



# SAFETY REPORT OF LILLY NAILS AB

Safety Assessor: Sara Aspengren, PhD Biology

## Part A - Cosmetic Product Safety Information

Product: #7205, 06 / Y5831 HAND CREAM STRAWBERRY

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	
Glycerin (vegetable)	56-81-5	200-289-5	Humectant
Ethylhexyl Cocoate	92044-87-6	295-366-3	Emollient
Cetearyl Oliviate, Sorbitan Oliviate	85116-80-9, 92202-01-2	2855323, 2960335	Emulsifier
Dimethicone	63148-62-9	613-156-5	Protective Agent, Spreading Agent
Panthenol	81-13-0	201-327-3	Moisturizing Agent
Parfum, Linalool, Eugenol, Coumarin	123-92-2, 77-83-8, 141-78-6, 121-32-4, 97-53-0, 91-64-5	204-662-3, 201-061-8, 205-500-4, 204-464-7, 911-369-0, 202-589-1, 202-086-7	Fragrance
Cetearyl Alcohol	67762-27-0	267-008-6	Consistency giving 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
Ammonium Acryloyldimethyltaurate/V P Copolymer	75-65-0	200-889-7	Thickening and Stabilizing Agent
Avocado (Persea Gratissima) Oil	8024-32-6	232-428-0	Emollient Agent
Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	Sunscreen Agent / UV-filter
Cetyl Palmitate, Sorbitan Palmitate, Sorbitan Oliviate	540-10-3, 26266-57-9, 92202-01-2	208-736-6, 247-568-8, 2960335	Emulsifying Agent
Wheat (Triticum Vulgare) Germ Oil, Tocopherol	8006-95-9, 59-02-9	310-127-6, 215-798-8	Spreadability Agent
Butyl Methoxydibenzoylmethane	70356-09-1	274-581-6	Sunscreen Agent / UV-filter
Tocopheryl Acetate	7695-91-2	231-710-0	Antioxidant / Moisturizing Agent

## Fragrance Allergens:

Based on the fragrance concentration in the product, **Linalool, Eugenol, Coumarin** 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	Cream white
Physical form	Cream
pH range	4,5-5,5
Fragrance	54361 Erdbeere

### 2.2

**Stability** The manufacturer performed an in-house stability test of the base formulation. The testing period was Feb 01 – Apr 01 2017 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 The packaging is airless, i.e. it is possible to dispense the product without air contact, and the product is therefore classified as a low risk product according to ISO 29621. According to the report "riktlinjer avseende bilaga I till Europaparlamentets och rådets förordning (EG) nr 1223/2009 om kosmetiska produkter (2013/674/EU)" challenge testing is not relevant for this type of product. Microbiological tests are performed on each product batch. The product is preserved with Rokonsal ND, 0.58 %, which has been successfully tested in an in house stability test (see section 2.2).

## 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			
Glycerin (vegetable)	56-81-5	99,5%		No hazardous
Ethylhexyl Cocoate	92044-87-6	100,0%		No hazardous
Cetearyl Oliviate, Sorbitan Oliviate	85116-80-9, 92202-01-2	100,0%		No hazardous
Dimethicone	63148-62-9	100,0%		No hazardous
Panthenol	81-13-0	100,0%		No hazardous
Parfum, Linalool, Eugenol, Coumarin	123-92-2, 77-83-8, 141-78-6, 121-32-4, 97-53-0, 91-64-5	100,0%	Linalool, Eugenol, Coumarin	H225, H226, H302, H317, H319, H336, H411, H412
Cetearyl Alcohol	67762-27-0	97,0%		H412
Phenoxyethanol, Benzoic Acid, Dehydroacetic acid	122-99-6, 65-85-0, 520-45-6, 771-03-9, 16807-48-0	100,0%		H302, H312, H315, H318, H332
Ammonium Acryloyldimethyltaurate/VP Copolymer	75-65-0	99,0%		No hazardous
Avocado (Persea Gratissima) Oil	8024-32-6	100,0%		No hazardous
Ethylhexyl Methoxycinnamate	5466-77-3	100,0%		No hazardous
Cetyl Palmitate, Sorbitan Palmitate, Sorbitan Oliviate	540-10-3, 26266-57-9, 92202-01-2	100,0%		No hazardous
Wheat (Triticum Vulgare) Germ Oil, Tocopherol	8006-95-9, 59-02-9	100,0%		No hazardous
Butyl Methoxydibenzoylmethane	70356-09-1	100,0%	1-[4-(1,1-dimethylethyl)-phenyl]-3-(4-methoxyphenyl)-propane-1,3-dione - 90%-100%	H413
Tocopheryl Acetate	7695-91-2	0,98		No hazardous

The primary packaging materials is a plastic bottle, which was made for cosmetic use and does not contain any harmful substances. The manufacturer has performed a successful in-house stability test of the packaging. The testing period was Feb 01 – Apr 01 2017.

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 hands (in adults).

## 6. Exposure to the cosmetic product

Product type	Leave on
The site of application	Hands
The surface area of application, cm <sup>2</sup>	200
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	1
Exposure adult, mg/kg/day	8,333333

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. As a worst case scenario 100 % absorption 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
		8,3333			
Aqua/Water	7732-18-5	6,741		Safe	according to CIR
Glycerin (vegetable)	56-81-5	0,417		Safe	according to CIR
Ethylhexyl Cocoate	92044-87-6	0,375	10000	26 667	according to CIR
Cetearyl Olivatate, Sorbitan Olivatate	85116-80-9, 92202-01-2	0,250		Safe	according to CIR
Dimethicone	63148-62-9	0,083		Safe	according to CIR
Panthenol	81-13-0	0,083	1000	12 000	according to CIR
Parfum, Linalool, Eugenol, Coumarin	123-92-2, 77-83-8, 141-78-6, 121-32-4, 97-53-0, 91-64-5	0,083		Safe	according to CIR
Cetearyl Alcohol	67762-27-0	0,062	750	12 000	according to CIR

Phenoxyethanol, Benzoic Acid, Dehydroacetic acid	122-99-6, 65-85-0, 520-45-6, 771-03-9, 16807-48-0	0,048		Safe	according to CIR
Ammonium Acryloyldimethyltaurate/V P Copolymer	75-65-0	0,042		Safe	according to CIR
Avocado (Persea Gratissima) Oil	8024-32-6	0,042		Safe	according to CIR
Ethylhexyl Methoxycinnamate	5466-77-3	0,042	5000	120 000	according to CIR
Cetyl Palmitate, Sorbitan Palmitate, Sorbitan Olivat	540-10-3, 26266-57-9, 92202-01-2	0,025		Safe	according to CIR
Wheat (Triticum Vulgare) Germ Oil, Tocopherol	8006-95-9, 59-02-9	0,017		Safe	according to CIR
Butyl Methoxydibenzoylmethane	70356-09-1	0,014	360	25 412	according to CIR
Tocopheryl Acetate	7695-91-2	0,008		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.