

FUZZY BRUSH LTD
78 YORK STREET
LONDON

W1H 1DP
UNITED KINGDOM

Attn: Jim Drew

Test Report No. CSA 211490/1
Issue Date: 13 November 2015

COSMETIC PRODUCT SAFETY REPORT

Sample Name: FUZZY BRUSH

Sample Reference:

The following Safety Assessment is carried out according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) which replaces all other regulations and directives.

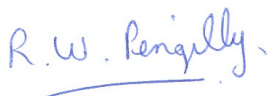
Summary

It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.

This assessment takes account of:

- a) The general toxicological profile of each ingredient used.
- b) The chemical structure of each ingredient.
- c) The level of exposure of each ingredient.
- d) The specific exposure characteristics of the areas on which the cosmetic product will be applied.
- e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

Signed for and on behalf of
SGS United Kingdom Ltd



Roger Pengilly
BSc, PhD, MRSC, CChem
Cosmetic Safety Assessor

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Part A – Cosmetic product safety information

1 Quantitative and qualitative composition of the cosmetic product

FUZZY BRUSH CHEWABLE TOOTHBRUSH WITH BREATH FRESHENER

INCI	CAS Number	EC Number	Conc. %
Plastic (from toothbrush)	N/ A	N/ A	90.66
Xylitol	87-99-0	201-788-0	8.84
Aroma	N/ A	N/ A	0.50

Ingredient Listing:

INGREDIENTS:

Xylitol, Aroma

The formula differs from that in CSA report 175328 in that there is no water present. This gives an effective concentration of Xylitol of approximately 95%.

The Aroma S8448 contains no allergens which should appear on the product ingredient list.

Physical/chemical characteristics and stability of the cosmetic product

The Fuzzy Brush Chewable Toothbrush is a breath freshener.

No Stability testing data were supplied with these formulations. The author I therefore unable to comment on the stability of this formulation.

3 Microbiological Quality

The formulation is not preserved. The microbiological quality should meet the following criteria:

The SCCS guidelines below must be followed.

According to the SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation 8th Revision (SCCS/1501/12) it is generally accepted that for cosmetics not intended for children under 3 years, or products that are not used in the eye area and on mucous membranes that the total viable count for aerobic mesophilic microorganisms should not exceed 1000 cfu/g or 1000 cfu/ml when tested in 1.0 g or 1.0 ml of the product. Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans must not be detectable in 0.1 g or 0.1 ml of the product.

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4 Impurities, traces, information about the packaging

No heavy metal specification was supplied with these formulations. The heavy metal specification should meet the following criteria:

The cosmetic regulation 1223/2009 prohibits the use of heavy metals such as lead, arsenic, cadmium, mercury and antimony unless they are present at trace levels and their presence is inevitable from correct manufacturing processes. The product must be safe. Best practice has been sort and it is my opinion that the most relevant study is that by Health Canada that has proposed the following levels for heavy metals:

Lead 10 ppm, Arsenic 3ppm, Cadmium 3 ppm, Mercury 3 ppm, and Antimony 5 ppm.

The plastic used in the toothbrush meets the requirement of BS EN71-3: 1995.

5 Normal and reasonably foreseeable use

This product is aimed at adults. The normal and foreseeable use for this product is as a Breath Freshener.

6 Exposure to the ingredients and the cosmetic formulation

The product will be applied on average once a day.

Estimated daily amount applied = 1.0g

Estimated adult body weight = 60kg

Relative amount applied = 16.66 mg/ kg bw/ day

Site of application: Mouth

Assumed retention factor = 0.05

Calculated daily exposure = 138mg/ day

Calculated relative daily exposure = 2.29mg/ kg bw/ day

(Compiled from SCCNFP/0690/03 and United States Environmental Protection Agency 2011 edition)

7 Exposure and toxicological profile of the substances

There are no nanoparticles in this formulation.

All of the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation 1223/2009.

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INGREDIENTS:**Xylitol**

CAS 87-99-0

EC No. 201-788-0

Xylitol is a humectant used in many cosmetic applications. There are no restrictions on its use in cosmetic regulation 1223 / 2009 it is considered acceptable for this application.

8 Undesirable effects and serious undesirable effects

No data has been supplied of any undesirable effects associated with this product.

9 Information on the cosmetic product

No other information was supplied on these products.

Part B – Cosmetic product safety assessment**1. Assessment conclusion**

The product is safe for use under normal or reasonably foreseeable use. It complies with EC regulation 1223/2009. The assessment is conditional on the responsible person complying with any conditions raised in this report. No stability data or heavy metal specification has been supplied for this product.

2. Labelled warnings and instructions of use

No additional labelling is required with this product.

3. Reasoning

The toxicological profile of substances in the Fuzzy Brush Chewable Toothbrush with breath freshener has been assessed. The formulation has been reviewed for the potential to be a skin irritant, sensitiser or photo-sensitiser.

All significant toxicological routes of absorption have been considered as well as the systemic effects. Margins of safety have been calculated where applicable.

Each ingredient has been assessed and the toxicological impact of any impurities present considered. Also any interactions between substances have been considered. No stability data has been assessed for this product.

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4. Assessor's credentials and approval of part B

Date: 13th November 2015

Dr. Roger Pengilly BSc, PhD, MRSC, CChem

End of Report

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