



**OXFORD BIOSCIENCES**  
Safety Assessment, Analysis, Research & Testing

**Oxford Biosciences Ltd.**

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## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Tangerine & Jasmine Eco Friendly Dry Shampoo

**DATE:** 12 July 2022

Responsible Person: Scott Masson  
**Scrubber Store Ltd**  
4 Stanhope House  
Adolphus Street  
London SE8 4LX



**PART A – Cosmetic Product Safety Information**

1. Quantitative and qualitative composition

	<b>Ingredient INCI name</b>	<b>CAS</b>	<b>Function</b>	<b>Limits</b>	<b>Amount</b>
1	Manihot utilissima root fiber	92456-72-9			52.50
2	Bentonite	1302-78-9	Absorbent, bulking,		42.50
3	Parfum		Fragrance, perfuming		5.00

Allergens present in this product and estimated amounts\*:  
Citral: 0.0012975%; Limonene: 1.358108625%; Benzyl Benzoate: 0.11%; Benzyl Salicylate: 0.11%; Geraniol: 0.11%; Linalol: 0.325%; Hexyl cinnamal: 0.22%; Citronellol: 0.275%

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Manihot utilissima root fiber**

Manihot utilissima root fiber is the fiber obtained from the roots of Manihot utilissima, Euphorbiaceae.

#### Ref. 1. 2 **Bentonite**

Bentonite is an absorbent aluminium phyllosilicate clay consisting primarily of montmorillonite, a very soft phyllosilicate group of minerals that typically form in microscopic crystals. Montmorillonite is a subclass of smectite, a 2:1 phyllosilicate with 2 tetrahedral sheets sandwiching a central octahedral sheet having greater than 50% octahedral charge; its cation exchange capacity is due to isomorphous substitution of Mg for Al in the gibbsitic plane. The particles are plate-shaped with an average diameter of approximately one micrometre.

#### Ref. 1. 3 **Parfum**

Perfume and aromatic compositions and their raw materials.

## **PART A – Cosmetic Product Safety Information** *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Loose Powder
<b>Colour</b>	Beige
<b>Aroma</b>	Floral
<b>pH</b>	n/a

\*RP: Responsible Person: Scrubber Store Ltd

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Scrubber Store Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Scrubber Store Ltd uses a BBE based on the results of Scrubber Store Ltd's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

#### 3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

#### 3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health

under the ISO 29621:2010 standard “Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products”.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

#### 4. Impurities, trace amounts of forbidden substances, & information about packaging material

##### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

##### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Tube
<b>Container Material</b>	Cardboard
<b>Airless Container</b>	No

Cardboard is a heavy-duty paper which ranges from a simple arrangement of a single thick sheet of paper to complex configurations featuring multiple corrugated and uncorrugated layers commonly used as a food container.

This material is safe for use in cosmetic packaging.

Scrubber Store Ltd confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Do not use on irritated or broken skin. If irritation occurs, discontinue use.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Head
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	1.14
Possible additional routes of exposure	none
Estimated skin surface area (cm <sup>2</sup> )	1010
Estimated amount of the product applied according to the SCCS (g/day)	4.00 g
Estimated retention factor according to the SCCS	.1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	5.74

## 7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Manihot utilissima root fiber	0.52500	0.30135
2	Bentonite	0.42500	0.24395
3	Parfum	0.05000	0.02870

**SED:** Systemic Exposure Dose

8. Toxicological profile of the ingredients in the formulation

Ingredient INCI name		MOS
1	Manihot utilissima root fiber	6636.80110
2	Bentonite	20496.00330
3	Parfum	245993.03140

*MOS: Margin of Safety*



#### *8. Toxicological profile of the ingredients in the formulation - continued*

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### **9. Undesirable effects and serious undesirable effects**

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Scrubber Store Ltd in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### **10. Additional information on the product**

No additional information is available and no additional studies were carried out.

## 11. References

- THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- MSDS of ingredients
- Commission Implementing Decision of 25<sup>th</sup> November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products
- SCCS - Opinions  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- CosIng: the European Commission database on cosmetic substances  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- REGULATION 1223/2009 ANNEXES  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## **PART B – Cosmetic Product Safety Assessment**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Citral: 0.0012975%; Limonene: 1.358108625%; Benzyl Benzoate: 0.11%; Benzyl Salicylate: 0.11%; Geraniol: 0.11%; Linalol: 0.325%; Hexyl cinnamal: 0.22%; Citronellol: 0.275%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

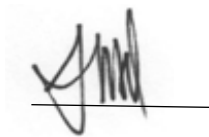
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

12 July 2022

*Date*