



SAFETY ASSESSMENT REPORT

According to the GSO 1943/2016 Regulation

1. COSMETIC PRODUCT SAFETY INFORMATION

1.1. PRODUCT INFORMATION

Product name: FGZ Professional Dr. Therapy Treatment Hair Volume Reduction

Study period: November 2019

Product category: Hair care product – Straightening and fixing

Purpose: Rinse off product

Main function: To change the appearance

Local application: The hair system

Contact with mucous membranes: Not expected

1.2. NAME OF THE SAFETY ASSESSOR

Name: Gian Di Gessé Giolo

Education: Chemist – CRQ SP nº 04262791

1.3. NAME AND ADDRESS OF THE PRODUCT MANUFACTURER

Company: T.C.I Indústria Cosmética Ltda - EPP

Address: Rua Maria Martins Araújo, nº 779, Franca – SP / 14403117 – Brazil

1.4. NAME AND ADDRESS OF THE PRODUCT DISTRIBUTER

Company: Fogazza Professional Comércio Exportação e Importação EIRELI - ME

Address: Rua Pinheiro Machado, 480, Vila São Lúcio / CEP 18603-760 – Botucatu / SP – Brazil

The company declares that the products are manufactured in accordance to the Normative Reference GSO ISO 22716 – Good Manufacturing Practices (GMP).

1.5. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INGREDIENTS (INCI NAME)	CAS NUMBER	FUNCTION	%
Aqua (Water)	7732-18-5	Solvent	67,257768314
Glyoxyloyl Carbocysteine	1268868-51-4	Hair Straightening	9,000000000
Glyoxyloyl Keratin Amino Acids	NA	Hair Straightening	9,000000000
Stearyl Alcohol	112-92-5	Viscosity Controlling	2,100000000
Ceteareth-20	68439-49-6	Surfactant	2,000000000
Glyceryl Stearate SE	11099-07-3	Emulsifying	2,000000000
Cetearyl Alcohol	67762-27-0	Emulsifying	1,850000000
Creatine	57-00-1	Conditioning	1,000000000
Propylene Glycol	57-55-6	Humectant	1,000000000
Cetyl Alcohol	36653-82-4	Viscosity Controlling	0,900000000
Parfum (Fragrance)	NA	Deodorant	0,800000000
Behentrimonium Chloride	17301-53-0	Conditioning	0,600000000
Cetrimonium Chloride	112-02-7	Antistatic	0,600000000
Polysorbate 60	9005-67-8	Emulsifying	0,450000000
Isopropyl Alcohol	67-63-0	Viscosity Controlling	0,200000000
Octadecyl Di-T-Butyl-4-Hydroxyhydrocinnamate	2082-79-3	Antioxidant	0,200000000
Butylphenyl Methylpropional	80-54-6	Perfuming	0,190320000
Disodium EDTA	139-33-3	Chelating	0,100081600
Bromelain	9001-00-7	Keratolytic	0,100000000
Lactic Acid	50-21-5	Humectant	0,089300000
Sodium PCA	28874-51-3	Conditioning	0,075000000


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Sodium Lactate	72-17-3	Humectant	0,060000000
Benzotriazolyl Dodecyl P-Cresol	125304-04-3	UV Absorber	0,050000000
Arginine	74-79-3	Conditioning	0,040000000
Cocodimonium Hydroxypropylhydrolyzed Keratin	NA	Conditioning	0,034000000
Hydrolyzed Silk	96690-41-4	Conditioning	0,030000000
Aspartic Acid	56-84-8	Conditioning	0,026000000
Linalool	78-70-6	Perfuming	0,022560000
PCA	98-79-3	Humectant	0,021350000
Alpha-Isomethyl Ionone	127-51-5	Perfuming	0,020800000
Coumarin	91-64-5	Perfuming	0,020800000
Hydrolyzed Wheat Protein	70084-87-6	Conditioning	0,017000000
Lactobionic Acid	96-82-2	Buffering	0,009700000
Hydrolyzed Keratin	69430-36-0	Conditioning	0,006970000
Glycine Soja Oil	8001-22-7	Emollient	0,006818000
Glycine	56-40-6	Conditioning	0,006400000
Alanine	56-41-7	Conditioning	0,006000000
Argania Spinosa Kernel Oil	223747-87-3	Conditioning	0,004545000
Bertholletia Excelsa Seed Oil	356065-50-4	Conditioning	0,004545000
Canola Oil	120962-03-0	Conditioning	0,004545000
Carapa Guaianensis Seed Oil	352458-32-3	Conditioning	0,004545000
Copaifera Officinalis Resin	8001-61-4	Film Forming	0,004545000
Corylus Avellana Seed Oil	84012-21-5	Masking	0,004545000
Elaeis Oleifera Kernel Oil	8002-75-3	Emollient	0,004545000
Gossypium Herbaceum Seed Oil	8001-29-4	Conditioning	0,004545000
Helianthus Annuus Seed Oil	8001-21-6	Emollient	0,004545000
Hydrolyzed Collagen	92113-31-0	Antistatic	0,004545000
Linum Usitatissimum Seed Oil	8001-26-1	Conditioning	0,004545000
Macadamia Ternifolia Seed Oil	128497-20-1	Emollient	0,004545000
Paraffinum Liquidum (Mineral Oil)	8012-95-1	Emollient	0,004545000
Pentaclethra Macroloba Seed Oil	866620-18-0	Emollient	0,004545000
Persea Gratissima Oil	8024-32-6	Conditioning	0,004545000
Prunus Amygdalus Dulcis Oil	8007-69-0	Conditioning	0,004545000
Tocopheryl Acetate	58-95-7	Antioxidant	0,004545000
Triticum Vulgare Germ Oil	68917-73-7	Emollient	0,004545000
Vitis Vinifera Seed Oil	8024-22-4	Emollient	0,004545000
Cocos Nucifera Oil	8001-31-8	Conditioning	0,004499550
Serine	56-45-1	Antistatic	0,004000000
Valine	72-18-4	Antistatic	0,003200000
Isoleucine	73-32-5	Antistatic	0,002000000
Proline	147-85-3	Conditioning	0,002000000
Threonine	72-19-5	Antistatic	0,002000000
Methylchloroisothiazolinone	26172-55-4	Preservative	0,001053000
Histidine	71-00-1	Antistatic	0,000800000
Phenylalanine	63-91-2	Conditioning	0,000800000
Potassium Sorbate	24634-61-5	Preservative	0,000770000
Sodium Benzoate	532-32-1	Preservative	0,000380000
Tetrasodium EDTA	64-02-8	Chelating	0,000380000
Methylisothiazolinone	2682-20-4	Preservative	0,000351000
Imidazolidinyl Urea	39236-46-9	Preservative	0,000204000
DMDM Hydantoin	6440-58-0	Preservative	0,000170000
Simmondsia Chinensis Seed Oil	90045-98-0	Emollient	0,000113650
Gardenia Taitensis Flower	NA	Conditioning	0,000045450
Iodopropynyl Butylcarbamate	55406-53-6	Preservative	0,000006800
Tocopherol	59-02-9	Antioxidant	0,000003636



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1.6. GERENAL SAFETY DECLARATIONS

In accordance to the GSO 1943 Regulation, the product:

- Is completely free from pork and all its derivatives;
- Is completely free from any filthy or decomposed substance;
- Is safe for human health when used under normal or reasonably foreseeable conditions of use;
- Has not been tested on animals.

1.7. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

Supplier's specifications for each raw material have been reviewed (Safety and Technical Data Sheets, MSDS and TDS).

PHYSICO-CHEMICAL SPECIFICATIONS		
ANALYSIS	METHOD	SPECIFICATIONS
pH (25°C)	PHmeter	2,00 – 2,50
Viscosity (25°C)	Viscometer	1.000 – 30.000 cps
Density (25°C)	Pycnometer	0,900 – 1,100 g/ml
ORGANOLEPTIC SPECIFICATIONS		
ANALYSIS	METHOD	SPECIFICATIONS
Appearance	Visual	Homogeneous Cream
Color	Visual	Light Yellow
Odor Description	Olfactory	Typical of Fragrance
SHELF LIFE AND STORAGE STABILITY		
SHELF LIFE > 30 months		Sun Illumination: Enduring
Period After Opening (PAO) – 6 months		Stove (45°C): Enduring
		Refrigerator (5°C): Enduring
		Room Temperature (25°C): Enduring

According to the GSO Regulation 1943, the product is homogenous, stable and its properties do not change during its shelf life when stored and used as per the instructions and warnings.

Regarding the pH range: Acceptable if necessary, to achieve the required efficacy, according to:

GSO 1943 (4.11): *"The pH of cosmetic products should be in the range (4 - 8) excluding the ranges in Annex 3 which are specific to certain ingredients. Certain products which formulated with pH values outside this range shall be acceptable if they have evidence to demonstrate that the pH is necessary to achieve the required efficacy and also have a demonstrable safety report."*

As a general rule, hair straighteners work by rearranging the chemical bonds within the hair fibers, through a process that involves breaking and/or forming very strong bonds. This requires the use of a heat source followed by the use of a product with a pH range between 2,00 to 2,50. The procedure is done by running a flat iron through moist hair, which breaks down the hair's hydrogen bonds, allowing water or water vapor to repenetrates the hair's fiber and rearrange its' hydrogen bonds, making the hair straight. At this point, applying a product within this range of pH will allow the cuticles to shut and preserve the hair smooth and shiny.


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1.8. MICROBIOLOGICAL QUALITY

Microbiological Quality: The product is unlikely to present, under normal production conditions, any kind of bio burden.

MICROBIOLOGY ANALYSIS	
ANALYSIS	SPECIFICATIONS
Aerobic Mesophilic Microorganisms (Bacteria + Yeast and Mould)	Limit to 1000 CFU/g or ml
Fecal and Total Coliforms	Absence in 1g or 1ml
<i>Candida albicans</i>	Absence in 1g or 1ml
<i>Staphylococcus aureus</i>	Absence in 1g or 1ml
<i>Pseudomonas aeruginosa</i>	Absence in 1g or 1ml
<i>Escherichia coli</i>	Absence in 1g or 1ml

Challenge Test:

The test has been performed for each strain mentioned below:

Escherichia coli
Staphylococcus aureus
Pseudomonas aeruginosa
Candida albicans
Aspergillus brasiliensis

→ Results are satisfactory.

The challenge test, microbiological analysis and its specifications are in accordance to all references below, as indicated in GSO 1943:

- GSO ISO 18416 – Microbiology – Detection of *Candida albicans*
- GSO ISO 18415 – Detection of Specified and Non-Specified Microorganisms
- GSO ISO 21149 – Cosmetics Microbiology: Enumeration and detection of aerobic mesophilic bacteria
- GSO ISO 21150 – Detection of *Escherichia coli*
- GSO ISO 22717 – Detection of *Pseudomonas aeruginosa*
- GSO ISO 22718 – Detection of *Staphylococcus aureus*
- GSO ASTM 640 06 – Standard Test Method for Preservatives in Water-Containing Cosmetics
- GSO ISO 17516 – Microbiology: Microbiological limits
- ISO 21148 – General Instructions for microbiological examination
- ISO 29621 – Guidelines for the Risk Assessment of Microbiologically Low-risk Finished Products

1.9. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

Properties of the packaging material: According to the presentation and the product's formula, the package is considered unlikely to affect its purity and stability.

Impurities: no migration is likely to occur from the final packaging to the product.

Contaminants: no potential chemical changes may be caused by instability of the product in contact with the final packaging


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Type of packaging material:

BOTTLE: 100% HDPE – High Density Polyethylene

CAP OR PUMP VALVE: 100% PP – Polypropylene

1.10. EXPOSURE TO THE SUBSTANCES

Product Category: Hair care product

Physical Form: Homogeneous Cream

Purpose: Rinse off product

Amount used per application: 50g per application

Part of body exposed to undiluted product: the hair system

Frequency of exposure to undiluted product: once a month

Contact with mucous membranes: Not expected

For each substance concentration please refer to section 1.5 – Quantitative and Qualitative Composition of the cosmetic product.

Legal Status: all ingredients present are permitted under the SASO and GSO 1943 Regulations.

1.11. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

Effects of the product as supplied:

- On the Skin: This product is unlikely to be sensitizing to human skin. Repeated exposure to the skin is unlikely to produce allergy by skin contact, except in cases of people with known allergic reaction to the specific allergens referred on the label. The absorption through the skin is considered limited. Exposure to this product is unlikely to produce phototoxic effects.
- On the Eye: Accidental exposure of the eye to the formulation as supplied may result in slight eye irritation.
- Following Ingestion: Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous. The ingestion of large quantities of the formulation as supplied may cause some irritation to the upper digestive tract.
- Of Inhaling (Respiratory): No considerable respiratory exposure of the product as supplied is foreseeable for this type of product and is unlikely to cause irritation of the nose and upper digestive tract.

Effects of the product as used:

- On the Skin: during its use, this product is unlikely to be sensitizing to human skin. Repeated exposure to the skin is unlikely to produce allergy by skin contact, except in cases of people with known allergic reaction to the specific allergens referred on the label. The absorption through the skin is considered limited. Exposure to this product is unlikely to produce phototoxic effects.
- On the Eye: during its use, accidental exposure of the eye to the formulation as supplied may result in slight eye irritation.
- Following Ingestion: during its use ingestion is not expected, and although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous. The ingestion of large quantities of the formulation as supplied may cause some irritation to the upper digestive tract.


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- Of Inhaling (Respiratory): during its use, no considerable respiratory exposure of the product as supplied is foreseeable for this type of product and is unlikely to cause irritation of the nose and upper digestive tract.

All information available refers to the relevant MSDS of each raw material that takes part in the formula of the product. The specific ingredients that have been chosen for the production of this product have been used for years, for the same products, without any known toxicity problems, under foreseeable conditions of use.

Allergen Factors of the Fragrance:

The fragrance (parfum) contains the following allergens which exceed the concentration of 0,01% for rinse off on products:

Butylphenyl Methylpropional
Alpha-Isomethyl Ionone
Coumarin
Linalool

1.12. TESTS ON THE COSMETIC PRODUCT

Patch Test (Dermatological): Satisfactory (Non Irritant –IP)

Other Tests: None presented.

Literature Data: Not Applicable.

In accordance to the GSO 1943 Regulation, the product is safe for human health when used under normal or reasonably foreseeable conditions of use.

1.13. HEAVY METALS CONCENTRATION

HEAVY METALS	LIMIT SPECIFICATIONS
<i>Lead (Pb)</i>	2 mg/kg
<i>Arsenic (As)</i>	0,5 mg/kg
<i>Cadmium (Cd)</i>	0,1 mg/kg
<i>Mercury (Hg)</i>	0,1 mg/kg
<i>Antimony (Sb)</i>	0,5 mg/kg
<i>Nichel (Ni)</i>	10 mg/kg

The specifications of our raw materials and finished products follow the regulations in force in the European Cosmetic Directives. In this sense, heavy metals are prohibited substances in cosmetics whenever they are listed in the lists of substances that cosmetic products should not contain, as dictated by the annexes of the EC 1223/2009.

Despite of the good manufacturing practices employed during the manufacturing process of this product, non-intended presence of small quantities of heavy metals are found, all of which are under the maximum concentration permitted.


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2. COSMETIC PRODUCT SAFETY EVALUATION

2.1. LABELLED WARNINGS AND INSTRUCTIONS OF USE

Producer's data have been reviewed and there is no need for further instructions of use as this is clear to the consumer from its presentation.

The presentation of the cosmetic product, and in particular its form, odor, color, appearance, packaging, labelling, volume or size, do not lead to confusion with foodstuffs or appear to be other than they are, and thus do not endanger the health or safety of consumers.

All ingredients referred to in the formula are correctly written on the label with their INCI names in descending order, in accordance to Article 5 of the GSO 1943 Regulation.

All claims written on the label are in compliance to the GSO 1943 Regulation and all its guidelines.

The label does not contain graphics or images or phrases that are inconsistent with Islamic traditions and prevailing social values in GCC countries.

2.2. REASONING

Taking under consideration the following topics:

- The composition of the product;
- The physicochemical properties of the raw material contained in the final product;
- The manufacturing process of the product;
- The microbial purity of the raw materials and final product;
- The properties of the packaging materials;
- The preservation efficacy of the final product;
- The chemical structure and toxicological properties of the raw materials;
- Studies on human volunteers / relevant literature;
- The level of exposure of the consumer to the final product;
- Data on documented undesirable effects to the product (no such data reported);
- Labelled warnings & instructions of use;

Having analyzed the data stating that the product does not contain:

- Prohibited substances;
- Restricted substances in discordance to their intended uses or restrictions or limits;
- Coloring agents other than those permitted or under the conditions allowed;
- Preservatives other than those permitted or above the concentrations allowed for specific purposes;
- UV-filters other than those permitted or above the limits or conditions laid down;

And additionally pondering that the Product Manufacturer / Responsible person is aware of the following:

- All necessary measurements have been followed for the product to comply with the Animal testing requirements of the EC 1223/2009 Regulation and the GSO 1943 Regulation.


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- The Responsible person / Product manufacturer is responsible for the accuracy of the information contained in the products dossier.
- The safety assessment relates to the information received up until the date the assessment was performed.

3. ASSESSMENT CONCLUSION

According to the best current scientific knowledge, I conclude that the product fulfils the requirements for safety for human health when used under normal or reasonably foreseeable conditions of use in accordance with the current GSO 1943 regulation.

All information provided by the technical dossier may be used, for any legal purpose.

In the case that any complaint is communicated to the Responsible person and/or Product manufacturer or if there is any alteration in the information regarding the product, these should be submitted and also taken into the consideration of the signatory of this certificate.



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