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

Company (Responsible Person)
My Oradent Toothpowder

Contact person
Abel Williams

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Manufacturing company (if different to above)
Ala Chemicals

Manufacturing address (if different to above)
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Product code
None stated

Product name
My Oradent Tooth Powder

Category of product
Teeth cleaning powder

Intended consumer group
All adults and teenagers

Our reference
HA3758

Date of report
7th June 2017, updated product name 18th March 2019

Contents

Cross-reference to sub-headings of Annex 1 of EC1223/2009

This section is added as an aid to inspecting authorities. All sub-headings listed in Annex 1 and detailed further in the Commission Implementing Decision 2013/674/EU are covered in this safety report as follows.

Annex 1 sub-heading	Section in this report
Part A	**Part A**
1. Quantitative and qualitative composition of the cosmetic product	Quantitative product composition is given in Section 1. Correct INCI names as given on the EU "cosing" database are used in this report and EINECS/CAS numbers and ingredient functions are exactly as listed on the respective cosing entry. Purity and analytical specifications of raw materials are on supplier certificates of analysis (referred to in Section 3).
2. Physical/chemical characteristics and stability of the cosmetic product	Relevant physical/chemical characteristics on raw materials are referred to in Section 3. Relevant physical/chemical characteristics of the finished product are given in Section 2. The overall stability and stability testing of the finished product are summarised in Section 4. The results of the preservative challenge test, where relevant for overall stability, is summarised in Section 5.
3. Microbiological quality	Summarised in Section 5
4. Impurities, traces, information about the packaging material	Raw material impurities are given in the certificates of analysis referred to in Section 3. Where unavoidable traces of prohibited substances are generally present in a particular raw material, this is detailed and commented on in the reference for that specific ingredient in Section 10 and Section 12. Relevant information on the packaging is given in Section 7.
5. Normal and reasonably foreseeable use	Summarised in section 6 and section 8
6. Exposure to the cosmetic product	Section 8
7. Exposure to the substances	Given in column 3 of Table 9
8. Toxicological profile of the substances	Systemic toxicity endpoints of relevance are summarised in Table 9. Local toxicity endpoints are summarised in Table 11. Suppliers' toxicity classifications, which are also taken into account in this report, are given in the CPL classifications on their safety data sheets which are referred to in Section 2. Specific exposure doses (SEDs), NOAEL values and margins of safety (MOS) are all given in Table 9. All justifications, other considerations, and sources of information for each ingredient are given in Section 10.
9. Undesirable effects and serious undesirable effects	Section 14
10. Information on the cosmetic product	Human studies of relevance are summarised in Section 13
Part B	**Part B**
1. Assessment conclusion	Section 1
2. Labelled warning and instructions of use	Section 2
3. Reasoning	Section 3
4. Assessor's credentials and approval of part B	Assessor's credentials and confirmation of approval of this document are given in Section 6. The date of approval is the date on the first page of the whole report

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PART A – Cosmetic Product Safety Information

1. Quantitative composition of the product

Trade name	Manufacturer(s)	INCI name	% wt trade name in final product
Water	Ala Chemical's Distillation Plant	Aqua	0.20
Micropharm 707 (toothpaste grade precipitated calcium carbonate, >99% CaCO3)	Saudi Carbonate Ltd.	Calcium Carbonate	96.28
Sodium Saccharin 20 Mesh	Tianjin Changjie Chemical Co. Ltd.	Sodium Saccharin	0.21
Texapon OC-P	PT BASF Care Chemical Indonesia	Sodium Lauryl Sulfate	1.90
Optamint 698714	Symrise Asia Pacific, Singapore	Aroma (containing the following allergens that require listing on the label: eugenol, geraniol, limonene)	1.41

Note: there are allergens present which require declaration on the label

2. Physical/chemical characteristics of the product (reference methods are listed separately in the PIF file for this product)

Appearance/colour:	White free-flowing powder
pH:	8.0-9.5 (aqueous dispersion)
Bulk density:	850-900 g/l
Lather volume check:	190-200ml
Retention on 325 mesh:	<0.5%

3. Raw material specifications, impurities and hazard classifications
All raw materials are from recognized cosmetic, food or pharmaceutical ingredient suppliers. Purity and analytical specifications of raw materials are contained on the relevant Certificates of Analysis / Sales Specifications, which are held by the manufacturer / Responsible Person in the PIF file for this product. Technically unavoidable traces of prohibited substances or other toxic impurities, where likely for the ingredient in question, are discussed in Section 10 along with their toxicological significance, and legal or recommended limits detailed in Section 12. Raw material physical characteristics and suppliers' EU hazard classifications are given in the safety data sheets, which are held in the PIF file. Perfume IFRA certificates, EU safety data sheets, and allergens lists are also held in the PIF file.

4. Results of stability testing and shelf life information
No stability testing has been done but since it is >96% calcium carbonate powder there is no mechanism for deterioration. The product has been on sale for several years in Pakistan, without signis of deterioration

A shelf life of 36 months from date of manufacture is currently assigned to this product based on stability

testing, microbiological testing where relevant, the physical nature of the product, the type of packaging used, and experience with this and similar products in the market.

5. Microbiological quality / challenge testing
Microbial checks on each batch are done: TVC Bacteria <150cfu/g, TVC Yeasts & moulds <150cfu/g. Batch testing indicates <10cfu/ml is normally achieved.

Challenge test not required since product is essentially anhydrous and cannot support growth of micro-organisms. The product is used by dipping damp toothbrush into the pot. This will not generally add water to the container. However, if some moisture is added to the pot the absorptive properties of the calcium carbonate would help prevent it being a growth medium for microbiological organisms.

6. Normal and reasonably foreseeable use and pack directions
Use as a typical tooth powder. Pack directions: “Use with soft toothbrush”. Normally, the tooth brush head is dampened and pushed into the powder to absorb a quantity of the product. Alternatively, it could be sprinkled onto a damp brush head.

7. Packaging Information on product contact parts

Packaging Supplier
SS Enterprise, Pakistan

Primary packaging Styles and Sizes
90g bottle with flip top cap

Materials of manufacture
Polypropylene jar and HDPE cap

Details of packaging compatibility tests
No specific compatibility test has been done but no packaging stability issues have been seen after several years on the Pakistani market.

8. External exposure estimates used in this safety report

a. Oral Exposures

IFRA category	6
Intended consumer	Teenager / Adult 60kg
Wash off or leave-on	Rinse-off
Normal site of application	Teeth
Other reasonably foreseeable use	None
Amount of substance applied per use	2
Frequency of use	2/day
Retention factor	5%
Calculated daily exposure (g/day)	0.20
Relative daily exposure per kg of body weight (mg/kg bw/day)	**3.3**
Surface area of site of application (cm^2)	N/A
Relative daily exposure per cm^2 exposed area (µg/cm^2/day)	N/A

Note: Exposure estimates are taken directly from Tables 2 and 3 of SCCS Notes of Guidance (SCCS/1501/12) where the particular product category is listed, or are otherwise estimated using the Guidance and our experience. Relative daily exposure figures are not intended to be the absolute maximum that a user may experience but represent 90th percentile exposures in the population. More detailed arguments for the figures we use are available on request. Data for adults refers to adults and teenagers aged 12 and over. Where different consumer categories are given the highest relative daily exposure figure is used for margin of safety calculations.

b. Dermal Exposure

Dermal exposure is unlikely with this product. Accidental skin contact on rinsing out the mouth will contribute a much lower internal exposure than the oral figures used.

c. Inhalation Exposure

Inhalation exposure is unlikely with this product

9. Systemic Toxicity Data and Calculations of Margins of Safety

INCI name	% weight	Relative daily external exposure (mg/kg/day) (Note i)	Oral Absorption % (Note ii)	SED mg/kg day (Note iii)	Oral NOAEL (Note iv)	Reference in Section 10	Critical toxicity effect	Margin of Safety (Note v)
Calcium Carbonate	96.28	3.2	100	3.2	6250 (upper safe level)	1	hypercalcaemia / renal effects	2000 [MOE]
Sodium Lauryl Sulfate	1.9	0.063	100	0.063	100	2	liver toxicity	1600
Aroma	1.41	0.047	100	0.047	see note	3	not known	see note
Sodium Saccharin	0.21	0.0069	100	0.0069	500	4	possible bladder cancer at high levels - unproven and not classified as carcinogen (cat 1A, 1B, or 2) in EU	72000

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Notes to Table 9

(i) Relative daily exposure to product (from Section 8) x % in product

(ii) Dermal absorption usually assumed conservatively to be 50% in line with SCCS recommendations. Reasons and references for figures lower than 50% are given in Section 10. For lip and oral products the absorption figure is set to 100%.

(iii) SED=Systemic Exposure Dose = Relative daily exposure x Absorption

(iv) No Observed Adverse Effect Level in mg/kg/day in an animal model oral route, unless otherwise stated. See reference in Table 10 for further information

(v) Margin of Safety = systemic NOAEL divided by the SED. Systemic NOAEL = oral NOAEL corrected for an oral bioavailability factor. For products with predominantly dermal exposure this factor is normally set to 50% in line with SCCS recommendations. Where other oral bioavailability factors are used, this is given in the reference in Table 10. For lip and oral products we make no correction for oral bioavailability. A MOS figure of >100 is generally considered to be safe if the NOAEL is based on animal studies. MOE = Margin of Exposure based on known safe oral intake levels in humans; a value of >1.0 is generally considered to be safe. <TTC means systemic exposure is less than “Threshold for Toxicological Concern” of 0.0015mg/kg/day, which is the threshold for toxicity for chemicals of unknown systemic toxicity with no structural alerts for genotoxicity and not suspected to be neurotoxic via anti-cholinesterase activity, according to the EFSA 2011 Draft Opinion on the Concept of Threshold of Toxicological Concern. We have first made the judgement that the ingredient does not contain, or is unlikely to contain, any structural alerts for genotoxicity. Our TTC calculation also assumes a conservative dermal absorption of 25%.

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10. References and Reasoning for Toxicity Effects on each Ingredient

1 CI 77220 and Calcium carbonate: common opacifying agent and white pigment for colour cosmetics and abrasive agent for oral care. It is also an approved food colorant in the EU as E170 and a natural component of human tissues. EFSA revaluated its use as a food additive in 2011 (http://www.efsa.europa.eu/en/efsajournal/doc/2318.pdf) and confirmed that an ADI is not required due to its very low toxicity but reiterated the SCF 2003 safe human upper limit (UL) of 2500mg/day for calcium, based on possible hypercalcaemia / renal effects in humans taking high dose supplements. This is equivalent to 6250mg/kg/day as calcium carbonate. It is not classified as a skin or eye irritant. Due to its insolubility in water, alcohols and oils its dermal absorption will be very low, but we assume 1% for calculation purposes.

2 Sodium Lauryl Sulfate (sodium dodecyl sulfate): a common surfactant used in general cleaning and dishwashing products, as well as various cosmetics products, including toothpaste and cleansing. The US EPA 2009 risk assessment have used a NOAEL value of 100mg/kg/day based on a 28 day oral rat study reported in www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0041-0004, and a supporting rat 2 year dietary study at 100mg/kg/day. Target organ across the various studies was reported to be liver or kidney. An oral NOAEL of 55mg/kg/day was found in a 13 week rat study on sodium dodecyl sulfate reported in OECD SIDS for Alkyl Sulfates, Alkane Sulfonates and α-Olefin Sulfonates (2007) (http://webnet.oecd.org/Hpv/UI/handler.axd?id=c6c3b7c1-9239-40d9-b51a-85a15e2411d6). Higher doses were not tested so we apply the EPA figure of 100mg/kg/day. A dermal NOAEL of 400mg/kg/day was quoted in the OECD report, based on dermal rat study for 3 and 13 weeks treated twice weekly. The EPA summary quoted a developmental toxicity study in rats, rabbits and mice which found no effects below 600mg/kg/day. A 2-generation rat reproductive toxicity study on the related alpha olefin C12 sulfonate summairsed by the EPA found no effects up to 285mg/kg/day. They referenced carcinogenicity studies at 1.5% in diet which showed no increase in tumour formation. The EPA summarised that dermal absorption was found to be 0.3%, but they used a conservative value of 1% for their calculations. We will use a figure of 5%. The substance is classified by suppliers as a skin and eye irritant, with C&L notifiers stating it to cause serious damage to the eyes above 20%. The US CIR in 2005 (IJT 24(S1); 89-98) have summarised it as being safe as used in rinse-off products but should be limited to 1% in leave-on products due to its strongly irritating properties. All the summary reports state that it is not a skin sensitiser.

3 Synthetic flavours (aromas) are secret recipes so a NOAEL value cannot be derived. Instead, the safety of the aroma is assured in terms of systemic toxicity by reference to compliance with the IFRA standards for the appropriate category (IFRA category 1 or 6), including confirmation that all the components are food flavouring compliant, i.e. contain GRAS or FEMA or EC flavour numbered components only. We confirm that this aroma does indeed comply. As with many synthetic aromas, the 100% ingredient is potentially classified as a skin and eye irritant and skin sensitiser (GHS classification H315, H317, H319). Minimisation of the risk of skin sensitisation is assured by compliance with the IFRA standards. Though individual components such as certain citrus oils may be phototoxic, this is considered within the IFRA regulation framework and the overall aroma at the maximum percentage given for the product category does not present any risk of phototoxicity or photosensitisation. A recent IFRA certificate has been provided by the aroma manufacturer and we can confirm that it complies with the IFRA category of relevance to the product, given at the top of Table 8. It is filed along with this safety assessment in the PIF file for the product.

4 Saccharin, Sodium Saccharin: a widely used food flavour and widely used also in oral care products. A NOAEL of 500mg/kg/day is from 2-generation long-term feeding study in rats, and from long-term monkey studies, summarised in 1993 WHO (FAO/WHO 41st report) (whqlibdoc.who.int/trs/WHO_TRS_837.pdf). Manufacturers safety datasheets (e.g. from Sigma Aldrich) confirm it is not classified as hazardous and no local toxicity issues have been reported. There are reports of possible bladder cancer at high levels - but these are unproven and it is not classified as a carcinogen (cat 1A, 1B, or 2) in the EU.

11. Local Toxicity Data on 100% active ingredient

Corrosivity, skin irritation, eye irritation and skin sensitisation data in this table are based on GHS (Global Harmonised Standard) classifications under the EU CLP regulations. Our data is taken where possible from the REACH dossier for that entry or from harmonised classifications. Failing that, we consult expert reports from other government or inter-governmental bodies. Weight of evidence summaries in SCCS and CIR opinions are also used in preference to individual suppliers' data. In the absence of the above, we use suppliers' classifications where specific validated test methods are referenced on the safety data sheet, or take a majority view from notifications to the C&L inventory on ECHA. Where no official or documentary data on the substance exists, we perform other literature searches or we read across from similar substances. Due to the nature of cosmetics being in contact with the skin for extended periods of time we will often err on the side of caution and will categorise an ingredient as hazardous when it is below the threshold for classification under GHS, especially when there have been reports of adverse events in consumers. Skin photosensitivity is based on examination of the chemical structure, UV absorption data, suppliers' data if available, and broader literature searching. Mucous membrane irritation data is taken as the same as eye irritation potential.

INCI name	% weight	Corrosivity	Eye Irritation (H319) or worse	Serious eye damage (H318) or worse	Skin irritant (H315) or worse	Skin sensitisation	Photo-toxicity
Calcium Carbonate	96.28	-	-	-	-	-	-
Sodium Lauryl Sulfate	1.9	-	Yes	Yes	Yes	-	-
Aroma	1.41	-	Yes	-	Yes	Yes	-
Sodium Saccharin	0.21	-	-	-	-	-	-

Note to Table 11: "-" means no local toxicity issues known for the given end point.

12. Restrictions and compliance with the EU annexes

INCI name	% weight	EU annex restriction details
Calcium Carbonate	96.28	None, but good practice would be to use food additive grade. As CI 77220 it is an approved colour for all types of products. The grade used here is stated to be toothpaste grade and it is of high purity. It is manufactured by the PCC process, so the chance of contamination with heavy metals is low.
Sodium Lauryl Sulfate	1.9	None: but due to its strongly irritating properties, the US CIR say it should be at no more than 1% in leave-on products.
Aroma	1.41	Confirmation is assumed if compliant with IFRA regulations and by the fact that all components are food flavour listed.
Sodium Saccharin	0.21	none

Perfume compliance to IFRA regulations

% Perfume in product	IFRA class	IFRA regulations edition on certificate	Maximum % allowed on IFRA certificate	Maximum % allowed under EU regulations
1.41	6	47	7.75	1.15

13. Human and in vitro toxicity studies on the finished product

No formal human studies and no in vitro toxicity studies have been carried out on the finished product

14. Reported Adverse Events

Product was new to the market when the safety report was written

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PART B – Cosmetic Product Safety Assessment

1. Assessment Conclusion

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use, and the product composition complies with EC Regulation 1223/2009 and all its annexes.

Systemic toxicity, including reproductive / developmental toxicity:	No concerns
Carcinogenicity / Mutagenicity	No concerns
Skin sensitisation	No particular concerns based on skin sensitisation data from animal or human studies on individual ingredients and their concentrations in the product, but there is always a chance that an individual may have a rare reaction to a particular ingredient.
Skin / oral mucosa irritancy	No concerns
Eye irritancy	No particular concerns but any foreign matter in the eye will have a tendency to irritate.
Phototoxicity and photosensitisation	No concerns
Microbiological safety	No concerns
Impact of product stability on safety	No concerns
Packaging safety issues	No concerns
Formation of toxic materials via chemical reaction	No concerns
Potential physical/flammability hazards	No concerns

2. Safety assessor's warnings and specific instructions required for safe use

The following warnings are required on both the inner and outer packaging

No particular warnings required

It is assumed that instructions or use of commonplace product type names (e.g. "tooth powder") as described in section 6 of Part A are used. No particular extra instructions are required for the safe use of this product.

3. Reasoning

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

(a) Potential systemic toxic effects

Table 9 gives the margin of safety for each of the ingredients used. It takes into account all systemic toxicity end points including organ toxicity, reproductive and developmental toxicity, blood and metabolic effects, and carcinogenicity. The end point that drives the NOAEL or other repeat dose toxicity value is given in the critical toxicity effect column, and is usually derived from repeat dose animal studies. If none is written it means that no toxicity was seen at the highest dose tested. Dermal absorption is the main route of entry but the possibility of inhalation and ingestion has also been considered. All the ingredients

used are considered safe because they have a margin of safety (MOS) of 100 or over or, for ingredients for which safe levels in the human diet have been calculated, have a margin of exposure (MOE) of 1.0 or greater.

The lowest margin of safety in this product is for Sodium Lauryl Sulfate with a MOS value of 1600.

(b) Carcinogenicity / mutagenicity / reproductive toxicity (CMRs)
None of the ingredients as added have harmonised classifications in the EU as carcinogens, mutagens or reproductive toxins (class IA, 1B or 2 under GHS). For those ingredients that do not have a harmonised classification, none are considered to be mutagenic based on weight of evidence of in vitro studies or/and vivo studies.

(c) Potential skin sensitisation effects
The main causes of skin sensitisation in cosmetics are perfume ingredients, essential oils and perfuming absolutes, certain other non-perfuming plant extracts containing high concentrations of terpenes, some preservatives, some hair dyes, and some UV filters.

(c1) Potential skin sensitisation from perfumes, synthetic aromas, essential oils and absolutes: The International Fragrance Research Association (IFRA) has a series of regulations designed to prevent sensitisation to perfumes, essential oils and absolutes. The maximum concentrations of various ingredients for different types of cosmetic products (in %) are based on a NESIL value (No Expected Sensitisation Induction Level) in µg/cm^2 from weight of evidence of both human (e.g. RIPT) and animal (e.g. mouse LLNA) studies. The calculations include a safety factor (SAF) of between 30 and 300 including a factor of 10 for inter-individual variability, as summarised in "Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients, IFRA Technical Dossier 2006". For a few perfuming actives such as Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde (Lyral) this QRA method has not been undertaken due to lack of data, but provisional limits have been derived by IFRA based on other, e.g. epidemiological, evidence. For perfumes, we have checked the relevant IFRA certificate and confirmed that the concentration of perfume complies in this product. For essential oils, absolutes and hydrosols, we have checked the maximum likely level of any IFRA regulated components and sensitisers and we confirm that the product complies with the regulations.

(c2) Potential skin sensitisation from other ingredients: The use of preservatives, UV filters and hair dyes is controlled by the EU on Annexes VI and VII and all toxicity endpoints, including skin sensitisation, are taken into account before an ingredient is listed. This product complies with any maximum concentration restrictions imposed by the Annexes. For most other skin sensitisers (i.e. excluding essential oils and perfumes), the final product would not be considered a risk if the final concentration is less than 0.01%, which is the limit for classification under the CLP regulations. These levels are not exceeded in the product.

(d) Potential skin / oral mucosa / eye irritation effects
In the calculation method for classification of mixtures of chemicals under the EU CLP regulations irritation is not significant if the total concentration of individual ingredients classified as category 2 (the lowest hazard category) eye or skin irritants is less than 10% by weight. For leave-on skin-care products we would look for a total of less than 10%, but higher concentrations in rinse-off products can be tolerated on wet skin due to the immediate dilution effect. Dilution with water moderates potential skin irritation but eye irritation can still be serious if product is caught in the eye. The contribution from chemicals classified as

corrosive, or as capable of causing serious damage to the eye (H317), has to be taken into account, using higher weighting factors than category 2 irritants. The final pH is also important and the pH should normally be between 3 and 10 to avoid a GHS irritant classification. Some cosmetic ingredients are classified as irritants (or worse) just because of the pH of the pure ingredient but it would be neutralised in the final product, and this factor also has to be taken into account. The eye irritancy / eye damage classification of some surfactants is due to a combination of the inherent irritancy of the surfactant molecule and the high pH at which it is sold.

The total concentration of ingredients with a classification of irritancy or worse in Table 11 is 3.3%.

Based on the total concentrations of such ingredients and how the product is used, skin and eye irritation are not considered significant.

(e) Potential phototoxicity / photosensitisation
This is a rinse-off product so phototoxicity is not an issue.

(f) Microbiological safety
This product is anhydrous and cannot support growth of microorganisms, and every batch is tested for microbial contamination versus EU standards (SCCS/1501/12 section 4-4.2).

The bulk of the product is anhydrous calcium carbonate that will help to prevent free moisture being available for microbial growth in the container.

It is assumed that the manufacturer is following Good Manufacturing Practice and that microbiological contamination of the final product is being minimised.

(g) Impact of product stability on safety
Given the observations / testing on the product to date, and experience with this type of product, stability is considered satisfactory and is not detrimental in terms of safety.

(h) Impact of packaging on safety
No chemical incompatibilities are expected between the primary packaging material (PP/HDPE) and the product, and this material(s) is regularly used to package similar cosmetic products in the EU. No deterioration has been seen in the final packaging after several years on the market.

Since these types of polymers / materials are generally allowed as food contact packaging in the EU it is considered unlikely that toxic substances will migrate from the packaging to the product.

(i) Consideration of possible chemical reactions
Our examination of possible reactive groups and chemical types of ingredients in this product indicates that there are unlikely to be any chemical reactions taking place that will affect the overall safety conclusions. Formation of nitrosamines in this product is not possible.

4. Purity conditions

This assessment assumes that only cosmetic, pharmaceutical or food grade ingredients are used. Certain ingredients may 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. Such ingredients are indicated in Table 12 of Part A. Assuming any restrictions indicated in Table 12 are met, there are unlikely to be significant traces of prohibited substances or Annex III–restricted impurities in the final product, and heavy metals are likely to be below acceptable limits (we use the 2012 Health Canada "technically unavoidable" limits of lead 10ppm, arsenic 3ppm, cadmium 3ppm, mercury 1ppm, and antimony 5ppm as guidance).

5. General notes and conditions of this safety report

a. This safety report has been generated in edit-protected pdf format. It is not valid if any details are manually changed or the report is electronically scanned or altered in any way.
b. This safety report only fully complies with Annex 1 of EC1223/2009 if it is filed in conjunction with the certificates of analysis, IFRA certificates, and safety data sheets for each ingredient. These are provided by the ingredient suppliers. EF Chemical Consulting Ltd does not compile or attach this documentation and the Responsible Person should ensure they are filed together – or provide an electronic link to them.
c. Original versions of challenge test reports, stability testing reports and dermatological testing must also be filed alongside the safety report in the PIF file.
d. The assessment assumes that all other aspects of EC regulation 1223/2009 is being complied with, especially adherence to Good Manufacturing Practices (GMP).
e. Although this document is entitled "Cosmetic Product Safety Report" we do not make any reassurances that the product is considered to be a cosmetic under the EU Cosmetics Regulation. For borderline products we recommend you consult the relevant EU guidance documents and take independent advice.
f. This document does not confirm that we agree with any claims made about the product or implied in the product name. EF Chemical Consulting Ltd is not involved in cosmetic claims support.
g. This assessment applies only to the ingredients listed and the specific application state. 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, or if the same formula is used for a product with a different application.
h. If new undesirable events or "Serious Undesirable Events" are reported then this safety report will require updating.
i. We try to use the European INCI names as listed in the EU's cosing database in the assessments, but we do not guarantee it. Please use our labelling consultancy service if you are unsure of the correct ingredients list to be printed on the label along with the correct perfume sensitisers to be listed.
j. Except for the main preservatives and ingredients where the margin of safety is less than 110, this assessment is valid for concentration variations of +/- 10% of the declared percentage, to allow for manufacturing variations. For products containing water, this assessment is also valid for dilutions of the above formula with up to 5% water, as long as the preservative level is maintained at the same concentration in the finished product.
k. 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. Even if the substance has been registered it is possible that the registration doesn't cover its use a cosmetic ingredient. Importers into the EU of products containing botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions. We do not make these checks.

6. Name and signature of assessor

Dr Edmund Hartley Fowles MA, MRSC, CChem

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

Positions and qualifications

2006 to date	Independent consultant chemist, toxicologist and cosmetic safety assessor, Director of EF Chemical Consulting Ltd, Chester UK
2002–2006	Technical manager all UK cosmetics and coatings ingredients, Performance Chemicals Division, Innospec Inc. (formerly Octel Inc.)
2000-2002	Section manager Octel Inc., Ellesmere Port UK, anti-foam and coatings ingredients
1991-1999	Senior chemist Rockwood Pigments R&D (formerly Laporte Pigments), Widnes, UK and Turin, Italy: iron oxide pigments and clay additives for cosmetics, and other 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, USA, inorganic materials
1985-1988	PhD, Leeds University, UK: transition metal complexes and catalysis
1984-1985	Scientist, Amersham International, Bucks UK.
1981-1984	Cambridge University, Natural Sciences (chemistry), degree grade: 2:1.

Postgraduate experience and course work in toxicology of cosmetics

Feb 2012	Attended 6-day advanced course on “Safety Assessment of Cosmetics in the EU” under Professor Vera Rogiers at VUB Universiteit, Brussels and passed the final course exam
2007 to date	Carried out safety assessments in compliance with firstly EC76/768 then EC1223/2009, strictly following EU guidance (in SCCS 1416/11 and other SCCS publications). Includes assessments for many well-known UK high street and supermarket brands.
2007	Chemist member of HAZOP panel for a new pilot plant: risk assessments and calculation of exposure scenarios for toxic gas and liquid emissions and comparison with workplace exposure limits, minimisation of risk of explosive mixtures, discussion of start-up and shut-down procedures
2005	Research & organisation of appropriate in vitro eye and skin irritation tests to classify new cosmetic ingredients
2004	2-day in-house course on compilation of EU safety data sheets
2004	3-day course on classification of chemicals and mixtures according to the EU Dangerous Substances Directive / CHIP
2004	Organisation of in vivo irritancy testing on new surfactants
2003-2006	Responsible for development of new cosmetic ingredients, for which the safety issues were an intimate aspect of market acceptability. Responsible also for formulation work, so familiar with all aspects of making finished cosmetics
2000–2006	CHIP classification of new product mixtures and generation of EU safety data sheets
1997-2002	In charge of COSSH for successive R&D departments: calculation of worst case exposure scenarios and suitability of extraction equipment
1993-2006	As part of development and installation of new plant processes, organised batch quality control, raw material control, training and was involved in most aspects of Good Manufacturing Practice (GMP)
1996-1997	Process optimisation of pigment manufacture to ensure heavy metal content met cosmetic and EU toy requirements