LASH CONTIONING SERUM XLASH

ALMEA LTD

1. COSMETIC PRODUCT DESCRIPTION

1.1. Product name

Lash conditioning serum Xlash

1.2. Reference

AP0658 (F03)

1.3. Brand name

Almea

1.4. Responsible person

Almea Ltd

2nd floor Queens house

180 Tottenham Court Road

London W1T 7PD

UNITED KINGDOM

1.5. Labelling

Annexe XI

1.6. Packaging

Primary packaging: plastic bottle of 3 and 6 ml and brush

Secondary packaging: cardboard box

1.7. Manufacturing and packaging site

Cosméprod

Avenue de Bruxelles, 83500 La Seyne-sur-Mer

2. COSMETIC PRODUCT SAFETY REPORT

PART A : INFORMATION

2.1. Qualitative and quantitative composition

#	INCI name	%	CAS number	Function	Ref. Annexe II.
1	Aqua	96,093000	7732-18-5	Solvent	0
2	Glycerin	1,111000	56-81-5	Denaturant	3
3	Hydroxyethylcellulose	0,550000	9004-62-0	Binding	43
4	Sodium chloride	0,500000	7647-14-5	Bulking	13
5	Alcohol	0,500000	64-17-5	Solvent	72
6	Panthenol	0,495000	81-13-0	Antistatic	159
7	Polyaminopropyl biguanide	0,300000	32289-58-0	Preservative	1960
8	Inositol	0,075000	87-89-8	Antistatic	483
9	Panthenyl ethyl ether	0,075000	667-83-4	Antistatic	983
10	Sodium hyaluronate	0,050000	9067-32-7	Skin conditioning	74
11	Caprylyl glycol	0,045000	1117-86-8	Emollient	179
12	1,2-Hexanediol	0,045000	6920-22-5	Solvent	930
13	Biotin	0,020000	58-85-5	Hair conditioning	803
14	Phenoxyethanol	0,012500	122-99-6	Preservative	17
15	Sodium citrate	0,012500	6132-34-3	Buffering	77
16	Acetyl cysteine	0,012500	616-91-1	Antioxydant	842
17	Acetyl methionine	0,012500	1115-47-5	Skin conditioning	1575
18	Lactis proteinum extract	0,012500	0	Skin conditioning	1961
19	Lactose	0,012500	63-42-3	Humectant	1962
20	Sodium benzoate	0,010000	532-32-1	Preservative	31
21	Polysorbate 20	0,010000	9005-64-5	Surfactant	170
22	Benzoic acid	0,010000	65-85-0	Preservative	347
23	Myristoyl pentapeptide-17	0,010000	0	Skin conditioning	931
24	Hippophae rhamnoides oil	0,009997	225234-03-7	Emollient	1963
25	Citric acid	0,007250	77-92-9	Buffering	27
26	Dehydroacetic acid	0,005000	520-45-6	Preservative	430
27	Diethyl phthalate	0,002250	84-66-2	Denaturant	953
28	Rhodiola rosea root extract	0,001500	0	Emollient	1368
29	Helianthus annuus seed oil	0,000002	8001-21-6	Emollient	244
30	Rosmarinus officinalis leaf extract	0,000001	84604-14-8	Antimicrobial	901

2.2. Physical/chemical characteristics and stability

2.2.1. Raw materials

#	Trade name	%	Annexe I.i	INCI
1	Eau osmosée	84,21	0	Aqua (100%)
2	904704 SymPeptide Xlash	10,00	437	Aqua (88,8%), Glycerin(10%), 1,2-Hexanediol (0,45%), Caprylyl glycol (0,45%), Myristoyl Pentapeptide-17 (0,1%), Sodium benzoate (0,1%), Benzoic acid (0,1%)
3	Follicusan DP	2,50	438	Aqua (70,62%), Alcohol (20%), Panthenyl ethyl ether (3%), Inositol (3%), Lactis proteinum extract (0,5%), Lactose (0,5%), Acetyl cysteine (0,5%), Acetyl methionine (0,5%), Phenoxyethanol (0,5%), Sodium citrate (0,5%), Dehydroacetic acid (0,2%), Citric acid (0,09%)
4	Cosmocil CQ	1,50	436	Aqua (80%), Polyaminopropyl biguanide (20%). Impurities : Arsenic (0,4ppm), Cadmium (1ppm), Chromium (10ppm), Iron (5ppm), Lead (10ppm), Mercury (1ppm), Zinc (100ppm).
5	Natrasol 250 HHR	0,55	435	Hydroxyethylcellulose (100%)
6	Sel raffiné séché alimentaire	0,50	10	Sodium chloride (100%). Impurities: Arsenic (1ppm), Cadmium (0,5ppm), Copper (2ppm), Lead (2ppm), Mercury (0,1ppm), Sulfates (600ppm).
7	D-Panthenol 75W	0,50	443	Panthenol (99%), Citric acid (1%). Impurities : Heavy metals (10 ppm)
8	Golden rose	0,15	441	Glycerin (74%), Aqua (25%), Rhodiola rosea root extract (1%)
9	Hysilk	0,05	152	Sodium hyaluronate (100%)
10	D-Biotin	0,02	439	Biotin (100%). Impurities : Heavy metals (10ppm), Lead (2ppm)
11	Berry oil (SHAJIO)	0,01	440	Hippophae rhamnoides oil (99,965%), Helianthus annuus seed oil (0,021875%), Rosmarinus officinalis leaf extract (0,013125%)
12	Tween 20	0,01	442	Polysorbate 20 (100%). Impurities : Ethylene oxide (1 ppm)

Annexe I.i.1 : MSDS

Annexe I.i.2 : TDS

i: raw material reference (table 2.2.1)

2.2.2. Finished product

Assessment of the Period After Opening (PAO): Annexe III.1 (only if durability > 30 months)

Stability test results: Annexe III.2

Finished product specifications: Annexe III.3

2.3. Microbiological quality

Challenge test: Annexe IV.1 Satisfactory, meets the relevant A-criteria

2.4. Impurities, traces, packaging material

Impurities: see raw material technical data sheet (Annexe I.i.2)

Primary packaging material: plastic

Packaging specifications: Annexe X

2.5. Normal and reasonably foreseeable use

Remove your make up and contact lenses, apply a thin line of serum to the base of the uper eyelashes. Apply serum once a day in the evening before going to bed. Try not to touch your eyes with the applicator.

2.6. Exposure to the cosmetic product

- Sites of application : eye contour
- Surface area of application : 3,2 cm^2
- Amount of product applied : 0,005 g
- Duration and frequency of use: 1 /day (leave-on)
- Primary exposure routes skin ; secondary exposure routes : eyes
- Targeted or exposed populations: Adults

2.7. Exposure to the substances

SED [mg/kg bw/day]: Systemic Exposure Dosage

A [g/day]: Amount of product applied daily

R: Retention factor

C [%]: Concentration of the ingredient in the finished product on the site of application

DAp [%]: Dermal Absorption

bw [kg]: average body weight

A = 0,005 g/day

R = 1,00

bw = 60 kg

Where data is missing, the maximum value of 100% is used for DAp.

#	INCI name	C [%]	DAp [%]	SED [mg/kg bw/day]
1	Aqua	96,0930	100,00	0,080077500
2	Glycerin	1,1110	7,34	0,000067956
3	Hydroxyethylcellulose	0,5500	100,00	0,000458333
4	Sodium chloride	0,5000	100,00	0,000416667
5	Alcohol	0,5000	21,00	0,000087500

#	INCI name	C [%]	DAp [%]	SED [mg/kg bw/day]
6	Panthenol	0,4950	100,00	0,000412500
7	Polyaminopropyl biguanide	0,3000	7,65	0,068046750
8	Inositol	0,0750	100,00	0,000062500
9	Panthenyl ethyl ether	0,0750	100,00	0,000062500
10	Sodium hyaluronate	0,0500	100,00	0,000041667
11	Caprylyl glycol	0,0450	100,00	0,000037500
12	1,2-Hexanediol	0,0450	80,00	0,000030000
13	Biotin	0,0200	100,00	0,000016667
14	Phenoxyethanol	0,0125	59,00	0,021866875
15	Sodium citrate	0,0125	100,00	0,000010417
16	Acetyl cysteine	0,0125	100,00	0,000010417
17	Acetyl methionine	0,0125	100,00	0,000010417
18	Lactis proteinum extract	0,0125	100,00	0,000010417
19	Lactose	0,0125	100,00	0,000010417
20	Sodium benzoate	0,0100	100,00	0,029650000
21	Polysorbate 20	0,0100	100,00	0,000008333
22	Benzoic acid	0,0100	100,00	0,029650000
23	Myristoyl pentapeptide-17	0,0100	100,00	0,000008333
24	Hippophae rhamnoides oil	0,0100	100,00	0,000008330
25	Citric acid	0,0073	100,00	0,000006042
26	Dehydroacetic acid	0,0050	100,00	0,014825000
27	Diethyl phthalate	0,0023	100,00	0,000001875
28	Rhodiola rosea root extract	0,0015	100,00	0,000001250
29	Helianthus annuus seed oil	0,0000	100,00	0,000000002
30	Rosmarinus officinalis leaf extract	0,0000	100,00	0,000000001

* For preservatives: A x R = 17,79 g/day is used (value given by the SCCNFP for the calculation of the MoS of preservatives, considering the worst case scenario where a consumer uses in the same day several cosmetic products containing the same preservative)

2.8. Toxicological profile of the substances

Annexe II.i.1 : MSDS

Annexe II.i.3 : Toxicological profil

i: Ingredient reference (table 2.1)

Interactions between substances: no known interactions between the substances of this product, no incompatibility between them according to the available data.

2.9. Undesirable effects and serious undesirable effects

None

2.10. Information on the cosmetic product

Safety tests on the finished product:

- Skin irritation (pure product): non irritating (primary irritation index 0) according to the patch test results on 11 volunteers.
- Results of the test performed in compliance with GLP standards: annexe V.1
- Eye irritation (pure product): practically non-irritating (index 0) according to the in-vitro HET-CAM test.
- Results of the test performed in compliance with GLP standards: annexe V.2

PART B : SAFETY ASSESSMENT

2.11. Assessment conclusion

As per article 10 of the regulation 1223/2009 and according to the information in part A, the finished product Xlash (formulation reference number AP0658 F03) is safe for human health when used under normal or reasonably foreseeable conditions of use, except for specific cases of sensibility. Therefore, it is compliant with the requirements of article 3 of the regulation 1223/2009 of 30 November 2009.

2.12. Labeled warnings and instructions of use

As per the data available on the product composition, labeled warnings and instructions of use are:

- Remove your make up and contact lenses, apply a thin line of serum to the base of the uper eyelashes. Apply serum once a day in the evening before going to bed. Try not to touch your eyes with the applicator.

Warnings to be labeled for substances listed in annexes III to VI of regulation 1223/2009: none

As per the data available on the product stability, labeled warnings and instructions of use are: none

2.13. Reasoning

Based on the results of the patch test on the finished product, there is no skin irritation under normal conditions of use.

The product is practically non-irritating to the eyes from the results of the HET-CAM test.

The table below shows the margin of safety (MoS) of ingredients. For an adult population, MoS ≥ 100 is considered acceptable (it is the same for babies when the product is applied to intact skin [SCCNFP/0557/02]). The margin of safety (MoS) of certain ingredients can't be assessed in the absence of their NOAEL value. In this case, the study of the safety of ingredients is based on the following elements:

- When an ingredient is listed in Annexes III to VI of Regulation (EC) 1223/2009, it can be considered safe when used under the conditions specified in those annexes [Colipa Guidelines for the Safety Assessment of a Cosmetic Product, Edition of 2004]. In particular, C max ≤ C for ingredients provided with an asterisk (*) in the table below.

- Regarding the other ingredients for which a value of C Max is available, they may be considered safe if C ≤ C Max.

- In the absence of MoS value or Cmax, an ingredient may be considered safe for cosmetic when its safety is recognized at higher doses in the food industry. [Commission implementing decision of 25 November 2013 on Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Official Journal of the European Union, 26/11/2013]. This is particularly the case when SED ≤ ADI or when the word OK appears in the ADI column, corresponding either to commonly eaten foods or for which safety is evident (honey, olive oil, etc.) or food additives whose toxicity is considered very low by JECFA.

- Finally, in the absence of other data, an ingredient can be considered safe when SED ≤ TTC [SCCS / SCHER / SCENIHR Opinion on Use of the Threshold of Toxicological Concern (TTC)

Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, SCCP / 1171 to 1108, 08/06/2012].

Reference sources for NOAEL values, C Max, TTC and ADI are mentioned in the Annexe II.i.3 – Profil toxicologique.

NOAEL [mg/kg bw/day]: No Oberved Adverse Effect Level

SED [mg/kg bw/day]: Systemic Exposure Dosage

MoS: Margin of Safety

C [%]: Concentration of the ingredient in the finished product on the application site

Cmax [%]: Maximum concentration of the ingredient in the finished product considered safe for human health under normal conditions of use. For ingredients with an asterisk (*), the specified value is the maximum allowed under Annexes III to VI of Regulation (EC) 1223/2009 concentration.

TTC [mg/kg bw/day]: Threshold of Toxicological Concern

ADI [mg/kg bw/day]: Acceptable Daily Intake

#	INCI name	NOAEL [mg/kg bw/day]	SED [mg/kg bw/day]	MoS	C	C Max	TTC	ADI
1	Aqua		0,0800775		96,093000			OK
2	Glycerin	1180	0,0000680	17364134	1,111000			
3	Hydroxyethylcellulose	5000	0,0004583	10909091	0,550000	6,0000		
4	Sodium chloride		0,0004167		0,500000			OK
5	Alcohol	2400	0,0000875	27428571	0,500000			OK
6	Panthenol	200	0,0004125	484848	0,495000	25,0000		OK
7	Polyaminopropyl biguanide*	36	0,0680468	529	0,300000	0,3000		
8	Inositol		0,0000625		0,075000			OK
9	Panthenyl ethyl ether		0,0000625		0,075000	5,0000		
10	Sodium hyaluronate		0,0000417		0,050000	2,0000		
11	Caprylyl glycol	300	0,0000375	8000000	0,045000	5,0000		
12	1,2-Hexanediol		0,0000300		0,045000	10,0000		
13	Biotin	10	0,0000167	600000	0,020000	1,0000		OK
14	Phenoxyethanol*	500	0,0218669	22866	0,012500	1,0000		
15	Sodium citrate	1200	0,0000104	115200000	0,012500	10,0000		OK
16	Acetyl cysteine		0,0000104		0,012500	0,1000		
17	Acetyl methionine		0,0000104		0,012500			OK
18	Lactis proteinum extract		0,0000104		0,012500			OK
19	Lactose		0,0000104		0,012500	9,4000		OK
20	Sodium benzoate*	500	0,0296500	16863	0,010000	0,5900		5,0000
21	Polysorbate 20		0,0000083		0,010000	50,0000		25,0000
22	Benzoic acid*	800	0,0296500	26981	0,010000	0,5000		
23	Myristoyl pentapeptide-17		0,0000083		0,010000	0,0100		
24	Hippophae rhamnoides oil		0,0000083		0,009997	0,7000		
25	Citric acid	1200	0,0000060	198620690	0,007250	4,0000		

#	INCI name	NOAEL [mg/kg bw/day]	SED [mg/kg bw/day]	MoS	C	C Max	TTC	ADI
26	Dehydroacetic acid*		0,0148250		0,005000	0,6000		
27	Diethyl phthalate	150	0,0000019	80000000	0,002250	50,0000		
28	Rhodiola rosea root extract	1430	0,0000013	1144000000	0,001500			OK
29	Helianthus annuus seed oil		0,0000000		0,000002	96,0000		
30	Rosmarinus officinalis leaf extract		0,0000000		0,000001			OK

Allergens :

The product does not contain any allergen to the available data.

Impurities from raw materials:

The table below shows the maximum concentration of impurities in the cosmetic product, equal to the amount of impurities in the raw materials mentioned in 2.2.1., and the corresponding SED.

The impurity can be considered safe for human health when SED≤ SED Max or when C ≤ C Max Annexes (ie when the impurity is a listed ingredient in Annexes III to VI of Regulation (EC) 1223/2009 for which purity criteria are met) or when SED≤ TTC.

C [%]: Concentration of the impurity in the finished product on the application site

DAp [%]: Dermal Absorption

SED [mg/kg mc/day]: Systemic Exposure Dosage

SED Max [mg/kg mc/day]: Maximum SED for which safety is justified (in the toxicological profile of the corresponding impurity Annexe II.i)

C Max Annexes [ppm]: Maximum allowed concentration of impurity in the finished product, derived from purity criteria of a listed ingredient in Annexes III to VI of Regulation (EC) 1223/2009 (as indicated in the toxicological profile of impurity).

TTC [mg/kg mc/day]: Threshold of Toxicological Concern

#	Impurity	C	DAp	SED	SED Max	C Max Annexes	TTC	Annexe II.i
1	Heavy metals	0,0520	10,00	0,0000004	0,067			11000
2	Arsenic	0,0148	10,00	0,0000001	0,670			11003
3	Cadmium	0,0178	10,00	0,0000001	0,330			11005
4	Chromium	0,1500	10,00	0,0000013	3,300			11006
5	Copper	0,0850	10,00	0,0000007	133,000			11007
6	Lead	0,1629	10,00	0,0000014	0,670			11009
7	Mercury	0,0160	10,00	0,0000001	0,067			11010
8	Sulfates	3,0000	100,00	0,0002500	16667,000			11013
9	Ethylene oxide	0,0001	100,00	0,0000000			0,003	11015
10	Zinc	1,5000	10,00	0,0000125	0,300			11017

Impurities from packaging items:

There is currently no information available concerning impurities from the primary packaging material, the responsible person shall keep the safety assessor informed as soon as information becomes available from the supplier.

M**icrobiological risk:**

The microbiological risk is controlled according to the results of the challenge test which conforms with criteria A.

According to the above information, it can be concluded that the finished product is safe for human health when used under normal or reasonably foreseeable conditions of use, except for specific cases of sensibility, considering:

- its presentation (and considering directive 87/357/EEC),
- its labeling information,
- its instructions of use and disposal,
- information from the responsible person.

Considering the information in part A paragraph 9 and the principles of cosmetic surveillance, if an abnormally high rate of adverse effects is reported after the product has been placed on the market, especially allergic reactions to contact, phototoxicity and / or photoallergy, skin irritations and / or ocular irritations consecutive to repeated applications, or if a serious adverse effect is found, the responsible person will have to ask for a new product safety assessment and notify without delay the information requested in article 23 of regulation 1223/2009 to the relevant competent authority.

Any change in product formulation, its recommendations of use, its targeted population, its allegations or any information likely to affect any of the information in Part A and therefore the safety for human health must be given to the attention of the person responsible for safety evaluation, which will perform, accordingly, a new safety assessment of the cosmetic product.

2.14. Assessor's credentials and approval of part B

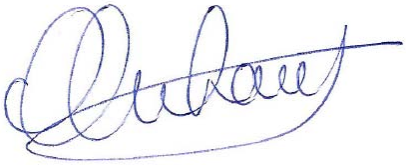
D. Jérémy Nuham

93, avenue du Bac,

94210 La Varenne Saint Hilaire

Qualifications : Diplôme d'Etat de Docteur Vétérinaire, Faculté de Médecine de Créteil, Université de Paris XII, Paris - Val-de-Marne.

Proof of qualification: annexe VI

Signature : 

JEREMY NUHAM

Signé numériquement par JEREMY NUHAM
Date: 17.08.2015 18:02:55 +0200

3. METHOD OF MANUFACTURING AND GMP

3.1. Description of the method of manufacturing

Annexe VII.1

3.2. Statement on compliance with GMP

Annexe VII.2

4. EVIDENCE FOR COSMETIC CLAIMS

The responsible person must be able to provide evidence for the claims that may be labeled on the cosmetic product. Moreover, the responsible person mustn't use allegations that go beyond the cosmetic regulations.

5. ANIMAL TESTING

The product has not been subjected to animal testing in order to meet the requirements of the regulation.

6. NOTIFICATION TO THE EUROPEAN COMMISSION

CPNP e-notification: annexe VIII