

PRODUCT INFORMATION FILE (PIF)

PIF No: PIF201909-69

PIF Prepared By/Date: 26.08.2021

Product name: Pre-Treatment 5ml	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 leave-on product intended to use on eyelashes.

2. COSMETIC PRODUCT SAFETY REPORT

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

INCI/Concentration	CAS	Function	EU Regulatory status
Aqua (45-50%)	7732-18-5	-	-
Alcohol (45-50%)	64-17-5	Solvent	The Food and Drug Administration (FDA) includes Alcohol (ethanol) on its list of direct food substances considered Generally Recognized as Safe (GRAS). FDA has also approved Alcohol for use in Over-the-Counter (OTC) antimicrobial drug

INCI/Concentration	CAS	Function	EU Regulatory status
			products.
APM-Acrylates Copolymer (0.5%)	-	Antistatic, Film forming, Binding	The CIR Expert Panel has concluded that this product is safe for use in cosmetics.

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 III of Regulation no 1223/2009 of the European Parliament and of the Council – list of substances which cosmetic products must not contain except subject to the restrictions laid down
- 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 V of Regulation no 1223/2009 of the European Parliament and of the Council – list of preservatives allowed 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	Liquid
Odor	Odorless
Boiling point/range	100 °C

Solubility in water	Soluble
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2.3 Stability of the cosmetic product

A shelf life of 36 months after manufacturing and 12 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.

Keep container closed when not in use. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep containers tightly closed.

3. Microbiological quality

This product belongs to Category 1 (possible contact with eye mucous membrane but this is not the direct contact and not intended use).

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 1 g or 1 ml of a cosmetic product of Category 2.

As the product contains over 20% of alcohol microbiological contamination has been avoided and no need to make challenge test and regular microbiological analysis.

4. Impurities and information about the packaging material

Product is packed into PET bottle and covered with ABS cap. Nozzle is from PE. Packaging material is stable under normal conditions of use.

The products comply with the effective EU regulations regarding plastic food contact materials which are fixed per 1935/2004 and 10/2011 including amendments.

The raw materials and packaging materials that are used in the manufacturing process at plastic bottles 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.

This material has proper certificate of conformity. The manufacturer is ensured that 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 leave-on product intended to use on eyelashes. The product can get to contact with mucous membrans of the eyes but this is not the intended use.

7. 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.

8. 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: If product gets in eyes rinse with water immediately. Keep the bottle closed.

Keep away from reach of children. For professional use only.

Instruction of use: Dip a cotton pad in the liquid. Process the eyelashes with liquid until full recovery.

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 Koitjärv

Safety Assessor

Date: 18.08.2021

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.

3. 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.

18.08.2021

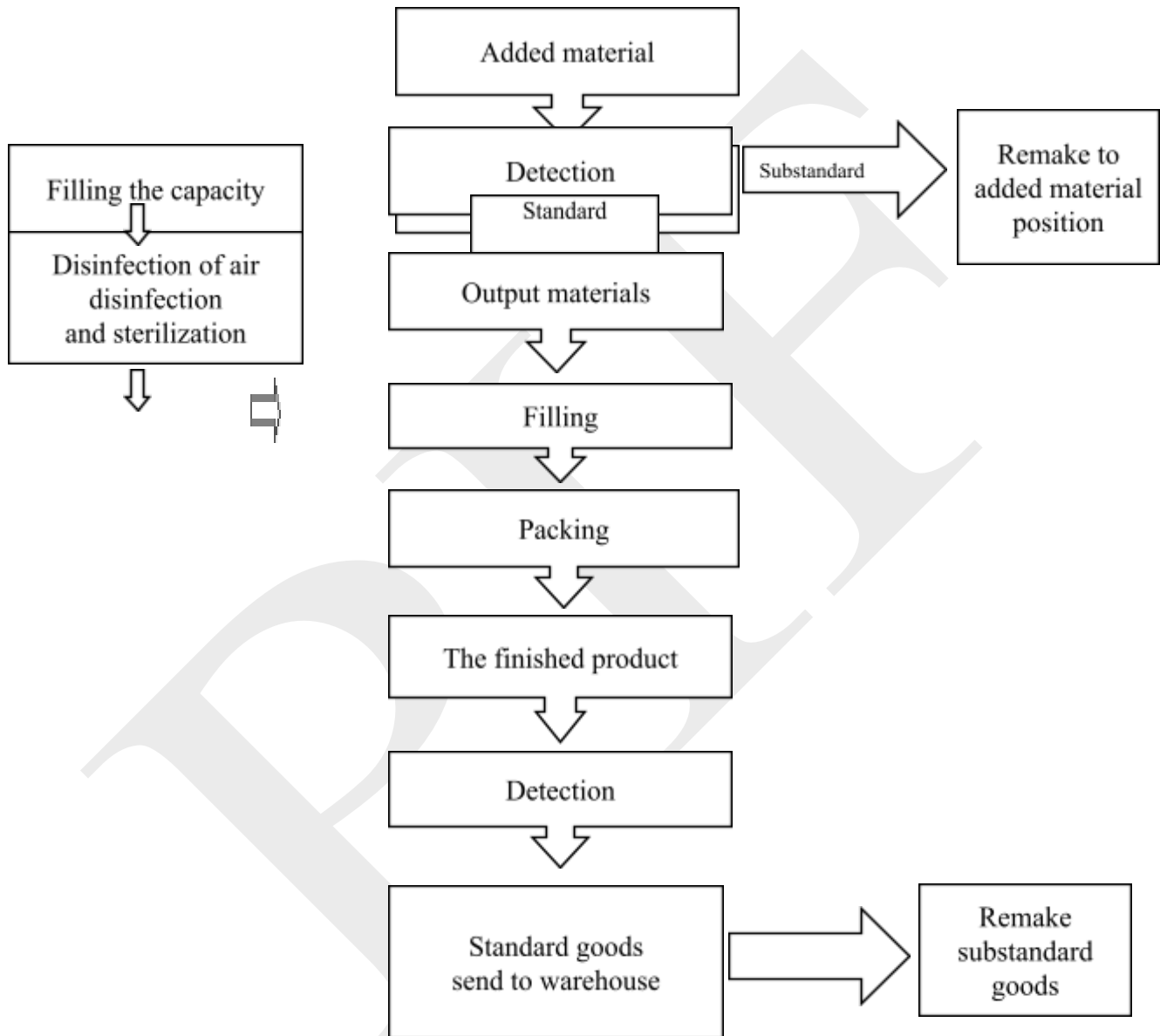
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Jaroslaw Kruszynski

PRODUCTION PROCESS



4. CLAIMS SUBSTANTATION

Claims are not established by Kohana LTD.

5. ANIMAL TESTING

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

6. 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.