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

Company ("Responsible Person")
Enzo (Cleaning products) Ltd

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Manufacturing company (if different to above)
Same as above

Manufacturing address (if different to above)
Same as above

Product code
Cov 001

Product name
Liquid Hand soap

Category of product
Liquid hand wash

Intended consumer group
All adults

Our reference
HA7865

Date of report
23 September 2013

Contents

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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 EC Guidelines to Annex 1 published 5th November 2012 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 Table 7. 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 referred to in Section 2.
2. Physical/chemical characteristics and stability of the cosmetic product	Relevant physical/chemical characteristics on raw materials are referred to in Section 2. Relevant physical/chemical characteristics of the finished product are given in Section 1. The overall stability and stability testing of the finished product are summarised in Section 3. The results of the preservative challenge test, where relevant for overall stability, is summarised in Section 4.
3. Microbiological quality	Summarised in Section 4
4. Impurities, traces, information about the packaging material	Raw material impurities are given in the certificates of analysis referred to in Section 2. 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. Relevant information on the packaging is given in Section 6.
5. Normal and reasonably foreseeable use	Summarised in section 5
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	Warnings are in Section 2, specific instructions of use relevant for safety are in Section 3
3. Reasoning	Section 4 and Section 5
4. Assessor's credentials and approval of part B	Assessor's credentials and confirmation of approval are given in Section 8. The date of approval is the date on the first page of the report

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PART A – Cosmetic Product Safety Information

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

Appearance/colour:	Opaque coloured viscous liquid
pH:	6.5-7.5
Viscosity:	8,000-14,000 cps

2. Raw material specifications and safety data sheets

All raw materials are from European cosmetic ingredient suppliers. Purity and analytical specifications of raw materials are contained on the Certificates of Analysis / Sales Specifications, which are held by the manufacturer / Responsible Person in the PIF file for this product. Raw material physical characteristics and suppliers' hazard classifications under CPL are given in the safety data sheets, which are held in the PIF file. Perfume IFRA certificates and allergens lists are also held in the PIF file.

3. Results of stability testing and shelf life information

Product has been tested for 3 months at RT dark, RT light, 30ºC, 37ºC, 45ºC & freeze/thaw and the manufacturer has concluded that it passes. The full report and results are filed with this safety assessment in the PIF file for this product.

A shelf life of at least 24 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.

4. Microbiological quality / challenge testing

Microbial checks on each batch are not done, and a challenge test has not been done. This product is a rinse-off hand wash so the risk to the consumer is low. It has a suitable preservative system (the MCIT/MIT is at about 1/3 the max allowable level), therefore a challenge test was not considered necessary.

5. Specific manufacturer's instructions / normal and reasonably foreseeable use

Use as a typical hand wash. Instructions: "Apply to hands agitate with water and rinse off"

6. Packaging Information

Packaging Supplier

Hooper Gibson (bottles) UCP (caps)

Packaging Styles and Sizes

5 litre HDPE container & cap (refill containers)

Materials of manufacture

HDPE

Details of packaging compatibility tests

No specific compatibility test has been done but no packaging issues have been seen after 1 year on the market.

7. Quantitative composition of the product

Trade name	Supplier(s)	INCI name	% by weight
LES 28	Surfachem	Sodium Laureth Sulfate (28%), Aqua	14
Surfac B4	Surfachem / Prime	Cocamidopropyl Betaine (30%), Aqua	3
Salt	Brentaag	Sodium Chloride	3
glycerine	Surfachem	Glycerin	1
Surfac CDE	Surfachem	Cocamide DEA	0.2
Linkcide KMC	Chemlink mixture	Methylchloroisothiazolinone / Methylisothiazolinone (3:1) (0.5-0.8%), Aqua	0.07
Cirrus 17	Surfachem	Styrene/Acrylates Copolymer	0.2
Surfac pearl 40	Surfachem	Sodium Laureth Sulfate (20%) Cocamidopropyl Betaine (1%) Glycol Cetearate (17%) Methylchloroisothiazolinone (0.0007%) Methylisothiazolinone (0.0003%) Aqua - balance	0.2
Citric acid	Surfachem	Citric Acid	0.01
Red Dye (Food Red 17)	Surfachem	CI 16035	0.009
aqua		Aqua	qs

8. Exposure estimates used in this safety report

a. Dermal Exposures

IFRA category	9A
Target consumer	Adult 60kg or children 15kg
Wash off or leave-on	Wash off
Site of application	Hand
Amount of substance applied per use	2g
Frequency of use	10/day
Retention factor	1%
Calculated daily exposure (g/day)	0.2
Relative daily exposure per kg of body weight (mg/kg bw/day)	**13.3**
Surface area of site of application (cm^2)	400
Relative daily exposure per cm^2 exposed area ($\mu g/cm^2$/day)	500

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.

b. Oral Exposure

Oral exposure is unlikely with this product

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 exposure (mg/kg/day) (Note i)	Dermal Absorption % (Note ii)	SED mg/kg day (Note iii)	NOAEL (Note iv)	Reference in Section 10	Critical toxicity effect	Margin of Safety (Note v)
Sodium Laureth Sulfate	3.96	0.53	100	0.53	225	1	none	430
Cocamidopropyl Betaine	0.902	0.12	50	0.060	214	2	none known	3600
Sodium Chloride	3	0.40	100	0.40	100 (Guideline daily intake)	3	Hypertension in high dose oral studies	250 [MOE]
Glycerin	1	0.13	100	0.13	10000	4	None	75000
Cocamide DEA	0.2	0.027	100	0.027	750	5	not known	28000
Methylchloroisothiazolinone / Methylisothiazolinone (3:1)	0.000562	7.5E-5	100	7.5E-5	2.8	6	Reduced water uptake / stomach irritation	37000
Styrene/Acrylates Copolymer	0.2	0.027	10	0.0027	1000	7	None	3.8E+5
Glycol Cetearate	0.034	0.0045	100	0.0045	1500	8	kidney and bladder toxicity	3.3E+5
Citric Acid	0.01	0.0013	100	0.0013	1200	9	Blood chemistry changes	9.0E+5
CI 16035	0.009	0.0012	100	0.0012	700	10	none	5.8E+5

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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 100%. Reasons and references for figures lower than 100% are given in Section 10

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

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

(v) Margin of Safety = NOAEL divided by the SED. A 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 levels in humans; a figure of less than 100 may be acceptable – see comment in Table 10. <TTC means systemic exposure is less than "Threshold for Toxicological Concern" of 0.0015mg/kg/day, which is the threshold for toxicity for non-genotoxic, non-neurotoxic chemicals according to the Cramer classification and EFSA 2011. This calculation assumes a conservative dermal absorption of 25%.

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10. References and Reasoning for Toxicity Effects on each Ingredient

1 Sodium Laureth Sulfate (SLES): Ubiquitous surfactant used in personal care and hand dishwashing products with ethoxylation number between 1 and 4 (typically between 2 and 3). NOAEL is highest dose tested in a 1994 90 day rat gavage study reported in the REACH dossier (http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ffa3b02-c2bb-2616-e044-00144f67d031/AGGR-6f2ad9ea-fd39-4c13-8c34-ebb4a259d362_DISS-9ffa3b02-c2bb-2616-e044-00144f67d031.html#section_1.1). No effects were seen at the highest dose. Reproductive and developmental toxicity studies also summarised on the REACH dossier confirm NOAELs of at least 300mg/kg/day. Anionic sulfated surfactants are normally quite irritating and supplier safety sheets generally classify 30% solutions of SLES as irritating to the skin and danger of serious damage to the eyes. Suppliers such as Cognis generally classify it as a serious eye irritant and a skin irritant.

2 Cocamidopropyl Betaine: Very widely used amphoteric surfactant, in both cosmetic cleaning products and in household cleaning products, used often in conjunction with SLES to reduce irritation potential of SLES. The toxicity is well summarised in the 2005 HERA assessment for this ingredient (http://www.heraproject.com/files/45-HH-E101023F-D12F-6A30-DEB0770E9BF8E4D0.pdf). The NOAEL is considered to be 1000mg/kg/day based on the highest dose tested in 28-day and 90-day oral rat gavage studies carried out by Henkel in 1991 using 30% solutions of the ingredient tested 5 days/week. This is equivalent to an overall NOAEL of 214mg/kg/day. The higher doses did give reversible forestomach lesions in the rats, which were considered a local irritant effect rather than a systemic effect. In vitro and in vivo mutagenicity tests were all negative. Foetal toxicity NOAEL has been measured as 286mg/kg/day in an OECD 414 5-19 day gavage study done in 2004. The only effects were reduced foetal weights. According to the HERA report, 30% solutions are classified as both skin and eye irritants whilst a 10% solution would not be classified as hazardous under GHS. However, the OECD 2006 SIDS initial assessment (http://webnet.oecd.org/hpv/ui/handler.axd?id=680f6bb5-102e-4f5f-a204-da86ab170aac) classifies the active material as an eye irritant but not a skin irritant. Since it is a charged water-soluble and fat-insoluble chemical, dermal absorption is expected to be very low but we assume it is a conservative 50% for calculation purposes. In the past, cases of skin sensitisation were reported due, according to HERA, to cocamidoamine and 3-dimethylaminopropylamine impurities, but reported cases are very low and modern grades are very low in these impurities (<0.3% total).

3 Sodium chloride: Common thickening agent for wash products and an impurity in many commercial surfactants. It is a natural component of the diet with a guideline daily intake in the UK of 6g/adult. This is equivalent to 100mg/kg/day. Only food grade sodium chloride should be used. At high concentrations it can cause a drying effect on the skin and it is classed in its pure form as a serious eye irritant (GHS classification H319).

4 Glycerin: Ubiquitous low toxicity ingredient in both cosmetics and the diet (from hydrolysis of fats) and an EU approved food additive in its own right (as E422). A NOAEL of 10000mg/kg/day is referenced in the OECD SIDS entry for glycerol (Feb 2002) based on a 1953 2 year oral animal study by Hine. There are no local toxicity issues with glycerin.

5 Cocamide DEA: foam booster and surfactant commonly used in rinse-off cosmetics. NOAEL is based on 28 day rat gavage study done by Henkel, referenced in IUCLID dataset in 2000 (http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/68603429.pdf). A 1-generation 1981 rat gavage developmental toxicity study also summarised under IUCLID found an NOAEL of >1000mg/kg/day. In common with many surfactants, it is a skin irritant with danger of serious damage to the eyes. Diethanolamine impurities can potentially cause carcinogenic nitrosamines to be formed in the presence of nitrating agents. This risk is controlled via compliance with the EU annex purity requirements and restrictions on its use: max 0.5% secondary amines/ethanolamines in finished product, maximum secondary amine content in raw material 5%, maximum nitrosamine content 50 ug/kg in raw material, do not use with nitrosating systems and keep in nitrite free containers.

6 Mixture of methylchloroisothiazolinone / methylisothiazolinone (3:1): Very common preservative mixture used in mostly in wash products. The NOAEL value is the one accepted in SCCS/1238/09, based on Rohm & Haas report no 96R-189 (1998) 2-generation reproductive toxicity in rats. The SCCS report summary confirms that high concentrations of the mixture are classified as corrosive and are probably a skin sensitiser. Human experience also indicates the mixture is a skin sensitiser.

7 Styrene/acrylates copolymer: Very widely used polymer in cosmetics as an opacifying agent and film former, and industrial grades are widely used in the adhesives, paints and inks markets. Skin absorption and bioavailability is expected to be very low due to its high molecular weight but we conservatively assign a value of 10% for calculation purposes. NOAEL is based on read across of results from 90 day oral rat study of high molecular weight cross-linked polyacrylates in rats (Lindenschmidt RC, Fundamental and Applied Toxicology, vol 17, Issue 1, July 1991 p128-135, abstract on http://www.sciencedirect.com/science/article/pii/027205909190245Y).

8 Glycol Cetearate: An emulsion stabilising and pearlising agent, not in common use in cosmetics, but chemically essentially the same as glycol distearate and glycol stearate which are commonly used, and their palmitate equivalents. It will tend to hydrolyse on the skin and in the body to low toxicity stearic and palmitic acids and to more toxic ethylene glycol. NOAEL is based on that of ethylene glycol given in the REACH dossier for glycol distearate which uses a NOAEL of 200mg/kg/day based on a 1986 2 year oral chronic toxicity / carcinogenicity rat study, with higher levels causing kidney toxicity and (according to another long term toxicity study under the REACH dossier for ethylene glycol) bladder toxicity (http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eb2cb3e-57e4-6c06-e044-00144f67d031/AGGR-40ab9913-5158-40ff-be02-81fc67e5b76f_DISS-9eb2cb3e-57e4-6c06-e044-00144f67d031.html#AGGR-40ab9913-5158-40ff-be02-81fc67e5b76f). Assuming an average ethylene glycol : stearate/palmitate ratio of 1 : 1.5, this gives a calculated NOAEL for ethylene glycol cetearate of 1500mg/kg/day. Glycol cetearate is not expected to have any local toxicity issues.

9 Citric Acid: Commonly used pH regulator in cosmetics and food and is an approved food additive in the EU (E330). It is also a natural component of many edible fruit and is a naturally occurring metabolite in humans. The NOAEL is derived from a 2 year rat study reported in the 2001 OECD SIDS summary for citric acid (http://www.chem.unep.ch/irptc/sids/OECDSIDS/77929.pdf). This report noted that normal daily intake can be up to 500mg/kg/day from combined diet and supplements. Like all small carboxylic acids, it is irritating to the skin and eyes in its pure form (classified as R36/37/38) but the irritancy effects are only due to the low pH and this is not a factor in most finished cosmetics.

10 CI 16035 (Curry Red): NOAEL from 2 year rat chronic and reproductive toxicity study (Borzelleca et al 1989), reported in SCCNFP/0791/04. No local toxicity effects are reported.

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11. Local Toxicity Data on 100% active ingredient

Skin/eye corrosion, skin irritation, eye irritation and skin sensitisation data in this table are based on GHS (Global Harmonised Standard) classifications. Our data is taken from the REACH register for that entry where test results are given for the specific substance in question. 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. Otherwise, we perform our own literature searches or we read across from similar substances. Skin photosensitivity is based on examination of the chemical structure, UV absorption data, suppliers' data if available, and broader literature searching.

INCI name	% weight	Corrosivity	Eye irritation	Skin irritation	Skin sensitisation	Photo-toxicity
Sodium Laureth Sulfate	3.96	-	Yes	Yes	-	-
Cocamidopropyl Betaine	0.902	-	Yes	Yes	-	-
Sodium Chloride	3	-	Yes	-	-	-
Glycerin	1	-	-	-	-	-
Cocamide DEA	0.2	-	Yes	Yes	-	-
Methylchloroisothiazolinone / Methylisothiazolinone (3:1)	0.000562	Yes	Yes	Yes	Yes	-
Styrene/Acrylates Copolymer	0.2	-	-	-	-	-
Glycol Cetearate	0.034	-	-	-	-	-
Citric Acid	0.01	-	Yes	Yes	-	-
CI 16035	0.009	-	-	-	-	-

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
Sodium Laureth Sulfate	3.96	none
Cocamidopropyl Betaine	0.902	none
Sodium Chloride	3	none
Glycerin	1	none
Cocamide DEA	0.2	Allowed with following restrictions: Max of 0.5% secondary amine in finished product, raw material spec of <5% secondary amine, nitrosamine <50ug/kg, do not use with nitrosating systems, and store in nitrite free containers. Surfac B4 complies.
Methylchloroisothiazolinone / Methylisothiazolinone (3:1)	0.000562	Approved preservative mixture: max 0.0015% (15ppm) of mixture of 3:1 MCIT/MIT. Expected to be banned in leave-on products in the near future.
Styrene/Acrylates Copolymer	0.2	none
Glycol Cetearate	0.034	none
Citric Acid	0.01	none
CI 16035	0.009	Approved colour for all types of cosmetic product. Must comply with purity requirements of E129.

13. Human studies on the finished product

No formal human studies have been carried out on the finished product

14. Reported Adverse Events

No adverse events reported since launch in 2012

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 irritancy	No concerns
Eye irritancy	Like all wash product containing surfactants or soaps the product will tend to irritate the eye if not washed out but no warning is required since the product is not used near the eyes.
Phototoxicity and photosensitisation	No concerns
Microbiological safety	No concerns
Impact of product stability on safety	No concerns
Packaging safety issues	No concerns

2. Safety assessor's warnings

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

No particular warning required.

3. Specific instructions required for safe use

It is assumed that instructions or use of commonplace product type names (e.g. "shampoo") as described in section 5 of Part A are used. No particular extra instructions are required for the safe use of this product.

4. Reasoning

This type of liquid hand soap 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. 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 SLES with a MOS value of 430.

(b) Carcinogenicity / mutagenicity
None of the ingredients are confirmed or suspected to be carcinogens, mutagens or reproductive toxins (class IA, 1B or 2 under GHS). Based on weight of evidence of in vitro studies, and in vivo studies where appropriate, none of the ingredients are considered to be mutagenic.

(c) Potential skin sensitisation effects
The main causes of skin sensitisation in cosmetics are perfume ingredients, essential oils, certain preservatives, certain hair dyes, and certain UV filters.

(c1) Potential skin sensitisation from perfumes, synthetic aromas, essential oils and absolutes: There are no such ingredients in this product.

(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 accounts before an ingredient is listed. This product complies with any restrictions imposed by the Annexes. For most skin sensitisers, the final product would not be considered a risk if the final concentration is less than 0.1%. These levels are not exceeded in the product (excluding any essential oils and perfumes).

(d) Potential skin / eye irritation effects
Total concentration of irritant ingredients = 8.2%.
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. For leave-on skin-care products we would look for a total of less than 10%. 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 and how the product is used, skin irritation is not considered significant but the product will have a tendency to irritate the eye if left in.

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

(f) Microbiological safety
No challenge test has been carried out but the microbiological risk to the consumer is low for such a hand wash and the product is preserved with a preservative system that normally works well in such a formula.

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.

5. Packaging assessment

No chemical incompatibilities are expected between the packaging material (HDPE) and the product, and this material(s) is regularly used to package foods in the EU. No deterioration has been seen in the final packaging after 12 months on the market.

6. 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.

7. General notes and conditions of this safety report

a. This safety report 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.
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. 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.
f. If new undesirable events or “Serious Undesirable Events” are reported then this safety report will need updating.
g. 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.
h. Except for the main preservatives, this assessment is valid for concentration variations of +/- 10% of the declared percentage, to allow for manufacturing variations. Also, for products containing water, this assessment is 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.
i. 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.

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8. 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

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