Additional motivations on the safety assessment

The product is found to be safe for its intended and reasonably foreseeable application.

These parts are in compliance with EC 1223/2009:

The MoS of each individual ingredient was found to be higher than 100. In MoS calculations, skin absorption of 100% absorption is used unless otherwise indicated. When a lower skin absorption < 100% is used, the value is derived from scientific data on absorption of the substance or substance group. All ingredients are commonly used in cosmetics and contain the necessary toxicological, chemical and physical information. The concentration of impurities in the raw materials are below detection limits and/or below necessary thresholds for safe use in a cosmetic application. Based on the chemical properties of the ingredients, under normal foreseeable conditions no chemical cross-reactions are expected. Attention has been given to formation of nitrosamines which are below detection limits. The product does not contain polycyclic aromatic hydrocarbons (PAHs) and/or heavy metals, or these substances are present at safe concentrations. The product does not contain CMR substances and/or substances presenting a health risk due to carcinogenicity, mutagenicity or reproductive effects of the ingredients. Therefore, the product does not present a human health hazard. We have concluded that the product does not contain any ingredients with a particle size in a range of 10- 100 nm (nano-particles). Therefore , the product is not subject to nanotechnological considerations. The product has an unknown or corrosive pH and if applicable: strong acids and bases may not have fully reacted in the end product. The challenge test and the microbiological control on each batch assure a microbial security. The stability of the product is guaranteed by a stability assessment. The packaging material was found to be suitable for cosmetic use. The interaction of the product with the packaging has been studied and was found to be negligible. Based on this, we can assume that the product will remain stable in the packaging. The production and storage of the product, its quality control and storage of raw materials are done according to the Good Manufacturing Practice guidelines described in the norm ISO 22716:2007. The labelling informs the consumer according to the EC 1223/2009. The presentation of the product is done correctly and the claims are correctly substantiated according to the directive 655/2013.

Approval of part B and assessor's credentials

Conclusion:
Based on the assessment performed in part A and the reasoning it can be concluded that the above product is safe as a cosmetic product for its intended use. The product is in compliance with EC/1223/2009.

CURRICULUM VITAE / RESUMÉ

Personal

Name	[redacted]
Address	[redacted]
Date of birth	[redacted]
Place of birth	[redacted]
Nationality	[redacted]
Work	+31 88 555 4600
Mobile	[redacted]
Medical Specialist Reg.no.	69050735601

Education

Feb. 2012	Free University Brussels, Toxicology Department, certificate Safety Assessor
April 2003 - Oct. 2007	AMC Amsterdam (prof.dr.J.D. Bos), dermatology internship
Sep. 1989 - July 1999	Erasmus University Rotterdam, Medical school
	Medical Degree 16th of July 1999 (cum laude)
Sep. 1990 - Feb. 1996	Master of Science: Chemistry RU Leiden (Organic Chemistry)

Professional Experience

Jan. 2008 - present	SkinConsult BV, researcher and safety assessor
Jan. 2008 - present	Dermatology Center Utrecht BV, founder and dermatologist
Jan. 2009 - present	VUmc, department of Dermatology Allergology, research
Sep. 2021 - present	Medicines Evaluation Board (CBG-Med), (external) Dermatology expert

F.A.A. Blok
2023-02-10