

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
Product N. SEY003		LODAS 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.

Company Info Island Scent Pty Ltd - Village Artisanal, Au Cap - AUCAP ND - Seychelles			
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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 "LODAS 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 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 : **LODAS EAU DE PARFUM**

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

Product Id : **SEY003**

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. : **3631865**

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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 FRESH]	1		12,0000000	CITRAL	5392-40-5	226-394-6
					CITRONELLOL	106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9	203-375-0 / 247-737-6 / 231-415-7 / 214-250-5
					FARNESOL	4602-84-0	225-004-1
					GERANIOL	106-24-1	203-377-1
					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				

MPSEY004 - [FRAGRANZA FRESH]

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

INCI Name	PCPC	CAS number	Einecs num.	Range
Notes				
CITRAL	CITRAL	5392-40-5	226-394-6	
CITRONELLOL	CITRONELLOL	106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9	203-375-0 / 247-737-6 / 231-415-7 / 214-250-5	
FARNESOL	FARNESOL	4602-84-0	225-004-1	
GERANIOL	GERANIOL	106-24-1	203-377-1	
LIMONENE	LIMONENE	138-86-3	205-341-0/931-893-3	
LINALOOL	LINALOOL	78-70-6	201-134-4	
PARFUM	FRAGRANCE			

SEY003 - LODAS EAU DE PARFUM

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

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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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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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 FRESH]	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 %	11,1521
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	AQUA						Qty %	3,0000
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	LIMONENE						Qty %	0,3778
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	LINALOOL						Qty %	0,2780
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	CITRONELLOL						Qty %	0,1511
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	CITRAL						Qty %	0,0369
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	GERANIOL						Qty %	0,0040
60 Kg		70 Kg	50 Kg	10 Kg				
Inci Name	FARNESOL						Qty %	0,0001
60 Kg	104.166.666,	70 Kg 121.654.501	50 Kg 86.805.555,5	10 Kg 17.361.111,1				

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 FRESH]	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 %	11,1521
60 Kg	0,37173524	70 Kg	0,31863021	50 Kg	0,44608229	10 Kg	2,23041144	
Inci Name	AQUA						Qty %	3,0000
60 Kg	0,10000000	70 Kg	0,08571429	50 Kg	0,12000000	10 Kg	0,60000000	
Inci Name	LIMONENE						Qty %	0,3778
60 Kg	0,01259200	70 Kg	0,01079314	50 Kg	0,01511040	10 Kg	0,07555200	
Inci Name	LINALOOL						Qty %	0,2780
60 Kg	0,00926716	70 Kg	0,00794328	50 Kg	0,01112059	10 Kg	0,05560296	
Inci Name	CITRONELLOL						Qty %	0,1511
60 Kg	0,00503760	70 Kg	0,00431794	50 Kg	0,00604512	10 Kg	0,03022560	
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	CITRAL						Qty %	0,0369
60 Kg	0,00122960	70 Kg	0,00105394	50 Kg	0,00147552	10 Kg	0,00737760	
Inci Name	GERANIOL						Qty %	0,0040
60 Kg	0,00013360	70 Kg	0,00011451	50 Kg	0,00016032	10 Kg	0,00080160	
Inci Name	FARNESOL						Qty %	0,0001
60 Kg	0,00000480	70 Kg	0,00000411	50 Kg	0,00000576	10 Kg	0,00002880	

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 FRESH, 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				

MPSEY004 - [FRAGRANZA FRESH]

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

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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

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

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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.

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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: LODAS 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. SEY003		LODAS 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	84,9251223
PARFUM (FRAGRANCE) FRAGRANCE		D	11,1520733
AQUA (WATER) SOLVENT	7732-18-5	F	3,0000043
LIMONENE	138-86-3	G	0,3777605
LINALOOL	78-70-6	G	0,2780152
CITRONELLOL	106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9	G	0,1511282
LODOICEA MALDIVICA EXTRACT PLANT DERIVATIVE		H	0,0750001
CITRAL	5392-40-5	H	0,0368881
GERANIOL	106-24-1		0,0040080

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. SEY003		LODAS 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. SEY003		LODAS 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
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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. SEY003		LODAS 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			

[Breve descrizione del metodo di fabbricazione, incluso il metodo di riempimento e stoccaggio del bulk.
Può contenere un riferimento incrociato a più dettagliate istruzioni relative ad uno specifico sito produttivo.
L'articolo 8 richiede l'osservanza delle GMP senza l'obbligo di certificazioni esterne.]

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. SEY003		LODAS 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. SEY003		LODAS 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. SEY003		LODAS EAU DE PARFUM	
Edition N.	4	Status	Validated
Emission Date	20/01/2021	Validation Date	16/03/2021

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