

SAFETY ASSESSMENT OU

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COSMETIC PRODUCT SAFETY REPORT

PART B – Cosmetic product safety assessment

Product: **TINT BASE**

Manufacturer: HELLO. By NAILSMADE

Address: Ukraine, 55200, Mykolaiv region, Pervomaisk, street Gvardiyska, 1/4, apart. 6

Tel. No.: +380931915665

Responsible Person:

Tiwatiwacom Sia

Address: Dzervju iela 6, Riga, LV-1019, Latvia

Email: hellogelua@gmail.com

1. Conclusion

Considering the exposure, chemical and toxicological information of this product during the safety assessment procedure, it is concluded that the product does not cause damage to human health under normal or reasonably foreseeable conditions of use.

The safety assessment report of this product is prepared for adults use. MoS>100 is found for raw materials where NOAEL were available. The calculation was performed assuming that dermal absorption is 100%. With this worst case study, it is evaluated that the use of this raw material in this product is safe.

The ingredients of the product are permitted ingredients for cosmetics. All raw materials are not toxic under normal or reasonably unforeseeable conditions of use at this concentration. The

product does not contain prohibited substances listed in annexes of Regulation (EC) No. 1223/2009. Composition of the product complies with the requirements of the Cosmetic Regulations. Following review of the information provided for the above product and its ingredients, the **product is considered safe** for the intended application and **complies with EC Regulation 1223/2009**

2. Labeled warnings and instruction of use

This product's presentation is in accordance with a Regulation no 1223/2009 of the European Parliament and of the Council about the labelling of cosmetic product. Restricted ingredients are properly listed on the package.

Labeled warnings: For professional use only. Can cause an allergic reaction. Keep away from direct sunlight. Avoid skin contact. Read directions for use carefully. Keep out of sunlight. Discontinue use if irritation occurs. Can cause an allergic reaction. Avoid eye contact, if eye contact occurs, flush with water and seek medical attention.

Instruction of use: Apply a base-substrate on degreased nails, then apply one or two layers of Tint Base and cover with a top. Cure each layer in an UV LED lamp for 1 minute.

Claim support: All claims on the label should be in compliance with (EC) Regulation 655/2013 and the guidelines to this Regulation.

3. Reasoning

This assessment is based on:

- The chemical and physical specification of the ingredients
- The general toxicological profile of the ingredients
- The level of exposure of the ingredients
- The specific exposure characteristics of the areas to which the cosmetic product will be applied
- Margin of Safety calculations if available
- The specific exposure characteristics of the population for which the cosmetic product is intended

This assessment is conducted in accordance with the Regulation no 1223/2009 of the European Parliament and of the Council. All the ingredients in the formulation are either commonly used in rinse-off products with low toxicity or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR).

Provided manufacturer's instructions are followed.

The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability and microbiological quality.

4. Assessor's credentials

Safety Assessor's CV and diploma are added to this report.

A handwritten signature in blue ink, appearing to read 'Meelika Koitjäär', is centered on the page.

Meelika Koitjäär

Safety Assessor

Date: 16.11.2022

This safety assessment is based upon information available at this date. The safety of the product should be reviewed on a regular basis. Reviews of this assessment should be conducted when new information becomes available.

CPNP Ref.	Product Name	Responsible Person	Category	Formulation Name	Version	1st notification date	Status
4179554	Top	TIWATIWACOM	Nail sculpting products	Nail Sculpting Products	1	01/03/2023	Notified
4104689	Smart Gel	TIWATIWACOM	Nail sculpting products	Nail Sculpting Products	1	17/11/2022	Notified
4104687	Tint Base	TIWATIWACOM	Nail sculpting products	Nail Sculpting Products	1	17/11/2022	Notified