MAIMI PAINT

Cosmetic product assessment and safety report

According to EC Regulation 1223/2009

ÍNDEX

1. INTRODUCTION

1.1. GENERAL APPROACH.

1.1.1. Product information.

Product name: VASELINE WITH HAZEL

Report data.

Date of issue: May 2022

Prepared and signed by the Technical Manager in accordance with European regulations, reports and scientific literature (art.10.1.c of the EC Regulation 1223/2009)

1.1.2. Brand/manufacturer.

Company Name : MAIMI PAINT SL

Address : c/Ciudad de Sevilla 5 46988 Paterna (Valencia)

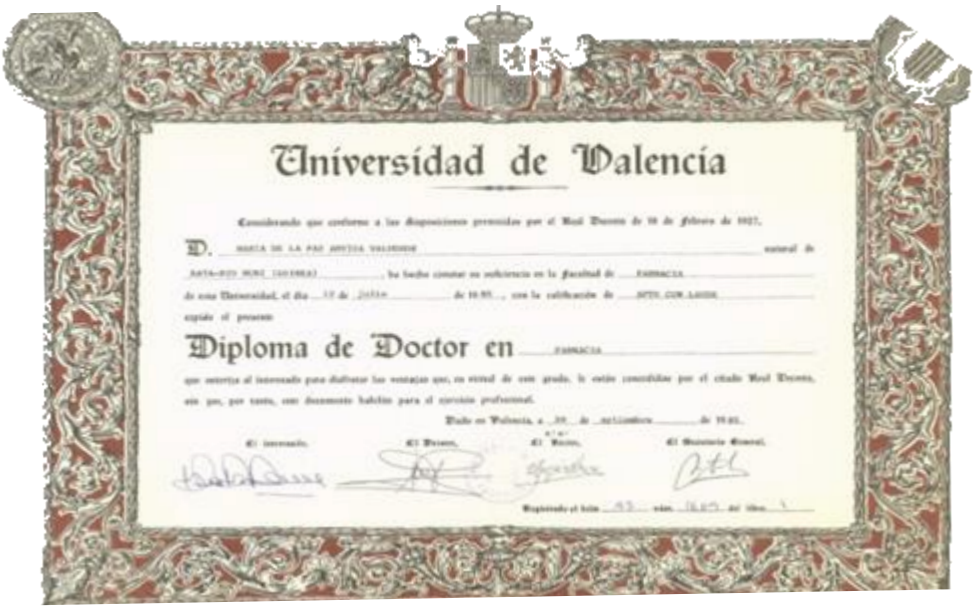
administracion@amtatto.es

1.1.3. Assessor credentials and approval of Part B.

Name: **Dra. Paz Arviza Valverde**.

Education and Curriculum Vitæ:

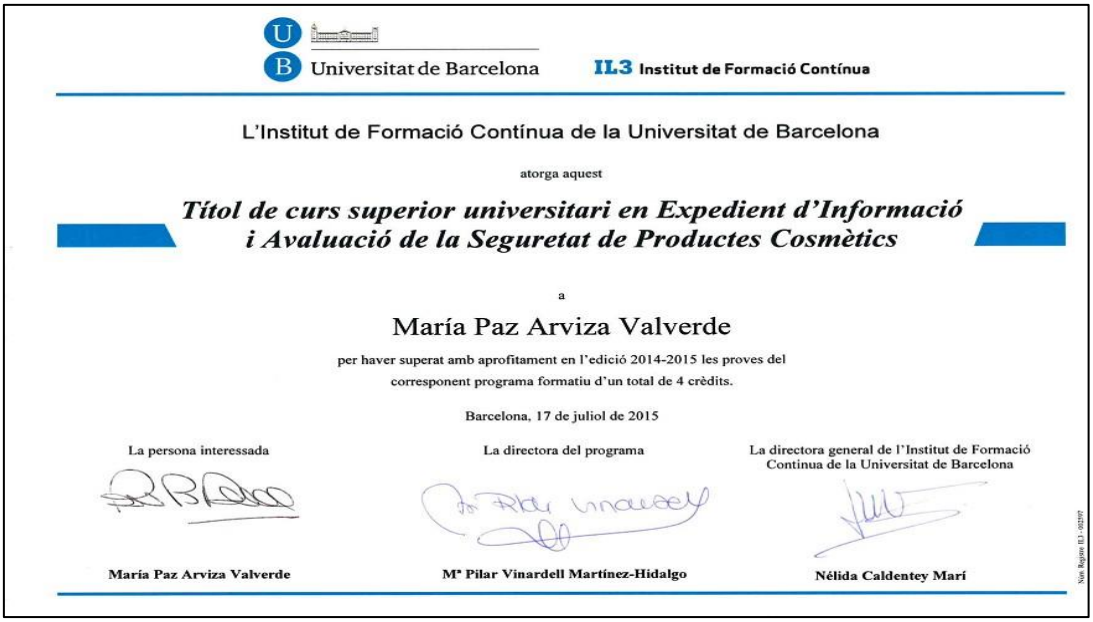
- The Assessor responsible for the preparation of this report is Paz Arviza Valverde, Doctor of Pharmacy by the University of Valencia (Spain), with a distinction "Cum Laude".
- For 32 years, and until 03/31/2013, she has worked as a civil servant as Director of Health of the Valencian Community, functionally dependent of the Spanish Agency of Medicines and Health Products, National Competent Authority in the Control and monitoring of cosmetics and personal care products.
- Since 04/04/2013,she works as consultant and adviser for different companies in the cosmetic sector, both in Spain and abroad.



Universidad de Valencia

D. [illegible]

Diploma de Doctor en [illegible]



Universitat de Barcelona IL3 Institut de Formació Contínua

L'Institut de Formació Contínua de la Universitat de Barcelona

atorga aquest

Títol de curs superior universitari en Expedient d'Informació i Avaluació de la Seguretat de Productes Cosmètics

a

María Paz Arviza Valverde

per haver superat amb aprofitament en l'edició 2014-2015 les proves del corresponent programa formatiu d'un total de 4 crèdits.

Barcelona, 17 de juliol de 2015

La persona interessada	La directora del programa	La directora general de l'Institut de Formació Continua de la Universitat de Barcelona
Maria Paz Arviza Valverde	Mª Pilar Vinardell Martínez-Hidalgo	Nélida Caldentey Marí

1.2. PRODUCT DEVELOPMENT CHARACTERISTICS.

Vaseline specially designed for use in tattooing and post treatment

HOW TO USE

Apply liberally on tattooed skin

CAUTIONS

Always keep the product hermetically sealed. Protect from light and moisture. Do not eat. Avoid contact with eyes

USE, USERS AND DISTRIBUTION.

All precautions for use, instructions and toxicological profile have been made taking in account the following aspects:

- The product is sold to the normal consumer.
- The product is indicated for adults.
- No professional assistance is required, either during the sale or during use.
- Waste that must be disposed of after use has no special requirements.

1.3. INSTRUCTIONS FOR USE.

The product is widely known by the normal consumer, so special instructions are not considered necessary. Has been taken in account:

- Compliance with EC Regulation 1223/2009
- Compliance with Commission Regulation 665/2013 of 10 July establishing common criteria for the justification of instructions for use in cosmetics.
- Information and instructions provided by the manufacturer.

2. COSMETIC PRODUCT SAFETY REPORT

2.1. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE COSMETIC PRODUCT.

The Responsible Person guarantees that the ingredients used are in accordance with the provisions of art.14 of EC Regulation 1223/2009. The data sheet of ingredients is reflected below:

R.M. INCI Name	% CALCULATED FOR EACH SUBSTANCE	FUNCTION	CAS NO	ENC NO
Paraffinum liquidum	64,93	HUMECTANT	8042-47-5	232-384-2
Hydrogenated Microcrystallne wax	19,98	FIXING AGENT	64742-60-5	264-038-1
Paraffin	14,98	SKIN CONDITIONING AGENT	64742-51-4	232-315-6
		SKIN CONDITIONING AGENT	8002-74-2	
AQUA	0,11	SOLVENT	7732-18-5	231-791-2
ETHANOL	0,0010	SOLVENT	64-17-5	200-578-6
HAMAMELIS VIRGINIANA, EXTRACTO	0,0001	SKIN PROTECTANT	84696-19-5	283-637-9
POTASSIUM SORBATE	0,000006	PRESERVATIVE	590-00-1	246-376-1
SODIUM BENZOATE	0,000006	PRESERVATIVE	532-32-1	208-534-8

Conclusions.- Declared ingredients are accepted for the described use as prescribed in EC Regulation 1223/2009, AnnexII - AnnexVII.

2.2. PHYSICOCHEMICAL CHARACTERISTICS AND COSMETIC PRODUCT STABILITY.

The certificates of analysis are enclosed, both for the physico-chemical characteristics and for the stability of the product. Subsequent analyzes may vary the data of this report and should be subject to modification of the report itself. The aspects to consider are:

- Look
- Color
- Scent
- pH

The MSDS (Material Safety Data Sheet) of the ingredients have been submitted.

2.3. MICROBIOLOGICAL QUALITY.

Throughout the manufacturing process, systems are required to ensure, through testing, the Microbiological Quality of the product, both in its contents, packaging and transportation.

Any change and / or modification of the Microbiological Quality control system must be communicated by the Person Responsible to the Safety Advisor immediately.

2.3.1. Materials.

The materials meet the standards set forth in the SCCS (Scientific Committee on Consumer Safety) Notes Guide (9th revision).

A copy of the MSDS's of ingredients used for this product and REACH fulfillment have been submitted.

2.3.2. Finished product.

The analyzes should have been carried out in accordance with the European Pharmacopoeia 6.5. 2009 (2.6.12, 2.6.13) by an accredited laboratory for standard ISO 17025 . The accredited results are:

AKLABS calidad

LABORATORIO CERTIFICADO SEGÚN LA NORMA ISO 9001:2015 Y NORMA ISO 22716:2008

INFORME DE ENSAYO: 22005182

DATOS FACILITADOS POR EL CLIENTE	DATOS DEL CLIENTE
Fecha de Producción: 31/03/2022 **Fecha de caducidad:** 31/03/2024 **Lote:** VWH-02-75 **Referencia del cliente:** Witch Hazel Flavour Vaseline **Muestreo:** En las instalaciones del cliente	**MAIMI PAINT S.L** C/Senda del Carmen nº8 Puerta 1 46119 - Náquera (VALENCIA)
LÍMITES DE REFERENCIA	**DATOS DEL LABORATORIO**
Los resultados en **rojo**, incumplen la legislación siguiente: Según los límites de establecidos en la norma ISO 17516:2014, sobre productos cosméticos Categoría 2.,.	**Fecha recepción y registro:** 18/03/2022 12:25:05 **Estado muestra:** APTO **Fecha inicio análisis:** 18/03/2022 **Fecha fin del análisis:** 23/03/2022 **Muestreado por el:** El Cliente **Categoría:** COSMETICOS **Tipo de muestra:** Prod Cosméticos

PARÁMETRO Unidades	RESULTADO	MÉTODO DE ENSAYO	LÍMITE DE REFERENCIA
Aerobios mesófilos a 32,5ºC (ufc/g)	< 10	ISO 21149-cosmR	<=1000
Mohos y levaduras a 25ºC (ufc/g)	< 10	ISO-16212-cosmR	<=1000
Detección Staphylococcus aureus / g	No detectado	ISO-22718-cosmP	No detectado
Detección Pseudomonas aeruginosa / g	No detectado	ISO-22717-cosmP	No detectado
Detección Escherichia coli / g	No detectado	ISO-21150-cosmP	No detectado
Detección Candida albicans / g	No detectado	ISO-18416-cosmP	No detectado

Los datos analíticos solo corresponden a las muestras sometidas a ensayo.
Este informe no deberá reproducirse total o parcialmente sin la aprobación por escrito del laboratorio.
El laboratorio no se hace responsable de la información suministrada por el cliente.
En el caso de muestras no tomadas por personal de Laboratorios AKLABS, el laboratorio no se responsabiliza de dicha actividad y ni de lo acontecido hasta la recepción de las muestras al laboratorio.

Director laboratorio
Juan Carmona Bernat
23/03/2022

INDUSTRIA ALIMENTARIA - MEDIO AMBIENTE - INDUSTRIA AGROPECUARIA - INDUSTRIA FARMACEÚTICA Y COSMÉTICA
C/Hungría nº 2 Castellón •12006 • Tel 964 500 365 • Tel 963 211 220 • Tel 937 064 920

2.3.3. Distribution.

These products are imported from Korea. Upon arrival and prior to distribution, the same microbiological analyzes as those mentioned for the finished product after production are carried out by an accredited laboratory.

A copy of COA of finished product has been submitted

Any deviation from the expected values should be notify to the Assessor as well as to carry out the actions determined by the market surveillance process.

2.3.4. Efficiency of the conservation system.

The product is not intended to be used:

- Around the eyes.
- In the mucous membranes.
- In damaged skin.
- In children under 3 years.
- In elderly people.
- In people who have low or immunosuppressed defenses.

Conclusions. - The product, in view of the results delivered, complies with that specified in the Guide on Microbiological Quality (SCCNFP/004/98).

2.4. PACKAGING MATERIAL: IMPURITIES, TRACES AND COMPATIBILITY.

Plastic containers must comply with European Parliament Directive 94/62 on packaging and packaging waste (ERE) regarding the level of concentration of heavy metals and also do not contain any SVHC substance, as amended by Directives 2004/12 and 2005/20 and with reference to heavy metals Regulations 1882/2003 and 219/2009, which set a maximum value of 100 ppm for the total content of lead, cadmium, mercury and chromium. The supplier will also have the certificates of quality and control of the processes.

The review of the MSDS provides sufficient information on the purity of the ingredients and no significant contaminants are observed

The compatibility is demonstrated by the stability tests performed and information provided

In view of the results obtained it is concluded that the packaging material is adequate since it maintains the characteristics of the product (physicochemical and microbiological) and does not appear to suffer losses.

2.5. EXPOSURE TO THE COSMETIC PRODUCT.

According to the SCCS Guidelines, the MoS (Safety Margin) has been calculated for each of the ingredients. In the absence of NOAEL (No observed adverse effect level) in some of them it has resorted to databases and bibliography.

Surface area	Parameters	Frequency	Estimated daily	Relatived amount	Retention	Calculated Daily	Calculated relative
(cm²)			Amount	Applied	Factor	exposure	daily exposure
565			0,51 g	7,9g	1	0,51	7,9 mg/kg bw/d

Dates have been obtained from distributor/supplier or from literature or calculated by analogy (for instance food, structure, medical uses, etc.). The safety of raw material is considered safe in the actual use when the maximum concentration in the product is below the SCCS's limit values.

Mos Value is the result of

$$MoS = \frac{NOAEL_{sys}}{SED}$$

The exhibition route is dermal.

The highest value of SED for the ingredients of this product with the highest concentration(Paraffinum)is 5,13 which implies that all products even with NOAEL lower than that of it have an MoS greater than 100. It should be considered that few and highly studied products have a NOAEL value around or below 100 and even in these taking in account the level of exposure the value of MoS is greater than 100

The exposure way is dermal and the obtained Mos are above 100

	%	NOAEL	SED	MoS
Paraffinum liquidum	65	1000	5,13	195
Hydrogenated Microcrystallne wax	20	1200	1,58	779
Paraffin	15	1100	1,18	932

The raw materials used to formulate this prod uct are all well known cosmetic product ingredients. They are present at typical concentrations where they are unlikely to cause irritation but may cause allergy in a small percentage of the general population. This formulation is typical of this product type. Products of similar composition have been widely used and well received in the market place.

Effects of the product as supplied on the skin:

The formulation as supplied may cause skin irritation especially if exposure is prolonged and/or repeated. However, under normal conditions of use exposure time will be short and the likelihood of causing skin irritation will be very low.

There are low concentrations of substances present in this product, which have allergenic activity. The concentrations present are sufficiently low for the level of use to ensure that people do not become sensitised. However, people who are already sensitised to a substance may react adversely to any product containing that substance even when present at extremely low concentrations.

Exposure to this product is unlikely to result in phototoxic effects.

It is unlikely to cause damage to internal organs following absorption through the skin.

Effects on the skin, of the product as diluted for use

Contact with the dilute solution is unlikely to cause skin irritation even if contact is prolonged and/or repeated.

Effects of the product as supplied on the eye

Accidental exposure of the eye to the product may result in slight eye irritation.

Effects on the eye of the product as diluted for use

Accidental exposure of the eye to the diluted product may result in slight eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed is likely to cause irritation to the mouth and upper digestive tract.

Effects on ingestion, of the product as diluted for use

The diluted product if swallowed may cause slight irritation to the mouth and upper digestive tract.

Effects of inhaling the product

Inhalation is an unlikely route of exposure.

In view of the above, the product is considered safe with normal, reasonable and expected use, with the considerations reflected.

2.6. TOXICOLOGICAL PROFILE OF COMPONENTS.

The toxicological data of the substances or ingredients contained in the formula of the product under evaluation are derived from the available information provided by raw material suppliers, available literature and existing databases: SCCP / SCCS, CIR, OECID SIDS, TOXNET, PUBMED, EFSA.EMEA, FDA, PubChem ...

To establish the toxicological profile, the recommendations of the SCCS have been followed "The SCCS's notes of guidance for testing of cosmetics substances and their safety evaluation" its 9th revision.

Attached Table with the toxicological characteristics of the components. In view of the above, in the quantities indicated the product is safe for use under normal conditions.

INGREDIENT	INFORMATION
Paraffinum liquidum	In the EU, the full refining history for petrolatum must be documented showing that the substance from which it is produced is not a carcinogen, i.e., the petrolatum must be properly refined. Petrolatum, which does not meet these requirements, is listed in Annex II of the Cosmetics Directive of the European Union (link is external) and must be used in cosmetics and personal care products..
Hydrogenated Microcrystallne wax	The CIR Expert Panel concluded that Ozokerite, Ceresin, Montan Wax, Paraffin, Microcrystalline Wax, Emulsifying Wax, Syntethic Wax and Synthetic Beeswax have, at most, a potential for mild skin irritation and mild or no eye irritation. The CIR Expert Panel concluded that these waxes do not result in dermal sensitization.
Paraffin	White mineral oil has a long history of safe use by humans in orally ingested and topically applied products. A re-evaluation of the use of certain mineral hydrocarbons used in the preparation of food items by regulators in the UK, however, prompted additional safety studies and a critical assessment of the toxicological effects of white mineral oil. As white mineral oil is present in many topically applied drug and non-drug products, it was of interest to review the toxicological effects of mineral oil produced by this route of exposure. Initial concern about possible tissue inflammation in liver and lymph nodes of rats after they orally ingested white mineral oils has been proven to be unfounded with no scientific basis for concern.These studies were reviewed in 1996 by the Cosmetic Toiletry and Fragrance Association's (now known as the Personal Care Products Council) Mineral Oil Task Force as part of an examination of available published scientific literature. After a review of the literature, which included findings of negligible skin penetration for topically applied white mineral oil, the CTFA Task Force determined that there was no valid scientific evidence in the published literature of any hazard

	identified for topical exposure to white mineral oil at any dose in multiple species. This determination is supported by the long history of safe human use of white mineral oil in drug and non-drug topically applied products.
AQUA	The quality of water used in the production of cosmetics and personal care products, called process water, is monitored according to Good Manufacturing Practices outlined in SCCS Guidelines, and in international guidelines on Good Manufacturing Practices known as ISO 22716. Some companies may also comply with the European Pharmacopeia standards for the purity of water used in drugs.
ETHANOL	In Europe, Alcohol Denat is Alcohol denatured with one or more denaturing agents in accordance with the national legislation of each European Union (link is external) (EU) country. All EU Member states recognize denaturing methods applied by any of the other EU nations. Brucine is not permitted to be used in cosmetics and personal care products marketed in Europe
HAMAMELIS VIRGINIANA, EXTRACTO	It is allowed for human consumption
POTASSIUM SORBATE	Sorbic Acid and Potassium Sorbate were practically nontoxic in acute oral toxicity studies. In subchronic studies, no significant adverse effects were observed when 10% Sorbic Acid was included in the diet. Sorbic Acid and Potassium Sorbate, at concentrations up to 10%, were practically nonirritating to the eye. Both ingredients at concentrations up to 10% were at most only slightly irritating to skin. Sorbic Acid and Potassium Sorbate have been tested for mutagenic effects using bacterial tests, genetic recombination tests, reversion assays, tests for chromosomal aberrations, sister chromatid exchanges and gene mutations. The weight of evidence of these tests indicates that these ingredients were not mutagenic. Potassium Sorbate at 0.1% in the diet or 0.3% in drinking water for up to 100 weeks was not carcinogenic. In other chronic studies, no carcinogenic effect was demonstrated by Sorbic Acid in diets containing up to 10% Sorbic Acid. No developmental effects have been observed with Potassium Sorbate. Formulations containing up to 0.5% Sorbic Acid and or Potassium Sorbate were not significant primary or cumulative irritants and not sensitizers.
SODIUM BENZOATE	The CIR Expert Panel noted that no adverse effects of Benzyl Alcohol were seen in chronic oral exposure studies. Effects of Benzoic Acid and Sodium Benzoate in chronic oral exposure studies were limited to reduced feed intake and reduced growth. At doses used in cosmetics and personal care products, the CIR Expert Panel was not concerned about potential reproductive and developmental effects.The CIR Expert Panel reviewed data that indicated that inhalation exposure to Benzyl Alcohol and Benzoic Acid did not result in adverse effects. Although, genotoxicity tests for these ingredients were mostly negative, there were some assays that were positive. Carcinogenicity studies, however, were negative.Clinical data indicated that in a few individuals these ingredients produced

	non-immunologic contact urticaria and non-immunologic immediate contact reactions, characterized by the appearance of wheals, erythema, and pruritis. In one study, 5% Benzyl Alcohol elicited a reaction, and in another study, 2% Benzoic Acid did likewise. Benzyl Alcohol, however, was not a sensitizer at 10%, nor was Benzoic Acid a sensitizer at 2%.Recognizing that the non-immunologic reactions were strictly cutaneous, likely involve a cholinergic mechanism, it was concluded that these ingredients could be used safely at concentrations up to 5%. Additionally, Benzyl Alcohol was considered safe at up to 10% for use in hair dyes.The limited body exposure, the duration of use, and the frequency of use were considered in concluding that the non-immunologic reactions would not be a concern.

2.7. UNDESIRABLE EFFECTS.

The market surveillance procedure is applied. The Technician responsible for the company will keep a constant follow-up of the existing scientific novelties, looking for information about similar products or their ingredients, with a direct contact with the manufacturer. If that there is a case reported of both product and ingredients, the Assessor will be advised that together with the Technical Manager he will evaluate its relevance by proposing the necessary measures to guarantee the safety of the product. In case it is relevant, it will be incorporated by the consultant to the present document.

3. ADDITIONAL INFORMATION

3.1. MANUFACTURE.

Manufacturer is made according to the established in the norms of Good Practices (GMP), according to information provided by the manufacturer

The production method used, which is considered appropriate for this type of products, has been provided

3.2. QUALITY CONTROL.

Analyzes are performed on the finished product of microbiological, physicochemical and challenge test. The parameters to be analyzed as critical have been obtained from the scientific evidence and toxicological study carried out by the manufacturer. Any changes that may occur in the formulation will be subject to a new study and review.

Likewise, an analysis of the physico-chemical and microbiological characteristics of each batch of production is performed.

3.3. NANOMATERIALS.

According to Article 16 of R 1223/2009 / EC, in cosmetic products, nanomaterials must be specified and controlled. The product subject of this report doesn't contain ingredients classified as nanomaterials in accordance with the SCCS GUIDE, according information provided by manufacturer.

3.4. PRESENCE OF SUBSTANCES CLASSIFIED AS CMR.

Control over these substances is included in article 15 of R 1223/2009 / EC. There are no substances in this product that can be considered as such, according information provided by manufacturer.

3.5. LABELING AND TRACEABILITY.

Procedures are applied to ensure traceability from the materials used in the manufacture to the finished product through the batch number which is reflected in the labeling of all the containers and which reflects all the data provided for in Article 19 of R1223 / 2009 /EC.

The container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

- The name or registered name and the address of the responsible person. Such information may be abbreviated in so far as the abbreviation makes it possible to identify that person and his address. If several addresses are indicated, the one where the responsible person makes readily available the product information file shall be highlighted. The country of origin shall be specified for imported cosmetic products;

• The nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;

• The date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3 ('date of minimum durability'). The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in point 3 of Annex VII or the words: 'best used before the end of'. The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability. Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol shown in point 2 of Annex VII followed by the period (in months and/or years);

• Particular precautions to be observed in use, and at least those listed in Annexes III to VI and any special precautionary information on cosmetic products for professional use;

• The batch number of manufacture or the reference for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;

• The function of the cosmetic product, unless it is clear from its presentation;

• A list of ingredients. This information may be indicated on the packaging alone. The list shall be preceded by the term 'ingredients'.

The following substances shall not, however, be regarded as ingredients:

I. iImpurities in the raw materials used;

II. Subsidiary technical materials used in the mixture but not present in the final product.

Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'parfum' or 'aroma'. Moreover, the presence of substances, the mention of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients in addition to the terms parfum or aroma.

The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients Colorants other than colorants intended to coloring hair may be listed in any order after the other cosmetic ingredients. For decorative cosmetic products marketed in several dye shades, all colorants other than colorants intended to coloring hair used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added. The CI (Colour Index) nomenclature shall be used, where applicable. shall be followed by the word 'nano' in brackets.

3.6. DETERMINATION OF THE AVERAGE LIFE OF THE PRODUCT AFTER THE OPENING.

The product half-life has been calculated using procedures developed by the company as there are no specific analytical protocols for each type of cosmetic product. These procedures take in account the results of the tests performed on this product or the like after storage of several months. These analyzes are shown in the corresponding section and prove that the product has a long half-life without open.

3.7. PRODUCT SAFETY TESTS.

For the assessment of safety have been taken in account:

a) The toxicological profiles of the components.

b) The absence of impurities or hazardous substances.

c) The exposure levels of the product and the ingredients.

d) Toxicological databases.

e) Relevant publications on similar products.

f) Results af attached patch test

7 / 8

3.8. ANIMAL TESTS.

No animal tests have been performed and only well-known materials / ingredients have been used, according information provided by manufacturer. . Manufacturer must provide some certification

3.9. CROSS INTERFERENCES.

The following possibilities have been considered:

- Formation of a precipitate.
- Evolution of a gas.
- Changes in the temperature of the ingredients when mixing.
- Changes in color.
- Separation of liquids
- Precipitation of particles in suspension.

May be considered the most frequent, although others may occur under certain conditions that are not reasonably expected. Revised scientific literature and the MSDS of the different ingredients are not considered foreseeable the occurrence of any of these interferences.

4. RESULT OF THE ASSESSMENT

It is estimated that, according to the data collected in the report and current knowledge, there is no safety risk for the product in human health under normal conditions of use, provided that the conditions are maintained and the recommendations of this report are applied.

The evaluated product seems to fulfill with the provisions of EC Regulation 1223/2009.

Any modification in any of the aspects contained in this report would entail revision of the report, as well as notification of changes in the information provided by the manufacturer.

Likewise, the commercialization must establish an adequate system of market surveillance , whose results may require modification and reassessment of the product.

Signed by: Paz Arviza Valverde

5. ANNEX

5.1. GMP.

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

DECLARACIÓN RESPONSABLE DE ACTIVIDADES DE FABRICACIÓN DE PRODUCTOS COSMÉTICOS

Nº Declaración: 5399 Fecha de la declaración: 23-12-2021

[X] INICIO DE LA ACTIVIDAD Fecha de inicio: 24-01-2022

[ ] MODIFICACIÓN DE LAS ACTIVIDADES PROPIAS Fecha de modificación:

- [ ] Traslado de instalaciones donde se desarrolla la actividad.
- [ ] Inclusión de nuevas plantas o ampliación de las instalaciones/actividade
- [ ] Fabricación de nuevas formas cosméticas.

[ ] COMUNICACIÓN (modificación sin tasa) Fecha de modificación:

Sección 1. DATOS DEL TITULAR DE LA ACTIVIDAD

Nombre y apellidos/Razón Social: MAIMI PAINT, S.L.

Domicilio/Sede social: CALLE CIUDAD DE SEVILLA, 5

Localidad: PATERNA Provincia: Valencia C.P.: 46988

Telefono: 648618188 Correo electrónico: administracion@amtattoo.es

NIF/NIE: B40612152

Sección 2. DATOS DE LA PERSONA QUE FIRMA LA DECLARACIÓN Y DATOS A EFECTOS DE NOTIFICACIÓN.

Nombre y apellidos: FRANCISCO-NAHUEL PAZ SEISDEDOS DNI: 26888556S

En calidad de Titular

Deseo ser notificado en relación con esta declaración:

Correo electrónico 1: administracion@amtattoo.es

Correo electrónico 2: fjguillamon@deltasesores.com

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

Página 1 de 6

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

DECLARACIÓN RESPONSABLE DE ACTIVIDADES DE FABRICACIÓN DE PRODUCTOS COSMÉTICOS

Sección 3. DATOS DE LA PERSONA CUALIFICADA DE CONTACTO.

Nombre y apellidos: IGNACIO LLORIS ASENSIO NIF/NIE: 52676133S

Telefono: 607314184 Correo electronico: nacholloris@icloud.com

✓ Tiene formación y experiencia de acuerdo con sus responsabilidades: conocimiento de la legislación aplicable a productos cosméticos, Buenas prácticas de fabricación, experiencia en empresas fabricantes o importadoras de cosméticos...

Sección 4. DATOS DE LAS ACTIVIDADES Y DE LAS INSTALACIONES .

			Actividades propias	Actividades subcontratadas
FABRICACIÓN	Fabricación del granel		X	
	Acondicionado	Envasado	X	
		Etiquetado	X	
IMPORTACIÓN				
	Almacenaje		X	
	Control			X

PLANTA 1

NOMBRE: MAIMI PAINT, S.L. NIF: B40612152

DIRECCIÓN: CALLE CIUDAD DE SEVILLA, 5

LOCALIDAD: PATERNA

PROVINCIA: Valencia C.P.: 46988

ACTIVIDAD/ES:

Actividad de Fabricación
Actividad de envasado
Actividad de Etiquetado
Actividad de Almacenaje

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

Página 2 de 6

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

DECLARACIÓN RESPONSABLE DE ACTIVIDADES DE FABRICACIÓN DE PRODUCTOS COSMÉTICOS

CATEGORIAS:

1.1 Productos para el cuidado de la piel

FORMAS COSMÉTICA

12 GELES

13 EMULSIONES

14 SUSPENSIONES

15 SOLUCIONES

16 OTROS

Sección 5. DECLARACIÓN DE CUMPLIMIENTO DE LA REGLAMENTACIÓN

Declaro que:

a) Cumplo con los requisitos y obligaciones inherentes al ejercicio de la actividad de fabricación establecidos en el anexo del Real Decreto 85/2018, de 23 de febrero, por el que se regulan los productos cosméticos, recogidos en el anexo 3 de esta declaración responsable, que me resultan de aplicación.

b) Dispongo de la documentación que así lo acredita.

c) Me comprometo a cumplir los requisitos referidos en la letra a) de este apartado durante todo el ejercicio de la actividad.

Sección 6. FIRMA DE LA DECLARACIÓN RESPONSABLE

D/Dª FRANCISCO-NAHUEL PAZ SEISDEDOS declara que son ciertos los datos aportados y que se compromete a presentar la documentación y a facilitar las inspecciones que sean requeridas por la AEMPS para la comprobación de la presente declaración.

En PATERNA a 23-12-2021

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89

DECLARACIÓN RESPONSABLE DE ACTIVIDADES DE FABRICACIÓN DE PRODUCTOS COSMÉTICOS

ANEXO. del Real Decreto 85/2018, de 23 de febrero, por el que se regulan los productos cosméticos

REQUISITOS PARA REALIZAR ACTIVIDADES DE FABRICACIÓN DE PRODUCTOS COSMÉTICOS

Las personas físicas o jurídicas que realicen actividades de fabricación de productos cosméticos, deben cumplir los siguientes requisitos:

1. Disponer de un sistema de calidad actualizado en el que se establecen las responsabilidades, los procesos y las medidas de gestión, que permiten garantizar que la fabricación de los productos cosméticos se realiza conforme a los principios de buenas prácticas de fabricación, a los que hace referencia el apartado 1 del artículo 8 del Reglamento sobre productos cosméticos. Se presumirá la conformidad con buenas prácticas de fabricación cuando la fabricación se ajuste a las normas armonizadas pertinentes, cuyas referencias hayan sido publicadas en el Diario Oficial de la Unión Europea.

2. Disponer de una estructura organizativa, con responsabilidades definidas y adecuada al tamaño de la empresa y al tipo de productos cosméticos que se fabrica, capaz de garantizar la calidad de los productos cosméticos fabricados, así como la ejecución de los controles que procedan para documentar los aspectos relacionados con la fabricación.

3. Disponer de personal suficiente con la cualificación adecuada, en virtud de su formación y experiencia y de acuerdo con sus responsabilidades, para llevar a cabo las actividades de fabricación, almacenamiento y control. Una de las personas cualificadas será identificada como persona de contacto a los efectos de la declaración responsable de actividades.

4. Disponer de programas de formación en buenas prácticas de fabricación y de programas de higiene y salud laboral, que permitan garantizar que las actividades se llevan a cabo correctamente y que se preserva la higiene de la producción y de los productos cosméticos fabricados.

5. Disponer de instalaciones y equipos para realizar las actividades de fabricación y acondicionado, suficientes y adecuados, cuyo diseño, ubicación e instalación permita su limpieza y desinfección, así como el correcto flujo de materiales, productos y personal de forma que se minimice el riesgo de contaminaciones cruzadas, así como de un sistema de obtención y tratamiento del agua utilizada en la producción que permita garantizar su calidad.

Dichas instalaciones deberán contar con áreas separadas o definidas para desarrollar, en su caso, las siguientes actividades:

a) Fabricación: con las instalaciones y medios necesarios para la fabricación y acondicionado de los productos cosméticos, en condiciones higiénico sanitarias adecuadas y mediante procedimientos que aseguren el cumplimiento de sus especificaciones.

b) Almacenamiento: para materias primas, productos intermedios, productos terminados y material de acondicionamiento. La disposición y organización de los locales permitirá la diferenciación de los productos cosméticos almacenados en función de su estado de inspección y su destino, así como su conservación en condiciones que aseguren el óptimo mantenimiento de los productos cosméticos.

6. Disponer de instalaciones, equipos, reactivos y patrones suficientes y adecuados para realizar las actividades de control y garantizar la calidad en materias primas, agua utilizada en la producción, material de acondicionamiento, controles en proceso y controles en productos terminados. Todos estos equipos se encontrarán identificados, mantenidos y calibrados para asegurar que sus parámetros se encuentran dentro de los límites de aceptación.

Se recurrirá a la cualificación y validación de instalaciones, equipos y procedimientos cuando ello resulte necesario para

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89

garantizar la calidad.

7. Disponer de procedimientos escritos de trabajo que describan todas las actividades de la empresa. Entre estos procedimientos se encontrarán, en particular, los siguientes:

a) Procedimientos de compra, recepción, liberación y almacenamiento que se apliquen a los suministros y de evaluación de los proveedores, que permitan garantizar que las materias primas y el material de acondicionamiento cumplen con los criterios de aceptación o especificaciones previamente establecidos.

b) Procedimientos para la realización de las operaciones de fabricación y acondicionado destinados a fabricar un producto acabado que cumpla con las especificaciones definidas. Estos procedimientos abarcarán la disponibilidad de la documentación necesaria, la realización de las comprobaciones en equipos y materiales, la realización de los controles pertinentes en proceso y el tratamiento de los graneles, productos intermedios y productos acabados resultantes, así como la eliminación de los residuos generados en la fabricación y control de los productos.

c) Procedimientos de liberación y control, que incluyan la toma de muestras y la realización de los ensayos, que aseguran que los materiales, graneles y los productos acabados solo se liberan si cumplen con los criterios de aceptación definidos. Se documentarán y registrarán los resultados, y las desviaciones, en su caso. Se conservarán las muestras requeridas.

d) Procedimientos de almacenamiento y expedición de los productos y de gestión de las devoluciones que garanticen la calidad del producto.

e) Procedimientos para el tratamiento y la investigación de los productos o materiales rechazados, así como para tomar las decisiones sobre el reprocesado de los productos y el tratamiento de los productos reprocesados, que incluyan los responsables designados para estas cuestiones.

f) Procedimientos para la revisión e investigación de las reclamaciones que aseguren un correcto tratamiento y seguimiento de las mismas, así como la adopción de las medidas oportunas para evitar su recurrencia y la comprobación de su alcance en los lotes producidos. Se registrarán los detalles y las conclusiones de la investigación.

g) Procedimiento de realización de auditorías internas, para supervisar la implementación de las buenas prácticas de fabricación de productos cosméticos.

h) Procedimiento para el archivo de la documentación relativa al sistema de calidad, especificaciones, certificados analíticos, etiquetado e instrucciones de uso de cada producto fabricado.

i) Procedimientos para ejecutar, dentro de su ámbito de actividades, las acciones oportunas en caso en que se tome una decisión de retirada de los productos del mercado. Si la persona que realiza la actividad de fabricación tiene la consideración de persona responsable de los productos, también deberá disponer de procedimientos para comunicar las retiradas de producto a las autoridades competentes que exige la regulación y para el seguimiento de las medidas de retirada.

8. Disponer de los registros que permitan verificar que las actividades se han llevado a cabo conforme a los procedimientos y especificaciones establecidas, así como de los registros que permitan garantizar la trazabilidad en la

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89

fabricación y en la distribución de los lotes fabricados.

9. Para las actividades subcontratadas, disponer de contratos escritos y firmados donde se describan las actividades subcontratadas y se definan los diferentes deberes y responsabilidades, incluidos el régimen de auditorías y comprobaciones; establecer el procedimiento para gestionar las reclamaciones y la documentación a facilitar por ambas partes; evaluar la capacidad del subcontratista para realizar las operaciones subcontratadas y proporcionar al subcontratista toda la información necesaria para llevar a cabo las operaciones correctamente.

CORREO ELECTRÓNICO
cosmetinstal@aemps.es

C/CAMPEZO,1 - EDIFICIO 8
28022 MADRID
FAX: 91 822 52 89