

PRODUCT INFORMATION FILE (PIF)

PIF No: PIF201909-64

PIF Prepared By/Date: 28.05.2021

Product name: Brow Sculpting Gel 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 leave-on 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	-	-

PVP (<10%)	9003-39-8	Antistatic, Film forming, Hair fixing	The CIR Expert Panel evaluated the scientific data and concluded that PVP (polyvinyl pyrrolidone) was safe as used in cosmetics and personal care products. The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake for PVP of 0-50 mg/kg body weight.
Alcohol Denat. (<10%)	-	Solvent	The CIR Expert Panel evaluated scientific data and concluded that this product is safe for use in cosmetics and personal care products if proper denaturants are used.
Glycerin (<5%)	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).
Triethanolamine (<1.25%)	102-71-6	Buffering, Emulsifying, Masking, Surfactant	According to Annex III/62. Leave-on products maximum allowed concentration 2.5%. Not allowed to use with nitrosating systems. Maximum secondary amine content: 0.5% Minimum purity: 99%
PEG-40 Hydrogenated Castor Oil (<5%)	61788-85-0	Emulsifying, Surfactant	The CIR Expert Panel concluded that the 130 PEGylated oil ingredients are safe in the present practices of use and concentration in cosmetics when formulated to be non-irritating.
Aloe Barbadosis Leaf Juice (<0.1%)	85507-69-3/94349-62-9	Emollient, humectant, skin conditioning	The CIR Expert Panel has concluded that this product is safe for use in cosmetics.
Panthenol (<0.1%)	81-13-0 / 16485-10-2	Hair conditioning, Skin conditioning	The CIR Expert Panel has concluded that this product is safe for use in cosmetics.
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.
Leuconostoc/Radish Root Ferment Filtrate (<0.1%)	84775-94-0	Antimicrobial	This product is safe for use in cosmetics.
Polysorbate 20 (<1%)	9005-64-5	Emulsifying, Surfactant	The CIR Expert Panel evaluated scientific data and concluded that this product is safe for use in cosmetics and personal care products.
Hydrogenated Starch Hydrolysate (<1%)	68425-17-2	Humectant	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.
Carbomer (<1%)	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	Emulsion stabilizing, Gel forming	The CIR Expert Panel evaluated the scientific data and concluded that Carbomer polymers were safe as ingredients in cosmetics and personal care products.
Acrylates Copolymer (<1%)	25133-97-5 / 25035-69-2 / 25212-88-8	Antistatic, Film forming, Binding	The CIR Expert Panel has concluded that this product is safe for use in cosmetics when formulated to avoid irritation.
Propylene Glycol (<1%)	57-55-6	Solvent, Humectant	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. The Joint FAO/WHO Expert Committee on Food Additives recommends a maximum daily oral intake of 25 mg Propylene Glycol/kg body weight/day.

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 (<1%)	70445-33-9	Skin conditioning	-
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.
Imidazolidinyl Urea (<0.3%)	39236-46-9	Preservative	Annex V/27 - it may be used at a maximum concentration of 0.6% in cosmetics and personal care products.
CI 16255 (<0.1%)	2611-82-7	Red Cosmetic colorant	CI 16255 is listed in Annex IV, Part I of the Cosmetics Directive of the European Union and may be used in all cosmetics and personal care products (E 124).

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 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	Gel
Color	Colorless
Odor	Characteristic
Solubility in water	Soluble
pH (25°C)	6.5 – 7.5

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 mesophilic 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 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* 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.

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5. Normal and reasonably foreseeable use

This is leave-on 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.

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. Keep out of reach of children.

Instruction of use: Apply evenly on your eyebrows. 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 leave-on 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 Koitjäärv

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.



kohana
PROFESSIONAL

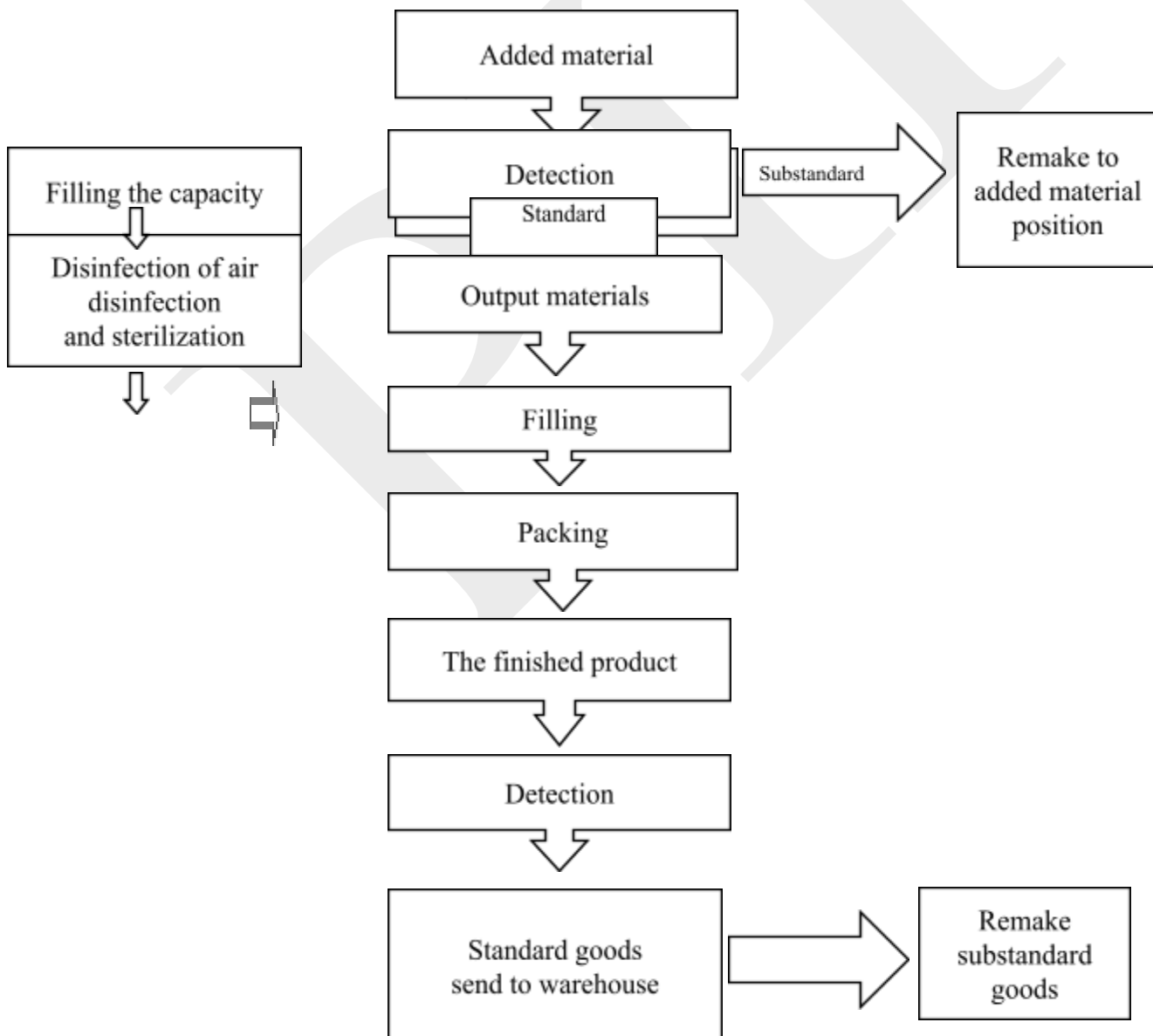
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PRODUCTION PROCESS



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.