



# SAFETY REPORT OF LILLY NAILS AB

Safety Assessor: Sara Aspengren, PhD Biology

## Part A - Cosmetic Product Safety Information

Product: #73015 / Y4901 FOAM WASH COTTON

Responsible person:

Lilly Nails AB

Stationsvägen 1F

435 37 Mölnlycke

Sweden

556841-0376

### 1. Quantitative and qualitative composition of the cosmetic product

INCI	CASNo	EINECSNo	Function
Aqua/Water	7732-18-5	231-791-2	
Sodium Lauroyl Sarcosinate, Sodium Lauryl Sulfoacetate	137-16-6, 1847-58-1	205-281-5, 217-431-7	Surfactant
Sodium Cocoyl Glutamate	68187-32-6	269-087-2	Anionic surfactant
Dicaprylyl Ether, Decyl Glucoside and Glyceryl Oleate	629-82-3, 54549-25-6, 25496-72-4, 111-03-5	211-112-6, 259-218-1, 247-038-6	Conditioning Agent
Coco-Glucoside	141464-42-8	604-232-9	Non-ionic surfactant
PEG-20 Glyceryl Laurate	51248-32-9	-	Surfactant non-ionic / Solubizer
Cocamidopropyl Betaine	61789-40-0	263-058-8	Foaming Agent
Panthenol	81-13-0	201-327-3	Moisturizing Agent
Phenoxyethanol, Benzoic Acid, Dehydroacetic acid	122-99-6, 65-85-0, 520-45-6, 771-03-9, 16807-48-0	204-589-7, 200-618-2, 208-293-9, 212-227-4	Preservative
Parfum, Citronellol, Benzyl Salicylate, Hexyl Cinnamal, Limonene, Linalool, Citral	106-22-9, 118-58-1, 101-86-0, 5989-27-5, 78-70-6, 5392-40-5	203-375-0, 204-262-9, 202-983-3, 227-813-5, 201-134-4, 226-394-6	Fragrance
Lactic Acid	50-21-5, 79-33-4	200-018-0, 201-196-2	pH-regulator
Propylene Glycol, Alcohol, Betula Alba Bark Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Urtica Dioica (Nettle) Leaf Extract	57-55-6, 7732-18-5, 64-17-5, 84012-15-7, 84604-14-8, 84082-60-0, 84012-40-8	200-338-0, 231-791-2, 200-578-6, 281-660-9, 283-291-9, 282-006-5, 281-685-5	Skin & Hair conditioning Agent

Fragrance Allergens:

Based on the fragrance concentration in the product, **Citronellol, Benzyl Salicylate, Hexyl Cinnamal and Limonene** must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

## 2. Physical/chemical properties and data on product's stability

### 2.1

Colour	Grey transparent
Physical form	Liquid
pH range	5,2-5,4
Fragrance	C1197-2 Warm Cotton

### 2.2

**Stability** The Producer performed an in-house stability test of the base formulation. The testing period was Aug 01 – Oct 01 2018 and the testing parameters were appearance, colour, odour, pH and bacterial growth.

Conclusion: The stability of the formulation is acceptable for this application.

According to the manufacturer the finished product life is at least 12 months after opening.

## 3. Microbiological quality

3.1 A challenge test has been performed on #73015 / Y4901 Foam Wash Blossom, through a third party laboratory. The test was performed according to the European Pharmacopeia, chapter 5.1.3. (Method description: Ph. Eur. 7, Chapter 5.1.3.) and resulted in germ status as singlets at 2, 7, 14 and 28 days.

## 4. Impurities, traces, and information on the packaging material

The raw materials for this product are purchased from manufacturers specialized in raw material for cosmetic use. Purity is guaranteed in MSDS documents.

INCI	CASNo	Purity / Conc in raw material	Allergens /Other Substances	Classification
Aqua/Water	7732-18-5			
Sodium Lauroyl Sarcosinate, Sodium Lauryl Sulfoacetate	137-16-6, 1847-58-1	100,0%		H332, H318
Sodium Cocoyl Glutamate	68187-32-6	100,0%		H319, H412
Dicaprylyl Ether, Decyl Glucoside and Glyceryl Oleate	629-82-3, 54549-25-6, 25496-72-4, 111-03-5	100,0%		H315,H318
Coco-Glucoside	141464-42-8	100,0%		H315,H318
PEG-20 Glyceryl Laurate	51248-32-9	100,0%		No hazardous
Cocamidopropyl Betaine	61789-40-0	100,0%		H318, H412
Panthenol	81-13-0	100,0%		No hazardous
Phenoxyethanol, Benzoic Acid, Dehydroacetic acid	122-99-6, 65-85-0, 520-45-6, 771-03-9, 16807-48-0	100,000%		H302,H312, H315, H318, H332
Parfum, Citronellol, Benzyl Salicylate, Hexyl Cinnamal, Limonene, Linalool, Citral	106-22-9, 118-58-1, 101-86-0, 5989-27-5, 78-70-6, 5392-40-5	100,0%	Citronellol, Benzyl Salicylate, Hexyl Cinnamal, Limonene	H315, H317, H319, H410
Lactic Acid	50-21-5, 79-33-4	100%		H315, H318 Lactic Acid
Propylene Glycol, Alcohol, Betula Alba Bark Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Urtica Dioica (Nettle) Leaf Extract	57-55-6, 7732-18-5, 64-17-5, 84012-15-7, 84604-14-8, 84082-60-0, 84012-40-8	98,8%	Ethyl alcohol, Phenoxyethanol, sel de potassium de l'acide 2,4-Hexadiène-oïque	H225, H302, H319, H315

The primary packaging material is a PET plastic bottle, which was made for cosmetic use and does not contain any harmful substances. The Producer has performed a successful in-house stability test of the packaging. The testing period was Aug 01 – Oct 01 2018.

The production equipment for this product is cleaned continuously according to GMP, see separate document describing the cleaning routine for production equipment. The production equipment is made of acid-proof stainless steel.

Considering the concentration of impurities that are expected in the used raw materials (according to MSDS), packaging material and production equipment, the concentration of impurities in the cosmetic product are negligible.

## 5. Normal use and predictable reasoning

5.1 Intended use of this product is one application per day on the face and artificial eye lashes (in adults).

## 6. Exposure to the cosmetic product

Product type	Rinse off
The site of application	The face and artificial eye lashes
The surface area of application, cm <sup>2</sup>	400
The amount per application, g	0,5
The duration and frequency of use	1 times/day
The normal and reasonably foreseeable exposure route(s)	Dermal
The targeted (or exposed) population(s)	Adults
The body weight, kg	60
Retention factor	0,01
Exposure adult, mg/kg/day	0,083333

Calculation according to the "SCCS's Notes of Guidance for the testing of cosmetic substances and their safety evaluation", 10th Revision.

Impact due to particle size (nano): The product contains no nanomaterials.

## 7. Exposure to the substances

See table below. The amount applied of each ingredient per kg bw (tot bw = 60 kg) and day has been calculated (SED). The SED was low for all ingredients. According to SCCS, Scientific Committee on consumer safety guidelines for rinse off product, 1 % absorption retention factor has been used. Margin of safety (MoS) is calculated by dividing systemic NO(A)ELs by the SED, when NO(A)EL or relevant Point of Departure (POD) is available in the present stage of knowledge.

INCI	CASNo	SED mg/kg bw/day at 100 absorption Total: mg/kg/day	Lowest reported NOAEL mg/kg bw	Margin of Safety (MOS)/ Comments	Source
		0,083333			
Aqua/Water	7732-18-5	0,0457		Safe	according to CIR
Sodium Lauroyl Sarcosinate, Sodium Lauryl Sulfoacetate	137-16-6, 1847-58-1	0,0175		Safe	according to CIR
Sodium Cocoyl Glutamate	68187-32-6	0,0070		Safe	according to CIR
Dicaprylyl Ether, Decyl Glucoside and Glycerol Oleate	629-82-3, 54549-25-6, 25496-72-4, 111-03-5	0,0033		Safe	according to CIR
Coco-Glucoside	141464-42-8	0,0033	1000	300 001	
PEG-20 Glyceryl Laurate	51248-32-9	0,0025		Safe	according to CIR
Cocamidopropyl Betaine	61789-40-0	0,0017		Safe	according to CIR
Panthenol	81-13-0	0,0006	1000	1 714 293	
Phenoxyethanol, Benzoic Acid, Dehydroacetic acid	122-99-6, 65-85-0, 520-45-6, 771-03-9, 16807-48-0	0,0005		Safe	according to CIR
Parfum, Citronellol, Benzyl Salicylate, Hexyl Cinnamal, Limonene, Linalool, Citral	106-22-9, 118-58-1, 101-86-0, 5989-27-5, 78-70-6, 5392-40-5	0,0004		Safe	according to CIR
Lactic Acid	50-21-5, 79-33-4	0,0004	570	1 368 005	
Propylene Glycol, Alcohol, Betula Alba Bark Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Urtica Dioica (Nettle) Leaf Extract	57-55-6, 7732-18-5, 64-17-5, 84012-15-7, 84604-14-8, 84082-60-0, 84012-40-8	0,0004		Safe	according to CIR

NO(A)EL values available from distributor/supplier or from literature or from databases;  
CIR (Cosmetic Ingredient Review).

#### 8. Toxicological profile of the substances

There is no indication of nanoparticles in this formulation.

For toxicological profile of ingredients, refer to MSDS for each raw material.

#### 9. Adverse effects and serious adverse effect

No undesired effects have been reported. Responsible person has set up a system to collect documents, establish causality and manage any undesirable effects caused by the product.

#### 10. Information on the cosmetic product

No additional information.