

PRODUCT INFORMATION FILE (PIF)

PIF No: PIF201909-62

PIF Prepared By/Date: 28.05.2021

Product name: Brow Lamination Lotion 7ml	Manufacturer: Kohana LTD
	Address: Suite 10182, 77 Sir 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

PART A – Cosmetic product safety information

1. Qualitative and quantitative composition of the product, function and EU regulatory data

INCI/Concentration	CAS	Function	EU Regulatory status
Aqua (<75%)	7732-18-5	-	-

Ammonium Thioglycolate (<5%)	5421-46-5	Hair waving	<p>According to Annex III/2a - Thioglycolic Acid and its salts and esters are listed in the Cosmetics Regulation of the European Union and may be used in hair waving or straightening products at 8% for general use and 11% for professional use when the pH is between 7 and 9.5. Thioglycolic Acid and its salts can also be used in depilatories and other hair products which are removed after application at 5% (pH 7 to 12.7) and 2% (pH 7 to 9.5), respectively. Other limitations apply and Conditions of Use and Warnings must be printed on the product label.</p>
Cetearyl Alcohol (<10%)	67762-27-0 / 8005-44-5	Emollient, Emulsifying, Emulsion stabilizing	<p>The CIR Expert Panel has concluded that this product is safe for use in cosmetics.</p>
Ceteareth-20 (<5%)	68439-49-6	Cleansing, Emulsifying, Surfactant	<p>The CIR Expert Panel evaluated the scientific data and concluded that these ingredients were safe for use in cosmetics when formulated to be non-irritating.</p>
Ethanolamine (<5%)	141-43-5	Buffering	<p>According to Annex III/61 –</p> <ul style="list-style-type: none"> - Not allowed to use with nitrosating systems. Minimum purity: 99% - Maximum nitrosamine content: 50 µg/kg - Maximum secondary amine content: 0.5% - Keep in nitrite-free containers <p>The U.S. Food and Drug Administration (FDA) includes Triethanolamine (TEA), Diethanolamine (DEA) and Ethanolamine on its list of allowed indirect food additives. These ingredients may be used in adhesives in contact with food and to assist in the washing or peeling of fruits and vegetables. Ethanolamine should be used only in rinse-off products.</p>

Glycerin (<1%)	56-81-5	Humectant, moisturizer	The Food and Drug Administration (FDA) includes Glycerin on its list of direct food additives considered Generally Recognized As Safe (GRAS).
Paraffinum Liquidum (<1%)	8012-95-1 / 8042-47-5	Antistatic, Skin protecting, Solvent, Emollient	The Food and Drug Administration (FDA) has reviewed the safety of Mineral Oil and permits its use as a multipurpose direct food additive. The FDA also permits its use in Over-the-Counter (OTC) skin protectant drug preparations and in ophthalmic emollients. Pharma grade white mineral oil is used which corresponds to European Pharmacopoeias and the American F.D.A. 21 CFR 178.3620 (a) and F.D.A. 21 CFR 172.878.
Chamomilla Recutita Flower Extract (<0.1%)	84082-60-0	Skin conditioning	-
Hydrolyzed Corn Protein (<0.1%)	100209-41-4	Antistatic, Hair conditioning	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.
Hydrolyzed Wheat Protein (<0.1%)	70084-87-6	Skin conditioning	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients. According to Annex III/307 - Maximum molecular weight average of the peptides in hydrolysates: 3,5 kDa
Hydrolyzed Soy Protein (<0.1%)	68607-88-5	Antistatic, Hair conditioning	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.
Dimethicone (<0.1%)	63148-62-9 / 9006-65-9 / 9016-00-6	Emollient, Skin conditioning, Skin protecting	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.
Parfum (<1%)	-	Parfuming	This product conforms to the Annex I and the latest IFRA guidelines (Amendment n°48). PARFUM: - Product name and code: ROSE PETALS SCENT MP.02309

Polyquaternium-6 (<1%)	26062-79-3	Antistatic, Film forming	-
Etidronic Acid (<1%)	2809-21-4	Chelating	According to Annex III/53 maximum allowed concentration is 0.2% as an etidronic acid in soaps and 1.5% in hair products.
Cetrimonium Chloride (<1%)	112-02-7	Antimicrobial, Antistatic, Emulsifying	According to Annex V/44 allowed concentration is 0.1%. But in this formulation this product is not used as preservative. SCCP/1087/07 - following concentration limits should apply for rinse-off cosmetic products: the total sum of <i>behentrimonium</i> , <i>cetrimonium</i> and/or <i>steartrimonium chloride</i> should not exceed a maximum level of 3%. Allowed concentration is not exceeded.
Ammonium Hydroxide (<1%)	1336-21-6	Buffering, Denaturant	The Food and Drug Administration (FDA) includes Ammonium Hydroxide on its lists of direct food substances affirmed as Generally Recognized as Safe (GRAS). It can be used at levels not to exceed good manufacturing practices. Both Ammonia and Ammonium Hydroxide are FDA approved indirect food additives. According to Annex III/4 - it is allowed for use at a maximum concentration of 6% as NH ₃ , and must be labeled, contains Ammonia if the concentration is above 2%.
Phenoxyethanol (<1%)	122-99-6	Preservative	Phenoxyethanol is listed as 2-Phenoxyethanol in Annex V/29 (preservative which cosmetic products may contain) of the Cosmetics Directive of the European Union and may be used in concentrations up to 1%. Allowed concentration is not exceeded.
Ethylhexylglycerin (<0.1%)	70445-33-9	Skin conditioning	-
Tetrasodium Glutamate Diacetate (<0.045%)	51981-21-6	Chelating	Tetrasodium Glutamate Diacetate are not restricted from use in any way under the rules governing cosmetic products in the European Union.
Tetrasodium EDTA (<0.1%)	64-02-8	Chelating	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.

Sodium Sulfito (<0.1%)	7757-83-7	Hair waving or straightening, Preservative	<p>The Food and Drug Administration (FDA) includes Sodium Sulfito on its list of substances considered Generally Recognized As Safe (GRAS) for use as chemical preservatives in food. The CIR Expert Panel evaluated the scientific data and concluded that all seven ingredients were safe as used in cosmetics and personal care products.</p> <p>According to Annex III/99:</p> <p>(a) Oxidative hair dye products - 0,67 % (as free SO₂)</p> <p>(b) Hair straightening products - 6,7 % (as free SO₂)</p> <p>(c) Self-tanning products for the face - 0,45 % (as free SO₂)</p> <p>(d) Other self-tanning products - 0,40 % (as free SO₂)</p> <p>According to Annex V/9: a maximum authorized concentration of 0.2%, expressed as free sulfur dioxide.</p>
Propylene Glycol (<0.1%)	57-55-6	Solvent, Humectant	<p>The CIR Expert Panel evaluated the scientific data and concluded that Propylene Glycol was safe for use as cosmetic ingredients when formulated as non-irritating.</p> <p>The Joint FAO/WHO Expert Committee on Food Additives recommends a maximum daily oral intake of 25 mg Propylene Glycol/kg body weight/day.</p>
Citronellol (<0.2%)	106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9	allergen	<p>Concentration exceeds 0,01% in rinse-off product</p>

This product does not contain substances which are listed in following Annexes:

- Annex II of Regulation no 1223/2009 of the European Parliament and of the Council – list of substances prohibited in cosmetic products.
- Annex IV of Regulation no 1223/2009 of the European Parliament and of the Council – list of coloring agents allowed for use in cosmetics product
- Annex VI of Regulation no 1223/2009 of the European Parliament and of the Council – list of UV-filters which cosmetic products may contain

2. Physical/Chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of the ingredients (substances and mixtures)

Purity and analytical specifications of raw materials are contained on the relevant Certificates of Analysis / Sales Specifications, which are held by the manufacturer.

Raw material physical characteristics and suppliers' hazard classifications are given in the safety data sheets, which are held by manufacture.

The physical/chemical specification of the ingredients are well known and commonly used in similar products. Their inclusions in the finished product at the specified concentrations do not give rise to any concerns.

2.2 Physical/chemical characteristics of the finished cosmetic product

Appearance	Cream
Color	White
Odor	Characteristic
Solubility in water	Soluble
pH (25°C)	9.30 – 9.50

2.3 Stability of the cosmetic product

A shelf life of 36 months after manufacturing and 6 months after opening is currently assigned to this product according to the stability testing, microbiological testing, the physical nature of the product, the type of packaging used, and experience with this and similar products in the market. Store at room temperature in a dry place. Keep out of direct sunlight.

3. Microbiological quality

3.1 Microbiological quality of ingredients (substances and mixtures)

Based on available information from the ingredient specifications (see section 1. Quantitative and qualitative composition– specification of ingredients), the ingredients used can be assessed as microbiologically safe.

3.2 Microbiological quality of the finished cosmetic product

This product belongs to Category 2.

It is generally accepted that for cosmetics classified in *Category 1*, the total viable count for aerobic mesophyllic microorganisms should not exceed 10^2 cfu/g or 10^2 cfu/ml of the product (cfu = colony forming unit). For cosmetics classified in *Category 2*, the total viable count for aerobic mesophyllic 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* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 0.1 g or 0.1 ml of a cosmetic product of Category 2.

Challenge Test

The efficacy of the preservation of a cosmetic product under development has to be assessed experimentally in order to ensure microbial stability and preservation during storage and use. This is done by challenge testing. The latter is mandatory for all cosmetic products that under normal conditions of storage and use, may deteriorate or form a risk to infect the consumer.

The inhibition of the growth of the organisms falls within acceptable microbiological limits established for a cosmetic product. Under the experimental conditions encountered the preservative system used should be considered valid for this cosmetic product. According to this test results, the manufacturer guarantees the efficacy of the preservation of this product experimentally by challenge testing. Test product confirms to the both criterions (A and B) and is acceptable. The preservation system shows efficacy against tested microorganisms.

4. Impurities and information about the packaging material

Regarding any traces and impurities from the raw materials please refer to Table 1 of Part A Quantitative and qualitative composition of the cosmetic product and section 8. Toxicological Profile of the Substances.

Product is packed into:

Transparent glass bottle

Material: glass bottle + plastic cap (PP), capacity: 7ml. Packaging material is stable under normal conditions of use.

Declaration: Manufacturer confirms that above described packaging items are specially made for cosmetics. The packaging does not contain any carcinogenes, mutagenes and reprotoxines.

The raw materials and packaging materials that are used in the manufacturing process comply with the requirements of the EU directive 94/62/EC and its amendments regarding the total level of lead, mercury, cadmium and hexavalent chromium, which is below 100 mg/kg.

Packaging details were not available at the time of review but packaging is of cosmetics quality and is chosen as not to lead to deterioration of the product.

5. Normal and reasonably foreseeable use

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

6. Undesirable effects and serious undesirable effects

This product is adult use only. Undesirable effects of ingredients are described in paragraph 8 but end-product undesirable effects are not detected or recorded. In case of undesirable effects or serious undesirable effects the responsible person should inform the safety assessor to evaluate the effect and update the safety report accordingly.

The product is manufactured in compliance with GMP practice.

7. Information on the cosmetic product

No animal studies have been carried out for finished products. All MSDS and TDS are available by customer.

PRE

PART B – Cosmetic product safety assessment

1. Conclusion

Considering the exposure, chemical and toxicological information of this product during the safety assessment procedure, it is concluded that the product does not cause damage to human health under normal or reasonably foreseeable conditions of use.

The safety assessment report of this product is prepared for adults use. MoS>100 is found for raw materials where NOAEL were available. The calculation was performed assuming that dermal absorption is 100%. With this worst case study, it is evaluated that the use of this raw material in this product is safe.

The ingredients of the product are permitted ingredients for cosmetics. All raw materials are not toxic under normal or reasonably unforeseeable conditions of use at this concentration. The product does not contain prohibited substances listed in annexes of Regulation (EC) No.

1223/2009. Composition of the product complies with the requirements of the Cosmetic Regulations. Following review of the information provided for the above product and its ingredients, the **product is considered safe** for the intended application and **complies with EC Regulation 1223/2009**.

2. Labeled warnings and instruction of use

This product's presentation is in accordance with a Regulation no 1223/2009 of the European Parliament and of the Council about the labelling of cosmetic product. Restricted ingredients are properly listed on the package.

Labeled warning: For professional use only. Avoid contact with eyes. In the event of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves. Contains thioglycolate. Follow the instructions. Keep out of reach of children.

Instruction of use: Apply evenly Brow Lamination Lotion to your eyebrows. Leave it on for 5-10 minutes. Remove lotion with lint-free applicator. Exact use instructions are written on the label.

Claim support: All claims on the label should be in compliance with (EC) Regulation 655/2013 and the guidelines to this Regulation.

3. Reasoning

This assessment is based on:

- The chemical and physical specification of the ingredients
- The general toxicological profile of the ingredients
- The level of exposure of the ingredients
- The specific exposure characteristics of the areas to which the cosmetic product will be applied
- Margin of Safety calculations if available
- The specific exposure characteristics of the population for which the cosmetic product is intended


This assessment is conducted in accordance with the Regulation no 1223/2009 of the European Parliament and of the Council. All the ingredients in the formulation are either commonly used in rinse-off products with low toxicity or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR).

Provided manufacturer's instructions are followed.

The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability and microbiological quality.

4. Assessor's credentials

Safety Assessor's CV and diploma are added to this report.



Meelika Koitjärv

Safety Assessor

Date: 28.04.2021

This safety assessment is based upon information available at this date. The safety of the product should be reviewed on a regular basis. Reviews of this assessment should be conducted when new information becomes available.

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

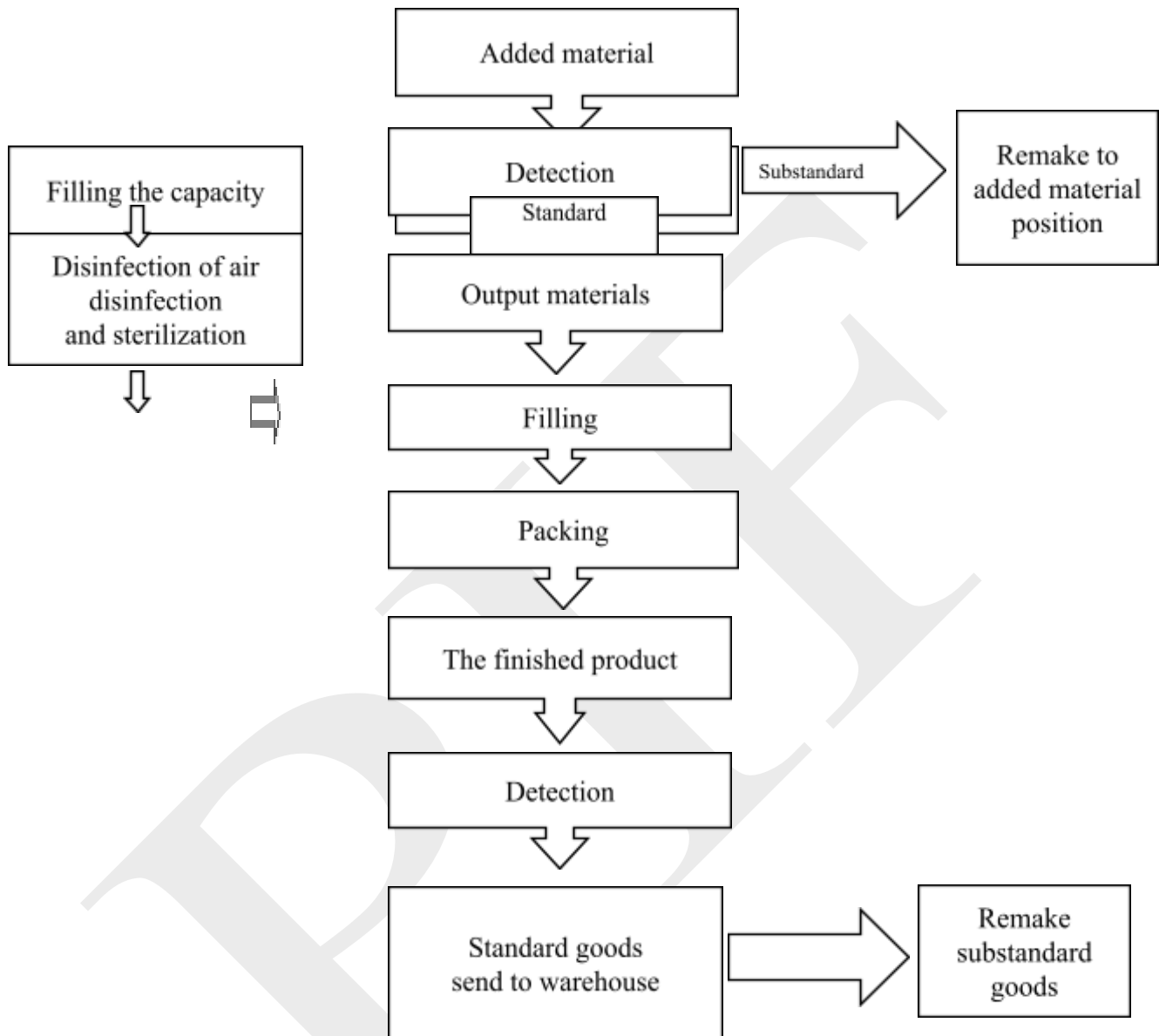
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Jaroslaw Kruszynski

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.