CoSiChem AG

Qualität, Schnelligkeit, Zuverlässigkeit

Cosmetic product safety report in accordance with Regulation (EC) No 1223/2009 on cosmetic products Article 10

Product

Trade name:	Pearl Smile Bleaching Gel
Formula ref. no.:	21107
Article no:	n. av.
Type of product:	teeth whitening product
Version:	--
Manufacturer / company placing the product on the market / importer:	Pearl Smile GmbH Königsallee 60 d D – 40212 Düsseldorf

Part A – Cosmetic product safety information

1. Quantitative and qualitative composition

The present assessment is based on the preparation method and the itemised qualitative and quantitative composition located in the Annex.

2. Physical/chemical characteristics and stability

The physico-chemical properties of the raw materials can be taken from the safety data sheets and technical specifications located in the Annex.

The finished product has the following physico-chemical properties:

form:	gel
colour:	white
pH-value:	5,0 – 5,4
viscosity:	highly viscous, 180 – 300 dPa*s
flashpoint:	n.app.

Storage conditions: There are no special storage conditions required.

Durability:
Shelf life of the product according to the manufacturer: 30 months
Period of use after opening according to the manufacturer: 12 months.

Results from storage trials:
The formulation was tested with regard to its physical and chemical stability with an accelerated stability test.

3. Microbiological quality

The efficiency of the contained preservatives was checked in a preservative efficacy testing.

For the evaluation following documents are available:
- microbiological specification (TDS) of the raw materials,
- result of the preservative efficacy testing.

4. Purity of raw materials, information about the packaging material

The purity of the raw materials can be taken from the technical specifications, which are included.

The packaging material corresponds to Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (or the previous Directive 2002/72/EC), if specific migration limits are met.
A declaration of conformity from the material manufacturer is available.

Additional information:
The purity of *Triethanolamine* must be at least 99 %, however the maximum content of secondary Alcoholamines as a raw material specific residue may not exceed 0,5 %. The maximum content of raw material specific residue of N - Nitrosodialkanolamine is 0,05 mg/kg. Storage of the product must be in receptacles free of nitrides.
CI 77891: The purity critiera for E171 according to Directive 95/45/EC have to be met.

5. Normal and reasonably foreseeable use

The product is used as teeth whitening product once a day. The gel is applied to a retainer and pressed against the teeth. After 30 min, the gel is rinsed off.
The product is not intended for use especially for children under 3 years of age or pregnant or nursing women.

6. Exposure to the cosmetic product

The scale of exposition yields from the conditions of use, as determined in the directions for use or from the product design.

Application site:	mouth
Surface area (A):	n. av.
Amount of product used (M):	10 g
Duration of application:	Rinse off
Retention factor (R):	0,2
Frequency (f):	1 /d
Foreseeable routes of exposure:	oral
Target market:	adults
Body weight(G):	60 kg
$Exp_{dermal} = (M \cdot f \cdot R)/G$	0,033 [g/kg/d]
$Exp_{oral} = (M \cdot f \cdot R)/G$	0,033 [g/kg/d]

7. Exposure to the substances

The systemic exposure dose (SED) is calculated for the components contained. This is the amount which could enter the bloodstream and therefore could be systemically available.
The margin of safety (MoS) is determined on the basis of the NOAEL (no observed adverse effects level), if appropriate toxicological data are available.
When calculating the SED an average body weight of 60 kg is assumed in general.
Instead of percutaneous permeation a value of 100% ingestion is assumed.

component	% (finished product)	% permeation (skin)	SED (component) [mg/kg/d]	NOAEL [mg/kg/d]	MoS = NOAEL / SED
Propylene Glycol	5	100	1,65	1200	727
Phenoxyethanol	0,45	100	0,149	200	1347
Triethanolamine	0,119	100	0,039	80	2037
Sodium Saccharin	0,1	100	0,033	ADI: 5	152
CI 77891	0,063	100	0,021	3500	168350
Ethylhexylglycerin	0,05	100	0,017	50	3030
(P) Linalool	0,0019	100	0,0006	117	186603
(P) Citral	0,0015	100	0,0005	125	252525

For components which have a MoS of at least 100 in the present formulation system toxic effects are not expected to present state of knowledge.

Some of the ingredients have already been examined by the SCCP (Scientific Committee on Consumer Products) and have been classified as safe for cosmetic use - possibly, under certain conditions of use.

The limit values and restrictions for use specified by the cosmetic regulation are met for the following ingredients:

Phenoxyethanol

A further consideration is therefore not necessary.

Assessment of further ingredients:

component	% (finished product)	% permeation (skin)	SED (component) [mg/kg/d]
Glycerin	71,2	100	23,50
Aqua	21,13	100	6,97
Carbomer	1	100	0,33
Mica	0,438	100	0,14
Urea Peroxide	0,25	100	0,08
(P) D-Limonene	0,1238	100	0,04

Based on the currently available toxicological data, these substances are not likely to be hazardous in the given concentrations.

Aroma

The safety of the Aroma in the present concentration and the intended use is confirmed by the manufacturer. (Safety assessment in the Annex)
If the perfume contains one or more of 26 specified substances, these substances must be listed in the "ingredients list" on the label if the concentration exceeds 0,001 % in ‚Leave-on'-products or 0,01 % in ‚Rinse-off'-products.
The used perfume oil contains the following of these substances in relevant concentrations:

(P) D-Limonene
(P) Linalool
(P) Citral

8. Toxicological profile of the substances

In order to create the profiles, information of the raw material manufacturers, available scientific literature, publications of the SCCP, BfR and other organizations were consulted.

The toxicological profiles of the materials and the underlying data sources are available in the archives of "CoSiChem AG" and can be reviewed there.

9. Undesirable effects

Data on undesirable effects and customer complaints is not available.

10. Further information on the cosmetic product

None.

Part B – Cosmetic product safety assessment

1. Assessment conclusion

Pearl Smile Bleaching Gel is suitable for cosmetical purpose, based on the toxicological data, not regarding unavailable information.
Health injuries are not known or expected under normal and foreseeable use.

2. Labelled warnings and instructions of use

We recommend you write down in the directions for use the following information:

The product should not be swallowed.
Avoid contact with the eyes.
Not to be used for children under three years of age. Not suitable for pregnant or nursing women.

The usage should be made clear from the packaging.

3. Reasoning

This assessment is based on the toxicological profile of the ingredients, the chemical structure, available toxicological / dermatological documentation of the raw material and studies of final products including microbiological tests, EEC - Safety Data Sheets, legal settlements, general obliging international assessments, recommendations of authorities and associations and experiences of commercialisation.

The product contains no substances classified as hazardous to health in concentrations which should be taken into account under normal and foreseeable use.

Sensitisation, exceeding the expected reactions of sensitive people, is not likely.

The product is stable against microbial contamination.

In terms of permitted ingredients and maximum allowable concentrations of constituents the legal standards of the EU Regulation 1223/2009 on cosmetics are met.

Attached Appendices and Documents

- Preparation method
- Quantitative composition
- Safety data sheets and technical specifications of the raw materials
- Microbiological tests and specification
- Toxicological short profiles of the components
- Specification and safety assessment of the Aroma
- Declaration of conformity packaging material
- Qualifications of the safety assessor

24.11.2015
Responsible for the safety assessment:

Jana Steinit

Pearl Smile Bleaching Gel

CAS	EINECS	chem. Bezeichnung / chemical description	INCI-Name	%	Einst. / symbol	R-Sätze / risk phrases	AGW / Beschränkungen / legal restrictions
56-81-5	200-289-5	Glycerin	Glycerin	71,2	n.a.	n.a.	
7732-18-5	231-791-2	Wasser	Aqua	21,13	n.a.	n.a.	
57-55-6	200-338-0	1,2-Propandiole	Propylene Glycol	5	n.a.	R 18	n.v.
9003-01-4	n.v.	Polyacrylsäure	Carbomer	1	Xi	R 36/38	n.v.
122-99-6	204-589-7	2-Phenoxyethanol	Phenoxyethanol	0,45	Xn	R 22-36	AGW: 20 ppm | 110 mg/m³ / V/29
12001-26-2	n.v.	Glimmer	Mica	0,438	n.a.	n.a.	
102-71-6	203-049-8	2,2',2''-Nitrilotriethanol	Triethanolamine	0,119	n.a.	n.a.	n.v./ III/62
6155-57-3	204-886-1	1,2-Benzisothiazol-3(2H)-on 1,1-dioxid, Natriumsalz, Dihydrat	Sodium Saccharin	0,1	n.a.	n.a.	n.v.
124-43-6	204-701-4	Hydrogenperoxid-Harnstoff	Urea Peroxide	0,25	O, C	R 8-34-37	n.v./ III/12
13463-67-7	236-675-5	Titandioxid	CI 77891	0,063	n.a.	n.a.	IV/143, VI/27
70445-33-9	408-080-2	3-(2-Ethylhexyloxy)propan-1,2-diol	Ethylhexylglycerin	0,05	Xi	R 41-52/53	
n.v.	n.v.	Aroma	Aroma	0,2	n.v.	n.v.	
5989-27-5	227-813-5	(R)-p-Mentha-1,8-dien	(P) D-Limonene	0,1238	Xi, N	R 10-38-43-50/53	AGW: 20 ppm | 110 mg/m³ / III/88
78-70-6	201-134-4	Linalool	(P) Linalool	0,0019	Xi	R 38-43	n.v./ III/84
5392-40-5	226-394-6	Citral	(P) Citral	0,0015	Xi	R 38-43	III/70

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Pearl Smile Bleaching Gel

CAS	INCI-Name	NOAEL (oral, rat) [mg/kg/d]	acute toxicity (oral, dermal, inhalativ)	Irritation	Sensitisation	Photo-toxicity	CMR	Other
56-81-5	Glycerin		LD50 (orl, rat): > 10000 mg/kg bw; LD50 (drm, rat): > 21900 mg/kg bw;	Eye: not irritating; Skin: not irritating;	not sensitising (Skin contact, Inhalation);	no indications	no effects (Cancerogen., Mutagen., Repro-Tox.);	Glycerin is generally approved without maximum limit for food (quantum satis); NOAEL: inhalative: 0,167 mg/l;
7732-18-5	Aqua		not acutely toxic;	Eye: not irritating; Skin: not irritating; Respiratory tract: not irritating;	not sensitising (Skin contact, Inhalation);	not phototoxic	no effects (Cancerogen., Mutagen., Repro-Tox.);	
57-55-6	Propylene Glycol	1200	LD50 (orl, rat): 20000 mg/kg bw; LD50 (drm, rabbit): 20800 mg/kg bw;	Eye: weakly irritating; Skin: weakly irritating;	weakly sensitising (Skin contact);		no effects (Cancerogen.); no effects (Mutagen.);	NOAEL (oral, rat) 2500 mg/kg BW. NOAEL fetal/ developmental (oral, rat, mouse, rabbit, hamster) 1200 - 1600 mg/kg BW
9003-01-4	Carbomer		not acutely toxic;	Eye, Skin: weakly irritating at high concentrations	not sensitising (Skin contact);		no indications (Mutagen.);	evaluated as safe for cosmetic use by CIR Expert Panel
122-99-6	Phenoxyethanol	200	LD50 (orl, rat): 1200 mg/kg bw; LD50 (drm, rabbit): 5000 mg/kg bw;	Eye: irritating; Skin: 10%: not irritating;	not sensitising (Skin contact, Inhalation);	no effects	no indications (Cancerogen., Mutagen., Repro-Tox.);	
12001-26-2	Mica			Skin: no indications;	no indications (Skin contact);		no indications (Mutagen.);	
102-71-6	Triethanolamine		LD50 (orl, rat): 8000 mg/kg bw; LD50 (drm, rabbit): 20 ml/kg bw;	Eye: not irritating; Skin: not irritating;	kaum sensitising (Skin contact);	20%: not phototoxic or photo-sensitising	no effects (Cancerogen.); no effects (Mutagen.);	NOAEL (oral, rat, 90d): 80 mg/kg bw; NOAEL (drm, mouse, 90d): 1000 mg/kg bw; NOAEL (inhal, rat, 28d): 0,25 mg/L; NOAEL (Teratogen, mouse, 10d): 1125 mg/kg bw;

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6155-57-3	Sodium Saccharin		LD50 (oral, rat): 14200 mg/kg;	Eye: weakly irritating; Skin: not irritating; Respiratory tract: not irritating;	not sensitising (Skin contact);		no final conclusion (Cancerogen.); no indications (Mutagen.);	ADI (WHO, 1993): 0 - 5 mg/kg BW
124-43-6	Urea Peroxide		LD50 orl rat: > 2000 mg/kg;	Eye: corrosive; Skin: corrosive; Respiratory tract: irritating;			no indications (Mutagen.);	
13463-67-7	CI 77891		LD50 (orl, rat): > 2150 mg/kg bw; LD50 (drm, rat): > 2000 mg/kg bw;	Eye: not irritating; Skin: not irritating;	not sensitising (Skin contact);	no indications	no indications (Cancerogen.); no indications (Mutagen.);	NOAEL (rat, 90 days, oral): 3500 mg/kg/d; NOAEC (rat, 90 days, inhalative): 10 mg/m³
70445-33-9	Ethylhexyl-glycerin	50	LD50 (orl, rat): > 2000 mg/kg bw; LD50 (drm, rat): > 2000 mg/kg bw;	Eye: 100%: irritating, 5%: not irritating; Skin: not irritating;	not sensitising (Skin contact);	no indications	no effects (Mutagen.);	evaluated as safe for cosmetic use by CIR Expert Panel
5989-27-5	(P) D-Limonene		LD50 (orl, rat): 4400 mg/kg bw; LD50 (drm, rabbit): > 2000 mg/kg bw;	Eye: weakly irritating; Skin: irritating;	sensib.NOEL (Human maximization test): 5517 µg/cm² (Skin contact);		no indications (Cancerogen., Mutagen., Repro-Tox.);	
78-70-6	(P) Linalool	117	LD50 (orl, rat): 2790 mg/kg bw; LD50 (drm, rabbit): 5610 mg/kg bw;	Eye: not irritating; Skin: 100%: irritating; 20% in Petrolatum: not irritating;	NOEL (Human maximization test): 13793 µg/cm² (Skin contact);		no indications (Mutagen.);	weakly sensitising; NOEL (Teratogen, rat, oral): 117 mg/kg; NOEL (Teratogen, rat, dermal): 250 mg/kg; NOAEL (reproductive): 365 mg/kg bw/day
5392-40-5	(P) Citral	125	LD50 (orl, rat): app. 4950 mg/kg bw; LD50 (drm, rabbit): 2250 mg/kg bw;	Eye: not irritating; Skin: irritating;	sensitising; NOEL (HRIPT): 1400 µg/cm² (Skin contact);		no indications (Mutagen.);	ADI (JECFA, 1998): 0 - 0,5 mg/kg bw; NOAEL (orl, rat): 200 mg/kg bw/day; NOAEL (orl, malternalt., rat): 125 mg/kg bw/day; NOAEL (inhal, teratogen., rat): 77 mg/kg bw/day

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