EF Chemical Consulting Ltd
Cosmetic Product Safety Report
In compliance with Annex I, EC Regulation 1223/2009

Company ("Responsible Person")
Carole Masson (Golden Smile)

Contact person
Carole Masson

Company address
3 rue Pontus de la Gardie, Montlegun, 11000 Carcassonne, FRANCE

Contact telephone number(s)
06 07 06 86 83

Company registration number
None

Manufacturing company (if different to above)
Dentech Laboratory, USA

Manufacturing address (if different to above)
400 College Ave, Angwin CA 94508, USA

Product code
Dentech formula: 77-1214-A

Product name
To be decided

Category of product
Tooth whitening kit

Intended consumer group
Adults

Instructions for use
See Section 6. Full instructions will be included with kit

Our reference
HA1933

Date of report
27th February 2012

Contents

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PART A – Cosmetic Product Safety Information

1. Physical/chemical characteristics of the product

Viscous, off-white, translucent gel
Viscosity specification >100,000cps (Brookfield)
Specific Gravity specification 1.10 +/- 0.05 g/ml
Odor: peppermint
pH specification: 6.5 +/- 0.3

2. Raw material specifications

Sodium bicarbonate is USP and Food Codex compliant
Glycerin is USP34, EP, and kosher grade
All other ingredients are either food or cosmetic grade

3. Results of stability testing

Results of stability testing were not available at the time of review

4. Microbiological quality / challenge testing

The product is anhydrous and contains a high concentration of sodium bicarbonate so it not able to support the growth of microorganisms: challenge tests are not relevant. Batch testing for microbiological contamination is not carried out.

5. Impurities and information about the packaging material

The product is contained within a plastic syringe. Exact material of construction is not known, but in common with most disposable syringes, it is probably polycarbonate.

6. Normal and reasonably foreseeable use

The product is intended for home customers (who would be expected to buy a separate drying lamp) and to spas and clinics that would have their own lamp. The teeth are first cleaned with a separate tooth cleaning wipe. The product is then applied to both sets of teeth using a mouth tray supplied with the product. Contact time is 10-20 minutes, during which an LED lamp is switched on in front of the moth. At the end of this period the mouth is washed out. At home, the product would be used every day for up to 6 days. In a clinic or spa, it would be applied 3 times and the customer may return for repeat treatments around 12 times per year.

7. Exposure estimates used in this safety report

7.1 Oral Exposures

IFRA category	6
Intended Consumer	Adults 60kg
Site of application	Teeth
Likely routes of exposure	Oral only
Amount of substance applied per use	2g/ treatment, total 6g for 3 treatments
Wash off or leave-on	Wash-off
Frequency of use	Use 1/day for calculations
Retention factor	10%
Calculated daily exposure	0.6g
Relative daily exposure (mg/kg bw/day)	10
Relative daily exposure (µg/cm^2/day)	Not applicable

Note: Exposure estimates are taken directly from Tables 2 and 3 of SCCS Notes of Guidance (SCCS/1416/11) where the particular product category is listed, or are otherwise estimated using the Guidance and our experience.

7.2 Dermal Exposure
Unlikely with this product

7.3 Inhalation Exposure
Inhalation exposure is unlikely with this product

8. Quantitative composition of the product, qualitative safety comments and compliance with Annexes II, III, IV, V and VI and IFRA regulations

INCI name	% by weight	EFC safety code (see Section 13)	EU Annex or IFRA regulated?	Limit imposed by EU annex / IFRA
Glycerin	69.0	F2-FA	no	
Sodium Bicarbonate	24.9	F2-FA	no	
Carbomer (Easygel DO, 3V Inc)	1.0	C1	no	
Polysorbate 20	1.0	F2-FA	no	
Sodium hydroxide	0.5	C3	no	
Potassium Sorbate	0.5	Ann-Pres	yes	0.8% (0.6% as the acid)
Sodium Fluoride	0.05	C5/C3	yes	0.27% (0.15% as F)
Aloe Barbadensis Leaf Juice	0.5	F2-OT	no	
Punic Granatum Seed Extract (CO2)	0.5	C1	no	
Anthemis Nobilis Flower Extract	0.05	C1	no	
Mentha Piperita Oil	2.0	IFR-1	No (doesn't contain any IFRA-regulated sensitisers	

9. Systemic Toxicity Data and Calculations of Margins of Safety

INCI name	Relative daily exposure (mg/kg/day) (Note i)	Oral Absorption (%) (Note ii)	SED mg/kg day (Note iii)	NOAEL (Note iv)	Reference in Section 10	Critical toxicity effect	Margin of Safety (Note v)
Glycerin	6.9	100	6.9	10000	a	**None**	1449.3
Sodium Bicarbonate	2.49	100	2.49	Not required	b	**None**	
Carbomer	0.1	100	0.1	3000	c	**none**	30000.0
Polysorbate 20	0.1	100	0.1	1000	d	**diarrhoea in oral studies**	10000.0
Sodium hydroxide	Not relevant: not present in final product						
Potassium Sorbate	0.05	100	0.05	2500	e	**liver tox (thought to be due to high K intake)**	50000.0
Sodium Fluoride	0.005	100	0.005	1.1	f	**stomach lesions / stomach toxicity**	220.0
Aloe Barbadensis Leaf Juice	0.05	100	0.05	88	g	**Gastric toxicity**	1760.0
Punic Granatum Seed Extract (CO2)	0.05	100	0.05	5000	h	**none**	100000.0
Anthemis Nobilis Flower Extract	0.005	100	0.005	25 (typical daily intake)	i	**none**	5000.0 (MOE)
Mentha Piperita Oil	0.2	100	0.2	100	j	**Kidney toxicity**	500.0

Notes to Table 9

(i) Relative daily exposure to product (see Section 7) x % in product
(ii) Oral absorption assumed to be 100%.
(iii) SED=Systemic Exposure Dose = Relative daily exposure x Dermal Absorption
(iv) No Observed Adverse Effect Level in mg/kg/day, usually derived from animal studies
(v) Margin of Safety = NOAEL divided by the SED. A figure of >100 is generally considered to be safe. MOE = Margin of Exposure based on known safe levels in humans; a figure of less than 100 may be acceptable.

10. References and Reasoning for Systemic Toxicity Effects on each Ingredient

(a) Glycerin: Referenced in OECD SIDS entry for glycerol (Feb 2002) to 1953 2 year oral study by Hine.

(b) Sodium bicarbonate: No definitive animal studies known but sodium bicarbonate is a component of the pH buffering system of the human body and we estimate human daily intake is typically 50-100 mg/kg/day.

(c) Carbomer: Sub-chronic (90 day) oral study of high molecular weight cross-linked polyacrylates in rats (Lindenschmidt RC, Fundamental and Applied Toxicology, vol 17, Issue 1, July 1991 p128-135.)

(d) Polysorbate 20: From 2007 summary by the Japanese Food Safety Commission, based on 13 week feeding studies (www.fsc.go.jp/english/evaluationreports/foodadditive/polysorbate_report.pdf)

(e) Potassium Sorbate / Sorbic acid: NOAEL from 3 month oral rat study done in 1954 and reported in WHO Food Additive series 67.29 (http://www.inchem.org/documents/jecfa/jecmono/40abcj15.htm). This is the basis of the international food additive ADI of 25mg/kg/day.

(f) Sodium Fluoride: NOAEL value taken from HSDB summaries of NTP programme data, referenced in SCCNFP/0653/03.

(g) Aloe Barbadensis Leaf Extract: Based on rat studies using whole leaf powder by Matsuda et al, referenced in Herbal Medicine: Biomolecular and Clinical Aspects (CRC Press, Benzie et al). This reference also reported that no signs of carcinogenicity were found in a 2 year rat study carried out in 2009 by Yomohira et al. Aloe vera leaf juice is sold worldwide in health food shops with maximum normal intake of 25g/day. Health food grade in USA has a specification of maximum 50ppm anthraquinone, which should also be applied to cosmetic grade.

(h) Punica granatum (pomegranate) seed extract: based on suppliers composition of CO2 extract >98% fatty acid triglycerides (mostly 18:3) and read across from other vegetable oils such as rapeseed and corn oil.

(i) Anthemis Nobilis Flower Extract: A typical daily oral intake of 25mg/kg/day was estimated from consumption of roman chamomile tea, e.g. Twinings Organic Pure Camomile, of 1 cup per day containing 1.5g of flowers. It has been widely drunk as a tea over the centuries and is widely used in cosmetics over many years with >700 products containing it listed on the EWG US database.

(j) Mentha Piperita (peppermint) oil: NOAEL based on various 90 day rat studies carried out 1990-2000 summarised in Handbook of Essential Oils (edited Baser and Buchbauer) p201.

11. Local Toxicity Data on 100% active ingredient

INCI name	Corrosivity	Skin irritation	Eye irritation	Skin sensitisation	Photo-sensitivity
Glycerin	-	-	-	-	-
Sodium Bicarbonate	-	-	-	-	-
Carbomer	-	-	-	-	-
Polysorbate 20	-	-	-	-	-
Sodium hydroxide	Not present in final recipe			-	-
Potassium Sorbate	-	Yes	yes	-	-
Sodium Fluoride	-	Yes	yes	-	-
Aloe Barbadensis Leaf Juice	-	-	-	-	-
Punic Granatum Seed Extract (CO2)	-	-	-	-	-
Anthemis Nobilis Flower Extract	-	-	-	-	-
Mentha Piperita Oil	-	yes	yes	-	-

Note to Table 11: "-" means no local toxicity seen for the given end point. Skin/eye corrosion, skin irritation, eye irritation and skin sensitisation data are based on suppliers CHIP and GHS classifications where test methods are referenced on the safety data sheet. Skin photosensitivity is based on structural activity relationships, UV absorption data, suppliers data where available and broader literature searching.

12. Human studies on the finished product

No human studies have been carried out on the finished product

13. EFC Qualitative Safety codes

Aqua: Water. No safety issues except that the source must be chosen to minimise microbial contamination of the finished product.
F1: Used without limit as a food in the EU or elsewhere in the world, and widely used in cosmetics with >10 years history of use and no significant health concerns reported. The pure material is considered not classified (non-hazardous) in the EU chemicals classification scheme.
F2-FA: Authorised food additive in the EU (with an E-number), or in the USA, Canada or Australia, and is widely used in cosmetics with >10 years history of use with no significant health concerns reported. The pure material is considered not classified (non-hazardous) in the EU chemicals classification scheme.
F2-OT: Accepted food supplement or food concentrate in EU, USA, Canada or Australia, and is widely used in cosmetics with >10 years history of use and no significant health concerns reported. The pure material is considered not classified (non-hazardous) in the EU chemicals classification scheme.
F3: In pure form can be irritating to skin or eyes or risk of serious damage to eyes (R36, R38 or R41 classified), with no other health concerns reported, is accepted as a food additive in the EU at low levels, is widely used in cosmetics for >10 years without significant adverse safety reports, and is used in the above formulation at a level well below the minimum at which it is expected to cause skin or eye irritation.
F4-FA: Authorised food additive in the EU (with an E-number), or in the USA, Canada or Australia. Not widely used in cosmetics but its edibility, together with its origin or chemical structure, indicates it is safe at the concentration used in the above product.
F4-OT: Accepted food supplement or food concentrate in EU, USA, Canada or Australia, or used as an edible foodstuff in other parts of the world, with no significant health concerns reported. Not widely used in

cosmetics but its edibility, together with its origin or chemical structure, indicates it is safe at the concentration used in the above product.
F5-FA: Classified as toxic or harmful under the EU system but is an accepted food additive in the EU. Detailed toxicity studies have been carried out to determine the maximum safe levels for ingestion and the overall exposure to the above product assuming 100% dermal absorption is well below this level.
C1: Widely used in cosmetics within broad limits with >10 years history of use, not classified as hazardous to human health in EU, and no significant health concerns reported in the literature.
C2: Detergent or cleaning chemical classified as non-hazardous or a skin or eye irritant in EU (R36 or R38 classified or R41, danger of serious damage to eyes), with no other health concerns reported. Widely used in cosmetics, with >10 years history of use. Generally used in rinse-off products but can also be used in leave-on products at low levels (see specific comment on the ingredient). Used in above product at a level below which it is expected to be irritating to skin or eyes in the stated application.
C3: In pure form can be irritating to skin or eyes or risk of serious damage to eyes (R36, R38 or R41 classified), or corrosive for pure acids and alkalis, with no other health concerns reported, but has >10 years history of widespread use in cosmetics without significant adverse safety reports. In this formulation, is used below a level at which it could cause irritation in line with EU or US (CIR) guidance.
C4-NC: Recently introduced cosmetic ingredient, or not widely used, but origin, chemical structure or toxicity studies indicates is safe to be used at the concentration used in the above product. The chemical structure, or/and toxicity studies or other information indicates it would considered as non-hazardous in the EU chemicals classification system.
C4-IRR: Recently introduced cosmetic ingredient, or not widely used, but origin, chemical structure or toxicity studies indicates is safe to be at the concentration used in the above product. The chemical structure or/and toxicity studies indicates it would considered as a skin or eye irritant (R36 or R38) in the EU chemicals classification system.
C4-CORR: Recently introduced cosmetic ingredient, or not widely used. The pure material is classified as corrosive to the eyes or skin in the EU chemicals classification system, but at the low levels in the above product, and considering the pH buffering of the system, it is safe as used.
C4-Harm: Recently introduced ingredient that is considered harmful or toxic under EU classification rules but is present at a level where it is not expected to cause any systemic or harmful effects.
C5: Classified as harmful or toxic in EU in pure form. Widely used in cosmetics for > 10 years and considered safe in cosmetics when used at the correct concentrations. Used in above product at a level well below the level at which any harm is likely, in line with EU or US (CIR) guidance.
IFR-1: Essential oil / absolute or fragrance oil/compound or aqueous distillate from essential oil production conforming to IFRA regulations in this product, taking into account restricted substances from all sources. For essential oils: widely used in cosmetics or aromatherapy products with >10 years history of use; not used at a level irritating to skin or eyes in leave-on products, and no expectation of oral toxicity effects for lip products.
IFR-2: Essential oil or absolute that has been recently introduced or is not widely used in mainstream cosmetics. Literature searches indicate it is safe to be used, either by composition information or widespread traditional use amongst indigenous people. Not used at a level irritating to skin or eyes in leave-on products. Use in this product conforms to IFRA regulations based on literature data for allergen concentrations.
Col: Listed in Annex IV of the EU Cosmetic Safety Regulations 76/768/EEC as a permitted colour, and used in line with any stated restrictions. Not a permitted a food colouring in the EU.
ColE: As for Col, but additionally is a permitted food colouring in the EU with an assigned E number and must conform to the purity requirements as detailed in the food colouring regulations. The Responsible Person is legally required to ensure that EU cosmetic or food grade colorants are being used.
Ann: Preservatives or UV filters listed in either Annex VI or VII of the EU Cosmetic Safety Regulations 76/768/EEC, and used in line with the stated limits
ARO: Flavour oils confirmed by the supplier as food-grade and only containing components that have FEMA numbers / GRAS listings

14. General notes and conditions of this assessment

1. This assessment applies to products manufactured, sold or marketed by the company named above as the responsible person. It cannot be transferred or sold to third parties, except with the agreement of EF Chemical Consulting Ltd.
2. This assessment applies only to the ingredients listed. A new assessment will be required if a raw material is substituted with a different INCI name, a different colour, or a different perfume or essential oil.
3. We try to use the European INCI names in the assessments, but we do not guarantee it. Please use our labelling consultancy service if you are unsure of the correct names to be printed.
4. Except for the main preservatives, this assessment is valid for concentration variations of +/- 20% of the declared percentage, to allow for manufacturing variations, as long as the margin of safety for the ingredient is 120 or greater. Also, for products containing water, this assessment is valid for dilutions of the above formula with water, as long as the preservative level is maintained at the same concentration. The assessment is also valid if ingredients are reduced or taken out as long as the missing percentage is replaced by water or an edible vegetable oil that is already listed.
5. In supplying this safety assessment EF Chemical Consulting Ltd makes no assurances that the individual substances or ingredients are registered or exempt under REACH. This is not usually an issue if the ingredient is sourced within the EU, but importers into the EU are warned that REACH notification rules apply once the annual imported quantity of a particular substance aggregated over all their products exceeds 1 TPA. Importers into the EU of products containing any botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions. We do not make these checks.

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PART B – Cosmetic Product Safety Assessment

1. Assessment Conclusion

The product is safe for use in the stated application, and complies with EC Regulation 1223/2009. This assessment is conditional on the Responsible Person complying with the conditions in the notes and any other purity restrictions listed.

2. Reasoning

This type of formulation has been in common use in cosmetics over many years without any particular concerns.

(a) Potential systemic toxic effects

Table 8a gives the margin of safety (or margin of exposure) for each of the ingredients used. All the ingredients used have a figure of 100 or over so are considered safe.

(b) Potential skin sensitisation effects

The main causes of skin sensitisation in cosmetics are perfume ingredients, essential oils, certain preservatives and certain UV filters. The International Fragrance Research Association (IFRA) has a series of regulations designed to prevent sensitisation to perfumes, essential oils and absolutes, and this product complies with these regulations. The use of preservatives and UV filters is controlled by the EU on Annexes VI and VII and all toxicity endpoints, including skin sensitisation, are taken into accounts before an ingredient is listed. This product also complies with any restrictions imposed by the Annexes.

In general, the final product would not be considered a potential skin sensitiser if the total concentration of skin sensitisers is less than 1%. These levels are not exceeded in the product.

(c) Potential skin / eye irritation effects

A general rule of thumb used in the classification of mixtures of chemicals under the EU REACH / CPL regulations is that skin or eye irritation is not significant if the total concentration of individual ingredients classified as irritant is less than 20% by weight. Additionally, the concentration of chemicals classified as corrosive or as capable of causing serious damage to the eye must be very low, and the pH should be between 3 and 10.

Based on the total concentrations of such ingredients as summarised in Table 11 skin and eye irritation are not considered significant.

(d) Potential phototoxicity

The product does not contain any known photosensitising ingredients. The product function is not a sunscreen so potential exposure to the sun is limited.

(e) Microbiological safety

The product is anhydrous and cannot support microbial growth. The packaging in a syringe will help prevent moisture ingression and the presence of an antifungal agent will help prevent growth in the unlikely chance of contamination with water.

3. Packaging assessment
Plastic syringes are used. The product is inert and would be compatible with any common plastic.

4. Required warnings and instructions for use
Not for use with children! Instruction for use along the lines given in Section 6 must be contained or printed on the box

5. Purity conditions
This assessment assumes that only cosmetic, pharmaceutical or food grade ingredients are used. Certain ingredients have particular purity restrictions imposed on them under the annexes to the EU regulation and this Safety Report is only valid if these requirements are met. The following is a list of such ingredients:

None

6. Name of Assessor
Dr Edmund Hartley Fowles MA, MRSC, CChem

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Summary of career for Dr Edmund Fowles, MA, CChem, MRSC

Feb 2012	Attended 6-day advanced course on “Safety Assessment of Cosmetics in the EU” under Professor Vera Rogiers at VUB Universiteit, Brussels
2006 to date	Independent consultant chemist and cosmetic safety assessor, Director of EF Chemical Consulting Ltd
2002–2006	Technical manager all UK cosmetics and coatings additives, Innospec Inc (formerly Octel) responsible for 2 cosmetic formulators. Responsibilities included cosmetic formulation development, performance validation of new products, irritancy testing on new products and safety datasheet generation.
2000-2002	Section manager Octel Inc, anti-foam and coatings additives responsible for technical service, new product development, safety datasheets and toll manufacture
1991-1999	Senior chemist Rockwood Pigments R&D (formerly Laporte Pigments), new product and process development on iron oxide pigments for cosmetics, coatings and construction industries. In 1992, gained the qualification of Chartered Chemist (CChem) from the Royal Society of Chemistry.
1988-1990	Postdoctoral research fellow, California Institute of Chemistry, inorganic catalysts
1985-1988	Studies towards achieving a PhD, Leeds University, transition metal complexes and homogenous catalysis
1984-1985	Scientist, Amersham International
1981-1984	Cambridge University, Natural Sciences degree (chemistry), degree grade: 2:1.

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