Cosmetic Product Safety Report
In compliance with Annex 1, EC Regulation 1223/2009

FLEXI MASK ROSE JELLY MASK

ANL COSMETIC LABORATORY
Technical Centre: Topley House, Office Suite 7
52 Wash Lane, Bury, Lancs, BL9 6AS

Cosmetic Product Safety Report

Report Number: ALCOS3543

Product Name: ROSE JELLY MASK

Number/Product Code:

Category of Product:

Intended Consumer Group of Product: Adults

Company Name:

Company Address:

Company Contact Details:

Company Responsible Contact:

Manufacturing Company: As Above

CPSR Completion Date: 12.03.2024

Product passed stability testing and Microbiological testing of GMP practices.

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Cosmetic Product Safety Report

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PART A

1. Quantitative & Qualitative Composition of the Cosmetic Product

Trade name of raw material	Supplier	INCI Name	CAS No.	Function	% raw material in final product 100ml Jar	% of raw material in daily application
Kieselguhr diatomaccous earth			61790-53-2	Skin Conditioning, Viscosity Controlling	>25	
Corn Starch			9005-25-8	Emollient, Skin Conditioning	>50	
Sodium Alginate			73049-73-7	Skin Conditioning, Skin Protecting.	>1	
Calcium Sulfate			10101-41-4	Masking, Tonic	>1	
Rose Extract				Skin Conditioning	>0.1	
Pectin			9000-69-5	Skin Conditioning	>0.1	
Sodium Hyaluronate			9067-32-7	Skin Conditioning	>1	

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ANL Cosmetic Laboratory

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Physical/Chemical Characteristics & Stability of the Cosmetic Product

Physical Description of the Product Jelly
Aroma Characteristic
Colour Powder
pH of Product 6
Stability Stable under normal handling conditions

INCI	Physical Description	Chemical Description
Kieselguhr diatomaccous earth	Appearance: Solid/ powder	Diatomaceous Earth functions as an abrasive ingredients used for abrading, smoothing or absorbent ingredients that have the capacity to absorb or soak up liquids., anticaking agent ingredients or processing aids that prevent powdered or granular substances from forming clumps., bulking
Corn Starch	Appearance: powder	Starch obtained from corn and sometimes used as an absorbent in cosmetics instead of or alongside talc. Generally, in powders corn starch lends a silky but dry feel and some find it is better at absorbing excess oil without looking cakey than pure talc-based powders.
Sodium Alginate	Appearance: Powder	Sodium Alginate is used as a thickener, gelling agent, stabilizer and emulsifier. Cosmetic companies take advantage of sodium alginate because they use it to help retain moisture in cosmetics. In addition, shampoo companies use it as a bubble stabilizer and thicken
Calcium Sulfate	Appearance: Powder	100% opacifying, whitening and filling agent for cosmetics. This anhydrous powder acts as a filler, keeping moisture away from the other ingredients in a formulation.

Rose Extract	Appearance:	Anti-inflammatory properties enable Rose Extract to help minimize redness and soothe irritation – making it ideal for all skin types (acneic, dry, mature, sensitive) because of its calming and healing abilities. In addition, Rose Extract is believed to be able to help reduce spots and discoloration.

Pectin	Appearance: White Powder	Pectin is a naturally occurring compound found in the cell. wall of plants. In cosmetics and personal care products, Pectin is used in the formulation of body and hand products, as well as makeup foundations, shampoos, hair conditioners, permanent waves, personal cleanliness products, and other hair products.
Sodium Hyaluronate	Appearance: Powder	This ingredient is a form of hyaluronic acid that is water soluble and acts as a humectant. Sodium Hyaluronate appears as a fiber or cream like powder that is added to products such as face washes, makeup removers and serums to make the skin healthier.

Raw Materials, Impurities and Traces.

Notes on Raw Materials, Impurities and Traces in the INCI

No impurities of concern were identified in the raw material data supplied.
All raw materials are from European cosmetic, food or pharmaceutical ingredient suppliers. Purity and analytical specifications of raw materials are contained on the Certificates of Analysis / Sales Specifications, which are held by the manufacturer / Responsible Person. Specific impurities, where relevant to the safety assessment, will be detailed also in Section 1. Traces of prohibited substances, where possible for the ingredient in question, are described in Section 10 and Section 12. Raw material physical characteristics and suppliers' hazard classifications under CPL are given in the safety data sheets.

Microbiological Quality

RESULTS ON Ph, STABILITY, SHELF LIFE & BACTERIA ANALYSIS

DATE	18.12.23	27.12.23	01.01.24	08.01.24	15.01.24	22.01.24	29.01.24	5.02.24	12.02.24
Tests EC1223/2009									
pH	6	6	6	6	6	6	6	6	6
Centrifugal Test @50	No Separation	No Separation	No Separation	No Separation	No Separation	No Separation	No Separation	No Separation	No Separation

DATE	18.12.23	27.12.23	01.01.24	08.01.24	15.01.24	22.01.24	29.01.24	5.02.24	12.02.24
Stability Tests EC1223/2009									
Odour	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Appearance	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Room Temp 24 - 25	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Accelerated 45	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal

DATE	18.12.23	27.12.23	01.01.24	08.01.24	15.01.24	22.01.24	29.01.24	5.02.24	12.02.24
Microbiological Testing of Final Product (GMP)									
Bacteria	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth

Mould	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Fungus	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth

DATE	19.02.24	26.02.24	04.03.24	11.03.2424	18.03.24
Tests EC1223/2009					
pH	6	6	6	6	6
Centrifugal Test @50	No Separation	No Separation	No Separation	No Separation	No Separation

DATE	19.02.24	26.02.24	04.03.24	11.03.2424	18.03.24
Stability Tests EC1223/2009					
Odour	Normal	Normal	Normal	Normal	Normal
Appearance	Normal	Normal	Normal	Normal	Normal
Room Temp 24 - 25	Normal	Normal	Normal	Normal	Normal
Accelerated 45	Normal	Normal	Normal	Normal	Normal

DATE	19.02.24	26.02.24	04.03.24	11.03.2424
Microbiological Testing of Final Product (GMP)				
Bacteria	No Growth	No Growth	No Growth	No Growth
Mould	No Growth	No Growth	No Growth	No Growth
Fungus	No Growth	No Growth	No Growth	No Growth

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Tests Performed	Test Method
Stability Test	Cosmetic Regulation EC 1223/2009
Microbiological Tests	Cosmetic Regulation EC 1223/2009

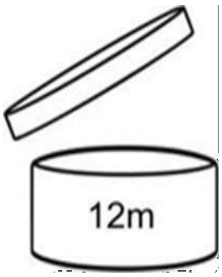
Challenge Testing - Not Performed on this product

Preservative Efficacy

Plate Count

Stability

On the information gained over the 12weeks of testing, a shelf life of 12 months was achieved.



Normal and Reasonably Foreseeable Use

Description of Intended Application & Directions for Use	Target use: Face. Wash Off product. Avoid contact with eyes. If sensitivity occurs, discontinue use.

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Packaging Information

Primary packaging style and sizes	.
Packaging Supplier	
Packaging Stability	Stability testing performed in the primary packaging, no deterioration to product or packaging were observed.

Exposure to the Cosmetic Product

Site of Application	Face
Surface Area of Application (cm^2)	15670
Amount Applied (g) per day	7.82g
Duration	Wash Off
Frequency	2.28/day
Retention Factor	1.0
Exposure Routes	Face
Target Population	Adults
Calculated Relative Daily Exposure (mg/kg bw/day)	123.20

Typical consumer use of the product is taken from the SCCS's Note of Guidance and the EPA Exposure Factors Handbook.

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Exposure to the Substances

a. Dermal Exposures

INCI	Calculated Relative Daily Exposure	Concentration % (w/w)	Dermal Absorption	Systemic Exposure Dosage
Kieselguhr diatomaccous earth	123.20	69.34673	100	85.435171
Corn Starch	123.20	24.92462	100	30.707131
Sodium Alginate	123.20	1.00502	100	1.2381846
Calcium Sulfate	123.20	0.50251	100	0.6190923
Rose	123.20	0.1	100	0.001
Pectin	123.20	1.00502	100	1.2381846
Sodium Hyaluronate	123.20	1.00502	100	1.2381846

Exposure data and method of calculation taken from the SCCS's Note of Guidance. The conventional conservative approach of assuming a dermal absorption of 100% is taken where appropriate. Note: Exposure estimates are taken directly from Tables 2 and 3 of SCCS Notes of Guidance (SCCS/1501/12) where the particular product category is listed, or are otherwise estimated using the Guidance and our experience. Relative daily exposure figures are not intended to be the absolute maximum that a user may experience but represent 90th percentile exposures in the population. More detailed arguments for the figures we use are available on request. Data for adults refers to adults and teenagers aged 12 and over. Where different consumer categories are given the highest relative daily exposure figure is used for margin of safety calculations.

b. Oral Exposure: Unlikely with this product.

c. Inhalation Exposure: Unlikely with this product.

Toxicological Profile of the Substance

9. Margin of Safety and Comments

INCI	Weight (%)	Daily Exposure Mg/kg/day	Margin of Safety (MOS)	NOAEL	SED
Kieselguhr diatomaccous earth	69.34673	123.20	154.50311	13200	85.435171
Corn Starch	24.92462	123.20	108.3136	3326	30.707131
Sodium Alginate	1.00502	123.20	**80.763401**	100	1.2381846
Calcium Sulfate	0.50251	123.20	258.44288	160	0.6190923
Rose Extract	0.10	123.20	200.123	120	0.54
Pectin	1.00502	123.20	10095.425	12500	1.2381846
Sodium Hyaluronate	1.00502	123.20	10660.769	13200	1.2381846

Notes to Table 9:
(i) Relative daily exposure to product (from Section 8) x % in product
(ii) Dermal absorption usually assumed conservatively to be 100%. Reasons and references for figures lower than 100% are given in Section 10
(iii) SED=Systemic Exposure Dose = Relative daily exposure x Dermal Absorption
(iv) No Observed Adverse Effect Level in mg/kg/day in an animal model, unless otherwise stated. See reference in Table 10 for further information
(v) Margin of Safety = NOAEL divided by the SED. A figure of >100 is generally considered to be safe if the NOAEL is based on animal studies. MOE = Margin of Exposure based on known safe levels in humans; a figure of less than 100 may be acceptable – see comment in Table 10. <TTC means systemic exposure is less than "Threshold for Toxicological Concern" of 0.0015mg/kg/day, which is the threshold for toxicity for chemicals of unknown systemic toxicity with no structural alerts for genotoxicity and not suspected to be neurotoxic via anti-cholinesterase activity, according to the EFSA 2011 Draft Opinion on the Concept of Threshold of Toxicological Concern. We have first made the judgement that the ingredient does not contain, or is unlikely to contain, any structural alerts for genotoxicity. Our TTC calculation also assumes a conservative dermal absorption of 25%.

10.Local Toxicity

INCI	Eye Irritant	Skin Irritant	Skin Sensitiser	Photo Sensitiser
Kieselguhr diatomaccous earth	Yes	No	No	No
Corn Starch	No	No	No	No
Sodium Alginate	No	No	No	No
Calcium Sulfate	No	No	No	No
RoseExtract	No	No	No	No
Pectin	No	No	No	No
Sodium Hyaluronate	No	No	No	No

Note: Local Toxicity Data on 100% active ingredient Skin/eye corrosion, skin irritation, eye irritation and skin sensitisation data in this table are based on GHS (Global Harmonised Standard) classifications. Our data is taken from the REACH register for that entry where test results are given for the specific substance in question. Failing that, we consult expert reports from other government or inter-governmental bodies. Weight of evidence summaries in SCCS and CIR opinions are also used in preference to individual suppliers' data. In the absence of the above, we use suppliers' classifications where specific validated test methods are referenced on the safety data sheet. Otherwise, we perform our own literature searches or we read across from similar substances. Skin photosensitivity is based on examination of the chemical structure, UV absorption data, suppliers' data if available, and broader literature searching. Mucous membrane irritation data is taken as the same as eye irritation.

Restrictions and Compliance with EU Annexes

INCI Name	% Weight	EU Annex Restrictions Details
Kieselguhr diatomaccous earth	69.34673	None
Corn Starch	24.92462	Annex II/306 – Due to the absence of THC restriction is not applied as no longer a narcotic.
Sodium Alginate	1.00502	Annex II/306 – Due to the absence of THC restriction is not applied as no longer a narcotic.
Calcium Sulfate	0.50251	None
Rose Extract	1.00502	None
Pectin	1.00502	None
Sodium Hyaluronate	1.00502	None

Perfume Compliance to IFRA Regulation

% Perfume in Product	IFRA Category	IFRA Regulations Edition on Certificate	Maximum % allowed on IFRA Certificate
None			

Human and in vitro toxicity studies

No human studies and no vitro toxicity studies have been carried out on the finished product.

No animal testing have been carried out on the finished product

Undesirable Effects and Serious Undesirable Effects

None Reported

Information on the Cosmetic Product

No further Information.

PART B

Assessment Conclusion

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use, and the product composition complies with EC Regulation 1223/2009 and all its annexes.

Systemic Toxicity including Reproductive/ Develpmental Toxicity	No Concerns
Carcinogenicity/ Mutagenicity	No Concerns
Skin Sensitisation	No Concerns
Skin Irritancy	No Concerns
Eye Irritancy	No Concerns
Phototoxicity and Photosensitisation	No Concerns
Microbiological Safety	No Concerns
Product Stability	No Concerns
Packaging Safety	No Concerns
Formation of Toxic Materials via Chemical Reaction	No Concerns

Labelled Warnings and Instructions for Use

The following warnings are required on both the inner and outer packaging Warning: avoid getting into the eyes. If product gets into the eyes wash out thoroughly with water and seek medical assistance. If sensitisation occurs, discontinue use. Label must list ingredients, allergens and all allergens naturally occurring in Essential Oils.

It is assumed that instructions or use of commonplace product type names (e.g. “serum”) as described in section 6 of Part A are used. No particular extra instructions are required for the safe use of this product.

Reasoning
This type of skincare formulation has been in common use in cosmetics over many years without any particular concerns.

(a) Potential systemic toxic effects
Table 9 gives the margin of safety for each of the ingredients used. It takes into account all systemic toxicity end points including organ toxicity, reproductive and developmental toxicity, blood and metabolic effects, and carcinogenicity. The end point that drives the NOAEL or other repeat dose toxicity value is given in the critical toxicity effect column, and is usually derived from repeat dose animal studies. If none is written it means that no toxicity was seen at the highest dose tested. All the ingredients used are considered safe because they have a margin of safety (MOS) of 100 or over or, for ingredients for which safe levels in the human diet have been calculated, have a margin of exposure (MOE) of 1.0 or greater.

(b) Carcinogenicity / mutagenicity / reproductive toxicity
None of the ingredients are confirmed or suspected to be carcinogens, mutagens or reproductive toxins (class IA, 1B or 2 under GHS). Based on weight of evidence of in vitro studies, and in vivo studies where appropriate, none of the ingredients are considered to be mutagenic.

(c) Potential skin sensitisation effects
The main causes of skin sensitisation in cosmetics are perfume ingredients, essential oils and perfuming absolutes, certain other non-perfuming plant extracts containing high concentrations of terpenes, some preservatives, some hair dyes, and some UV filters.

(c1) Potential skin sensitisation from perfumes, synthetic aromas, essential oils and absolutes: The International Fragrance Research Association (IFRA) has a series of regulations designed to prevent sensitisation to perfumes, essential oils and absolutes. The maximum concentrations of various ingredients for different types of cosmetic products (in %) are based on a NESIL value (No Expected Sensitisation Induction Level) in µg/cm2 from weight of evidence of both human (e.g. RIPT) and animal (e.g. mouse LLNA) studies. The calculations include a safety factor (SAF) of between 30 and 300 including a factor of 10 for inter-individual variability, as summarised in "Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, IFRA Technical Dossier 2006". For a few perfuming actives such as Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral) this QRA method has not been undertaken due to lack of data, but provisional limits have been derived by IFRA based on other, e.g epidemiological, evidence. For perfumes, we have checked the relevant IFRA certificate and confirmed that the concentration of perfume complies in this product. For essential oils, absolutes and hydrosols, we have checked the maximum likely level of any IFRA regulated components and sensitisers and we confirm that the product complies with the regulations.

(c2) Potential skin sensitisation from other ingredients: The use of preservatives, UV filters and hair dyes is controlled by the EU on Annexes VI and VII and all toxicity endpoints, including skin sensitisation, are taken into account before an ingredient is listed. This product complies with any maximum concentration restrictions imposed by the Annexes. For most other skin sensitisers (i.e. excluding essential oils and perfumes), the final product would not be considered a risk if the final concentration is less than 0.01%, which is the limit for classification under the CPL regulations. These levels are not exceeded in the product.

(d) Potential skin / eye irritation effects
Total concentration of irritant ingredients = 0.5-1.0%.
A general rule of thumb used in the classification of mixtures of chemicals under the EU REACH / CPL regulations is that skin or eye irritation is not significant if the total concentration of individual ingredients classified as irritant is less than 20% by weight. For leave-on skin-care products we would look for a total of less than 10%. Additionally, the concentration of chemicals classified as corrosive or as capable of causing serious damage to the eye must be very low, and the pH should be between 3 and 10. Based on the total concentrations of such ingredients as summarised in Table 11 and how the product is used skin irritation is not considered significant but the product will have a tendency to irritate the eye if left in.

(e) Potential phototoxicity / photosensitisation
This is a leave on product, phototoxicity is not an issue.

(f) Microbiological safety
The current batch of the named product has been tested for microbial contamination v. EU industry standards. It is assumed that the manufacturer is following Good Manufacturing Practice and that microbiological contamination of the final product is being minimised.

(g) Impact of product stability on safety
Given the observations / testing on the product to date, and experience with this type of product, stability is considered satisfactory and is not detrimental in terms of safety.

(h) Impact of packaging on safety
No chemical incompatibilities are expected between the primary packaging material (PE/PP) and the product, and this material(s) is regularly used to package similar cosmetic products in the EU. No deterioration has been seen in 8-week compatibility tests in the final packaging. Since this packaging is specifically stated as compliant with food contact packaging legislation in the EU it is considered unlikely that toxic substances will migrate from the packaging to the product.

(i) Consideration of possible chemical reactions
Our examination of possible reactive groups and chemical types of ingredients in this product indicates that there are unlikely to be any chemical reactions taking place that will affect the overall safety conclusions. Formation of nitrosamines in this product is not possible. The concentration of nitrate is very small and it needs to be reduced to nitrite before it can potentially form nitrosamines with residual diethanolamine from the Cocamide DEA. Chemical reducing conditions don't exist in the product in this packaging so there is no risk of formation of nitrosamines.

4. Purity conditions
This assessment assumes that only cosmetic, pharmaceutical or food grade ingredients are used. Certain ingredients may have particular purity restrictions imposed on them under the annexes to the EU regulation and this Safety Report is only valid if these requirements are met. Such ingredients are indicated in Table 12 of Part A. Assuming any such restrictions are met, there are unlikely to be significant traces of heavy metals or any other prohibited or Annex III – restricted impurities in the final product.

General Notes on Conditions of this Safety Report and Assessor's Credentials

a. This safety report has been generated in edit-protected pdf format. It is not valid if any details are manually changed or the report is electronically scanned or altered in any way.

b. This safety report applies to products manufactured, sold or marketed by the company named above. It cannot be transferred or sold to third parties, except with the agreement of ANL Cosmetic Laboratory.

c. This safety report only fully complies with Annex 1 of EC1223/2009 if it is filed in conjunction with the certificates of analysis, IFRA certificates, and safety data sheets for each ingredient. These are documentation and the Responsible Person should ensure they are filed together – or provide an electronic link to them.

d. Original versions of challenge test reports, stability testing reports and dermatological testing must also be filed alongside the safety report in the PIF file.

e. The assessment assumes that all other aspects of EC regulation 1223/2009 is being complied with, especially adherence to Good Manufacturing Practices (GMP).

f. Although this document is entitled "Cosmetic Product Safety Report" we do not make any reassurances that the product is considered to be a cosmetic under the EU Cosmetics Regulation. For borderline products we recommend you consult the relevant EU guidance documents and take independent advice.

g. This document is produced based on the formulation, ingredients and safety data sheets provided by the customer. It is only valid for this product and the formulation supplied, any variations to formulation or ingredients must be documented and the product safety reassessed.

h. This document does not confirm that we agree with any claims made about the product or implied in the product name. ANL Cosmetic Laboratory are not involved in cosmetic claims support.

i. This assessment applies only to the ingredients listed and the specific application state. A new assessment will be required if a raw material is substituted with a different INCI name, a different colour, or a different perfume or essential oil, or if the same formula is used for a product with a different application.

j. If new undesirable events or "Serious Undesirable Events" are reported then this safety report will require updating.

k. We try to use the European INCI names as listed in the EU's cosing database in the assessments, but we do not guarantee it.

l. Except for the main preservatives and ingredients where the margin of safety is less than 110, this assessment is valid for concentration variations of +/- 10% of the declared percentage, to allow for manufacturing variations. For products containing water, this assessment is also valid for dilutions of the above formula with up to 5% water, as long as the preservative level is maintained at the same concentration in the finished product.

m. In supplying this safety assessment ANL Cosmetic Laboratory makes no assurances that the individual substances or ingredients are registered or exempt under REACH. This is not usually an issue if the ingredient is sourced within the EU, but importers into the EU are warned that REACH notification rules apply once the annual imported quantity of a particular substance aggregated over all their products exceeds 1 TPA. Even if the substance has been registered it is possible that the registration doesn't cover its use a cosmetic ingredient. Importers into the EU of products containing botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions. We do not make these checks.

4 Name of assessor
A. Leach Technical Director AL-BIOSERVICES/ANL Cosmetic Laboratory BSc

Assessor Career

Internal Auditors Course.

R.S.A. Health and Safety Management for Small Business Part 1

BSc Technology - University of Bolton

SDS Training using REACH software

Essentials Oil Training Course run by Aromahead Institute

Working knowledge on CosIng

Angie has been working within in the cosmetic business for over 20 years. Starting off working at Northern Aromatics as a Q.C Chemist in their perfumery department. Working at Personal care manufacturers , with detail to CPSR on company products ,a cosmetic chemist and safety assessor over the last 3 years. Angie makes her own products after visiting craft fairs, her interest in natural products came to a height when her son developed eczema , she developed her own products. Started up her own business 10 years ago, she is currently working with large cosmetic /perfume companies , down to small scale producers and has great understanding on a wide range of products.