

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Zero-Odour Deodorant with Orange and Mandarin TIN

DATE: 27 November 2020

Responsible Person: Giovanna Mantini
[Redacted]
[Redacted]
[Redacted]
[Redacted]



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 **Sodium bicarbonate**

Sodium bicarbonate or sodium hydrogen carbonate is the chemical compound with the formula NaHCO_3 . It is edible and commonly known as bicarbonate of soda or baking soda.

Ref. 1. 2 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

Ref. 1. 3 **Cocos nucifera oil**

Cocos nucifera oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, *Cocos nucifera* L., Palmaceae. The oil is high in saturated fats therefore it is slow to oxidise and, thus, resistant to rancidification. About 60% of the fatty acids in coconut oil are medium chain triglycerides (MCT) 12 carbon atoms or shorter.

Coconut oil is also listed as a substance Generally Recognized as Safe (GRAS) by the US FDA. The safety of Coconut oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1986 and 2011. The CIR Expert Panel evaluated the scientific data and in 2017 reaffirmed their earlier conclusions that Coconut oil is safe for use as a cosmetic ingredient.

Ref. 1. 4 **Butyrospermum parkii butter**

Butyrospermum parkii butter is the fat obtained from the fruit of the Shea tree, *Butyrospermum parkii*, Sapotaceae. The tree has been recently reclassified as *Vitellaria paradoxa* although the INCI name still remains *Butyrospermum parkii* butter.

About 85 to 90% of the fatty acid composition is stearic and oleic acids.

Typical fatty acid profile:

- oleic acid (40-60%)
- stearic acid (20-50%)
- linoleic acid (3-11%)
- palmitic acid (2-9%)
- linolenic acid (<1%)
- arachidic acid (<1%)

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that *Butyrospermum parkii* butter is safe in the present practices of use and concentration described in this safety assessment.

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. 1.5 **Cetyl alcohol**

Cetyl alcohol, palmityl alcohol or 1-hexadecanol, is a fatty alcohol with the molecular formula $C_{16}H_{34}O$.

The Food and Drug Administration (FDA) includes fatty alcohols including Cetyl alcohol on its list of food additives permitted for direct addition to food as multipurpose food additives. The safety of Cetyl alcohol has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Cetyl alcohol was safe for use as a cosmetic ingredient. In 2005, the CIR Expert Panel considered available new data on Cetyl alcohol and reaffirmed the above conclusion.

Ref. 1.6 **Euphorbia cerifera cera**

Euphorbia cerifera cera is a wax obtained from the Candelilla, Euphorbia cerifera, Euphorbiaceae.

The Food and Drug Administration (FDA) includes Candelilla wax, on its list of substances considered Generally Recognized As Safe (GRAS) for direct addition to food. The safety of plant waxes has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Euphorbia cerifera (Candelilla) wax was safe for use in cosmetics and personal care products. In 2003, the CIR Expert Panel considered available new data on this ingredient and reaffirmed the above conclusion.

Ref. 1.7 **Tocopherol**

Tocopherol is a series organic compounds with vitamin E activity consisting of various methylated phenols which feature a chromanol ring, with a free hydroxyl group on the aromatic ring that can donate a hydrogen atom to reduce free radicals, and a hydrophobic side chain which allows for penetration into biological membranes.

The Food and Drug Administration (FDA) includes Tocopherol on its list of nutrients considered Generally Recognized As Safe (GRAS).

Ref. 1.8 **Citrus aurantium dulcis peel oil**

Citrus aurantium dulcis peel oil is the volatile oil obtained by expression from the fresh peel of the ripe fruit of the sweet orange, Citrus aurantium var. dulcis, Rutaceae.

Ref. 1.9 **Citrus nobilis peel oil**

Citrus nobilis peel oil is the oil expressed from the peel of the Mandarin, Citrus nobilis, Rutaceae.

PART A – Cosmetic Product Safety Information *continued*

2. Physical & chemical properties and stability *continued*

2.1.2 Physical/chemical properties of the cosmetic product

Appearance	Solid/Pressed Powder
Colour	Yellow
Aroma	Citrus
pH	n/a

*RP: Responsible Person: Dani & Jo 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 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo 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 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

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.

Container	Tin
Container Material	Epoxy phenolic lined aluminium
Airless Container	No

EPA is an epoxy phenolic resin. Phenolic resins are prepared by the reaction of phenol or substituted phenol with an aldehyde, especially formaldehyde, in the presence of an acidic or basic catalyst. With a large global production representing 1-5 million tonnes/year, these resins are ubiquitous and therefore have a long history of safe use. EPA polymers are high modulus, relatively heat resistant, and have good properties against chemical leaching.

The supplier provided test results which confirmed the epoxy did not leach into products in the containers.

Dani & Jo 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:

Not for human or animal consumption

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	Underarms
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2
Possible additional routes of exposure	none
Estimated skin surface area (cm ²)	200
Estimated amount of the product applied according to the SCCS (g/day)	1.50 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	22.08

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Cocos nucifera oil	5797.10140
2	Butyrospermum parkii butter	5797.10140
3	Sodium bicarbonate	611.59420
4	Zea mays starch	1275.36230
5	Cetyl alcohol	19323.67150
6	Euphorbia cerifera cera	7246.37680
7	Tocopherol	7246.37680
8	Citrus aurantium dulcis peel oil	14492.75360
9	Citrus nobilis peel oil	14492.75360

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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MoS value above 600 then the conclusion is that they are safe for use in this formulation.

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 Dani & Jo 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 25th 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
- 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

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*:

Limonene: 2.528125%; Linalol: 0.0140625%

* 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.

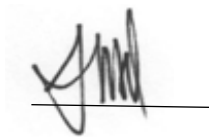
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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
- 10+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



Signature

27 November 2020

Date

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Zero-Odour Deodorant with Lemon and Lemon Verbena
TIN

DATE: 27 November 2020

Responsible Person: Giovanna Mantini
[Redacted]
[Redacted]
[Redacted]
[Redacted]



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 **Sodium bicarbonate**

Sodium bicarbonate or sodium hydrogen carbonate is the chemical compound with the formula NaHCO_3 . It is edible and commonly known as bicarbonate of soda or baking soda.

Ref. 1. 2 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

Ref. 1. 3 **Cocos nucifera oil**

Cocos nucifera oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, *Cocos nucifera* L., Palmaceae. The oil is high in saturated fats therefore it is slow to oxidise and, thus, resistant to rancidification. About 60% of the fatty acids in coconut oil are medium chain triglycerides (MCT) 12 carbon atoms or shorter.

Coconut oil is also listed as a substance Generally Recognized as Safe (GRAS) by the US FDA. The safety of Coconut oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1986 and 2011. The CIR Expert Panel evaluated the scientific data and in 2017 reaffirmed their earlier conclusions that Coconut oil is safe for use as a cosmetic ingredient.

Ref. 1. 4 **Butyrospermum parkii butter**

Butyrospermum parkii butter is the fat obtained from the fruit of the Shea tree, *Butyrospermum parkii*, Sapotaceae. The tree has been recently reclassified as *Vitellaria paradoxa* although the INCI name still remains *Butyrospermum parkii* butter.

About 85 to 90% of the fatty acid composition is stearic and oleic acids.

Typical fatty acid profile:

- oleic acid (40-60%)
- stearic acid (20-50%)
- linoleic acid (3-11%)
- palmitic acid (2-9%)
- linolenic acid (<1%)
- arachidic acid (<1%)

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that *Butyrospermum parkii* butter is safe in the present practices of use and concentration described in this safety assessment.

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. 1.5 **Cetyl alcohol**

Cetyl alcohol, palmityl alcohol or 1-hexadecanol, is a fatty alcohol with the molecular formula $C_{16}H_{34}O$.

The Food and Drug Administration (FDA) includes fatty alcohols including Cetyl alcohol on its list of food additives permitted for direct addition to food as multipurpose food additives. The safety of Cetyl alcohol has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Cetyl alcohol was safe for use as a cosmetic ingredient. In 2005, the CIR Expert Panel considered available new data on Cetyl alcohol and reaffirmed the above conclusion.

Ref. 1.6 **Euphorbia cerifera cera**

Euphorbia cerifera cera is a wax obtained from the Candelilla, *Euphorbia cerifera*, Euphorbiaceae.

The Food and Drug Administration (FDA) includes Candelilla wax, on its list of substances considered Generally Recognized As Safe (GRAS) for direct addition to food. The safety of plant waxes has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that *Euphorbia cerifera* (Candelilla) wax was safe for use in cosmetics and personal care products. In 2003, the CIR Expert Panel considered available new data on this ingredient and reaffirmed the above conclusion.

Ref. 1.7 **Tocopherol**

Tocopherol is a series organic compounds with vitamin E activity consisting of various methylated phenols which feature a chromanol ring, with a free hydroxyl group on the aromatic ring that can donate a hydrogen atom to reduce free radicals, and a hydrophobic side chain which allows for penetration into biological membranes.

The Food and Drug Administration (FDA) includes Tocopherol on its list of nutrients considered Generally Recognized As Safe (GRAS).

Ref. 1.8 **Citrus limon peel oil**

Citrus limon peel oil is the volatile oil obtained from the fresh peel of the Lemon, *Citrus limon* (L.), Rutaceae.

Ref. 1.9 **Lippia citriodora leaf oil**

Lippia citriodora leaf oil is the volatile oil derived from the leaves of *Lippia citriodora*.

PART A – Cosmetic Product Safety Information *continued*

2. Physical & chemical properties and stability *continued*

2.1.2 Physical/chemical properties of the cosmetic product

Appearance	Solid/Pressed Powder
Colour	Yellow
Aroma	Citrus
pH	n/a

*RP: Responsible Person: Dani & Jo 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 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo 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 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

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.

Container	Tin
Container Material	Epoxy phenolic lined aluminium
Airless Container	No

EPA is an epoxy phenolic resin. Phenolic resins are prepared by the reaction of phenol or substituted phenol with an aldehyde, especially formaldehyde, in the presence of an acidic or basic catalyst. With a large global production representing 1-5 million tonnes/year, these resins are ubiquitous and therefore have a long history of safe use. EPA polymers are high modulus, relatively heat resistant, and have good properties against chemical leaching.

The supplier provided test results which confirmed the epoxy did not leach into products in the containers.

Dani & Jo 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:

Not for human or animal consumption

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	Underarms
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2
Possible additional routes of exposure	none
Estimated skin surface area (cm ²)	200
Estimated amount of the product applied according to the SCCS (g/day)	1.50 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	22.08

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Cocos nucifera oil	5797.10140
2	Butyrospermum parkii butter	5797.10140
3	Sodium bicarbonate	611.59420
4	Zea mays starch	1275.36230
5	Cetyl alcohol	19323.67150
6	Euphorbia cerifera cera	7246.37680
7	Tocopherol	7246.37680
8	Citrus limon peel oil	14492.75360
9	Lippia citriodora leaf oil	14492.75360

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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MoS value above 600 then the conclusion is that they are safe for use in this formulation.

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 Dani & Jo 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 25th 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
- 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

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*:

Limonene: 1.176875%; Linalol: 0.00203125%

* 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.

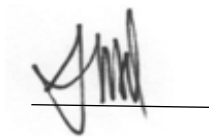
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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
- 10+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



Signature

27 November 2020

Date