



SAFETY REPORT OF LILLY NAILS AB

Safety Assessor: Sara Aspengren, PhD Biology

Part A - Cosmetic Product Safety Information

Product: #24201 / Y5813 CITRUS OIL

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
Simmondsia Chinensis (Jojoba) Seed Oil	90045-98-0	289-964-3	Moisturizing Agent
Parfum, Limonene, Citral, Geraniol, Linalool, Citronellol, Eugenol	8008-57-9, 2230569, 8008-56-8, 5989-27-5, 5392-40-5, 106-24-1, 78-70-6, 106-22-9, 97-53-0	307-891-8, 284-515-8, 227-813-5, 226-394-6, 203-377-1, 201-134-4, 203-375-0, 202-589-1	Fragrance Oil
Tocopheryl Acetate	7695-91-2	231-710-0	Antioxidant / Moisturizing Agent

Fragrance Allergens:

Based on the fragrance concentration in the product, **Limonene, Citral, Geraniol, Linalool, Citronellol and Eugenol** 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 Yellow Transparent

Physical form Liquid

pH range N / A

Fragrance Orange & Lemongrass C2215/3

2.2

Stability The manufacturer performed an in-house stability test of the formulation. The testing period was Feb 01 – Apr 01 2019 and the testing parameters were appearance, colour, odour 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 product does not contain water and 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)” it is not relevant to perform challenge testing on water free products.

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
Simmondsia Chinensis (Jojoba) Seed Oil	90045-98-0	100,0%		No hazardous
Parfum, Limonene, Citral, Geraniol, Linalool, Citronellol, Eugenol	8008-57-9, 2230569, 8008-56-8, 5989-27-5, 5392-40-5, 106-24-1, 78-70-6, 106-22-9, 97-53-0	100,0%		H226, H304, H315, H317, H400, H410, H411
Tocopheryl Acetate	7695-91-2	98,0%		No hazardous

The primary packaging material is a 10 ml / 40 ml glass 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 2019.

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 nails and cuticles (in adults).

6. Exposure to the cosmetic product

Product type	Leave on
The site of application	Nails and cuticles
The surface area of application, cm ²	10
The amount per application, g	0,1
The duration and frequency of use	1 time/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	1,66667

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)EL_{sys} 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
		1,6667			
Simmondsia Chinensis (Jojoba) Seed Oil	90045-98-0	1,642		Safe	according to CIR
Parfum, Limonene, Citral, Geraniol, Linalool, Citronellol, Eugenol	8008-57-9, 2230569, 8008-56-8, 5989-27-5, 5392-40-5, 106-24-1, 78-70-6, 106-22-9, 97-53-0	0,017		Safe	in this concentration
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.