

COSMETIC PRODUCT SAFETY REPORT

Product type	The product is intended for professional use on the skin around the eyes
Product name	ENZY NEUTRAL ENZYMATIC NEUTRALIZER
Category/Application	Rinse-off cosmetic for professional treatments on the skin around the eyes
Marketing Authorisation Holder	P.H.U. Natura, ul. Kilińskiego 18/20, 42 - 200 Częstochowa
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This Safety Report has been prepared in accordance with Annex I of the Regulation Of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on cosmetic products.

Report authorized by:

mSc. Eng. Katarzyna Flis, Safety Assessor

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LIST OF ABBREVIATIONS:

CPSR - Cosmetic Product Safety Report

CMR - Carcinogenic, Mutagenic or Reprotoxic substances

GMP - Good Manufacturing Practice

PAO - Period After Opening

SCCS - Scientific Committee for Scientific Committee on Consumer Safety

RIVM - National Institute for Public Health and the Environment

Eprod - Estimated daily exposure to the cosmetic product per kg body weight, in depending on the amount and frequency of application used (Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application)

SED - Systemic Exposure Dose

MoS - Margin of Safety

CIR - Cosmetic Ingredient Review

FDA - Agency for Food and Drug Administration

GRAS - Generally Recognized as Safe

ECHA - European Chemicals Agency

HSDB - Hazardous Substance Database

MSDS - Material Safety Data Sheet

SDS - Safety Data Sheet

TDS - Technical Data Sheet

PART A - Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

The person ordering the report is responsible for information on the quantitative and qualitative composition of the product, including the trade names of raw materials, information on suppliers.

The manufacturer declares that the final product and all ingredients of the cosmetic have not been tested on animals in accordance with art. 18 of Regulation 1223/2009/EC, as well as the cosmetic product does not contain CMR substances of categories 1A and 1B and 2 in accordance with Regulation 1272/2008/EC.

The manufacturer confirms that the cosmetic is manufactured in accordance with the GMP quality system.

1.1 Raw material recipe

No .	Trade name or chemical name	INCI Name	Content in the product (%)	Function
1.	Citric acid, GHP	Citric Acid		PH regulator
2.	Prodew 500, Barentz	Sodium PCA, Sodium Lactate, Arginine, Aspartic Acid, PCA, Glycine, Alanine, Serine, Valine, Proline, Threonine , Isoleucine , Histidine, Phenylalanine, Aqua		Active ingredient
3.	D-Panthenol 75%, GHP Sp. z o.o. sp.k.	D-Panthenol, Aqua		Active ingredient
4.	Sharomix EG10- COSMOCHEM (FEOG)	Phenoxyethanol, Ethylhexylglycerin, Aqua		Preservative
5.	Pineapple extract Bromelain 1200 gdu/g, EMMA TRADE	Sativus Fruit Pineapple Extract (Pineapple Extract), Bromelain		Active ingredient
6.	Papaya extract 6000 USP u/mg, EMMA	Carica Papaya Fruit Extract (Carcia papaya		Active ingredient

	TRADE	L), Papain		
7.	Glycerin, GHP Sp. z o.o. o.o. sp.k.	Glycerin		Solvent
8.	Sodium hyaluronate, EMMA-TRADE	Sodium Hyaluronate		Active ingredient

G.	Hydroxyethylcellulose , DERMAPROJECT MIROSLAW BOROWSKA ST.	Hydroxyethylcellulose		Active ingredient
10.	Distilled water	Aqua		Solvent

The provided material safety data sheets and certificates of analysis allow for the identification of the substances used and a detailed description of their properties along with data on contaminants. The information contained in the safety data sheets of individual raw materials allows for the assessment of toxicological properties.

The identification of substances used in the production of the cosmetic is included in Annex 2.

2. Physical/chemical properties and stability of the cosmetic product

2.1 Physical/chemical properties of the finished cosmetic product Application The product is intended for professional treatments on the skin around the eyes. **Form:** liquid
Uniformity: Homogeneous fluid without mechanical impurities
pH: 3.5 - 4

2.2 Stability of the finished cosmetic product

The physicochemical stability test showed that the product is stable under varying temperature conditions. The test result is included in **Attachment No. 3**.

The shelf life of the cosmetic product is set at 24 months from the date of production.

The shelf life was determined on the basis of:

- composition of the finished product
- the estimated time of consumption of the cosmetic product by the consumer
- analysis of individual cosmetic ingredients
- experience related to the presence of a product with a similar composition on the market

3. Microbiological quality

3.1 Microbiological quality of substances and mixtures

The raw materials used do not raise any objections from the point of view of microbiological purity. For raw materials with a low microbiological risk, no microbiological purity assessment was carried out. The remaining raw materials in terms of quantity and quality meet the microbiological requirements that allow them to be used in the production of the cosmetic.

3.2 Microbiological quality of the finished cosmetic product

Stress test Cosmetic product in accordance with PN-EN ISO 17516. The test result is included in Attachment No. 3.

4. Impurities, trace amounts, information about the material from which the packaging was made

4.1 Trace content of prohibited substances

The content of undesirable substances, heavy metals resulting from contamination of raw materials and migration from the packaging should not affect the safety of the cosmetic product.

According to the documentation provided by the manufacturers of the raw materials that are part of the product, no impurities are found and the purity of the raw materials used in the product does not raise any objections. Possible contamination with prohibited substances or residues of prohibited substances appearing in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 are acceptable in trace quantities provided that their amount is unavoidable for technological reasons (Article 17 of the above-mentioned Regulation).

In the absence of binding specific regulations for heavy metals, many health institutions around the world have developed their own criteria for assessing the safety of trace amounts of heavy metals in cosmetics through a reliable scientific toxicological analysis. Due to the introduction of internal restrictions by some of the Member States, it is recommended that the content of heavy metals in the finished product does not exceed the following values: Arsenic, Cadmium - 5ppm, Mercury - 1ppm, Antimony and Lead - 10ppm.

Conclusion: In the assessed cosmetic product, the content of heavy metals and substances not allowed as impurities in the finished product on the basis of the presented raw material documentation is within the above-mentioned limits and does not pose a threat under normal and predictable conditions of use of the cosmetic product.

4.2 Significant properties of the material from which the packaging was made

Type of packaging	Manufacturer
1. 10 ml bottle, dark purple, glass, fi 18 mm	1. MEPING Europe Sp. z o. o., ul. K. Jeżewskiego 3a/27, 02-796 Warsaw
2. Dropper 18/415, 52 mm tube, grooved with first opening control, nut and pear black matte, PP and glass	2. MEPING Europe Sp. z o. o., ul. K. Jeżewskiego 3a/27, 02-796 Warsaw

According to the manufacturer's declaration, the packaging is stable under normal and foreseeable conditions of use. The packaging meets the requirements for packaging in contact with food.

The results of the mass-package compatibility test confirmed the lack of interaction of the product with the packaging. Compatibility test report. The results can be found in **Annex 3**.

Conclusion: The type of packaging used does not adversely affect the stability of the product.

5. Normal and reasonably foreseeable use

The product is intended for professional treatments to be applied to the skin around the eyes. Rinse-off product. The exact description of the application should be included on the product label.

6. Exposure to cosmetic product

Product type:	Rinse-off product
Place of application:	Surface of the eye area
Quantity in single use:	0.02 g
Frequency of use:	1x day
Retention rate:	0.01
Application area:	24 cm ²
Target population	Adults
Body weight	60 kg

* SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation

7. Exposure to substances

7.1 Calculation of the safety margin

Based on the exposure to the cosmetic product, in accordance with SCCS/1647/22 guidelines and using data from manufacturers of substances, opinions of the SCCS scientific committees, EFSA, toxicological databases (see Annex 2 for data references), a safety margin was calculated.

Daily product exposure is:

$$E_{\text{prod}} = \text{product quantity} \times \text{frequency} \times Fr / \text{body weight}$$

$$E_{\text{prod}} = 0.00000333 \text{ mg/kg bw/day}$$

The dose of systemic exposure for the device was calculated from the formula:

$$SED = E_{\text{prod}}(\text{mg/kg bw/day}) \times C(\%)/100 \times DAp(\%)/100$$

where:

DAp - transepidermal absorption; if unknown, 100% is taken

C - maximum concentration of the ingredient in the product

Margin of safety for use

$$MoS = NOAEL / SED$$

Ingredients according to INCI	Maximum possible concentration ingredient in finished product (%)	SED	MoS
Citric Acid	0.5	0.00000001665	MoS>100
Sodium PCA	0.15	0.0000004995	MoS>100
Sodium Lactate 12	0.12	0.0000003996	MoS>100
Arginine	0.08	0.0000002664	MoS>100
Aspartic Acid	0.052	0,0000000017316	MoS>100
PCA	0.0427	0.000000142191	MoS>100
Glycine	0.0128	0.00000000042624	MoS>100
Alanine	0.012	0.0000000003996	MoS>100
Serine	0.008	0.0000000002664	MoS>100
Valine	0.0064	0.00000000021312	MoS>100
Proline	0.004	0.00000001332	MoS>100
Threonine	0.004	0.00000001332	MoS>100
Isoleucine	0.004	0.00000001332	MoS>100
Histidine	0.016	0.0000000005328	MoS>100
Phenylalanine	0.016	0.0000000005328	MoS>100
D- Panthenol	3.75	0.0000124875	MoS>100
Phenoxyethanol	0.915	0.0000000304695	MoS>100
Ethylhexylglycerin	0.115	0,0000000038295	MoS>100
Sativus Pineapple Fruit Extract (Pineapple Extract)	0.5	0.00000001665	MoS>100
Carica Papaya Fruit Extract (Carcia papaya L)	0.5	0.00000001665	MoS>100
Bromelain	0.5	0.00000001665	MoS>100
Papain	0.5	0.00000001665	MoS>100
Glycerin	5	0.0000001665	MoS>100
Sodium Hyaluronate	0.7	0.0000000002331	MoS>100
Hydroxyethylcellulose	0.1	0.000000333	MoS>100

The toxicological profile of the substances contained in the cosmetic product together with data on the source of information is included in Annex 2.

8. Adverse reaction and serious adverse reaction

According to the manufacturer's declaration, no undesirable effects and serious undesirable effects were observed after the use of the cosmetic preparation. Taking into account the toxicological profile of the substance, the route of exposure, the conditions of use of the product, no interactions that could affect the safety of use of the product, if used as intended, are anticipated.

From the data resulting from the toxicological assessment of the product, no objections are drawn regarding the ingredients used and the expected side effects resulting from them.

In accordance with the requirements set out in art. 23 of Regulation 1223/2009/EC, the responsible person is obliged to document and report the adverse reaction caused by the cosmetic product.

In the event of a serious adverse reaction, the responsible person shall notify the relevant state authorities. The action of the responsible person and the solution to the problem in this case can be found in the guide on the websites of *the European Commission - Guidelines on reporting serious adverse reactions*:

http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/sue_reporting_guidelines_en.pdf

A system should be implemented to respond to any reported cases of serious adverse reaction after the cosmetic product used.

Information on the adverse reaction must be updated and made available to the person conducting the safety assessment for the possible need to include changes in the safety report (art. 10 sec. 1 letter C. of Regulation 1223/2009/EC).

G. Cosmetic product information

The product has not been tested on animals in accordance with art. 18 of the Regulation of the European Parliament and of the Council (EC) of 30 November 2009 on cosmetic products. Most of the substances used in the product are well known with a long history of safe use and show a lack of irritant and sensitizing properties.

Note:

The information on the packaging should be adapted to the requirements of Regulation 1223/2009/EC.

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PART B - Cosmetic product safety assessment

1. Evaluation conclusion

It is concluded that the cosmetic product is safe when used as intended, in accordance with the instructions for use and under foreseeable conditions. The product does not pose a foreseeable risk to human health when used intentionally. The safety assessment was made on the basis of the composition declared by the manufacturer and on the basis of the data provided on the ingredients and the finished product. The ingredients used and their amounts in the cosmetic product are acceptable for use in cosmetics in accordance with Regulation 1223/2009 of 30 November 2009

2. Warnings and instructions for use on the label

Taking into account the guidelines of art. 19 of Regulation 1223/2009 of On November 30, 2009, it is not required to provide additional warnings on the product label due to the presence of specific ingredients.

Taking into account the Regulation of the European Parliament No. 1223/2009 of November 30, 2009 and the Act of October 4, 2018 on cosmetic products, the following information should be included on the packaging:

- Name and surname/ Company of the person responsible,
- Nominal quantity of the cosmetic in the package in units of weight or volume at the time of packaging,
- The date until which a given cosmetic product stored under appropriate conditions fully retains its original properties, and in particular remains in accordance with art. 3 ("date of minimum durability"),
- Batch number or other data allowing identification of the cosmetic batch
- Function of the cosmetic, if it is not clear from the product presentation
- List of ingredients according to the names adopted in the International Nomenclature of Cosmetic Ingredients (INCI): AQUA, PANTHENOL, Glycerin, PINEAPPLE Sativus FRUIT EXTRACT, CARICA PAPAYA FRUIT EXTRACT, BROMELAIN, Papain, SODIUM PCA, sodium lactate, ARGININE, ASPARTIC acid, PCA, GLYCINE, ALANINE, Serine, Valine, PROLINE, THREONINE, ISOLEUCINE, HISTIDINE, PHENYLALANINE, SODIUM HYALURONATE, HYDROXYETHYLCELLULOSE, CITRIC acid, PHENOXYETHANOL, ETHYLHEXYLGLLLLYCERINE.

3. Reasoning

- The product subject to the safety assessment is intended for professional procedures on the skin around the eyes.
- During the research on the product, the physicochemical stability of the finished product and its compatibility with the packaging were confirmed, the shelf life of the cosmetic was estimated. The ingredients used in the formulation show no irritant or sensitizing properties.

- The cosmetic product is placed on the market and there is no information regarding side effects reported so far.
- The ingredients used to obtain the cosmetic mass have been used in the permitted concentrations and conditions of use laid down in Regulation 1223/2009/EC.
- The risk assessment of the components was made on the basis of a hazard analysis of toxicological data, a systemic analysis per product component, in justified cases a safety margin was determined.
- For the components for which the PODsys systemic toxicity value was available, a safety margin was determined. In all cases, MoS was greater than 100.
- The toxicological assessment of the ingredients contained in the cosmetic product (Annex 2) was made on the basis of the data contained in:

- safety data sheet of individual substances
- the CIR Cosmetic Ingredients Database
- fDA database
- hSDB database
- SCCS reviews
- opinion OF ECHA (European Chemicals Agency).

Updating the report should be performed each time in the case of:

- changing the recipe by the manufacturer,
- the appearance of new information about the ingredients,
- change of ingredient supplier (if the raw material quality documentation is different from the declared raw material),
- changing the packaging and the supplier of packaging in direct contact with the cosmetic,
- any change in the chemical composition, scope and manner of use, production process or other relevant data that may affect the safety of the product.

- Expert Qualifications and Part B Approval

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Proof of qualification of the person conducting the safety assessment is made available upon request by e-mail k.flis@lecoeur.pl

Turtle, on 25.08.2025

Signature