

III. Safety assessment

Part A – Cosmetic product safety information

1. Quantitative and qualitative composition

Supplier	Trade name	INCI	CAS no.	Function	Concentration (% w/w)
-	-	Propylene Glycol	57-55-6	Solvent	32%
-	-	Glycerin	56-81-5	Solvent	30.50%
-	-	Aqua	7732-18-5	Solvent	28.30%
-	-	Sodium Bicarbonate	144-55-8	Oral Care	3%
-	-	Xanthan Gum	11138-66-2	Binding	2%
-	-	Aloe Barbadensis Leaf Juice	94349-62-9	Skin conditioning	2%
-	-	Carbomer	9007-17-4	Viscosity controller	1%
-	-	Menthol	89-78-1	Perfuming	0.50%
-	-	Citric Acid	5949-29-1	Buffering	0.50%
-	-	Sodium Chlorite	7758-19-2	Bleaching	0.10%
-	-	Punica Granatum Seed Extract	84961-57-9	Skin conditioning	0.05%
-	-	Chamomilla Recutita Flower Extract	84082-60-0	Skin conditioning	0.05%

2. Physical/chemical characteristics and stability of the cosmetic product

Stability:

Physical/chemical characteristics:

Parameter	Method	Laboratory	Result	Internal code
pH				
Density				
Dry content				

3. Microbiological quality

Parameter	Analysis	Laboratory	Result	Internal code

4. Impurities, traces, information about the packaging material

No impurities have been reported.

Packaging

Packaging material: 3 ml vials with applicable gel

5. Normal and reasonably foreseeable use

Uses (primary/other foreseeable):

Primary: Teeth

Secondary: Gums and lips

Other foreseeable: Ingestion

6. Exposure to the cosmetic product

Targeted population: Adults

Sites of application: Tooth (stay on product - application is short term, but worst-case is assumed)

Surface area application: -

Retention factor: 0.05 (SCCNFP 0321/00 - toothpaste)

Used amount: 1.5 g (Suppliers recommendation)

Body weight: 60 kg

Frequency of application: 1 time/day

Calculated relative daily exposure (face cream): **1.25 mg/kg bw/day**

7. Exposure to the substances

Ingredient	Calculated relative daily exposure (mg/kg bw/day)	Concentration (% w/w)	SED (mg/kg bw/day)
Propylene Glycol	1.25	32%	0,4
Glycerin	1.25	30.50%	0,38125
Aqua	1.25	28.30%	0,35375
Sodium Bicarbonate	1.25	3%	0,0375
Xanthan Gum	1.25	2%	0,025
Aloe Barbadensis Leaf Juice	1.25	2%	0,025
Carbomer	1.25	1%	0,0125
Menthol	1.25	0.50%	0,00625
Citric Acid	1.25	0.50%	0,00625
Sodium Chlorite	1.25	0.10%	0,00125
Punica Granatum Seed Extract	1.25	0.05%	0,000625
Chamomilla Recutita Flower Extract	1.25	0.05%	0,000625

8. Toxicological profile of the substances

– see ingredient file for each separate substance

Ingredient	NOAEL (≥ 90 d) (mg/kg bw/day)	SED (mg/kg bw/day)	MoS (> 100 safe)
Propylene Glycol	1700	0,4	> 100
Glycerin	2000	0,38125	> 100
Aqua	>5000	0,35375	> 100
Sodium Bicarbonate	N/A	0,0375	> 100
Xanthan Gum	250	0,025	> 100
Aloe Barbadensis Leaf Juice	2000	0,025	> 100
Carbomer	1136	0,0125	> 100
Menthol	188	0,00625	> 100
Citric Acid	4000	0,00625	> 100
Sodium Chlorite	3	0,00125	> 100
Punica Granatum Seed Extract	N/A	0,000625	> 100
Chamomilla Recutita Flower Extract	2000	0,000625	> 100

9. Undesirable effects and serious undesirable effects

Date	Complaint (by intended use)	Action
	...	
Date	Complaint (by unintended use)	Action
	...	

The supplier has confirmed that no undesirable effects or serious undesirable effects of this cosmetic product has been reported or, where relevant, cosmetic products with a similar formulation.

10. Information on the cosmetic product

(other testing on the cosmetic product)

Part B – Safety assessment**Smilebright**

1. Assessment conclusion

Based on the present knowledge we conclude that the product does not pose any risk to human health by foreseeable use. The product contains perfume. No special precautions or special instructions are mandatory.

Regarding the ingredient Sodium Chlorite, it is interconverted with Chlorine Dioxide in water (before administration to animals) and the human gut (after ingestion), so the mixture of these chemical species exists in water or the body. Based on this, toxicity information on sodium chlorite includes toxicity information for chlorine dioxide. Although ingestion of ingredients in the assessed product is unavoidable, when considering the limited time of exposure and low concentration of the sodium chlorite in the product, negative effects of Chlorine Dioxide on human organism following usage of the product, are not expected. The product is not intended to be used by children under 12 years of age.

The product contains ingredients of low toxicity where no NOAEL could be determined. These ingredients are in widespread use as food and cosmetic ingredients and their use is considered safe. The assessment was based on the information provided by the supplier at the time of this assessment.

2. Labelled warnings and instructions of use

Mandatory labeling/warnings: None

Supplementary instructions: Use instructions for exact exposure.

Directions for use:

- Brush your teeth to clean them.
- Distribute half a vial (1.5 ml) of gel in the mouthpiece.
- Turn on the mouthpiece light and bite down on the mouthpiece.
- Wait 10 minutes until the light turns off automatically.
- Remove the mouthpiece and rinse your mouth with water.

Do not use if you have braces. If you are pregnant consult your doctor before using the product.

The product is not intended to be used by children under 12 years of age.

3. Reasoning

The safety assessment for the product was done based on information from the supplier and other information publicly available. All substances are evaluated and the MoS calculation, where possible, of each substance is above 100, which is considered safe.

Exposure: Absorption is set to 100%. Exposure area and duration is set according to SCCS guidelines.

NOAEL: Values have been checked in various literatures, primarily based on 90 d. oral repeated toxicity studies. For substances where no NOAEL was established, classification and possible risk was evaluated and found safe at their individual concentrations.
