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Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Eco Natural Toothpaste Powder - Wild Mountain Thyme

DATE: 25 April 2023

Responsible Person: Alessandro Rocchi
Zerolla LTD
Springfield Farm,
Lewes Road
Haywards Heath RH17 7NG

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PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Sodium bicarbonate	144-55-8	Abrasive, buffering,		34.00
2	Calcium carbonate	471-34-1	Abrasive, buffering,	IV/124	17.50
3	Charcoal powder	8021-96-6	Abrasive, anticaking,		15.00
4	Diatomaceous earth	61790-53-2 / -	Absorbent, binding,		15.00
5	Dicalcium phosphate	7757-93-9	Abrasive, bulking,		8.00
6	Xylitol	87-99-0	Humectant, skin		4.50
7	Thymus vulgaris oil	84929-51-1	Fragrance, perfuming		4.00
8	Menthol	1490-04-6 / 2216	Denaturant, fragrance,		1.00
9	Tocopherol	1406-66-2 /	Antioxidant, fragrance, skin		1.00

Allergens present in this product and estimated amounts*:
Limonene: 0.0176%; Geraniol: 0.0024%; Linalol: 0.1608%; Citral: 0.0056%

* 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

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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.

The Food and Drug Administration (FDA) has reviewed the safety of Sodium Bicarbonate and determined that this ingredient was Generally Recognized As Safe (GRAS) for direct addition to food. Sodium Bicarbonate has also been approved as a skin protectant and an anticarries active ingredient in Over-the-Counter (OTC) drug products. The safety of Sodium Carbonate and related ingredients has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Sodium Bicarbonate was safe as acosmetic ingredient. In 2005, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on Sodium Bicarboante and reaffirmed the above conclusion.

Ref. 1. 2 **Calcium carbonate**

Calcium carbonate is a chemical compound formed by three main elements: carbon, oxygen and calcium. Molecular formula: $CaCO_3$

Ref. 1. 3 **Charcoal powder**

Charcoal powder is the dried, carbonaceous material obtained from the heating of organic substances. Molecular formula: C.

Ref. 1. 4 **Diatomaceous earth**

Diatomaceous earth is a mineral material consisting chiefly of the siliceous frustules and fragments of various species of diatom.

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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 **Dicalcium phosphate**

Dicalcium phosphate, also known as dibasic calcium phosphate, Calcium hydrogenorthophosphate, or calcium monohydrogen phosphate, is a dibasic calcium phosphate containing calcium ions (Ca2+) together with inorganic phosphate anions and has the molecular formula $CaHPO_4$. Dicalcium phosphate is produced by the neutralisation of calcium hydroxide with phosphoric acid, which precipitates the dihydrate as a solid. Commercial Dicalcium Phosphate is not a chemically-discrete entity, but is a mixture of varying amounts of dicalcium and monocalcium phosphates, Phosphoric Acid, calcium carbonate, and impurities, depending on the origin of the raw material and procedures employed in its industrial production. Dicalcium Phosphate is used chiefly in animal feeds, and is also used as a mineral supplement in cereals and other foods. In November 2016 the Cosmetic Ingredient Review (CIR) Expert Panel evaluated the scientific data and concluded that Dicalcium phosphate is safe as a cosmetic ingredient in this product in the present practices of use and concentration.

Ref. 1. 6 **Xylitol**

Xylitol is a 5-carbon sugar alcohol also known as a polyol, polyhydric alcohol, or polyalcohol. It has the formula $C_5H_{12}O_5$ and is an achiral isomer of pentane -1,2,3,4,5-pentol, also known as 1,2,3,4,5-Pentahydroxypentane. Xylitol is commonly used in the food industry as an alternative to sucrose, and is categorised by the FDA as a food additive. In Europe, as a food additive, it is known by the European safety number E967.

Ref. 1. 7 **Thymus vulgaris oil**

Thymus vulgaris oil is the volatile oil obtained from the whole plant of the Thyme, Thymus vulgaris L., Lamiaceae.

Ref. 1. 8 **Menthol**

Menthol is an organic compound obtained from corn mint, peppermint or other mint oils. A waxy, crystalline substance, clear or white in color, it is solid at room temperature. The main form of menthol occurring in nature is (–)-menthol. Menthol has local anesthetic and counter-irritant qualities. Molecular formula: $C_{10}H_{20}O$

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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. 9 **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).

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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	White
Aroma	Floral/minty
pH	n/a

*RP: Responsible Person: Zerolla 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 PAO 12M period.

2.2.1 Zerolla LTD confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Zerolla LTD uses a PAO 12M based on the results of Zerolla 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

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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.

Container	Jar
Container Material	Glass
Airless Container	No

Glass is resilient and resistant to most solvents and represents a low hazard in terms of chemical leaching. Glass can be attacked by weak acids or bases and thus can leach sodium and calcium ions into the cosmetic product.

Zerolla 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.

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5. Normal and reasonably foreseeable use

The current label advice:

Pop a tablet into your mouth & chew with conviction. Brush sensually for 2 mins. Rinse & repeat two times a day. Well behaved kids can use it too, under adult supervision.

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	Mouth
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	2
Possible additional routes of exposure	none
Estimated skin surface area (cm^2)	0
Estimated amount of the product applied according to the SCCS (g/day)	2.75 g
Estimated retention factor according to the SCCS	.05
Target group	Child
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.16

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7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Sodium bicarbonate	0.34000	0.03672
2	Calcium carbonate	0.17500	0.01890
3	Charcoal powder	0.15000	0.01620
4	Diatomaceous earth	0.15000	0.01620
5	Dicalcium phosphate	0.08000	0.00864
6	Xylitol	0.04500	0.00486
7	Thymus vulgaris oil	0.04000	0.00432
8	Menthol	0.01000	0.00108
9	Tocopherol	0.01000	0.00108

***SED**: Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Sodium bicarbonate	114923.74730
2	Calcium carbonate	341269.84130
3	Charcoal powder	308641.97530
4	Diatomaceous earth	308641.97530
5	Dicalcium phosphate	918981.48150
6	Xylitol	2901234.56790
7	Thymus vulgaris oil	657407.40740
8	Menthol	2944444.44440
9	Tocopherol	4629629.62960

***MOS**: Margin of Safety*

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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 Zerolla 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.

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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

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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: 0.0176%; Geraniol: 0.0024%; Linalol: 0.1608%; Citral: 0.0056%

* 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.

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4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild
Oxford Biosciences Ltd.
The Oxford Science Park
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Oxfordshire
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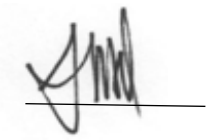
Experience and qualifications:

- 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

25 April 2023

Date