Cosmetic Product Safety Report

(Redacted form for public access at point of sale)

Product	Navy Signature Moisturising Mask Pump Bottle 100ml or 150ml
Responsible Person	Cosy Cottage Soap Limited
CPSR Number	SA7363
Latest CPSR Update	09 December 2021

PART B – Cosmetic Product Safety Assessment

1. Assessment Conclusion

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use in the general population (including whilst pregnant or breast-feeding), and the product composition complies with EC Regulation 1223/2009 and all its annexes.

Systemic toxicity, including reproductive / developmental toxicity:	No concerns.
Carcinogenicity / Mutagenicity	No concerns
Skin sensitisation	No particular concerns based on skin sensitisation data from animal or human studies on individual ingredients and their concentrations in the product, but there is always a chance that an individual may have a rare reaction to a particular ingredient.
Skin irritancy	No concerns
Eye irritancy	No particular concerns but any foreign matter in the eye will have a tendency to irritate.
Phototoxicity and photosensitisation	No concerns
Microbiological safety	No concerns
Impact of product stability on safety	No concerns
Packaging safety issues	No concerns
Formation of toxic materials via chemical reaction	No concerns
Potential physical/flammability hazards	No concerns

2. Safety assessor's warnings and specific instructions required for safe use

The following warnings (or similar wording) are required on both the inner and outer packaging

No particular warnings required

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

3. Reasoning

This type of plant-oil and clay-based formulation with essential oils / perfume 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. Dermal absorption is the main route of entry for most products but the possibility of inhalation and ingestion has also been considered. For lip and oral care products the main route of entry is oral. 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.

The lowest margin of safety in this product is for Bentonite with a MOS value of 1800.

(b) Carcinogenicity / mutagenicity / reproductive toxicity
None of the ingredients as added have harmonised classifications in the EU as carcinogens, mutagens or reproductive toxins (class 1A, 1B or 2 under GHS). For those ingredients that do not have a harmonised classification, none are considered to be mutagenic based on weight of evidence of in vitro studies or/and vivo studies. The product contains Salicylic Acid which has a harmonised reprotoxic category 2 classification. It has been reviewed by the SCCS and approved for use as a preservative (Annex V/3) allowed up to 0.5%.

(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 $\mu g/cm^2$ 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 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 hazard identification under the CPL regulations. These levels are not exceeded in the product.

(d) Potential skin / eye irritation effects
In the calculation method for classification of mixtures of chemicals under the EU CLP regulations irritation is not significant if the total concentration of individual ingredients classified as category 2 (the lowest hazard category) eye or skin irritants is less than 10% by weight. For leave-on skin-care products we would look for a total of less than 10%, but higher concentrations in rinse-off products can be tolerated on wet skin due to the immediate dilution effect. Dilution with water moderates potential skin irritation but eye irritation can still be serious if product is caught in the eye. The contribution from chemicals classified as corrosive, or as capable of causing serious damage to the eye (H317), has to be taken into account, using higher weighting factors than category 2 irritants. The final pH is also important and the pH should normally be between 3 and 10 to avoid a GHS irritant classification. Some cosmetic ingredients are classified as irritants (or worse) just because of the pH of the pure ingredient but it would be neutralised in the final product, and this factor also has to be taken into account. The eye irritancy / eye damage classification of some surfactants is due to a combination of the inherent irritancy of the surfactant molecule and the high pH at which it is sold.

The total concentration of ingredients with a classification of irritancy or worse in Table 11 is <0.5%.

Based on the total concentrations of such ingredients as summarised in Table 11 and how the product is used, skin and eye irritation are not considered significant.

(e) Potential phototoxicity / photosensitisation
The product contains known phototoxic ingredients but not at a level to cause concern, individually or in combination in the defined product set.

(f) Microbiological safety
An appropriate preservative challenge test has been carried out and has passed, and it is recommended that every batch is tested for microbial contamination v. EU standards (SCCS/1501/12 section 4-4.2).

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 (glass) and the product, and this material(s) is regularly used to package similar cosmetic products in the EU. The material used is considered appropriate for the product type described. No deterioration has been seen in 6-month compatibility tests in the final packaging.

Since these types of polymers / materials are generally allowed as food contact packaging in the EU it is considered unlikely that toxic substances will migrate from the packaging to the product. The Responsible Person should ensure that any impurities in the primary packaging will not affect the finished cosmetic 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. No interactions are expected between different individual ingredients in the product. Formation of nitrosamines in this product is not possible.

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 restrictions indicated in Table 12 are met, there are unlikely to be significant traces of prohibited substances or Annex III–restricted impurities in the final product, and heavy metals are likely to be below acceptable limits (we use the 2012 Health Canada "technically unavoidable" limits of lead 10ppm, arsenic 3ppm, cadmium 3ppm, mercury 3ppm, and antimony 5ppm as guidance).