAL CONTAMINATION AND THE COMPATIBILITY WITH PRIMARY CONTAINER.

THIS PRODUCT IS CLASSIFIED AS LEAVE ON PRODUCT AND THE RECOMMENDED PAO IS 36 MONTHS.

MP231 - [ALCOOL BUONGUSTO]

Technical Parameters	Expected values	M.U.	Method	Notes
TECHNICAL PARAMETERS	[Vedi TDS Fornitore]			

INCI Name	PCPC	CAS number	Einecs num.	Range
Notes				
ALCOHOL	ALCOHOL	64-17-5	200-578-6	

MPSEY001 - [COCO DE MER]

Technical Parameters	Expected values	M.U.	Method	Notes
TECHNICAL PARAMETERS	See supplier TDS			

INCI Name	PCPC	CAS number	Einecs num.	Range
Notes				
LODOICEA MALDIVICA EXTRACT	LODOICEA MALDIVICA EXTRACT			
ALCOHOL	ALCOHOL	64-17-5	200-578-6	

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Physical/chemical characteristics and stability				
Report on the safety of cosmetic products				
Ref. art. 11/b-part 2-section Information on the safety of cosmetic products				

MPSEY003 - [FRAGRANZA FLEUR]

Technical Parameters	Expected values	M.U.	Method	Notes
TECHNICAL PARAMETERS	See supplier TDS			

INCI Name	PCPC	CAS number	Einecs num.	Range
Notes				
BENZYL ALCOHOL	BENZYL ALCOHOL	100-51-6	202-859-9	
BENZYL BENZOATE	BENZYL BENZOATE	120-51-4	204-402-9	
BENZYL SALICYLATE	BENZYL SALICYLATE	118-58-1	204-262-9	
CITRAL	CITRAL	5392-40-5	226-394-6	
COUMARIN	COUMARIN	91-64-5	202-086-7	
EUGENOL	EUGENOL	97-53-0	202-589-1	
FARNESOL	FARNESOL	4602-84-0	225-004-1	
GERANIOL	GERANIOL	106-24-1	203-377-1	
HYDROXYCITRONELLAL	HYDROXYCITRONELLAL	107-75-5	203-518-7	
LIMONENE	LIMONENE	138-86-3	205-341-0/931-893-3	
LINALOOL	LINALOOL	78-70-6	201-134-4	
PARFUM	FRAGRANCE			

SEY002 - FANM EAU DE PARFUM

Technical Parameters	Expected values	M.U.	Method	Notes
APPAREANCE	Liquid			
COLOUR	Transparent-yellow			
[Odore/gusto]	Characteristic			
pH (pHmeter)	N.A.			
VISCOSITY	NA			
PAO (PERIOD AFTER OPENING)	36 months			
ALCOHOLIC GRADE	80,0000 - 85,0000			

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles

Product N. SEY002 **FANM EAU DE PARFUM**

Edition N. 4 **Status** Validated
Emission Date 20/01/2021 **Validation Date** 16/03/2021

Physical/chemical characteristics and stability

Report on the safety of cosmetic products

Ref. art. 11/b-part 2-section Information on the safety of cosmetic products

TA001 - WATER

Technical Parameters	Expected values	M.U.	Method	Notes
TECHNICAL PARAMETERS	No Data sheet			

INCI Name	PCPC	CAS number	Einecs num.	Range
Notes				
AQUA	WATER	7732-18-5	231-791-2	

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Microbiological quality	
Report on the safety of cosmetic products	
Ref. art. 11/b-section 3 part A-Information on the safety of cosmetic products	

THE PRODCUT IS HYDROALCOHOLIC AND THEREFORE UNFAVOURABLE TO MICROBIAL GROWTH.

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Product N. SEY002		FANM EAU DE PARFUM	
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Impurities, tracks, information on packing material			
Report on the safety of cosmetic products			
Ref. art. 11/b-section 4 part A-Information on the safety of cosmetic products			

IMPURITIES AND EXPOSURES TO THE PRODUCT COMPOSITION HAVE BEEN EVALUATED UNIMPORTANT.
THE PRODUCT DOES NOT CONTAIN SUBSTANCES CONSIDERED NANOMATERIALS OR CMR.

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Product N. SEY002		FANM EAU DE PARFUM	
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Normal and reasonably foreseeable use			
Report on the safety of cosmetic products			
Ref. art. 11/b-section 5 part A-Information on the safety of cosmetic products			

THIS PRODUCT IS CLASSIFIED AS: EAU DE PARFUM
IT IS A REFERENCE TO BE USED TO PERFUME BODY.

PRODUCT APPEARENCE DOES NOT INDUCE TO IMPROPER USE.
RECOMMENDED USE: ONCE A DAY

EACH HYPOTESIS OF EXPOSURE, DISCUSSED BY COSMETIC EUROPE AND APPROVED BY SCCS MIGHT BE
MODIFIED TO DETERMINE DIFFERENT SED DATA IF REQUESTED AND IF IT DOESN'T ENTAIL IMPROPER USE.

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Cosmetic product exposure	
Report on the safety of cosmetic products	
Ref. art. 11/b-section 6 part A-Information on the safety of cosmetic products	

EXSPOSURE TO PRODUCT:

LOCATION: BODY
PRODUCT QUANTITY APPLICABLE: ABOUT 1 g
DURATION AND FREQUENCY: SEE ABOVE
EXSPOSURE WAYS: SKIN (RETENTION 10%)
TARGET: ADULTS
SECONDARY EXSPOSURE: NONE

SED calc. type	QTA		Amount of product applied			
Toxicity Type	7		NO (A) EL			
Cosmetic Category	[Profumo alcolico]					
Application qty.	1					
Application N.	2,0000					
Frequency	[2 volte / giorno]					
% Ritenzione	10					
Body weigth Kg	60	B.W. Kg 70	B.W. Kg 50	B.W. Kg 10	B.W. Kg 0	B.W. Kg 0

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Exposure to substances			
Report on the safety of cosmetic products			
Ref. art. 11/b-section 7 part A-Information on the safety of cosmetic products			

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Exposure to substances	
Report on the safety of cosmetic products	
Ref. art. 11/b-section 7 part A-Information on the safety of cosmetic products	

MOS							
Ingredient	Qty %	Toxicity Val.	60 Kg	70 Kg	50 Kg	10 Kg	
[ALCOOL BUONGUSTO]	84,5000						
[FRAGRANZA FLEUR]	12,0000						
WATER	3,0000						
[COCO DE MER]	0,5000						

The MoS (margin of Safety) is applied in the definition of the evaluation of the risk in the use of a cosmetic ingredient in a cosmetic formulation. The Mos of a substance can be calculated by dividing the lowest NO (A) EL for his SED. For the calculations used refers to "THE SCCP'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION - X REVISION".(*)

(*)a POD value is identified which represents, in the calculation of the MOS, the reference BDML, NOAEL or LOAEL selected by the evaluator.

It is necessary to remember that this type of assessment provides reliable data only if it is available the value of NO (A) EL ("not Observed (Adverse) Effect Level").

In case it is not available the NO (A) EL, and the safety assessor decide to use a different toxicological data, the result obtained must be considered as a simple support provided to the safety assessment.

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Exposure to substances
Report on the safety of cosmetic products
Ref. art. 11/b-section 7 part A-Information on the safety of cosmetic products

MOS Inci

Inci Name	ALCOHOL						Qty %	84,9250
60 Kg	70,651	70 Kg 82,426	50 Kg 58,875	10 Kg 11,775				
Inci Name	PARFUM						Qty %	10,7118
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	AQUA						Qty %	3,0000
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	BENZYL SALICYLATE						Qty %	0,6109
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	HYDROXYCITRONELLAL						Qty %	0,5509
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	LIMONENE						Qty %	0,0881
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	LODOICEA MALDIVICA EXTRACT						Qty %	0,0750
60 Kg	80.000,000	70 Kg 93.333,209	50 Kg 66.666,667	10 Kg 13.333,333				
Inci Name	COUMARIN						Qty %	0,0218
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	LINALOOL						Qty %	0,0116
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	BENZYL BENZOATE						Qty %	0,0016
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	BENZYL ALCOHOL						Qty %	0,0013
60 Kg	12.500.000,0	70 Kg 14.584.990,7	50 Kg 10.416.666,6	10 Kg 2.083.333,33				
Inci Name	GERANIOL						Qty %	0,0012
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	EUGENOL						Qty %	0,0004
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	CITRAL						Qty %	0,0002
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	FARNESOL						Qty %	0,0001
60 Kg	125.000.000	70 Kg 145.772.594	50 Kg 104.166.666	10 Kg 20.833.333,3				

The MoS (margin of Safety) is applied in the definition of the evaluation of the risk in the use of a cosmetic ingredient in a cosmetic formulation. The Mos of a substance can be calculated by dividing the lowest NO (A) EL for his SED. For the calculations used refers to "THE SCCP's NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION-X REVISION".(*)

(*)a POD value is identified which represents in the calculation of the MOS the reference BDML, NOAEL or LOAEL selected by the evaluator.

It is necessary to remember that this type of assessment provides reliable data only if it is available the value of NO (A) EL ("not Observed (Adverse) Effect Level").

In case it is not available the NO (A) EL, and the safety assessor decide to use a different toxicological data, the result obtained must be considered as a simple support provided to the safety assessment. To define an ingredient safety it is necessary that MOS calculation is major than 100.

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Exposure to substances
Report on the safety of cosmetic products
Ref. art. 11/b-section 7 part A-Information on the safety of cosmetic products

SED						
Ingredient	Qty %	60 Kg	70 Kg	50 Kg	10 Kg	
[ALCOOL BUONGUSTO]	84,5000	2,817	2,414	3,380	16,900	
[FRAGRANZA FLEUR]	12,0000	0,400	0,343	0,480	2,400	
WATER	3,0000	0,100	0,086	0,120	0,600	
[COCO DE MER]	0,5000	0,017	0,014	0,020	0,100	

The SED ("Systemic Exposure Dosage") represents the expected value of absorption per Kg of body weight, calculated on the basis of the cosmetics category selected in the dossier header. Linked data are: g/application; frequency/n° applications; % absorption/retention.

For the calculations used refers to "THE SCCP's NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION-X REVISION", compared to the amount of daily use, according to Colipa, for the calculation of the SED.

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Exposure to substances
Report on the safety of cosmetic products
Ref. art. 11/b-section 7 part A-Information on the safety of cosmetic products

SED Inci

Inci Name	ALCOHOL						Qty %	84,9250
60 Kg	2,83083333	70 Kg	2,42642857	50 Kg	3,39700000	10 Kg	16,98500000	
Inci Name	PARFUM						Qty %	10,7118
60 Kg	0,35706000	70 Kg	0,30605143	50 Kg	0,42847200	10 Kg	2,14236000	
Inci Name	AQUA						Qty %	3,0000
60 Kg	0,10000000	70 Kg	0,08571429	50 Kg	0,12000000	10 Kg	0,60000000	
Inci Name	BENZYL SALICYLATE						Qty %	0,6109
60 Kg	0,02036400	70 Kg	0,01745486	50 Kg	0,02443680	10 Kg	0,12218400	
Inci Name	HYDROXYCITRONELLAL						Qty %	0,5509
60 Kg	0,01836400	70 Kg	0,01574057	50 Kg	0,02203680	10 Kg	0,11018400	
Inci Name	LIMONENE						Qty %	0,0881
60 Kg	0,00293600	70 Kg	0,00251657	50 Kg	0,00352320	10 Kg	0,01761600	
Inci Name	LODOICEA MALDIVICA EXTRACT						Qty %	0,0750
60 Kg	0,00250000	70 Kg	0,00214286	50 Kg	0,00300000	10 Kg	0,01500000	
Inci Name	COUMARIN						Qty %	0,0218
60 Kg	0,00072800	70 Kg	0,00062400	50 Kg	0,00087360	10 Kg	0,00436800	
Inci Name	LINALOOL						Qty %	0,0116
60 Kg	0,00038800	70 Kg	0,00033257	50 Kg	0,00046560	10 Kg	0,00232800	
Inci Name	BENZYL BENZOATE						Qty %	0,0016
60 Kg	0,00005200	70 Kg	0,00004457	50 Kg	0,00006240	10 Kg	0,00031200	
Inci Name	BENZYL ALCOHOL						Qty %	0,0013
60 Kg	0,00004400	70 Kg	0,00003771	50 Kg	0,00005280	10 Kg	0,00026400	
Inci Name	GERANIOL						Qty %	0,0012
60 Kg	0,00004000	70 Kg	0,00003429	50 Kg	0,00004800	10 Kg	0,00024000	
Inci Name	EUGENOL						Qty %	0,0004
60 Kg	0,00001200	70 Kg	0,00001029	50 Kg	0,00001440	10 Kg	0,00007200	
Inci Name	CITRAL						Qty %	0,0002
60 Kg	0,00000800	70 Kg	0,00000686	50 Kg	0,00000960	10 Kg	0,00004800	
Inci Name	FARNESOL						Qty %	0,0001
60 Kg	0,00000400	70 Kg	0,00000343	50 Kg	0,00000480	10 Kg	0,00002400	

The SED ("Systemic Exposure Dosage") represents the expected value of absorption per Kg of body weight, calculated on the basis of the cosmetics category selected in the dossier header. Linked data are: g/application; frequency/n° applications; % absorption/retention.

For the calculations used refers to "THE SCCP's NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION-X REVISION", compared to the amount of daily use, according to Colipa, for the calculation of the SED.

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Toxicological profile of substances					
Report on the safety of cosmetic products					
Ref. art. 11/b-section 8 part A-Information on the safety of cosmetic products					

ACCORDING TO CHAPTER V ART.18 ANIMAL TESTING OF REGULATION 1223/09 FOR THE EVALUATION TO CUTANEOUS SENSIBILITY AND OCULAR IRRITATION, IT HAS BEEN CONSIDERATED THAT:

ALL THE SUBSTANCES PRESENT IN THIS PRODUCT ARE RAW MATERIALS OF CONSOLIDATED USE IN COSMETIC INDUSTRY AND PHARMACOPOEIA.
SUBSTANCES INCLUDED IN ATTACHEMNET V ARE CONTAINED IN THE FORMULATION IN QUANTITIES COMPLIANT WITH THE REGULATION REG.1223/09.

THE ALLERGENIC SUBSTANCES CONTAINED IN THE FRAGRANCE FLEUR, PRODUCED BY DIADEMA COSMETICI, ARE STATED ON THE LABEL.
THE SAFETY IS GUARANTEED BY IFRA CERTIFICATE, IN LINE WITH 48th AMENDAMENT.
ALL RAW MATERIALS HAVE BEEN CHOSEN ACCORDING TO TECHNICAL AND SAFETY DATA SHEETS.
DENATURATION OF ALCOHOL IS COMPLIANT FOR COSMETIC USE (SEE SUPPLIER DATA SHEET ATTACHED)
ALL THE PRODUCTION PROCESSES OF THE FINISHED PRODUCT HAVE BEEN SUPERVISED IN ORDER TO AVOID ANY EXTERNAL CONTAMINATION.
STERILISED STEEL CONTAINERS AND PURIFIED WATER ARE INVOLVED FOLLOWING THE FABRICATION, PACKAGING AND TECHNICAL SHEETS.
FORMULA INGREDIENTS ARE NOT SUPPOSED TO CAUSE IRRITATIONS OR INTOLERANCES.
IT DOES NOT CONTAIN SUBSTANCES CLASSIFIED AS CMR 1A OR CMR 1B.
IT DOES NOT CONTAIN SUBSTANCES CLASSIFIED AS NANOMATERIALS, ACCORDING TO THE DEFINITION OF REGULATION 1223/09 (SEE ATTACHED CERTIFICATES).

INFORMATION SOURCE:
RAW MATERIALS SUPPLIER DATA
TOXICOLOGICAL DATA PRESENT IN DATABASE.
DATA COMING FROM PRODUCT POST-COMMERCIALISATION SAFEGUARD.

Components toxicological informations					
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MP231 - [ALCOOL BUONGUSTO]

Type of Toxicological Test	Value	Descr. Value	M.U.	Reference	Method
NO (A) EL	0,0000 [Vedi MSDS fornitore]				

MPSEY001 - [COCO DE MER]

Type of Toxicological Test	Value	Descr. Value	M.U.	Reference	Method
NO (A) EL	0,0000 See supplier MSDS				

MPSEY003 - [FRAGRANZA FLEUR]

Type of Toxicological Test	Value	Descr. Value	M.U.	Reference	Method
Notes					

Toxicological Protocols 0,0000 See supplier MSDS
Compliant with 48th IFRA amendment

INCI toxicological informations					
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Inci Name ALCOHOL

Function SOLVENT

Toxicity Type NO (A) EL [7_NO(A)EL]

Toxicity Val. 200

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles

Product N. SEY002

FANM EAU DE PARFUM

Edition N. 4

Status Validated

Emission Date 20/01/2021

Validation Date 16/03/2021

Toxicological profile of substances

Report on the safety of cosmetic products

Ref. art. 11/b-section 8 part A-Information on the safety of cosmetic products

Inci Name BENZYL ALCOHOL

Toxicity Type NO (A) EL [7_NO(A)EL]

Toxicity Val. 550

Inci Name FARNESOL

Toxicity Type NO (A) EL [7_NO(A)EL]

Toxicity Val. 500

Inci Name LODOICEA MALDIVICA EXTRACT

Function PLANT DERIVATIVE

Toxicity Type NO (A) EL [7_NO(A)EL (POD)]

Toxicity Val. 200

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021

Undesirable effects and serious unwanted effects	
Report on the safety of cosmetic products	
Ref. art. 11/b-section 9 part A-Information on the safety of cosmetic products	

NOWADAYS NO NEGATIVE EVENTS HAVE BEEN REGISTERED AFTER PRODUCT USE.
FOR POTENTIAL NEGATIVE EVENTS, THE RESPONSIBLE PERSON IS TRACKABLE ON THE LABEL.

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021

Conclusions of the evaluation	
Report on the safety of cosmetic products	
Ref. art. 11/b-part B section 1-safety evaluation of cosmetic product	

COSMETIC SAFETY REPORT RELATED TO ART.3 REG. 1223/09

“Comercialized cosmetic products are safe for human health if used in normal terms”

Name: FANM EAU DE PARFUM

Category: EAU DE PARFUM

Safety evaluation has been realized in accordance with (CE)_1223/09 Regulation, Attachment I.

On the base of available informations about healthcare effects and ingredients of the products, it is considered that the cosmetic is SAFE for the consumer during normal use.

The product does not contain ingredients of genetically modified organisms or animals derivation.

None ingredients have been classified as carcinogenic, mutagen or toxic for reproduction (CMR) of 1A, 1B and 2 of (CE)_1272/2008 Regulation.

The product has not been tested on laboratory animals.

Risks evaluation is based on specific physical-chemical, microbiological, toxicological features and ingredients of the product, taking into account the aim, terms, exposure, packaging, labelling and the probability to cause undesirable effects.

Safety evaluation data are available on request at ISLAND SCENT PTY LTD.

Amendments of this evaluation will be realized in case of changes in the product formulation and process, or in case of warning by consumers.

Scientific motivations are referred to chapters about: component quality, toxicology and previous experience of the undersigned, law terms about possible percentage use of preservative and restricted ingredients. Safety assessor considers the risk level of the product ACCEPTABLE.

Date: 20-01-2021

Sign: Dr. Milena Terenghi

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N. 4	Status Validated		
Emission Date 20/01/2021	Validation Date 16/03/2021		

Warnings and instructions shown on the label
Report on the safety of cosmetic products
Ref. art. 11/b-part B section 2-safety evaluation of cosmetic product

THE LABEL IS COMPLIANT AND DOES NOT NEED FURTHER USE INSTRUCTIONS (ART.19 1D REGULATION 1223/09).
 THE APPEARANCE OF THE PRODUCT DOES NOT INDUCE TO IMPROPER USE.
 THE PRODUCT IS NOT SPECIFICALLY FORMULATED FOR CHILDREN OR SENSITIVE ZONES. (MUCOSA ECC..)

DEFINITION COMPOSITION STANDARD LABEL

MANUFACTURER'S CERTIFICATE FUNCTION	CAS NUMBER	Range	% VAL
ALCOHOL SOLVENT	64-17-5	A	84,9256115
PARFUM (FRAGRANCE) FRAGRANCE		D	10,7118771
AQUA (WATER) SOLVENT	7732-18-5	F	3,0000216
BENZYL SALICYLATE	118-58-1	G	0,6109244
HYDROXYCITRONELLAL	107-75-5	G	0,5509240
LIMONENE	138-86-3	H	0,0880806
LODOICEA MALDIVICA EXTRACT PLANT DERIVATIVE		H	0,0750005
COUMARIN	91-64-5	H	0,0218402
LINALOOL	78-70-6	H	0,0116401
BENZYL BENZOATE	120-51-4		0,0015600
BENZYL ALCOHOL	100-51-6		0,0013200
GERANIOL	106-24-1		0,0012000

Range	Min Value	Max Value
A	75,00000	100,00000
A1N	0,00000	0,00000
A2N	0,00000	0,00000
B	50,00000	75,00000
BN	0,00000	0,00000
C	25,00000	50,00000
CN	0,00000	0,00000
D	10,00000	25,00000
DN	0,00000	0,00000
E	5,00000	10,00000
F	1,00000	5,00000
FN	0,00000	0,00000
G	0,10000	1,00000
H	0,01000	0,10000

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021
Motivation			
Report on the safety of cosmetic products			
Ref. art. 11/b-part B section 3-safety evaluation of cosmetic product			

IN ATTACHMENT REPORT "Estimation of acute oral toxicity using the No Observed Adverse Effect Level from the 28 day repeated dose toxicity studies in rats" AND " TOXICOLOGICAL EVALUATION OF A COSMETIC PRODUCT (COSMETICA ITALIA 2013).

DERMAL ABSORPTION: 10%.

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021

Information about the assessor and approval of part B	
Report on the safety of cosmetic products	
Ref. art. 11/b-part B section 4-safety evaluation of cosmetic product	

CURRICULUM VITAE MILENA TERENGHI
PHARMACIST-COSMETOLOGIST

REGISTERED TO PHARMACISTS ROSTER n° 8399 dal 13/07/1989
DATE AND PLACE OF BIRTH: 26/06/1963, Seregno (Mi), ITALY.
FISCAL CODE: TRNMLN63H66I625S
TELEPHON NUMBER: 3358299064 - 0362638439

EDUCATION

DEGREE ACHIEVED IN IIS Cesare Correnti, Milano nell'A.S. '81-82
GRADUATION IN PHARMACY, Università degli Studi di Milano, A.A. 1987.
GRADUATION THESIS: "Aspetti del metabolismo durante l'esercizio fisico"
SPECIALIST DEGREE IN COSMETIC TECHNOLOGY AND SCIENCES, Università di Ferrara, A.A. 2004-2005. FINAL GRADES: 30/30 CON LODE.
DEGREE THESIS: "Valutazione dell'efficacia preservante in preparati cosmetici di un nuovo composto"

Milena Terenghi

Safety assesor

Name : DOTT.SA MILENA TERENGHI
Address : VIA A.EINSTEIN 27
Zip : 20832
City : [DESIO]
Notes :

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021
Description of the manufacturing method			
in compliance with good manufacturing practices			
Ref. art. 11/c			

10 - PHASE 1 - (- Liv. 1)

- A) IN APPROPRIATE CONTAINER WEIGH 1 AND ADD 2 UNDER SLOW SHAKING UNTIL SOLUTION CLEAR
- B) ADD 3.4 UNDER SLOW SHAKING UNTIL CLEAR SOLUTION
- C) LEAVE TO MACERATE FOR ONE MONTH IN A FRESH ENVIRONMENT, DRY AND AWAY FROM LIGHT. FILTER AND PROCEED WITH INFLACONING

20 - PACKAGING PHASE - (- Liv. 1)

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021
Evidence of the effects attributed to the product			
Ref. art. 11/d			

THE PERFUMING IS DUE TO THE PRESENCE OF 12% OF FRAGRANCE.

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021
Data on the animal testing carried out			
Ref. art. 11/e			

[Devono essere raccolte le informazioni di cui le aziende cosmetiche sono in possesso o ci si può ragionevolmente aspettare che siano in grado di ottenere.]

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY002		FANM EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021

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