

SAFETY ASSESSMENT OF COSMETIC PRODUCT

Cosmetic product listed below do not pose a risk to human health and meets the requirements of the Regulation of the European Parliament and Council Regulation (EC) No. 1223/2009 of 30 November 2009 relating to cosmetic products (Journal of Law UE L 342/59 with all amendments).

IDENTIFICATION OF THE PRODUCT AND COMPANY

DATE	08.09.2021
VERSION	1
PRODUCT NAME	KERATIN CARE SPECIAL REPAIR THERAPHY SOS SHAMPOO
PRODUCER	Vitak hair cosmetics Dublin, D18 CV48, IE
RESPONSIBLE PERSON	Vitak hair cosmetics Dublin, D18 CV48, IE

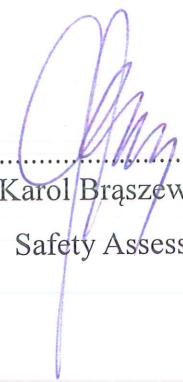
REMARK

1. Any qualitative and quantitative change in the composition, any changes in the scope or manner of use needs to be re-examined by a safety assessor.
2. This opinion does not apply to cases of people who have an allergy to any component of the product being evaluated.
3. With the current state of knowledge the safety assessor can only estimate that the cosmetic product does not have any foreseeable risk to human health under normal, foreseeable conditions of use.

DATE

08.09.2021

SIGNED BY


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Karol Braszewski
Safety Assessor

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. ASSESSMENT CONCLUSION

The product **KERATIN CARE SPECIAL REPAIR THERAPY SOS SHAMPOO** is safe and does not pose a reasonably foreseeable risk to the human health when it is used in declared manner, according to the instruction and in reasonably foreseeable conditions, taking into account the current state of knowledge.

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE.

No comments are submitted to the content of the label.

Responsible person is liable for the content of the label and compliance of label elements and the label itself with the law.

3. REASONING

The conclusion derived in point 1 is based on:

- Safety assessment of each raw material used in manufacturing the cosmetic product, including:
 - ✓ Risk assessment based on toxicological profile of each ingredient, taking into account, in justified cases, read-across approach.
 - ✓ Analysis of systemic exposition to the ingredients.
 - ✓ Margin of safety calculations.
- Reports and results of each tests of the finished cosmetic product.

The raw materials and ingredients are typical cosmetic substrates and are usually applied in the cosmetic industry. Moreover, all ingredients included in assessed product are used in compliance with the annexes III – VI of the Regulation of the European Parliament and of the Council (WE) No 1223/2009 with all amendments.

The available data is sufficient to conduct safety assessment. The toxicological profile of the used ingredients is satisfactory and has been selected according to the type and intended purpose of the cosmetic. For ingredients for which the systemic toxicity - NOAEL parameter was available, margins of safety were determined, which in all cases satisfy a relationship $MoS \gg 100$. For ingredients for which there are no available chronic toxicity values or other systemic toxicological data allowing to assess the substance as safe, other sources like opinions of CIR, FDA, SCCS, as well as a documented history of safe use can be cited. Furthermore, the following data was taken into account in the safety assessment:

- The purity of the raw materials – does not raise objections
- Interactions between the product and material of the packaging – not expected
- Interactions between ingredients – not expected
- The physicochemical and microbiological stability – proven by tests
- Patch test report – non irritating properties of the product have been proven. Potential allergic reactions cannot be excluded in patients who have an allergy to any ingredient of the product.

4. ASSESSOR'S CREDENTIALS

4.1. Name and address of the Safety Assessor

mgr inż. Karol Brąszewski

ul. Zamenhofa 36/24

90-547 Łódź

Phone: +48 608 390 944

4.2. Proof of qualification of Safety Assessor

EDUCATION

2004 – 2005	Postgraduate studies at the Faculty of Biotechnology and Food Sciences, Lodz University of Technology, specializing in cosmetology.
1998 – 2000	Graduate studies at the Faculty of Organization and Management, Lodz University of Technology, Institute of Management, specializing in Marketing and Management.
1996 – 1998	Studies of the Faculty of Chemistry, Lodz University of Technology, Institute of General and Ecological Chemistry, specialty chemical technology.
1994 – 1996	College studies at the Lodz University of Technology, diploma engineering chemist at the Institute of General and Ecological Chemistry.

EXPERIENCE

Since 01.11.2019	Director R&D, Delia Cosmetics Sp. z o.o
Since 2015	Head of Dr Szmich – Centre of Research and Development of cosmetics, pharmaceuticals and medical devices.
Since 2012	Member of the Business Council of the Faculty of Biology and Environmental Protection, University of Lodz
01.06.2007 – 31.10.2019	Director R&D and Production, Delia Cosmetics Sp. z o.o.
2006 – 2016	Lecturer at Lodz University of Technology, Faculty of Biotechnology and Food Sciences, Postgraduate specialization cosmetology
01.10.2004 – 31.05.2007	Chief Technologist - Head of Production and Quality Control, Quality Management Representative Delia Cosmetics Sp. z o.o.
01.09.2003 – 30.09.2004	Technologist, Delia Cosmetics Sp. z o.o.
15.10.2001 – 31.08.2003	Technologist, BARBRA Sp. z o.o.
15.09.1999 – 30.09.2000	Production specialist, Cosmetic Factory Pollena Ewa S.A.

TRAINING

12.2009	Training in new technologies and applications of active ingredients in cosmetics IMCD COM TECH, Bergamo, Italy
05.2006	Training in technology nail polish and active ingredients Durlin France, Bergerac, France
03.2005	Training in the new trends and technology in the colour cosmetics Engelhard Netherlands
04.2004	Training in the new trends and technology in the colour cosmetics Engelhard Netherlands
02.2004	Training on the new developments in the technology of hair dyes jos.H.Lowenstein Sons, USA

4.3. APPROVAL of part B / conclusion of safety of the product

Based on all accessible data on the cosmetic product **KERATIN CARE SPECIAL REPAIR THERAPHY SOS SHAMPOO**, I state that this product is approved for use as intended.

The influence of this cosmetic product on human safety and health, was estimated according to the present state of knowledge. Revision of this safety assessment will be made as soon as new information becomes available. This report fulfils the formal requirements for influence assessment on the safety of cosmetics on human health, included in the Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 with all subsequent amendments.

The cosmetic product can be manufactured, if the production complies with the guidelines included in Regulation of the European Parliament and of the Council (WE) No 1223/2009 with all amendments.

Safety Assessor does not bear responsibility for the authenticity of the data provided by the responsible person.

DATE

06.01.2019

SIGNATURE

Karol Braszewski
Safety Assessor