

PRODUCT INFORMATION FILE (PIF)

PIF No: PIF201909-63

PIF Prepared By/Date: 03.06.2021

Product name: Brow Fixing Lotion 7ml	Manufacturer: Kohana LTD
	Address: Suite 10182, 77Sir John Rogersons Quay, Dublin 2 , Ireland
	Telephone: +353 01 6111512
	Responsible Person: Jaroslaw Kruszynski

1. DESCRIPTION OF THE COSMETIC PRODUCT

This is rinse-off product intended to use on eyelashes.

2. COSMETIC PRODUCT SAFETY REPORT FINISHED COSMETIC PRODUCT

1. QUANTITATIVE COMPOSITION OF THE FINISHED COSMETIC PRODUCT

INCI	CAS nr	Function	Conc. (% w/w)
Aqua	7732-18-5	Solvent	>75 - <=100
Cetearyl Alcohol	67762-27-0	Emollient/ Emulsifying/ Emulsion stabilizing	>5->=10
Hydrogen Peroxide 9% (0.45%)	7722-84-1	Antimicrobial/ Oxidising	<=2

Cetareth-20		68439-49-6		Cleansing/ Surfactant/ Emulsifying	>1->=5	
Paraffinum Liquidum (Mineral Oil)		8012-95-1		Antistatic/ Emollient/ Skin protecting/ Solvent	>1->=5	
Glycerin		56-81-5		Humectant/ Hair conditioning/ Skin conditioning/ Skin protecting	<=0,1	
Panthenol		81-13-0		Antistatic/ Hair conditioning/ Skin conditioning	<=0,1	
Simethicone	Soft water		7732-18-5	Antifoaming/	<=0,1	0.075
	Polydimethyls iloxane	8050 -81-5	63148-62-9	Hair conditioning/ Skin conditioning/ Emollient		0.01
	Glyceryl monostearate		123-94-4			0.005
	Sodium carboxymethy l cellulose		9004-32-4			0.005
	Ethoxylated sorbitan monostearate		9005-67-8			0.005
Laureth-3		3055-94-5		Surfactant/ Cleansing/ Emulsifying	>0,1-<=1	
Sodium Lauryl Sulfate		151-21-3		Surfactant/ Cleansing/ Emulsifying	>0,1-<=1	
Disodium Pyrophosphate		7758-16-9		Anticorrosive/ Buffering/ Chelating	<=0,1	
Sodium Stannate		12058-66-1		Light stabilizer/ Viscosity controlling	<=0,1	
Phosphoric Acid		7664-38-2		Buffering	<=0,1	
Polysorbate 20		9005-64-5		Surfactant/ Cleansing/ Emulsifying	<=0,1	
Parfum		/			<=0,1	

INCI	CAS	EU regulatory status
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Hydrogen Peroxide 9% (0.45%)	7722-84-1	<p><u>Annex III/12</u> Products intended for eyelashes: maximum concentration in ready for use preparation 2% of H₂O₂.</p> <p><u>To be printed on label:</u> For professional use only. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them. Contains hydrogen peroxide.</p>
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Parfum ingredients	Concentration in Parfum %	Concentration in finished product %	Labelling requirements
Isoamyl Acetate	43	0.043	
Ethyl Butyrate	7.7	0.0077	
Linalool	1.05	0.00105	<0,01 % - no need to indicate on label
Eugenol	0.77	0.00077	<0,01 % - no need to indicate on label
Citronellol	0.45	0.00045	<0,01 % - no need to indicate on label
Limonene	0.34	0.00034	<0,01 % - no need to indicate on label

2. PHYSICO/CHEMICAL PROPERTIES AND STABILITY OF THE FINISHED COSMETIC PRODUCT

2.1 PHYSICOCHEMICAL PROPERTIES

Appearance	Form: creamy emulsion fluid Colour: milky-white
Odour	Characteristic
pH	2.40 - 2.60 at 20 °C
Specific weight	0.89-1.0 g/ml
Water solubility	soluble
Partition coefficient: n-octanol/water	NA
Viscosity at 20 °C	7.000 – 12.000cPs (S6-RPM10)

2.2 PHYSICAL STABILITY

Under reasonably foreseeable conditions the product is stable.

- Shelf life in closed packaging is 36 months.

- Open product should be used within 6 months.

Product may decay and/or have a violent reaction.

OXYGENATED WATER: decays rapidly with the risk of explosion through the effect of light, heat and contact with alkaline metals.

Stability test for the finished product is ongoing.

2.3 CONCLUSION

The product is physico-chemically stable under decay preventive conditions:

- Keep the product tightly closed, away from heat and direct sunlight. Avoid extreme temperatures. Store away from food and beverages.

3. MICROBIOLOGICAL PROPERTIES AND STABILITY OF THE FINISHED COSMETIC PRODUCT

3.1 MICROBIOLOGICAL INSPECTIONS

According to the SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation 9th Revision¹ it is generally accepted that for cosmetics classified in:

- Category 1 – baby products, products used in the eye area and on mucous membranes – the total viable count for aerobic mesophilic microorganisms should not exceed 10^2 CFU/g or 10^2 CFU/ml of the product
- Category 2 - the total viable count for aerobic mesophilic microorganisms should not exceed 10^3 CFU/g or 10^3 CFU/ml of the product.

Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable:

- Category 1 – in 1 g or 1 ml of the product
- Category 2 – in 0.1 g or 0.1 ml of the product

Quantitative and qualitative limits are based on the European Standard EN ISO 17516:2014 Cosmetics – Microbiology – Microbiological limits.

The finished product is classified as Category 1 – used in the eye area.

¹ SCCS/1564/15 - Revision of the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 9th revision

Results of examination

Parameter	Unit	Result	Method
Mesophilic aerobic microorganisms	CFU /1g	< 10	EVS-EN ISO 21149*
<i>Pseudomonas aeruginosa</i>	detection / 1 g	not detected	EVS-EN ISO 22717*
<i>Escherichia coli</i>	detection / 1 g	not detected	EVS-EN ISO 21150*
<i>Staphylococcus aureus</i>	detection / 1 g	not detected	EVS-EN ISO 22718*
<i>Candida albicans</i>	detection / 1 g	not detected	EVS-EN ISO 18416*
Molds and yeasts	CFU /1g	< 10	EVS-EN ISO 16212*

The method marked with an asterisk * is not accredited.

CFU – colony forming unit

Test for aerobic mesophilic bacteria in the finished product showed $< 1 \times 10^1$ CFU/1.0 g which meets the requirements of microbiological limits for cosmetics in Category 1. Pathogenic microbes *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are absent from the test sample.

3.2 MICROBIOLOGICAL STABILITY

Preservative challenge test was not performed because the product contains hydrogen peroxide and microbiological contamination has been avoided. The microbiological test confirmed no pathogens in the product and aerobic mesophilic bacteria CFU in 1.0 g of product was $< 1 \times 10^1$ CFU/1.0 g

3.3 CONCLUSION

Considering all data on microbiology, the finished product is microbiologically stable.

All original data regarding microbiological tests performed on finished product are attached in Product Information File (PIF) Annex. Available data on the ingredients are attached in PIF Annex and stated in corresponding SDS's or MSDS's.

4. IMPURITIES, TRACES, PACKAGING

4.1 IMPURITIES AND TRACES IN FINISHED PRODUCT

The cosmetic regulation EC N°1223/2009 prohibits the use of heavy metals such as lead, arsenic, cadmium, mercury, and antimony unless they are present at trace levels and their presence is inevitable from correct manufacturing processes.

The German Federal Office of Consumer Protection and Food Safety (BVL) has published a report on Technically Avoidable Heavy Metal Contents in Cosmetic Products². They found that

² Bund, B. Technically avoidable heavy metal contents in cosmetic products. *J Consum Prot Food Saf* **12**, 51–53 (2017). <https://doi.org/10.1007/s00003-016-1044-2>

heavy metal contents in cosmetic products exceeding the following values are considered as technically avoidable:

Element	Cosmetic products in general (mg/kg)	Toothpaste (mg/kg)
Lead (Pb)	2.0 ^a	0.5
Cadmium (Cd)	0.1	0.1
Mercury (Hg)	0.1	0.1
Arsenic (As)	0.5 ^b	0.5
Antimony (Sb)	0.5	0.5

^aFor the products make-up powder, rouge, eye shadow, eye liner, kajal, as well as theater, fan or carnival make-up: 5 mg/kg

^bFor theater, fan or carnival make-up: 2.5 mg/kg

Health Canada has published a Guidance on Heavy Metal Impurities in Cosmetics³. This study proposed the following levels for heavy metals:

Element	Cosmetic products in general (mg/kg)
Lead (Pb)	10
Cadmium (Cd)	3
Mercury (Hg)	3
Arsenic (As)	3
Antimony (Sb)	5

Ppm - parts per million (1 ppm=1µg/g, 1 mg/kg, 1 mg/L)

Results for heavy metal analysis for the finished product have not been submitted for consideration.

After reviewing the ingredients used in making the finished product, it can be concluded that if present they are in the limits proposed by BVL and Health Canada.

³ Health Canada, Guidance on Heavy Metal Impurities in Cosmetics. 2012.
<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/guidance-heavy-metal-impurities-cosmetics.html> Last accessed 13.03.2021

4.2 RELEVANT CHARACTERISTICS OF PACKAGING MATERIAL

The finished cosmetic product is packaged into a:

- Glass bottle
- Plastic cap

Product size: 7 ml

4.3 PACKAGING PROCEDURE

Product is packaged into 7 ml glass bottle with a plastic cap. A semi-automated bottling machine is used for product packaging.

4.4 IDENTIFICATION OF THE BATCH NUMBER

Batch number sticker is placed on the bottom of the product.

Batch number consists of:

- 1 number indicating the procedure nr
- 2 numbers indicating the date of production
- 2 numbers indicating the year of production in reverse
- 2 numbers indicating the month of production
- 2 numbers indicating the batch of production

For example:

Lot: 231120126

5. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS ON HUMAN HEALTH REPORTED DURING USE

No data on undesirable effects was submitted for consideration.

Undesirable and serious undesirable effects should be monitored and stored in complaint forms added to the PIF.

6. INFORMATION ON THE FINISHED COSMETIC PRODUCT

6.1 TOXICOLOGICAL DATA ON FINISHED PRODUCT

Toxicological data on the finished product is derived from the toxicological data of hazardous components – Hydrogen peroxide. The finished product has not been tested on animals.

Toxicological data is taken from the finished product MSDS, which can be found in the Product Information File.

PART B – Cosmetic product safety assessment

1. REASONING

This cosmetic product safety assessment is conducted in accordance with Regulation EC N°1223/2009.

The finished product safety assessment is based on:

- Physico-chemical and toxicological profile of the ingredients
- Physico-chemical and microbiological stability of the finished product
- Exposure parameters to the finished product
- The level of exposure to the ingredients
- Margin of Safety calculations if NOAEL is available

1.1 PHYSICO-CHEMICAL AND MICROBIOLOGICAL DATA ON THE FINISHED PRODUCT

Physico-chemically the product is stable under appropriate storage conditions to prevent decay of the product:

- Keep the product tightly closed, away from heat and direct sunlight. Avoid extreme temperatures. Store away from food and beverages.

Microbiologically the product is stable.

1.2 AVAILABLE SAFETY DATA

Margin of Safety > 100 is calculated for raw materials where NOAEL is available. Since the product is used in the eye area, the assumption was made that dermal absorption is 100%. With the worst-case scenario calculations, it is evaluated that the use of the ingredient in the finished product is safe for consumer use.

The ingredients in the finished product are permitted for use in cosmetics. None of the raw material ingredients are toxic under normal and reasonably foreseeable conditions of use at the concentrations in the finished product. The product does not contain prohibited substances listed in annexes of Regulation EC N°1223/2009.

1.3 PRECONDITIONS FOR USE AND ENVISAGED EXPOSURE OF THE TARGET GROUP TO THE PRODUCT

The finished product is for professional use only. The beauticians using this product should have had a training for this exact or similar product use.

The product is intended to be used on eyebrows. The product should not get into contact with skin.

2. ASSESSMENT CONCLUSION

According to Regulation EC N°1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products the product is safe for human health when used under normal or reasonably foreseeable conditions of use.

3. LABELLED WARNINGS AND INSTRUCTIONS OF USE

3.1 STATEMENTS FOR PARTICULAR LABELLING OR INSTRUCTIONS OF USE

Labelling must comply with the requirements of EC N°1223/2009.

In accordance with Art. 19 of Regulation EC N°1223/2009, there is a need to label a particular warning.

1) IT IS NECESSARY TO LABEL THE FOLLOWING PARTICULAR WARNING:
ATTENTION! Avoid skin contact, in case of contact with eyes, rinse immediately with plenty of water. Keep the bottle tightly closed and out of the reach of children. May cause allergic reaction. Contains hydrogen peroxide.

2) IT IS NECESSARY TO LABEL THE FOLLOWING PARTICULAR INSTRUCTIONS OF USE:

Apply Brow Fixing Lotion on the brows with Lint-free applicator and hold 10 min. If you would like to color during lamination process, apply brow color mix to the brows (1:1 Brow Color+ Fixing Lotion), hold brow color mix on for 5-10 min. Remove with lukewarm water.

3.2 LABELLING OF THE FINISHED COSMETIC PRODUCT

● MANDATORY MENTIONS

Date of expiry shall be noted on the product packaging with:

- Period after opening (6 months) open jar symbol.



● CLAIM SUPPORT

All claims on the product label should follow (EC) Regulation 655/2013 and the guidelines to this Regulation.

- SUGGESTED INCI LIST

INCI: Aqua, Cetearyl Alcohol, Cetareth-20, Paraffinum Liquidum (Mineral Oil), Hydrogen Peroxide, Laureth-3, Sodium Lauryl Sulfate, Glycerin, Panthenol, Simethicone, Disodium Pyrophosphate, Sodium Stannate, Phosphoric Acid, Polysorbate 20, Parfum

4. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

NAME:	Triin Truu
POSITION:	Cosmetic Safety Assessor
QUALIFICATIONS:	MSc (Biomedicine), Safety Assessment of Cosmetics in the EU – Training Course 2020
TELEPHONE:	+372 508 2697
E-MAIL:	triin.truu@skinsafe.com
CV INCLUDED IN ANNEX	

DATE: 03.06.2021

DIGITALLY SIGNED

2. MANUFACTURING METHOD IN COMPLIANCE WITH GOOD MANUFACTURING PRACTICE

Manufacturer: Kohana LTD

Kohana LTD hereby declare that the manufacturing process follows the Good Manufacturing Practices (GMP) requirements and is manufactured in compliance with the harmonized standards EVS-EN ISO 22716: 2008 "Cosmetics. Good Manufacturing Practices (GMP). Guidelines on Good Manufacturing Practices".

GMP includes scope, terms and definitions, personnel requirements, space requirements, equipment criteria, raw material and packaging specifications, manufacturing guidelines, finished product specifications, quality control, surveying, waste management, subcontracting, complaints and returns plan, internal audits, documentation.

14.04.2021

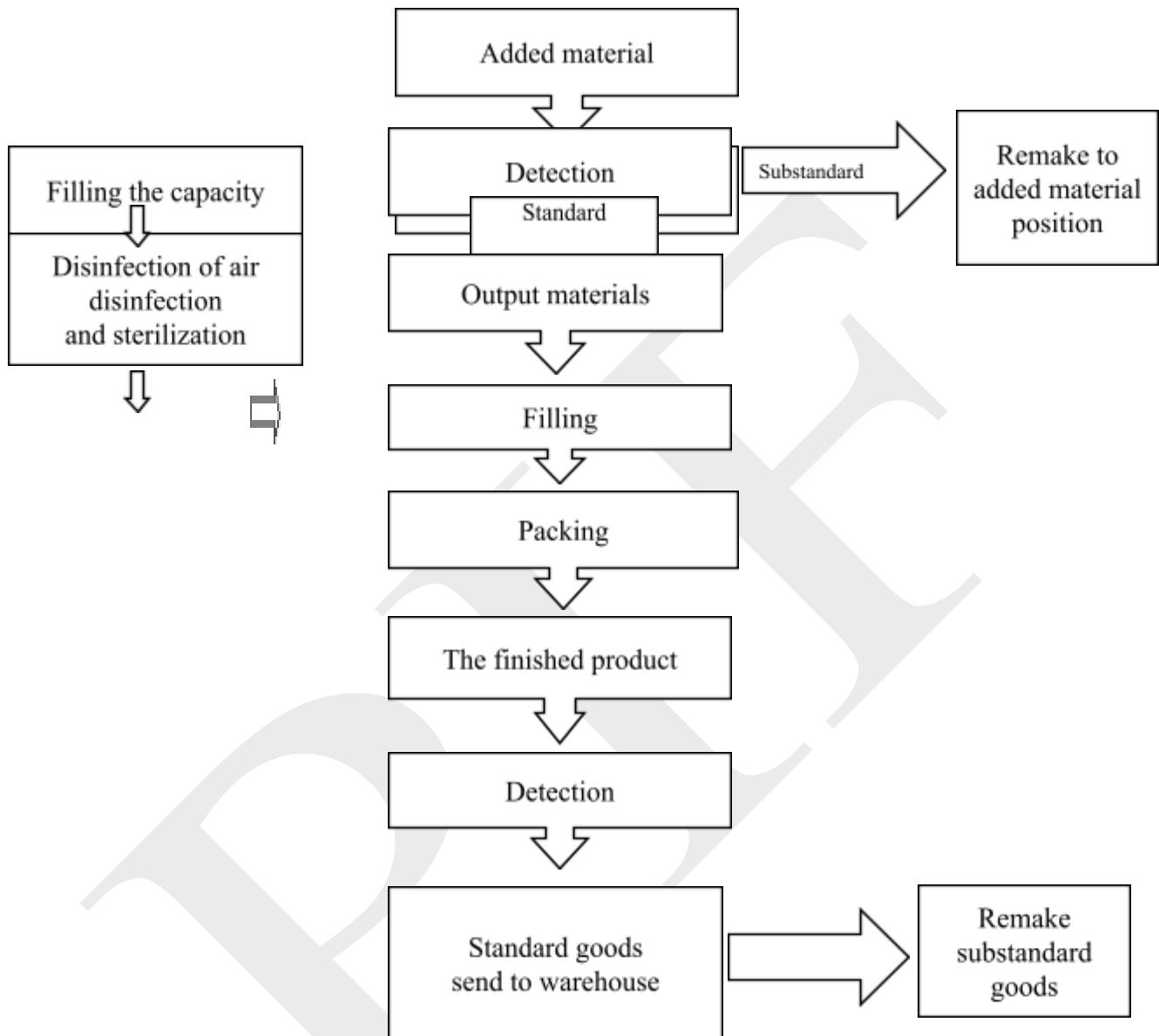
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Jaroslav Kruszynski

PRODUCTION PROCESS



3. CLAIMS SUBSTANTIATION

Claims are not established by Kohana LTD.

4. ANIMAL TESTING

Kohana LTD hereby declares, that products have not been used in animal testing.

5. COSMETIC PRODUCT LABELING (packaging):

The cosmetic product label includes the following information:

- Product name
- Product weight
- Instruction for use
- Function of the cosmetic product
- Conditions of storage
- Precautions for use
- List of ingredients
- Name and address of the responsible person
- The country of origin if the product is imported from countries outside of the EU
- Date of minimum durability or period after opening
- Identification number (EAN code)
- Hazards identification

All information contained in product labeling are indelible, easily legible and written with visible lettering.