

Declaration of Product Safety for Gelpolish

Responsible Person:
Dutch Nail Store

I guarantee that this cosmetic product made available on the EU market is safe for human health when used under normal or reasonably foreseeable conditions of use.

Signed 2024-05-17



Name	F.A.A. Blok
Company position	Safety Assessor
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SkinConsult



9001:2015

Legal

This declaration is not a cosmetic product safety assessment as meant in article 10, paragraph 2 of Regulation (EC) No. 1223/2009, but an assessment conclusion as meant in Regulation (EC) No. 1223/2009, Annex I, Part B, and as such, confirms a safety assessment has been drafted and that the conclusion is identical to that of this declaration. The cosmetic product safety assessment in its entire form is made available by the responsible person as meant in Regulation (EC) No. 1223/2009, article 4 in the Product Information File as meant in Regulation (EC) No. 1223/2009, article 11.

This declaration is only valid for the product stated on the first page and only with regards to the composition of the product at the time it underwent the safety assessment. This declaration only determines that the assessed product is in accordance with applicable laws and regulations, such as Regulation (EC) No. 1223/2009, which were valid at the time the product was assessed. This declaration expressly does not apply to any and all changes made to the assessed product, including, but not limited to, changes in its composition, ingredients or manufacturing process, as well as any and all changes to applicable laws and regulations which have occurred after the date on which this declaration was drafted.

Pursuant to Regulation (EC) No. 1223/2009, article 11, paragraph 2 it is the responsibility of the Responsible Person to recertify a changed product by submitting the product for a safety assessment as meant in article 10 of Regulation (EC) No. 1223/2009. The product is assessed pursuant to the version of Regulation (EC) No. 1223/2009: 'On Cosmetic Products' and its amendments which was valid at the time this declaration was drafted. The safety assessor has drafted the safety assessment to the best of its knowledge, basing its conclusions on all documentation and information received. The safety assessor has followed education in relevant fields as meant in Regulation (EC) No. 1223/2009, article 10, paragraph 2 and is certified and recognized as a cosmetic Safety Assessor under European law.

Toxicology

I have reviewed the toxicology of the individual components of this product. All relevant toxicological endpoints have been taken into account. Margin of Safety (MoS) values are all well above the threshold for safety (> 100), indicating that the ingredients at their reported use levels are safe for use in this product

Raw materials

All raw materials including primary packaging are guaranteed to be suitable for cosmetics by their supplier and/or manufacturer. For all raw materials, an impurity profile has been made. All impurities were below their respective thresholds of toxicological concern.

Stability

The stability of the product has been tested. No interaction between the packaging and the product was seen. The product does not degrade significantly over time. It has been determined that the product is not susceptible to microbial attack.

Label

The label complies to EC 1223/2009. The expiration date has been determined experimentally with stability testing. Claims that are made comply with the Commission Regulation(EC) No 655 / 2013. From its presentation it is clear what the function of the product is.

GMP

Manufacturing quality is ensured through Good Manufacturing Practice (GMP). The supply chain of this product complies with GMP and/or is GMP certified.

Product history

The product has not caused any adverse health effects nor serious adverse health effects. The Responsible Person has a system in place for cosmetovigilance.

