PRODUCT INFORMATION FILE

DORO

DORO EYE CREAM CONTAINS 3 FORMULA

While preparing the Product Information File;

- Cosmetics Law No. 5321
- Cosmetics Regulation
- Annexes of Cosmetics Regulation
- Guideline on Safety Assessment in Cosmetic Products Version 2.0
- Guideline on What to Include in the Cosmetic Product Information File Version 1.0
- Guideline on the Stability of Cosmetic Products and the Duration of Use After Opening Version 1.0
- Guideline on Products Bordering with Cosmetic Products Version 2.0
- Guideline on Claims of Cosmetic Products Version 3.0
- Guideline on Microbiological Control of Cosmetic Products Version 1.0
- European Commission(the sccs notes of guidance 9th revision)
- Regulation (EC) No 1223/2009 Of The European Parliament And Of The Council of 30 November
- http://www.efsa.europa.eu/en/efsajournal/doc/1387.pdf (MW>500, 10% dermal absorption)
- Chemical Safety Information from Intergovernmental Organizations
- http://www.gimex.cz/benzyl-alcohol-phenoxyethanol

According to the Cosmetics Regulation, the Product Information File must contain:

1. Information about the Manufacturer of the Product
2. Qualitative and Quantitative Composition of the Cosmetic Product; Code Number and Identity of the Supplier in case of a perfume and a perfume combination
3. Control criteria regarding the Physical/Chemical Properties, Stability and Compliance of the Cosmetic Product with the Microbiological Specification
4. Manufacturing method in accordance with the provisions of the Cosmetic Good Manufacturing Practices Guide; Training and working documents indicating the manufacturer has the appropriate level of professional competence or required experience
5. Safety assessment for human health in the finished product
6. Information about the person who will make the safety assessment
7. Existing information about the adverse effects that may be caused by the use of cosmetic products
8. Information about scientific studies proving the claimed effects of the cosmetic product or substance

According to the Cosmetics Regulation, the Product Safety Assessment Report should consist of the following parts:

Part A: Cosmetic Product Safety Information

1. Qualitative and quantitative composition of the cosmetic product
2. Physical/chemical properties and stability of the cosmetic product
3. Microbiological quality
4. Information about impurities, residues, packaging material information
5. Normal and reasonably foreseeable use
6. Exposure to cosmetic product
7. Exposure to the substances in the formula
8. Toxicological profile of the substances in the formula
9. Undesirable effects and serious adverse effects
10. Information about the cosmetic product

Part B: Cosmetic Product Safety Assessment

1. Evaluation result
2. Warnings and instructions for use on the label
3. Justification
4. Information about the safety assessment officer and the approval of Part B

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I-INTROUCTION

1.INFORMATION ABOUT THE COSMETIC PRODUCT

Name of the Product: DORO EYE CREAM CONTAINS 3 FORMULA

Physical Form of the Product: No Rinsed Product

Chemical Description of the Product: Mixture O/W Emulsion

Category of the Product: A.1. Skin Care Products

Sub-Category of the Product: A.1.3. Eye area products

Quantity of the Product: 15 ML

2.INFORMATION ABOUT THE MANFUACTURER OF THE PRODUCT

Name of the Manufacturer: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Address of the Manufacturing: HALİL RIFAT PAŞA NEIGHBORHOOD YÜZER HAVUZ STREET BİRLİK APARTMENT NO: 17-19 INTERIOR DOOR NO: 5 ŞİŞLİ / İSTANBUL/TURKEY

Address of Product Information File: HALİL RIFAT PAŞA NEIGHBORHOOD YÜZER HAVUZ STREET BİRLİK APARTMENT NO: 17-19 INTERIOR DOOR NO: 5 ŞİŞLİ / İSTANBUL/TURKEY

Phone Number of the Manufacturer:

Fax Number of the Manufacturer:

Mail Address of the Manufacturer: www.massimofazzi.ch

doro@karengp.com

3. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE COSMETIC PRODUCT

Name of the Product: DORO EYE CREAM CONTAINS 3 FORMULA

Physical Form of the Product: No Rinsed Product

Manufacturer: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Address of the Manufacturing: HALİL RIFAT PAŞA NEIGHBORHOOD YÜZER HAVUZ STREET BİRLİK APARTMENT NO: 17-19 INTERIOR DOOR NO: 5 ŞİŞLİ / İSTANBUL/TURKEY

Chemical Description of the Product: Mixture O/W Emulsion

Category of the Product: A.1. Skin Care Products

Sub-Category of the Product: A.1.3. Eye area products

• INCI Name, CAS Number, EINECSIELICS Numbers of Product Components:

NAME OF RAW MATERIAL	INCI NAME	CAS No	EINECS	FUNCTION	% RATE	LEGAL LIMITATION	Annexes of Cos. Reg.
AQUA	AQUA	7732-18-5	231-791-2	SOLVENT	50 - 75	-	-
GLYCERIN	GLYCERIN	56-81-5	200-289-5	HUMECTANT SKIN CONDITIONING SKIN PROTECTING	10 - 25	-	-
CARBOMER	CARBOMER	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4		EMULSION STABILISING GEL FORMING VISCOSITY CONTROLLING	1 - 5	-	-

TRIETHANOLAMINE	TRIETHANOLAMINE	102-71-6	203-049-8	BUFFERING SURFACTANT - EMULSIFYING FRAGRANCE SURFACTANT - CLEANSING	1 - 5	-	-
DIMETHICONE	DIMETHICONE	63148-62-9 / 9006-65-9 / 9016-00-6		ANTIFOAMING SKIN CONDITIONING - EMOLLIENT SKIN CONDITIONING SKIN PROTECTING	0.1 - 1	-	-
LACTIC ACID	LACTIC ACID	50-21-5	200-018-0	BUFFERING HUMECTANT SKIN CONDITIONING	0.1 - 1	-	-
PEG-40 HYDROGENATED CASTOR OIL	PEG-40 HYDROGENATED CASTOR OIL	61788-85-0		SURFACTANT - EMULSIFYING SURFACTANT - CLEANSING	0.1 - 1	-	-
SODIUM HYALURONATE	SODIUM HYALURONATE	9067-32-7		HUMECTANT SKIN CONDITIONING	0.01 - 0.1	-	-
VACCINIUM MYRTILLUS FRUIT EXTRACT	VACCINIUM MYRTILLUS FRUIT EXTRACT	84082-34-8	281-983-5	SKIN CONDITIONING - MISCELLANEOUS	0.01 - 0.1	-	-
AESCULUS HIPPOCASTANUM BARK EXTRACT	AESCULUS HIPPOCASTANUM BARK EXTRACT	8053-39-2	232-497-7	ASTRINGENT SKIN CONDITIONING TONIC	0.01 - 0.1	-	-
CHAMOMILLA RECUTITA EXTRACT	CHAMOMILLA RECUTITA EXTRACT	84082-60-0	282-006-5	SKIN CONDITIONING	0.01 - 0.1	-	-
COFFEA ARABICA SEED EXTRACT	COFFEA ARABICA SEED EXTRACT	84650-00-0	283-481-1	FRAGRANCE SKIN CONDITIONING	0.01 - 0.1	-	-

CUCUMIS SATIVUS FRUIT EXTRACT	CUCUMIS SATIVUS FRUIT EXTRACT	89998-01-6	289-738-4	SKIN CONDITIONING - EMOLLIENT SKIN CONDITIONING	0.01 - 0.1	-	-
ETHYL PALMITATE	ETHYL PALMITATE	628-97-7	211-064-6	SKIN CONDITIONING - EMOLLIENT PERFUMING	0.01 - 0.1	-	-
PROPANEDIOL	PROPANEDIOL	504-63-2 / 26264-14-2	207-997-3	SOLVENT VISCOSITY CONTROLLING	0.01 - 0.1	-	-
TOCOPHERYL ACETATE	TOCOPHERYL ACETATE	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	ANTIOXIDANT SKIN CONDITIONING	0.01 - 0.1	-	-
CITRIC ACID	CITRIC ACID	77-92-9 / 5949-29-1	201-069-1	BUFFERING CHELATING FRAGRANCE	0.01 - 0.1	-	-
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	70445-33-9	408-080-2	DEODORANT SKIN CONDITIONING	0.01 - 0.1	-	-
TETRASODIUM GLUTAMATE DIACETATE	TETRASODIUM GLUTAMATE DIACETATE	51981-21-6	257-573-7	CHELATING	0.01 - 0.1	-	-
TARTARIC ACID	TARTARIC ACID	133-37-9 / 147-71-7 / 87-69-4	205-105-7 / 205-695-6 / 201-766-0	BUFFERING FRAGRANCE	0.01 - 0.1	-	-
GLUCONIC ACID	GLUCONIC ACID	526-95-4	208-401-4	CHELATING PERFUMING	0.01 - 0.1	-	-

NAME OF RAW MATERIAL	INCI NAME	CAS No	EINECS	FUNCTION	% RATE	LEGAL LIMITATION	Annexes of Cos. Reg.
SODIUM BENZOATE	SODIUM BENZOATE	532-32-1	208-534-8	PROTECTIVE	0.1 – 0,5	0,5 %	V/1
POTASSIUM SORBATE	POTASSIUM SORBATE	24634-61-5 / 590-00-1	246-376-1 / -	PROTECTIVE	0.1 – 0,5	0,6 %	V/4
PHENOXYETHANOL	PHENOXYETHANOL	122-99-6	204-589-7	PROTECTIVE	0.01 - 0.1	1 %	V/29

· Purpose and Place of Use of the Product: moisturizing the eye area - around the eyes.

· Instruction for Usage of the Product: After cleansing thoroughly, apply a small amount of product morning and evening by massaging around the eyes.

4.USE OF THE PRODUCT

DORO EYE CREAM CONTAINS 3 FORMULA the brand and named product is offered to the consumer in 15 ML packaging. Primary packaging of the product is 15 ML plastic packaging, secondary packaging is cardboard box.

Label Information of the Product:

Label information of the primary packaging of the product:

DORO EYE CREAM CONTAINS 3 FORMULA

Available as a label in the finished product section.

Composition: Aqua, Glycerin, Carbomer, Triethanolamine, Dimethicone, Sodium Benzoate, Lactic Acid, Peg-40 Hydrogenated Castor Oil, Potassium Sorbate, Sodium Hyaluronate, Vaccinium Myrtillus Fruit Extract, Phenoxyethanol, Aesculus Hippocastanum Bark Extract, Chamomilla Recutita Extract, Coffea Arabica Seed Extract, Cucumis Sativus Fruit Extract, Ethyl Palmitate, Propanediol, Tocopheryl Acetate, Citric Acid, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Tartaric Acid, Gluconic Acid.

Usage: After cleansing thoroughly, apply a small amount of product morning and evening by massaging around the eyes.
Warnings: Keep out of reach of children. Avoid contact with eyes and mucous membranes, if any, Rinse with plenty of lukewarm water. Do not swallow. Do not use on damaged skin. Keep away from direct sunlight and heat sources.

Manufacturing firm: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Cover mark : 12M

Date of Manufacturing: 07.03.2023

Net 15 ML

Barcode: 8684054000616

Label information of the secondary packaging of the product:

Available as a label in the finished product section.

DORO EYE CREAM CONTAINS 3 FORMULA

Available as a label in the finished product section.

Composition: Aqua, Glycerin, Carbomer, Triethanolamine, Dimethicone, Sodium Benzoate, Lactic Acid, Peg-40 Hydrogenated Castor Oil, Potassium Sorbate, Sodium Hyaluronate, Vaccinium Myrtillus Fruit Extract, Phenoxyethanol, Aesculus Hippocastanum Bark Extract, Chamomilla Recutita Extract, Coffea Arabica Seed Extract, Cucumis Sativus Fruit Extract, Ethyl Palmitate, Propanediol, Tocopheryl Acetate, Citric Acid, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Tartaric Acid, Gluconic Acid.

Usage:. After cleansing thoroughly, apply a small amount of product morning and evening by massaging around the eyes.

Warnings: Keep out of reach of children. Avoid contact with eyes and mucous membranes, if any. Rinse with plenty of lukewarm water. Do not swallow. Do not use on damaged skin. Keep away from direct sunlight and heat sources.

Manufacturing firm: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Cover mark : 12M

Date of Manufacturing: 07.03.2023

Net 15 ML

Barcode: 8684054000616

II) INFORMATION ABOUT RAW MATERIALS

III) INFORMATION ABOUT THE FINISHED PRODUCT

The finished product is subjected to organoleptic (physical appearance) examination. As a result of this examination, it is in the desired criteria in terms of physical appearance. The product does not contain dyes. It has a homogenous thick cream structure.

The physicochemical properties of the product are included in the annexes of this part, in the analysis report and in the 9th section of the product's MSDS.

The product's msds is presented for your information in the annexes of this section.

Stability tests of the product are presented for your information in the annexes of this section.

Microbiology test results analysis report of the product is presented for your information in the annexes of this section.

Screening Stress test results of the product are presented for your information in the annexes of this section.

IV) MANUFACTURING METHOD AND COMPLIANCE WITH GOOD MANUFACTURING PRACTICES

INFORMATION ABOUT MANUFACTURER OF THE PRODUCT

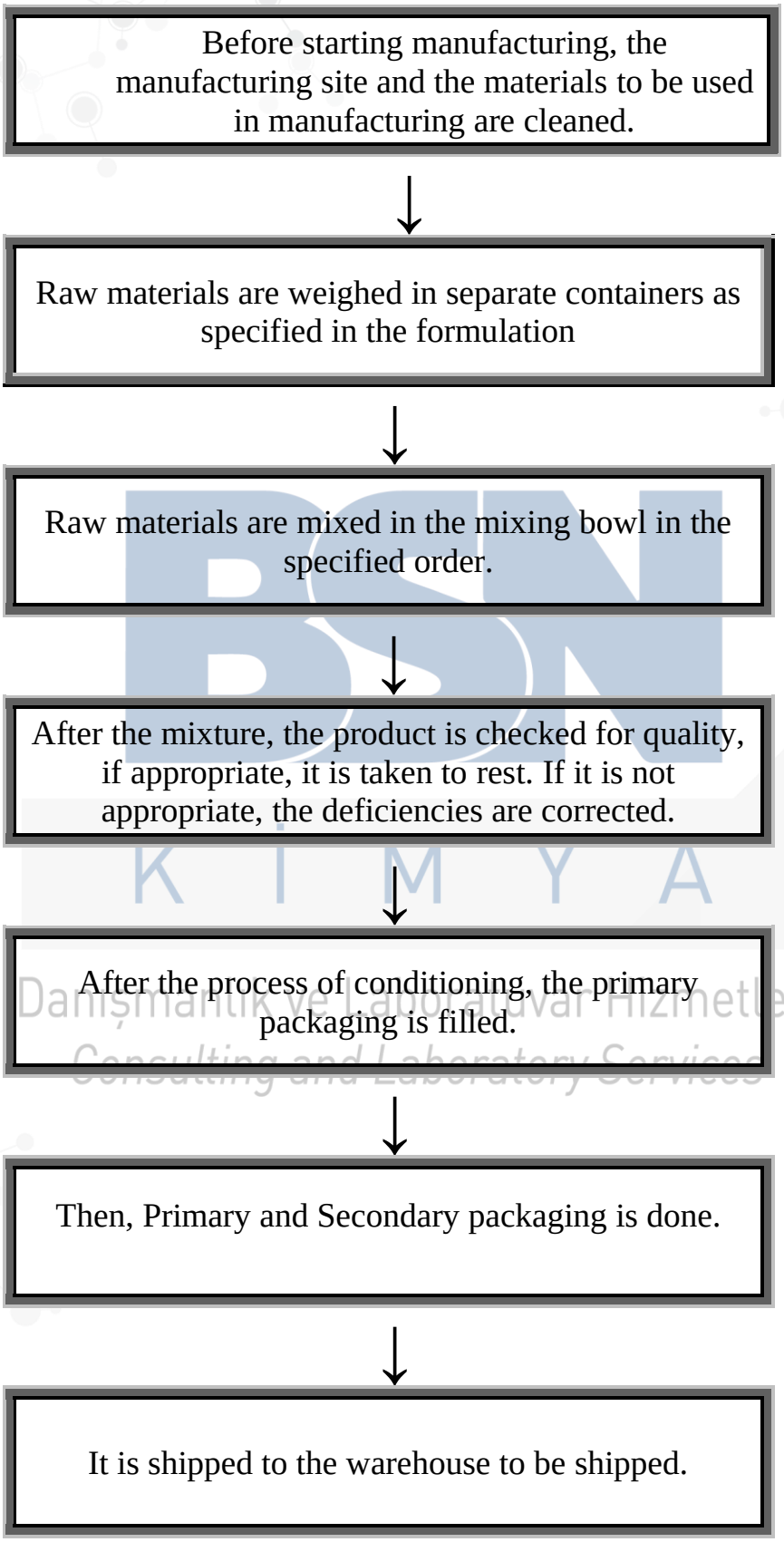
Name of the Product: DORO EYE CREAM CONTAINS 3 FORMULA

Physical Form of the Product: No Rinsed Product

Manufacturer: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Address of the Manufacturing: HALİL RIFAT PAŞA NEIGHBORHOOD YÜZER HAVUZ STREET BİRLİK APARTMENT NO: 17-19 INTERIOR DOOR NO: 5 ŞİŞLİ / İSTANBUL/TURKEY

Manufacturing Method: Presented in the form of Manufacturing Flow chart.



V) PRODUCT SAFETY ASSESSMENT REPORT ACCORDING TO THE COSMETICS REGULATION

COSMETIC PRODUCT SAFETY REPORT

Name of the Product: DORO EYE CREAM CONTAINS 3 FORMULA

Physical Form of the Product: No Rinsed Product

Manufacturer: KAREN AVIATION TOURISM REAL ESTATE ADVERTISING CONSULTANCY IMPORT EXPORT INDUSTRY AND TRADE

Address of the Manufacturing: HALİL RIFAT PAŞA NEIGHBORHOOD YÜZER HAVUZ STREET BİRLİK APARTMENT NO: 17-19 INTERIOR DOOR NO: 5 ŞİŞLİ / İSTANBUL/TURKEY

Chemical Description of the Product: Mixture O/W Emulsion

Category of the Product: A.1. Skin Care Products

Sub-Category of the Product: A.1.3. Eye area products

Part A: Cosmetic Product Safety Information

1. Qualitative and quantitative properties of the cosmetic product

NAME OF RAW MATERIAL	INCI NAME	CAS No	EINECS	FUNCTION	% RATE	LEGAL LIMITATION	Annexes of Cos. Reg.
AQUA	AQUA	7732-18-5	231-791-2	SOLVENT	50 - 75	-	-
GLYCERIN	GLYCERIN	56-81-5	200-289-5	HUMECTANT SKIN CONDITIONING SKIN PROTECTING	10 - 25	-	-

CARBOMER	CARBOMER	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4		EMULSION STABILISING GEL FORMING VISCOSITY CONTROLLING	1 - 5	-	-
TRIETHANOLAMINE	TRIETHANOLAMINE	102-71-6	203-049-8	BUFFERING SURFACTANT - EMULSIFYING FRAGRANCE SURFACTANT - CLEANSING	1 - 5	-	-
DIMETHICONE	DIMETHICONE	63148-62-9 / 9006-65-9 / 9016-00-6		ANTIFOAMING SKIN CONDITIONING - EMOLLIENT SKIN CONDITIONING SKIN PROTECTING	0.1 - 1	-	-
LACTIC ACID	LACTIC ACID	50-21-5	200-018-0	BUFFERING HUMECTANT SKIN CONDITIONING	0.1 - 1	-	-
PEG-40 HYDROGENATED CASTOR OIL	PEG-40 HYDROGENATED CASTOR OIL	61788-85-0		SURFACTANT - EMULSIFYING SURFACTANT - CLEANSING	0.1 - 1	-	-
SODIUM HYALURONATE	SODIUM HYALURONATE	9067-32-7		HUMECTANT SKIN CONDITIONING	0.01 - 0.1	-	-
VACCINIUM MYRTILLUS FRUIT EXTRACT	VACCINIUM MYRTILLUS FRUIT EXTRACT	84082-34-8	281-983-5	SKIN CONDITIONING - MISCELLANEOUS	0.01 - 0.1	-	-

AESCULUS HIPPOCASTANUM BARK EXTRACT	AESCULUS HIPPOCASTANUM BARK EXTRACT	8053-39-2	232-497-7	ASTRINGENT SKIN CONDITIONING TONIC	0.01 - 0.1	-	-
CHAMOMILLA RECUTITA EXTRACT	CHAMOMILLA RECUTITA EXTRACT	84082-60-0	282-006-5	SKIN CONDITIONING	0.01 - 0.1	-	-
COFFEA ARABICA SEED EXTRACT	COFFEA ARABICA SEED EXTRACT	84650-00-0	283-481-1	FRAGRANCE SKIN CONDITIONING	0.01 - 0.1	-	-
CUCUMIS SATIVUS FRUIT EXTRACT	CUCUMIS SATIVUS FRUIT EXTRACT	89998-01-6	289-738-4	SKIN CONDITIONING - EMOLLIENT SKIN CONDITIONING	0.01 - 0.1	-	-
ETHYL PALMITATE	ETHYL PALMITATE	628-97-7	211-064-6	SKIN CONDITIONING - EMOLLIENT PERFUMING	0.01 - 0.1	-	-
PROPANEDIOL	PROPANEDIOL	504-63-2 / 26264-14-2	207-997-3	SOLVENT VISCOSITY CONTROLLING	0.01 - 0.1	-	-
TOCOPHERYL ACETATE	TOCOPHERYL ACETATE	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	ANTIOXIDANT SKIN CONDITIONING	0.01 - 0.1	-	-
CITRIC ACID	CITRIC ACID	77-92-9 / 5949-29-1	201-069-1	BUFFERING CHELATING FRAGRANCE	0.01 - 0.1	-	-
ETHYLHEXYLGLYCERIN	ETHYLHEXYLGLYCERIN	70445-33-9	408-080-2	DEODORANT SKIN CONDITIONING	0.01 - 0.1	-	-
TETRASODIUM GLUTAMATE DIACETATE	TETRASODIUM GLUTAMATE DIACETATE	51981-21-6	257-573-7	CHELATING	0.01 - 0.1	-	-
TARTARIC ACID	TARTARIC ACID	133-37-9 / 147-71-7 / 87-69-4	205-105-7 / 205-695-6 / 201-766-0	BUFFERING FRAGRANCE	0.01 - 0.1	-	-
GLUCONIC ACID	GLUCONIC ACID	526-95-4	208-401-4	CHELATING PERFUMING	0.01 - 0.1	-	-

NAME OF RAW MATERIAL	INCI NAME	CAS No	EINECS	FUNCTION	% RATE	LEGAL LIMITATION	Annexes of Cos. Reg.
SODIUM BENZOATE	SODIUM BENZOATE	532-32-1	208-534-8	PROTECTIVE	0.1 – 0,5	0,5 %	V/1
POTASSIUM SORBATE	POTASSIUM SORBATE	24634-61-5 / 590-00-1	246-376-1 / -	PROTECTIVE	0.1 – 0,5	0,6 %	V/4
PHENOXYETHANOL	PHENOXYETHANOL	122-99-6	204-589-7	PROTECTIVE	0.01 - 0.1	1 %	V/29

Comment by the Safety Evaluator:

The compliance of the raw materials used in the composition of the product DORO EYE CREAM CONTAINS 3 FORMULA with the regulation and its annexes has been checked. The product does not contain any prohibited raw materials. Limited components are within legal limits.

Physicochemical properties and MSDS documents for raw materials are presented for your information in Part 2 of the Product Information File, Information About Raw Materials.

2. Physical/Chemical Properties and Stability of the Cosmetic Product

a) Physical / Chemical Properties of the Substance or Mixtures

PHYSIOCHEMICAL PROPERTIES OF WATER	
MOLECULAR FORMULA	H2O
MOLECULAR WEIGHT	18
BOILING POINT	100 °C
MELTING POINT	0

PHYSIOCHEMICAL PROPERTIES OF GLYCERIN	
PHYSICAL FORM	Liquid
PURITY	100
DENSITY	3.17
RESOLUTION	1 000 g/L @ 25 °C
COLOUR	CHARACTERISTIC
SMELL	ITS OWN LIGHT SMELL
MELTING POINT	19 °C
BOILING TEMPERATURE	290 °C

PHYSIOCHEMICAL PROPERTIES OF CARBOMER	
PHYSICAL FORM	WHITE POWDER
RESOLUTION	CLEAR
COLOUR	CHARACTERISTIC
SMELL	LIGHT ACETIC
MELTING POINT	NOT AVAILABLE
BOILING TEMPERATURE	NOT AVAILABLE

PHYSIOCHEMICAL PROPERTIES OF TRIETHANOLAMINE	
PHYSICAL FORM	Liquid
PURITY	100
DENSITY	1.114 g/cm³ 20 °C
RESOLUTION	1 000 g/L 20 °C
COLOUR	CHARACTERISTIC
SMELL	ITS OWN LIGHT SMELL
MELTING POINT	20.5 °C
BOILING TEMPERATURE	336.1 °C

PHYSIOCHEMICAL PROPERTIES OF LACTIC ACID	
PHYSICAL FORM	LIQUID
Ph	2,8
FLASH POINT	110 °C
DENSITY	1.2 g/cm³ at 20 °C
RESOLUTION	WATER INSOLUBLE
COLOUR	PALE
SMELL	ODORLESS
BOILING POINT	122 °C

PHYSIOCHEMICAL PROPERTIES OF PEG-40 HYDROGENATED CASTOR OIL	
PHYSICAL FORM	Liquid
Ph	6-8
FLASH POINT	>175 °C
DENSITY	1.04 g/cm³
RESOLUTION	-

COLOUR	Brownish-yellow or yellow
SMELL	CHARACTERISTIC
BOILING POINT	-

PHYSIOCHEMICAL PROPERTIES OF SODIUM HYALURONATE	
PHYSICAL FORM	POWDER SOLID
RESOLUTION	CLEAR
COLOUR	LIGHT CREAM
SMELL	NO INFORMATION AVAILABLE
PH	5.5-7.5

PHYSIOCHEMICAL PROPERTIES OF TOCOPHERYL ACETATE	
PHYSICAL FORM	LIQUID
FLASH POINT	225.5 ° C - CLOSED CUP
COLOUR	LIGHT GREEN
SMELL	ITS OWN LIGHT SMELL
MELTING POINT	NO

PHYSIOCHEMICAL PROPERTIES OF CITRIC ACID	
PHYSICAL FORM	SOLID
Ph	1,7
FLASH POINT	-
DENSITY	1.67 g/cm³ at 20 °C
RESOLUTION	WATER SOLUBLE

COLOUR	PALE
SMELL	ODORLESS
BOILING POINT	200 °C

PHYSIOCHEMICAL PROPERTIES OF ETHYLHEXYLGLYCERIN	
PHYSICAL FORM	LIQUID
Ph	-
FLASH POINT	121 °C
DENSITY	1.1 g/ml
RESOLUTION	WATER SOLUBLE
COLOUR	PALE
SMELL	ODORLESS
BOILING POINT	>245 °C

PHYSICOCHEMICAL PROPERTIES OF TARTARIC ACID	
PHYSICAL FORM	SOLID
Ph	1,6
FLASH POINT	150 °C
DENSITY	1,76 g/cm³
RESOLUTION	WATER SOLUBLE
COLOUR	WHITE
SMELL	ODORLESS
BOILING POINT	399 °C

PHYSICOCHEMICAL PROPERTIES OF PHENOXYETHANOL	
PHYSICAL FORM	LIQUID
Ph	7
FLASH POINT	-
DENSITY	1.11 g/cm3
RESOLUTION	WATER SOLUBLE
COLOUR	PALE
SMELL	CHARACTERISTIC
BOILING POINT	244.3 °C

PHYSICOCHEMICAL PROPERTIES OF SODIUM BENZOATE	
PHYSICAL FORM	LIQUID
PURITY	100
DENSITY	1.5 g/cm³ 20 °C
RESOLUTION	556 g/L @ 20 °C
COLOUR	CHARACTERISTIC
SMELL	CHARACTERISTIC
MELTING POINT	436 °C
BOILING TEMPERATURE	-

PHYSICOCHEMICAL PROPERTIES OF POTASSIUM SORBATE	
PHYSICAL FORM	SOLID
PURITY	100
DENSITY	1.36 g/cm³ 23.5 °C
RESOLUTION	1.95 g/L @ 20 °C
COLOUR	CHARACTERISTIC
SMELL	ODORLESS
MELTING POINT	250 °C
BOILING TEMPERATURE	-

PHYSIOCHEMICAL PROPERTIES OF TOCOPHERYL ACETATE	
PHYSICAL FORM	LIQUID
FLASH POINT	225.5 ° C - CLOSED CUP
COLOUR	LIGHT GREEN
SMELL	ITS OWN LIGHT SMELL
MELTING POINT	NO

PHYSICOCHEMICAL PROPERTIES OF PROPANEDIOL	
PHYSICAL FORM	LIQUID
PURITY	100
DENSITY	1.05 g/ml
RESOLUTION	Dissolve in water ure.
COLOUR	CHARACTERISTIC
SMELL	CHARACTERISTIC
MELTING POINT	-24.55 °C
BOILING TEMPERATURE	208.95 °C

Comment by the Safety Evaluator:

Physicochemical properties of the raw materials used have been examined in line with the information obtained from the MSDS of the raw materials used and given in a table. It can be used for incompatibility date of products during mixing.

b) Physical / Chemical Properties of the Finished Cosmetic Product

PARAMETER	METHOD	SPECIFICATION
Appearance	Visual	CREAM
Smell	Sensory	PERFUMED
Solubility	-	INSOLUBLE IN WATER
Density *(g/L)* (20°C)	Pycnometer	1.08
pH (20°C)	Ph meter	5.5
Solubility in Water	-	NOT FULL SOLUBLE
Viscosity (20°C) (cP)	(Soif NDJ -4 sp.3 12rpm)	6000

Comment by the Safety Evaluator:

DORO EYE CREAM CONTAINS 3 FORMULA has the appearance of a homogenous cream as a result of the physicochemical results obtained from the analysis report in the section of Information About the Finished Product in Part 3.

c) Durability / Stability Information

As a result of the Stability tests given in Information about the Finished Product section in Part 3, it has been observed that there is little change in the physical form of the product due to temperature. In addition, it was observed that there was no change in its chemical structure.

This situation does not cause any change in the stable structure, quality and shelf life of the product. In line with this information, the shelf life of the product predicted by the manufacturer is at least 24 months.

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3. Microbiological Quality

a) Microbiological quality of substances and mixtures

Special attention should be paid to raw materials most sensitive to microbial growth (e.g. water-based mixtures, protein-rich ingredients, vegetable or animal raw materials).

b) Microbiological quality of the finished product

Category 1:As a result of the microbiological screening tests of cosmetic products applied to the eye area, mucosa, damaged skin, children under three years of age, the elderly and people with a severely weakened immune response, the number of microorganisms that can form colonies must comply with the allowed limits.

Category 2:Other products

Acceptance criteria for the finished product are as follows:

- Total number of aerobic mesophilic microorganisms should be less than 100 cfu/g in Category 1 class and less than 1000 cfu/g in Category 2 class.
- Total number of mold and yeast should be less than 100 cfu/g in Category 1 class and less than 1000 cfu/g in Category 2 class.
- The number of microorganisms should be less than 100 cfu/g in the eye area and baby products, as well as in non-rinsed products.

• Pathogenic microorganisms called Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans should never be present in the finished cosmetic product.

In the microbiological quality of the finished product regarding the microbiological sensitivity, there is a difference between the three product categories:

1. Low microbiological risk products: Scientific verification should be provided for products with low microbiological risk, where screening-stress testing or microbiological quality tests are not required on the finished product (for example; products with alcohol content > 20% , products based on organic solutions, high/low pH products, hot-filled products above 60 ˚C).

2. Low microbiological risk products: Disposable products and products that cannot be opened: Scientific justification should be provided for disposable products and non-opening products (for example, packages that help to dose the product without contact with air), where only microbiological quality testing is required for the finished product.

3. All other products that require both screening-stress testing and microbiological quality testing on the finished product.

Comment by the Safety Evaluator:

Microbiological analysis report of the product is presented for your information in Part III of the product information file. Microbiological results were found below the legal limit values.

The cosmetics manufacturer must ensure that the devices and materials are clean, the products are free of pathological microorganisms, by following Good Manufacturing Practices and Microbiological Quality Management, designing and following special cleaning, sanitation and control procedures.

Procedures should also include microbiological control of raw material, bulk and finished products, packaging materials, personnel, equipment, preparation and storage rooms.

4. Information about Impurities, Residues, Packaging Material

A – Impurities and Residues

When the MSDSs of the raw materials used are examined, it is seen that there is no impurity. In addition, it does not seem possible to deliberately detect impurity material in the formulation of the product.

There is no residue observed in the finished product. Since it is stable under normal conditions, it is considered that there will be no residue that can be contaminated from the package over time and during the shipment period.

B – Packaging Material

The product is presented to the consumer in 15 ML plastic packaging. Primary packaging of the product is 15 ML plastic packaging, secondary packaging is cardboard box.

Msds has been examined about the packaging material and information is presented in Part 2, Information about Raw Materials.

The primary packaging and cover of the product is not expected to react with the product with the statement of the company. Therefore, no impurities are expected from here.

5. Normal and Reasonably Foreseeable Use

a) Label Information of the Product: DORO EYE CREAM CONTAINS 3 FORMULA

Planned Use: eye area care

Normal Use: eye area

Reasonably foreseeable Use: eye area care.

b) Warnings on the Label of the Product: For external use. Keep out of reach of children. Avoid contact with eyes and mucous membranes, if any. Rinse with plenty of lukewarm water. Do not swallow. Do not use on damaged skin. Keep away from direct sunlight and heat sources.

c) Normal and Reasonably Foreseeable Use and Use of the Product

Quantity: Around the eyes, 0,02 g of product not rinsed.

d) Usage and Frequency of Use of the Product: Around the eyes, 0,02 g without rinsing is suitable for use.

6. Exposure to Cosmetic Product

Exposure information for the cosmetic product, considering Part A (5), the product type (rinsed, non-rinsed):

Product Type / category	No Rinse Product
Normal Area of Application	Around the eyes
Reasonably foreseeable Use	cream issue
Surface area of the applied area	Around the eyes 24 cm^2
Amount of product applied(g)	0,02 g
Frequency of use	2/day
Contact time of product	8 hours
Normal exposure routes	Dermal
Reasonably foreseeable exposure routes (e.g. oral exposure for toothpaste and lip gloss or inhalational exposure for aerosols and solvents)	None
The targeted or exposed person/persons	Adults
Retention Factor(R) Remainder after washing	1.0
Calculated Daily exposure g/day	0,02
Calculated Relative Daily Exposure (mg/kg/weight /day) (A value)	0,33

7. Exposure to Cosmetic Product Components

• If the amount of dermal absorption (ug/cm") on the unit surface is known:

SED=[DAa(jlg/cm2) x ıo-3(mgl ug) x SSA (cnr') x F(day-I) x R] / [60 (kg)]

• If the amount of dermal absorption of the applied product is known:24

SED = A(mglkg body weight/day) X C() / 100 X DAp () / 100

SED (mg/kg body weight/day): Systematic Exposure Dosage

A (mg/kg body weight/day): Daily exposure to a cosmetic product depending on the amount of product applied per kg of body weight and on the frequency of application

C (): Concentration of the substance whose exposure is to be calculated in the finished product

DAp ( ): Percentage of dermal absorption of the product (obtained as a result of an experiment simulating the conditions of use, if unknown, the product is considered to have 100% absorption). When the molecular weight is above 500 Da and the log Pow is less than -1 or greater than 4, the dermal absorption value can be accepted as 10%. The percentage of dermal absorption can be taken as 25% for products with active ingredient greater than 5% (for 50g/kg solids or 50g/L liquids). If the active substance is 5% or less, the percentage of dermal absorption can be used as 75%.

DAa (µg/cm2)= (Daily exposure of a 60 kg personXSEDx1000)/ CM2

• Calculation of Safety Interval: was made as follows and is indicated in the SED 1 table.

SED = A (mg/kg bw/day) x C ()/100 x DAp ()/100

A : 0,33 mg/kg bw/day

C :

DAp : 100

SED :

·Purpose and Place of Use of the Product: It is a non-rinsing product used for moisturizing and care of the skin.

· Instructions for Usage of the Product: Apply a small amount of product on perfectly cleansed face and neck. Massage gently until completely absorbed.

Taking 8th Revision of SCSS Guidance Notes and the Guideline on Cosmetic Product Information Assessment Annex 3, Table 1 as a reference, the amount of daily exposure was used as a value calculated for DORO EYE CREAM CONTAINS 3 FORMULA, which is: 0,33 mg/kg body weight/day. Average body weight is taken as 60 kg for an adult.

SED 1: CALCULATED RAW MATERIAL COMPONENT SED TABLE

INCI Name of Raw Material	Concentration C()	Retention Factor R	Dermal Absorption DAa (ıiwcm^2)	Dermal Absorption DAp()	SED (mg/kg bw/day)
AQUA	75	1,0	618,75000	100	0,24750
GLYCERIN	25	1,0	206,25000	100	0,08250
CARBOMER	5	1,0	41,25000	100	0,01650
TRIETHANOLAMINE	5	1,0	41,25000	100	0,01650
DIMETHICONE	1	1,0	8,25000	100	0,00330
LACTIC ACID	1	1,0	8,25000	100	0,00330
PEG-40 HYDROGENATED CASTOR OIL	1	1,0	8,25000	100	0,00330
SODIUM HYALURONATE	0.1	1,0	0,82500	100	0,00033
VACCINIUM MYRTILLUS FRUIT EXTRACT	0.1	1,0	0,82500	100	0,00033
AESCULUS HIPPOCASTANUM BARK EXTRACT	0.1	1,0	0,82500	100	0,00033
CHAMOMILLA RECUTITA EXTRACT	0.1	1,0	0,82500	100	0,00033
COFFEA ARABICA SEED EXTRACT	0.1	1,0	0,82500	100	0,00033

CUCUMIS SATIVUS FRUIT EXTRACT	0.1	1,0	0,82500	100	0,00033
ETHYL PALMITATE	0.1	1,0	0,82500	100	0,00033
PROPANEDIOL	0.1	1,0	0,82500	100	0,00033
TOCOPHERYL ACETATE	0.1	1,0	0,82500	100	0,00033
CITRIC ACID	0.1	1,0	0,82500	100	0,00033
ETHYLHEXYLGLYCERIN	0.1	1,0	0,82500	100	0,00033
TETRASODIUM GLUTAMATE DIACETATE	0.1	1,0	0,82500	100	0,00033
TARTARIC ACID	0.1	1,0	0,82500	100	0,00033
GLUCONIC ACID	0,1	1,0	0,82500	100	0,00033

Calculated SED for Protecting Agent = A (mg/kg bw/day) x C ()/100 x DAp ()/100

A : 0,33 mg/kg bw/day

C :

DAp : 100

SED :

SED 2: CALCULATED PROTECTIVE SED TABLE

INCI Name of Raw Material	Concentration C()	Retention Factor R	Dermal Absorption DAa (ıiwcm^2)	Dermal Absorption DAp()	SED (mg/kg bw/day)
SODIUM BENZOATE	0,5	1,0	91,18644	100	1,34500
POTASSIUM SORBATE	0.5	1,0	91,18644	100	1,34500
PHENOXYETHANOL	0.1	1,0	18,23729	100	0,26900

The A value for protective agents was taken as 269,00 mg/kg body weight/day. (Guideline Version 3.0 on Safety Assessment in Cosmetic Products)

• MoS calculations of the raw materials whose SED values are indicated in the tables above for DORO EYE CREAM CONTAINS 3 FORMULA are made according to the formulation below and are shown in the MoS TABLE.

• Calculation of Safety Interval: ?

SED = **A** (mg/kg bw/day) x **C** (%)/100 x **DAp** (%)/100

A : 0,33 mg/kg bw/day

C : ? %

DAp : 100 %

NOAEL : ?

SED = 0,33 X ?/ 100 X 100 / 100

SED = ? mg/kg bw/day

MoS = NOAEL / SED

MoS 1 : CALCULATED RAW MATERIAL INGREDIENT MoS TABLE

INCI Name of Raw Material	SED (mg/kg bw/ day)	NOAEL (mg/kg bw/day)	MoS (NOAEL/SED)	ASSESSMENT RESULT MoS> 100
AQUA	0,24750	-	NOT CALCULATED	Safe to use in this product at this concentration.
GLYCERIN	0,08250	2000	24242,42424	Safe to use in this product at this concentration.
CARBOMER	0,01650	1512	91636,36364	Safe to use in this product at this concentration.
TRIETHANOLAMINE	0,01650	1000	60606,06061	Safe to use in this product at this concentration.
DIMETHICONE	0,00330	1000	303030,303	Safe to use in this product at this concentration.
LACTIC ACID	0,00330	570	172727,2727	Safe to use in this product at this concentration.
PEG-40 HYDROGENATED CASTOR OIL	0,00330	500	151515,1515	Safe to use in this product at this concentration.
SODIUM HYALURONATE	0,00033	600	1818181,818	Safe to use in this product at this concentration.
VACCINIUM MYRTILLUS FRUIT EXTRACT	0,00033	1000	3030303,03	Safe to use in this product at this concentration.
AESCULUS HIPPOCASTANUM BARK EXTRACT	0,00033	300	909090,9091	Safe to use in this product at this concentration.
CHAMOMILLA RECUTITA EXTRACT	0,00033	5000	15151515,15	Safe to use in this product at this concentration.
COFFEA ARABICA SEED EXTRACT	0,00033	2000	6060606,061	Safe to use in this product at this concentration.
CUCUMIS SATIVUS FRUIT EXTRACT	0,00033	-	NOT CALCULATED	Safe to use in this product at this concentration.
ETHYL PALMITATE	0,00033	1000	3030303,03	Safe to use in this product at this concentration.

PROPANEDIOL	0,00033	1000	3030303,03	Safe to use in this product at this concentration.
TOCOPHERYL ACETATE	0,00033	500	1515151,515	Safe to use in this product at this concentration.
CITRIC ACID	0,00033	2000	6060606,061	Safe to use in this product at this concentration.
ETHYLHEXYLGLYCERIN	0,00033	1000	3030303,03	Safe to use in this product at this concentration.
TETRASODIUM GLUTAMATE DIACETATE	0,00033	300	909090,9091	Safe to use in this product at this concentration.
TARTARIC ACID	0,00033	145	439393,9394	Safe to use in this product at this concentration.
GLUCONIC ACID	0,00033	2000	6060606,061	Safe to use in this product at this concentration.

MoS 2 : CALCULATED PROTECTIVE INGREDIENT MoS TABLE

INCI Name of Protective Ingredients	SED (mg/kg bw/ day)	NOAEL (mg/kg bw/day)	MoS (NOAEL/SED)	ASSESSMENT RESULT MoS> 100
SODIUM BENZOATE	1,34500	500	371,7472119	Safe to use in this product at this concentration.
POTASSIUM SORBATE	1,34500	750	557,6208178	Safe to use in this product at this concentration.
PHENOXYETHANOL	0,26900	375	1394,052045	Safe to use in this product at this concentration.

8. Toxicological Profile of Cosmetic Product Ingredients

In the safety assessment of this product, the IFRA certificate of conformity provided by the manufacturer was used together with MoS calculations.

INCI Name of Raw Material	Toxicology Profile (if applicable, LD50 value, Toxicological information in MSDS of the substance etc.)
GLYCERIN	Acute aquatic toxicity: Not determined Persistence and degradability: Not available. Bioconcentration Factor: Not determined Mobility in soil: Not available. Results of PBT and vPvB assessment: Not determined Other adverse effects: Not available.
LACTIC ACID	Acute toxicity Oral: No data available Symptoms: Possible symptoms:, mucosal irritations Dermal: No data available Skin corrosion/irritation Remarks: Mixture causes skin irritation. Serious eye damage/eye irritation Remarks: Mixture causes serious eye damage. Respiratory or skin sensitization No data available Germ cell mutagenicity No data available Carcinogenicity No data available Reproductive toxicity No data available Specific target organ toxicity - single exposure No data available Specific target organ toxicity - repeated exposure No data available Aspiration hazard No data available

PEG-40 HYDROGENATED CASTOR OIL	Acute toxicity LD50 Oral - Rat - > 20.000 mg/kg LC50 Inhalation - Rat - 4 h - > 2,06 mg/l (OECD Test Guideline 403) Dermal: No data available Skin corrosion/irritation Skin - Rabbit Result: No skin irritation (OECD Test Guideline 404) Serious eye damage/eye irritation Eyes - Rabbit Result: No eye irritation Respiratory or skin sensitization Maximization Test - Guinea pig Result: Did not cause sensitization on laboratory animals. Germ cell mutagenicity Tests on bacterial or mammalian cell cultures did not show mutagenic effects. In vivo tests did not show mutagenic effects Carcinogenicity No data available Reproductive toxicity Did not show teratogenic effects in animal experiments. Specific target organ toxicity - single exposure No data available Specific target organ toxicity - repeated exposure No data available Aspiration hazard No data available

SODIUM HYALURONATE	Acute toxicity LD50 Oral - Rat - > 800 mg/kg Remarks: Nutritional and Gross Metabolic:Changes in:Other changes. (RTECS) Inhalation: No data available Dermal: No data available Skin corrosion/irritation No data available Serious eye damage/eye irritation No data available Respiratory or skin sensitization No data available Germ cell mutagenicity No data available Carcinogenicity No data available Reproductive toxicity No data available Specific target organ toxicity - single exposure No data available Specific target organ toxicity - repeated exposure No data available Aspiration hazard No data available
ETHYL PALMITATE	Acute toxicity Shall not be classified as acutely toxic. Skin corrosion/irritation Shall not be classified as corrosive/irritant to skin. Serious eye damage/eye irritation Shall not be classified as seriously damaging to the eye or eye irritant. Respiratory or skin sensitisation Shall not be classified as a respiratory or skin sensitiser. Germ cell mutagenicity Shall not be classified as germ cell mutagenic. Carcinogenicity Shall not be classified as carcinogenic. Reproductive toxicity Shall not be classified as a reproductive toxicant. Specific target organ toxicity - single exposure Shall not be classified as a specific target organ toxicant (single exposure). Specific target organ toxicity - repeated exposure Shall not be classified as a specific target organ toxicant (repeated exposure). Aspiration hazard Shall not be classified as presenting an aspiration hazard.

SODIUM BENZOATE	Acute oral toxicity LD50 Rat: 3,140 mg/kg (External MSDS) Symptoms: Nausea, Vomiting, Stomach/intestinal disorders Acute inhalation toxicity Symptoms: Possible symptoms:, mucosal irritations Acute dermal toxicity This information is not available. Skin irritation Rabbit Result: No irritation OECD Test Guideline 404 Eye irritation Rabbit Result: irritating OECD Test Guideline 405 Causes serious eye irritation. Sensitisation This information is not available. Germ cell mutagenicity Genotoxicity in vivo Chromosome aberration test Rat male Oral Bone marrow Result: negative Method: OECD Test Guideline 475 Genotoxicity in vitro Ames test Escherichia coli/Salmonella typhimurium Result: negative Method: OECD Test Guideline 471 Carcinogenicity This information is not available. Reproductive toxicity This information is not available. Teratogenicity This information is not available. Specific target organ toxicity - single exposure This information is not available. Specific target organ toxicity - repeated exposure This information is not available. Aspiration hazard This information is not available.
POTASSIUM SORBATE	Acute toxicity Shall not be classified as acutely toxic. Exposure route Endpoint Value Species Source oral LD50 10.500 mg/kg rat ECHA dermal LD50 >2.000 mg/kg rat ECHA Skin corrosion/irritation Shall not be classified as corrosive/irritant to skin. Serious eye damage/eye irritation Causes serious eye irritation. Respiratory or skin sensitisation Shall not be classified as a respiratory or skin sensitiser. Summary of evaluation of the CMR properties Shall not be classified as germ cell mutagenic, carcinogenic nor as a reproductive toxicant •

	Specific target organ toxicity - single exposure Shall not be classified as a specific target organ toxicant (single exposure). • Specific target organ toxicity - repeated exposure Shall not be classified as a specific target organ toxicant (repeated exposure). Aspiration hazard Shall not be classified as presenting an aspiration hazard. Symptoms related to the physical, chemical and toxicological characteristics • If swallowed data are not available • If in eyes Irritating to eyes • If inhaled data are not available • If on skin data are not available Other information None
PROPANEDIOL	Acute toxicity LD50 Oral - Rat - male and female - 10.500 mg/kg Inhalation: No data available LD50 Dermal - Rat - male and female - > 4.200 mg/kg Skin corrosion/irritation Skin - Rabbit Result: Mild skin irritation - 24 h (OECD Test Guideline 404) Serious eye damage/eye irritation Eyes - Rabbit Result: No eye irritation (OECD Test Guideline 405) Respiratory or skin sensitization Draize Test - Guinea pig Result: Does not cause skin sensitization. Germ cell mutagenicity No data available Test Type: Hamster Test system: Lungs Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 476 Result: negative Species: Mouse Application Route: Oral Result: negative Carcinogenicity No data available Reproductive toxicity No data available Specific target organ toxicity - single exposure No data available Specific target organ toxicity - repeated exposure No data available Aspiration hazard No data available

TOCOPHERYL ACETATE	acute toxicity: LD50 rat (dermal): > 3,000 mg/kg Irritation and corrosion: non-irritant Skin irritation and skin corrosion: Not irritating to the skin. Mucous membrane irritation (eye irritation): Not irritating to the eyes. Skin sensitization: Not irritating to the skin. Dermal/percutaneous absorption: No aspiration hazard expected. Repeated dose toxicity (normal 28- or 90-day studies): Not known Mutagenicity/genotoxicity: No mutagenic effects were found in various tests with bacteria and mammals. Carcinogenicity: No carcinogenic effect was observed in long-term animal studies where the substance was administered in high concentrations through ingestion. Reproductive toxicity: The results of animal experiments did not show any indication of a reproductive harm effect. Toxicokinetics:- Photo-induced toxicity:-

9.Undesirable effects and serious adverse effects

No undesirable effects and serious adverse effects were reported for x.

When a serious and undesirable effect is observed in the use of the product, you can apply for an undesirable effect/serious adverse effect report form.

10.Information about the cosmetic product

No in vivo, ex vivo or in vitro studies have been performed for the product DORO EYE CREAM CONTAINS 3 FORMULA.

There are no claims about product promotion.

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment Decision

In the safety assessment made for DORO EYE CREAM CONTAINS 3 FORMULA, the product is SAFE for ADULTS, considering the general toxicological profile of each ingredient used in the product composition, its chemical structure, the evaluations (CIR) in the panel of cosmetic product ingredients, exposure levels, total daily exposure and the safety limits of each ingredient calculated over maximum values. No special assessment has been made for UNDER 3.

Microbiological analysis report of the product is presented for your information in Part III of the product information file. Microbiological results were found below the legal limit values.

MoS calculations are made for the raw materials with NOAEL values and presented in a table. Compliance of raw materials with Cosmetics regulation and its annexes has been investigated, and no inconvenience has been encountered.

Considering the worst-case scenario, it has been observed that these raw materials are safe to use in this product. Product components are in the class of ingredients that are allowed to be used in cosmetic products. All raw materials in the product composition are non-toxic under normal or reasonably foreseeable conditions when used at concentrations indicated in the formulation.

It is a rinsing product used as skin care. It is appropriate for daily use. The safety assessment report for this product has been prepared for adult use. Its target audience is children and adults over 3 years old.

Specifications of the finished product and of raw material received from manufacturers for every raw material were evaluated.

Label incompatibilities:

The previous label was updated and a new label was created.

According to the product stability results, the shelf life of the product is minimum 24 months.

It looks like DORO EYE CREAM CONTAINS 3 FORMULA. Th smell of the product comes from the perfume named PROFUMO 1 used.

The product is presented to the market in 15 ML plastic packaging and boxes.

2. Warnings and Instructions for Use on the Label

·Warnings on the Label of the Product: For external use. Keep out of reach of children. Avoid contact with eyes and mucous membranes, if any. Rinse with plenty of lukewarm water. Do not swallow. Do not use on damaged skin. Keep away from direct sunlight and heat sources.

Usage and Frequency of Use of the Product: 1/2 of the head and neck area, 1.54 g without rinsing is suitable for use.

3. Justification

The finished cosmetic product has been evaluated by considering the raw material components, packaging material and manufacturing method it contains. The Product Safety Assessment Report has been prepared by taking the Cosmetics Law No. 5324, Annexes of the Regulations, Guidelines on Safety Assessment in Cosmetic Products, European Commission, SCCS guideline notes as references.

Compliance of raw materials with Cosmetics regulation and its annexes has been investigated. No inconvenience has been found.

A chemical reaction that may arise from the manufacturing method of the cosmetic product and an interaction that may occur as a result of the reaction of the raw materials with each other is not expected.

According to the product stability results, the shelf life of the product is minimum 24 months.

The products are not expected to interact with the packaging material.

4.Information about the Person performing the Safety Assessment and Approval of Part B

This report has been prepared in line with the available data. The report should be revised in case of changes in product content, stability information, and concentrations or packaging material.

Name of the safety evaluator:	**EMRE AKÇA**
Profession of the safety evaluator:	**CHEMIST**
Date of preparation :	**03.08.2023**
Report approval:	Emre AKÇA Kimyager Diploma No: 627 T.C. No: 38287819848

ANNEX1:ALLERGEN DETERMINATION AND ANALYSIS CERTIFICATES OF PERFUME COMPONENTS

VI) DOCUMENTS OF THE SAFETY EVALUATOR

T.C.
YÜZÜNCÜ YIL ÜNİVERSİTESİ
FEN-EDEBİYAT FAKÜLTESİ
LİSANS DİPLOMASI

Düzenleme Tarihi : 20.04.2005

Diploma No : 627

01/08/1980 tarihinde **KUZÖREN** 'de doğan **ŞÜKRÜ/AYŞEDUDU** oğlu **Emre AKÇA** Yüzüncü Yıl Üniversitesi FEN-EDEBİYAT FAKÜLTESİ **KİMYA Bölümü** öğretim programını, Yükseköğretim Kanunu ve ilgili yönetmeliklere göre 14.07.2004 tarihinde tamamlayıp KİMYAGER ünvanını alarak, Türkiye Cumhuriyeti kanunlarının tanıdığı bütün hak ve yetkilerden yararlanmak üzere kendisine bu diploma verilmiştir.

Prof.Dr.Yücel AŞKIN
REKTÖR

Prof.Dr. Erksin GÜLEÇ
DEKAN

KİMYAGERLER DERNEĞİ
TURKISH CHEMISTS' SOCIETY

CERTIFICATE

EMRE AKÇA

Kimyagerler Derneği tarafından
23-24 Şubat 2017 tarihlerinde düzenlenen
Kozmetik Ürünlerde Güvenlilik
Değerlendirme Kursu Uygulamalı Programına
katılmış ve bu belgeyi almaya hak kazanmıştır.

This is to certify that
EMRE AKÇA *has attended*
Safety Assessment Course in Cosmetic
Products *certification programme organized by*
The Chemists Society
On 23th – 24nd of February, *2017.*

Ahmet AKTAŞ
Eğitmen

İkram CENGİZ
Kimyagerler Derneği Başkanı

www.kimyager.org

Belge No:KÜD-RH:2017-0050

VII) DECLARATION ABOUT UNDESIRABLE EFFECTS

A cosmetic product placed on the market in accordance with Article 6 of the Cosmetic Regulation must be safe for human health when applied under normal and predictable conditions by the manufacturer, or when applied in accordance with the product presentation, labeling, explanations on its use or the recommended usage conditions by considering the information provided by the manufacturer.

Considering all warnings on the packaging of a cosmetic product, end users and healthcare professionals notify the Institution of undesirable effects and serious adverse effects that arise as a result of correct use and are thought to be related to the product (determined by medical report/doctor report and laboratory tests, if any) directly or through the health institutions they work with. Manufacturers, on the other hand, report serious adverse effects to the Institution within 15 business days without delay.

(2) Undesirable effects caused by misuse and complaints about product quality or consumer dissatisfaction are not considered within this scope.

No undesirable effects and serious adverse effects have been reported for the Product DORO EYE CREAM CONTAINS 3 FORMULA. If there is, corrective action will be organized and necessary information and documents will be provided. When a serious and undesirable effect is observed in the use of the product, you can apply with the undesirable effect/serious adverse effect report form at www.titck.gov.tr .

Università degli Studi di Ferrara

CENTRO DI COSMETOLOGIA
UNIVERSITA' DI FERRARA
Direttore: prof. Michele Simonato

Via Fossato di Mortara 17/19 – 44121 Ferrara
Tel.,Fax,Segreteria tel.: 0532.455.295
sito: www.unife.it/centro/cosmetologia
e-mail: cosm@unife.it

PATCH TEST OCCLUSIVO SU PELLE SENSIBILE

(Occlusive Patch Test on sensitive skin / Patch Test Occlusif sur peau sensible)

RISULTATI ***/RESULTS/RESULTATS*** (Serie: 29/ 6)

Il campione è contraddistinto dalla sigla:
The sample carries the name / l'èchantillon se distingue par le sigle:

MASSIMO FAZZI

EYE CREAM

cod. 250823

Il test occlusivo è stato eseguito utilizzando il prodotto:
The occlusive test was performed by using the product/le test occlusive a été executé utilisant le produit:

tal quale/ ***as it is/ tel quel*** **(X)** **diluito/*diluted/ dilué*** **1:20** **(.)**

Ulteriori informazioni gentilmente fornite dal cliente:
Further information kindly provided by the costumer:
Ulterieures informations gentilement fournies par le client:

_dichiarazione che il prodotto cosmetico sottoposto a test non contiene alcuna sostanza di cui è proibito l'uso in prodotti cosmetici e di igiene corporale (legislazione CE), che gli agenti conservanti introdotti nella formula del prodotto figurano nella lista positiva approvata dalla CE, che essi sono utilizzati ad una concentrazione conforme all'uso previsto da questa legge

_declaration that the tested cosmetic product does not contain any substance which is forbidden by the EC legislation as far as the use of cosmetic and personal hygiene products is concerned, that the preservatives in the formula are in the list of the accepted components approved by the EC and are used in a concentration provided for by the law

_déclaration que les produit cosmetique soumis à test ne contient aucune substance don't est interdit l'usage dans les produits cosmetiques et dans l'hygiéne corporelle (legislation CE), que les élements conservants introduit dans la formule du produit figurent sur la liste positive approuvée par la CE, que ceux-ci sont utilisés à une concentration conforme aux disposition de la loi

MASSIMO FAZZI

EYE CREAM

cod. 250823

Tabella 3 (Table 3/Tableau 3)

Volont. n°	Eta' *(Age)*	Sesso *(Sex)*	ERITEMA *(erythema/erythéme)*		EDEMA *(oedema/oedéme)*		VESCICOLE *(blisters/vesicles)*	
			15'	24h	15'	24h	15'	24h
1	25	F	0	0	0	0	-	-
2	20	F	1	1	0	0	-	-
3	23	F	0	0	0	0	-	-
4	26	F	0	0	0	0	-	-
5	29	F	0	0	0	0	-	-
6	32	F	0	0	0	0	-	-
7	22	F	0	0	0	0	-	-
8	23	F	0	0	0	0	-	-
9	23	M	0	0	0	0	-	-
10	21	F	0	0	0	0	-	-
11	24	F	0	0	0	0	-	-
12	25	F	0	0	0	0	-	-
13	31	F	1	1	0	0	-	-
14	20	F	0	0	0	0	-	-
15	23	F	0	0	0	0	-	-
16	24	F	0	0	0	0	-	-
17	33	F	0	0	0	0	-	-
18	21	M	0	0	0	0	-	-
19	23	M	0	0	0	0	-	-
20	25	F	0	0	0	0	-	-

Tabella 3 Riassunto dei risultati del patch test

Table 3 / Tableau 3 *Summary of the patch test results / Resumé des resultats du patch test*

Figura 1 (Figure 1)

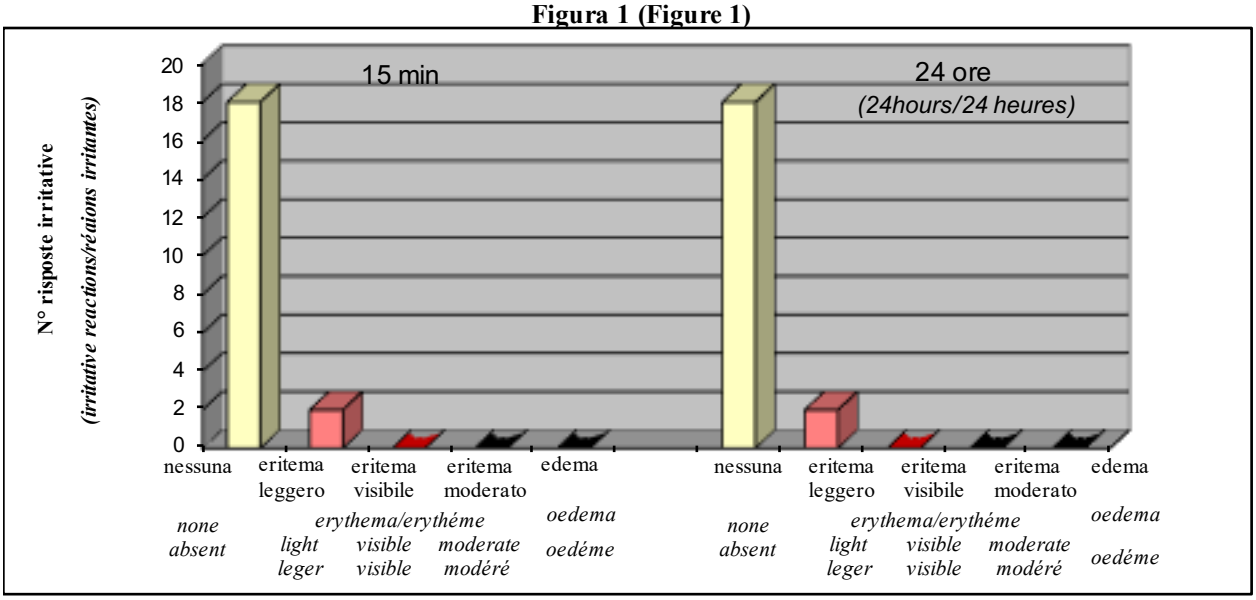

Figura 1 Numero di risposte irritative (eritematose e/o edematose) riscontrate a 15 minuti e a 24 ore dalla rimozione del patch (in situ per 48 ore). Le reazioni eritematose sono state suddivise in tre gruppi in base al grado dell'eritema: leggero, ben visibile o moderato/grave.

Figure 1 *Number of irritative reactions (erythematous and/or oedematous) encountered at 15 minutes and at 24 hours after the removal of the patch (in situ for 48 h). Erythematous reactions have been sorted out into three groups according to the reaction degree: light, clearly visible and moderate/serious erythema.*

Figure 1 *Nombre de réactions irritantes (erythemateuses et/ou oedemateuses) rencontrées à 15 minutes et 24 heures du deplacement du patch (in situ pour 48 h). Les reactions erythemateuses ont été sous divisées en 3 groupes sur la base du niveau de la réaction: leger bien visible ou modéré/grave.*

Figura 2 (Figure 2)

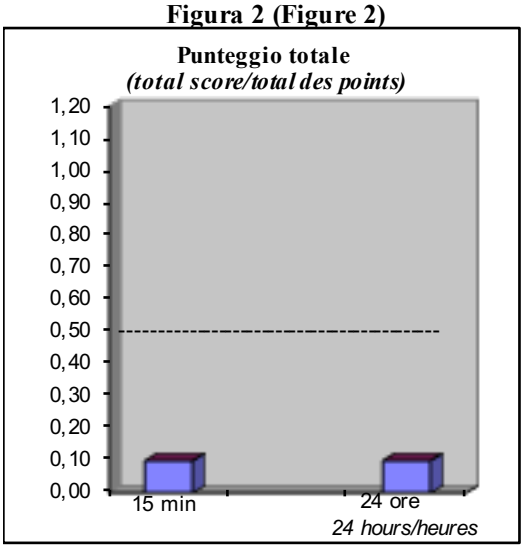

Figure 2 Indice medio di irritazione (punteggio totale).
I punteggi relativi a risposte eritematose leggere, ben visibili e moderate/gravi (incluso l'eventuale edema associato) sono indicati rispettivamente in blu, rosso e nero. La linea tratteggiata indica il limite oltre il quale il prodotto testato è lievemente irritante

Figure 2 *Mean index of irritation (total score).*
The scores due to light, clearly visible and moderate/serious erythematous reactions (including the associated oedema) are shown in blue, purple and black, respectively. The dashed line indicates the treshold above which the product is to be classified as slightly irritating

Figure 2 *L'indice moyen d'irritation (total des points).*
Les points dus aux reactions erythemateuses legeres, bien visibles, modérées/graves sont indiqués respectivement en bleu, rouge sombre et noir. La ligne hachurée indique le seuil au-delà duquel le produit testé est classifié comme legerement irritant

Il prodotto dermatologicamente testato, applicato tal quale in condizioni occlusive alla cute sana di 20 volontari con pelle sensibile sulla base di test oggettivi (Ramette) e soggettivi (questionario Misery modificato), ha ottenuto un indice medio di irritazione pari a

0,10 (zero,dieci) dopo 15 minuti dalla rimozione della Finn Chamber
0,10 (zero,dieci) dopo 24 ore dalla rimozione della Finn Chamber

In base alla scala utilizzata (Tabella 2), il prodotto può essere classificato come:

The dermatologically tested product, applied as it is under occlusive condition on the healthy skin of 20 volunteers with sensitive skin based on objective test (Ramette) and subjective questionnaire (Misery modified), resulted in a mean index of irritation of

0,10 *(zero,ten) 15 minutes after the removal of the Finn Chamber*
0,10 *(zero,ten) 24 hours after the removal of the Finn Chamber*

According to the evaluation scale used (Table 2), the product can be classified as:

Le produit testé dermatologiquement, appliqué tel quel dans les conditions occlusives sur la peau saine de 20 volontaires avec peau sensible (sur la base de Ramette et du questionnaire de Misery) a obtenu un indice moyen d'irritation égal à

0,10 *(zero,dix) aprés 15 minutes du deplacement du Finn Chamber*
0,10 *(zero,dix) aprés 24 heures du deplacement du Finn Chamber*

Sur la base de l'echelle utilisée (Tableau 2), le produit peut etre classifié comme:

MASSIMO FAZZI

EYE CREAM

cod. 250823

NON IRRITANTE se applicato su cute umana sensibile

NOT IRRITATING *if applied to sensitive human skin*

NON IRRITANT *s'applique sur la peau humaine sensible*

DATA: 30/5/2023

Coordinatore
Dott.ssa Leda Montesi (Farmacista Cosmetologa)

Sperimentatore
Dott. Simone Sbrenna (Medico Farmacologo)

Responsabile delle prove
Prof. Michele Simonato (Medico Tossicologo)

Supervisione
Dott. Alex Gezzi (Medico Dermatologo)

STABILITY TEST RESULT

The following results are obtained from 3 months accelerated stability test.

Product name: D'ORO EYE CREAM
Test Started Date:15.12.2022
Test Finished Date:16.03.2023

1)The test was performed at 40°C during 3 months.

	Parameter	**Method**	**Standard**	**First Measuring (Starting)**	**1.Month**	**2. Months**	**3.Months**
Physicochemical Analysis	**Appearance**	Organoleptic	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace
	Color		White	White	White	White	White
	Odor		With Parfume	With Parfume	With Parfume	With Parfume	With Parfume
	Product Form		Mold	Mold	Mold	Mold	Mold
	pH of Finish Product(PH (% 1) (45-60 ˚C)	pH meter	5,50 +/- 5%	5,65	5,66	5,61	5,65

2)The test was performed at 25°C and 60% relative humidity during 3 months.

	Parameter	**Method**	**Standard**	**First Measuring (Starting)**	**1.Month**	**2. Months**	**3.Months**
Physicochemical Analysis	**Appearance**	Organoleptic	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace
	Color		White	White	White	White	White
	Odor		With Parfume	With Parfume	With Parfume	With Parfume	With Parfume
	Product Form		Mold	Mold	Mold	Mold	Mold

	pH of Finish Product(PH (% 1) (45-60 ˚C)	pH meter	5,50 +/- 5%	5,64	5,66	5,67	5,66

3) The test was performed at 4°C during 3 months.

	Parameter	**Method**	**Standard**	**First Measuring (Starting)**	**1.Month**	**2. Months**	**3.Months**
Physicochemical Analysis	**Appearance**	Organoleptic	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace	Liquid with spunlace
	Color		White	White	White	White	White
	Odor		With Parfume	With Parfume	With Parfume	With Parfume	With Parfume
	Product Form		Mold	Mold	Mold	Mold	Mold
	pH of Finish Product(PH (% 1) (45-60 ˚C)	pH meter	5,50 +/- 5%	5,63	5,64	5,65	5,66

4)The test was performed at 40°C during 3 months.

MICROBIOLOGICAL TESTS	Total Bacteria Count cfu/g) [4]	<100	0	0	0	0	0	0	0	0
	Mould Count (cfu/g) [4]	<10	0	0	0	0	0	0	0	0
	total mezophyl aero bacterium Esherichia coli Staphyloccoccus Aureus Pseudomonas Aureginosa Candida Albicans Mold and Ferment	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence

5) The test was performed at 25 °C during 3 months

MICROBIOLOGICAL TESTS	Total Bacteria Count cfu/g) [4]	<100	0	0	0	0	0	0	0	0
	Mould Count (cfu/g) [4]	<10	0	0	0	0	0	0	0	0
	total mezophyl aero bacterium Esherichia coli Staphyloccoccus Aureus Pseudomonas Aureginosa Candida Albicans Mold and Ferment	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence

6) The test was performed at 4 °C during 3 months

MICROBIOLOGICAL TESTS	Total Bacteria Count cfu/g) [4]	<100	0	0	0	0	0	0	0	0
	Mould Count (cfu/g) [4]	<10	0	0	0	0	0	0	0	0
	total mezophyl aero bacterium Esherichia coli Staphyloccoccus Aureus Pseudomonas Aureginosa Candida Albicans Mold and Ferment	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence	Absence

BSN

KİMYA

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