SAFETY ASSESSMENT OF COSMETIC PRODUCT

The below named product, having composition, purpose and instruction of usage as declared by its manufacturer, is not hazardous to human health and complies with Directive 76/768/EEC and is created in accordance with Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 2009 on cosmetic products (Official Journal. EU L 342, 22.12.2009, p.59).

Product: **195 NENESS LIBRES 33 ML**

Producer: Neness Sp. z o.o.
Pod Lasem 50a
44-210 Rybnik

BM/195/06/2023

The safety assessor can estimate that, given the present level of knowledge, the product does not show any foreseeable risk to human health under conditions of normal use.

NOTE:

1. Each modification of the chemical composition, scope and method of use or the trade name of the product should be reviewed again by the person assessing safety of the product.

2. The opinion does not apply to subjects allergic to any ingredient of the assessed product.

Date: 01.06.2023

Table of Contents:

PART A

PART B

1. Assessment conclusion
2. Warnings and instructions for use displayed on the label
3. Reasoning
4. Assessor's qualifications and approval of part B

1. **General information on the product**

Product name	**195 NENESS LIBRES 33 ML**
Characteristics of use	For external use
Producer	Neness Sp. z o.o.
Contact phone numbers	+48 537 870 131
Person responsible	Mariusz Kubiak

PART A

1. **Physical / chemical characteristics and stability of the cosmetic product.**

1.1 **195 NENESS LIBRES 33 ML**

Trade name	INCI name	CAS	Function in the recipe	Concentration in % by weight
FREE F61-4297	Parfum	-	Fragrance composition	12
HP Ethyl alcohol	Alcohol denat.	64-17-5	Fragrance carrier	88

1.2 Fragrance compositions.

Trade name	INCI name	CAS	Function in the recipe	Concentration in % by weight	Supplier
FREE F61-4297	Parfum	-	Fragrance composition	12	SFA

2. **Physical / chemical characteristics and stability of the cosmetic product.**

2.1 Final product.

Chemical (Trade) Name	pH	Density
195 NENESS LIBRES 33 ML	**-**	0,815-0,820 g/m^3

2.2 Raw Materials.

2.2.1 HP Ethyl alcohol.

The content of ethyl alcohol in %	90
The content of methanol in ppm	4.2
Acidity in g/l	0.0
Water content in %	4.0
The content of the higher alcohols in mg/kg	0.0
Density in g/cm^3	0.799

2.3 Characteristics of fragrance compositions used in the production.

2.3.1 **FREE F61-4297**

Properties	Brown liquid
pH	N/A
Density in 20°C	0.980-1.000
Solubility	Insoluble in water

2.4 Stability of the cosmetic product.

The product is stable.

3. Microbiological quality.

Microbiological testing and test of the effectiveness of preservation are not required for the analyzed products. Alcohol> 20% present in the composition inhibits the growth of micro-organisms (according to PN-EN ISO 29621). For such products microbiological and preservation challenge tests are not performed.

4. Contamination, traces, information about the material from which the packaging is made.

4.1 Information on the packaging.

Type of packaging	Glass bottle with atomizer
Microbiological purity	Compatible
Stability	The product is stable
Possible interactions of contamination	N/A
Result of the test for compatibility of the substance with packaging material	The product is stable

5. Intended use of the product.

5.1 Normal use.

Product	Method of use
195 NENESS LIBRES 33 ML	The use recommended for perfume. Applied to the skin and hair.

5.2 Intended use of the product.

Product	Method of use
195 NENESS LIBRES 33 ML	None

6. Exposure to the effect of the cosmetic product.

Application area	Skin, hair
Application surface	>1.14%
Amount of product used	>2g
Frequency of use	1/day
Possible hazards	None
Target group	Adults

6.1 SED value

$$SED = \frac{N \, x \, M \, x \, C \, x \, A}{60}$$

where:
N - number of applications / day, N = 1
M - mass of applied product [mg], M = 2000 mg
C - share of a component in the applied product
A - retention factor, A = 100%
60 - body mass

	Qualitative composition – Trade name	Composition In %	SED
1	**VICTOIRE M65-5785**	12	4
2	HP Ethyl alcohol	88	29,33

7. Exposure to the effect of substances.

For ingredients that may be relevant from a toxicological point of view, the rate of the exposure SED is calculated in the first place. SED of a specified component is the amount that enters the bloodstream (and thus systematically exerts its function), which is dependent on the absorption of the outer skin layer. Since there are no data concerning the penetration of individual components, we must take into account the total absorption (= 100%).

8. Toxicological profile of the substances.

None of the ingredients used by the producer is included on the list of substances which use in cosmetic products is prohibited (Annex II: Regulation of the European Parliament and Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic products.)
In the case of cosmetic products, "Margin of Safety" (MoS) is used for the assessment of the components. This indicator of safety assessment of a component is calculated by dividing the maximum value of NO(A)EL by the calculated rate of SED. To assess a substance as safe, MoS must have value of at least 100.
For the raw materials used, there are no values of NO(A)EL. Therefore, for the purpose of the assessment, other information on the allergic effect of a component and on the absorption of the product will be used.

8.1 Toxicological profile of the individual substances.

8.1.1 HP Ethyl alcohol.

The data comes from the website: *http://chem.sis.nlm.nih.gov/chemidplus/m64-17-5*
Acute toxicity: mouse - by inhalation – LC50: 39 mg/m^3/4h
Mouse - intraperitoneally – LD50: 528 mg/kg
Mouse - intravenously – LD50: 1973 mg/kg
Mouse - orally – LD50: 3450 mg/kg
Mouse - subcutaneously – LD50: 8285 mg/kg

8.1.2 **VICTOIRE M65-5785**

This mixture itself was not subject to toxicological test. Therefore, it must be considered and dealt with as if it caused health hazard and, consequently, all possible precautions must be used.

9. Adverse reactions and serious adverse reactions.

There is no data on the subject.

10. Information on the cosmetic product.

Dermatological patch testing showed no adverse skin reactions. It can be concluded that, in practice, the product does not contribute to the occurrence of allergic skin reactions.

Test results:

Product	Patch test
195 NENESS LIBRES 33 ML	Negative result

PART B

1. Assessment conclusion.

The substances used are components frequently applied in the cosmetics industry. In the indicated concentrations, the substances should not cause adverse reactions in people who are not allergic to any of the ingredients.

None of the substances exceeds the concentrations that could cause an allergic skin reaction. The product does not contain preservatives and dyes. Fragrance does not cause irritation. This is confirmed by dermatological patch testing.

The product meets all the microbiological standards and may be regarded as a well-preserved product.

2. Warnings and instructions for use displayed on the label.

It is not necessary to display any warnings on the label.

3. Reasoning.

On the basis of the data presented above, when the product was used correctly, no degree of risk was detected. It should of course be noted that in case of the hypersensitivity to any component of the product, adverse effects cannot be excluded. However, the concentration of all the substances

does not exceed the standards which would define the content of the component as potentially dangerous and that might cause allergic reactions.

4. **Assessor's qualifications and approval of part B.**

Taking into account the general toxicological characteristics of the components, chemical composition and the degree of exposure, the cosmetic **195 NENESS LIBRES 33 ML** is harmless to health – with the normal and indicated use of the product, applied in a reasonable manner and with observance of all warnings and instruction of the use of the product.

The data contained in this safety assessment and evaluation (opinions) are based on the present state of knowledge. Any subsequent change in the recipe or a modification or addition of data relevant to the safety assessment will mean the cancellation of this report / this assessment.

Confirmation of the efficacy of the product is irrelevant.

Data on testing on animals is irrelevant, because no testing was carried out on animals.

Author: MSc., Eng. Władysław Jamróz
WPJ International, Władysław i Piotr Jamróz sp. j., ul. Majora 26/2, 31-422 Krakow, Poland

Qualifications of the safety assessor:

1976 – MSc. in the Department of Chemistry, with specialization in Chemical Engineering; Krakow University of Technology.

Professional experience:

1. 1983 - 1992 – Technologist in "Scan – Anida".
2. 1995 - present – own business "WPJ International" in the sector of the production of cosmetics: development and modification of existing recipes of cosmetics, preparation of necessary documentation.

NOTICE

In accordance with the Cosmetics Act of 30 March 2001 (Journal of Laws No. 42, item 473 with later amendments) and Regulation 1223/2009 - EC (Journal of Laws EU L 342 of 22.12.2009, p. 59), a producer of cosmetic products is required to keep reports of the testing of: stability, compatibility with packaging, dermatological testing, safety assessment certificate with all the documents that are necessary to issue such a certificate, a certificate confirming the presence of sunscreen and waterproofness (if declared), the results of the challenge test (preservation test) and microbiological purity certificates for each production batch. In the case of application tests, they are made to confirm the performance of the product (e.g. moisturizing, slimming) and for the confirmation of their marketing objectives.

PRODUCT TESTING

Type of test	**STATUS and report number**
Safety assessment	Performed
Microbiological test	Not required
Stability test	At the producer's facility
Dermatological patch test	Performed P/165/01/2021