

Test Report

Client name : Guangdong Nuojo IM Biotech Co., Ltd.

Address : NO.2, Building 9, Liandong Innovation and Technology Centre, No.2 Guangxin Street, Guangzhou (Qingyuan) Industrial Transfer Park, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong

The following sample was submitted and identified by the client as FAMISOO PMU PIGMENT (1 formulation).

Report No : CDT24122001CPG

Case No : CDT2412000628-101(CDT2412000845-001)

Region of Origin : China

Region of Destination : EU

Sample Receiving Date : Sept.09 - Oct.11, 2024

Test Period : Sept.09 - Dec.19, 2024

Test Requested

This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.

Test Results

Please refer to the following pages.

Summary

It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.

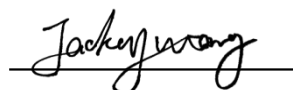
This assessment takes account of:

- a) The general toxicological profile of each ingredient used.
- b) The chemical structure of each ingredient.
- c) The level of exposure of each ingredient.
- d) The specific exposure characteristics of each ingredient on the areas on which the cosmetic product will be applied.
- e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

If there is an adverse reaction from using this formulation then the undersigned should be informed so that the formulation can be further reviewed.

NI: No increase in number of viable micro-organisms compared to the previous reading.

Shenzhen CDT Testing Technology Co., Ltd



Wang hao/ Jackey

Report writer

Test Report

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

CDT is requested to review the safety of the product formula FAMISOO PMU PIGMENT for consumer health and no other part of the product. The product is for EU market and intended for application for keeping it in good condition by adults. The net weight of this product (The formula under assessment) is 1000ml per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the CDT Scientific Archives.

Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ ELINCS	Conc. %	Intended Function
Aqua	7732-18-5	231-791-2	68.0000000000	Solvent
Rosin	8050-09-7	232-475-7	1.0000000000	Increase the viscosity and stability of pigments, prevent the aggregation of pigment crystal particles, enhance coloring strength and brightness
Glycerin	56-81-5	200-289-5	20.0000000000	Denaturant / Humectant / Skin Conditioning / Skin Protecting / Solvent / Viscosity Controlling
Hamamelis Virginiana Extract	84696-19-5	283-637-9	1.0000000000	Converge/anti-inflammatory/antioxidant/ and soothe the skin
Benzyl Alcohol	100-51-6	202-859-9	0.8000000000	Improving skin moisture/ anti-inflammatory/ antibacterial/ and anti itch effects and functions
Carbon Black	1333-86-4	215-609-9	3.2000000000	Adjust color effect
CI#77492	11115-92-7	N/A	4.0000000000	Colorant
CI#77491	1309-37-1	N/A	2.0000000000	Colorant

FRAGRANCE ALLERGENS

No parfum is present in the formulation

2. Physical/chemical characteristics and stability of the formulation

2.1 The product is a black liquid .

2.2 The stability test result on formulation, by third party laboratory (CDT report no. CDT24121401YDS), with a testing period of Sept.09, 2024 - Dec.14, 2024, was submitted and reviewed.It is the responsibility of manufacturer or responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

Testing conditions : $5 \pm 1^{\circ}\text{C}$, $25 \pm 1^{\circ}\text{C}$ and $45 \pm 2^{\circ}\text{C}$ with 70% humidity for 3 months

Testing parameters : Appearance, Odour, pH Value Change (20°C) and Total Plate Counting, CFU/g

Conclusion: The stability of the formulation is acceptable for this application.

3. Microbiological quality

3.1 The microbiological test results on formulation, with reference to European Pharmacopoeia 10.0

2.6.12 and 2.6.13, by third party laboratory (CDT report no. CDT24121401WDS), with a testing period of

Test Report

Sept.09, 2024 - Sept.19, 2024, was submitted and reviewed based on following criteria as required by SCCS Notes of Guidance.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	E. Coli, P.aeruginosa, S.aureus and C.albicans
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	< 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	< 1000 cfu/g or 1000 cfu/ml	not detectable in 1g or 1 ml

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopoeia 10.0 5.1.3, by third party laboratory (CDT report no. CDT24121401WDS), with a testing period of Sept.09, 2024 - Sept.19, 2024, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
		Log reduction			
Criteria A	E.coli, P.aeruginosa, S.aureus	2	3	/	NI
	C. albicans	/	/	2	NI
	A. brasiliensis (niger)	/	/	2	NI
Criteria B	E.coli, P.aeruginosa, S.aureus	/	/	3	NI
	C. albicans	/	/	1	NI
	A. brasiliensis (niger)	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved criteria B and is acceptable for this application.

4. Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test results on formulation, by third party laboratory (CDT report no. CDT24121402ZDS), with a testing period of Sept.09, 2024 - Dec.14, 2024, was submitted and reviewed based on following criteria.

	The maximum permissible limit quoted from Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) (Published online:06 Oct 2016)					The maximum permissible limit is quoted from German Health No. 7/1992, Session 45 from Nov 14, 1991
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit in cosmetic products in general (mg/kg)	≤0.5b	≤ 0.1	≤2.0a	≤0.5	≤0.1	≤10

A For the products make-up powder, rough, eye shadow, eyeliner, kajal, as well as theater, fan or carnival make-up: 5 mg/kg

b For theater, fan or carnival make-up: 2.5 mg/kg

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 The client has supplied the following list of packaging parts for this product as the immediate container.

No.	Immediate Container	Material
1.	Pack	HDPE bottle
2.	Mask Towel	Bottle PP; Pump PS; Straw PE

4.3 For the packaging materials, the test results of total Lead (Pb), Cadmium (Cd), Mercury (Hg), Chromium VI (Cr (VI)), by third party laboratory (CDT report no. CDT24121401ZDS), with a testing period

Test Report

of Sept.09, 2024 - Dec.14, 2024, indicate the total amount of lead, cadmium, mercury and chromium (VI) is less than 100ppm .

Conclusion: The heavy metal content of the packaging material is acceptable.

- 4.4 Packaging compatibility test results on packaging material, tested together with the formulation, by third party laboratory (CDT report no. CDT24121401TDV), with a testing period of Sept.09,2024-Nov.01,2024

, was submitted and reviewed.

Testing conditions : $5 \pm 1^{\circ}\text{C}$, $25 \pm 1^{\circ}\text{C}$ and $45 \pm 2^{\circ}\text{C}$ with 70% humidity for 3 months

Testing parameters : Appearance and Appearance of the package

Conclusion: The stability of the packaging material is acceptable.

5. Normal and reasonably foreseeable use

This product is typically applied to any part of the body. Ingesting this product will be a misuse

6. Exposure to cosmetic product

Product type: Embroidery cosmetics

Use category: Embroidery with patterns

Physical form: Liquid

The site(s) of application: All skin

The surface area(s) of application: 565 cm^2

The amount per application: 10 g (Indicated by client)

The duration of exposure: 120 minutes

The frequency of use: 2 times per year (Indicated by client)

The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact

The targeted (or exposed) population(s): Adults

The body weight: 60 kg

7. Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.

For toxicological profile of ingredients, refer to Annex 1.

Systemic Exposure Dose(SED) is derived for each substance, taking into account of 50 % bioavailability as a default value for oral and dermal absorption, and 100 % bioavailability for inhalation, unless otherwise specified. Margins of safety(MoS) is calculated by dividing systemic NO(A)ELsys by the SED, when NO(A)EL or relevant Point of Departure(POD) is available in the present stage of knowledge.

8. Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

9. Information on the cosmetic product

No valid GMP certificate on manufacturing setting covering the scope of mask product has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.

Test Report

PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments. Provided the manufacturer's instructions are followed, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

2. Recommended labelled warnings and instructions of use

Use as directed.

Keep out of reach of children.

Do not use on damaged, broken skin or skin with predisposed conditions.

Avoid contact with the eye. Rinse eyes immediately should the liquid gets into them.

Stop using the product if redness and itching develops. If symptoms persist, consult a doctor.

3. Reasoning

All the ingredients in the formulation are either reported to be used in cosmetic or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR). No CMR substance is indicated to be intentionally added to the formulation.

Margin of Safety (MoS) was derived for all ingredients except those which No Observed (Adverse) Effect Levels (NO(A)ELs) or other Point of Departure (POD) were not available. For ingredients that MoS cannot be derived, their safety is substantiated by history of safe use at similar levels in related cosmetic products, reference doses, TTC approach, etc. Detailed explanation is given in the individual ingredient toxicological summary in annex 1.

This formulation is not expected to cause skin and respiratory damage, and does not produce phototoxicity. Under normal and reasonably foreseeable conditions of use, it is unlikely to cause damage to the internal organs of most consumers through the skin. Accidental contact with the eyes may cause slight irritation, but it is expected to be minimal after rinsing. Under normal and reasonably foreseeable conditions of use, there are some substances that may cause allergies, but the levels are low and are not expected to cause allergic reactions in most users. However, sensitized individuals may react to extremely low concentrations of allergens.

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, microbiological quality, and preservative efficacy. No valid GMP certificate on manufacturing setting covering the scope of mask product has been submitted by the time of assessment. The product has to be manufactured in GMP compliance setting in order to comply with the EU Cosmetic Regulation. It is recommended to submit the corresponding valid GMP certificate.

4. Assessor's credentials and approval of Part B

Date: Dec.19, 2024

Wang hao/ Jackey Registered Toxicologist

The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, Shenzhen CDT Testing Technology Co., Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

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Test Report

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***** End of Report *****