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 most wash product containing surfactants or soaps the product will tend to irritate the eye if not washed out and an appropriate warning is required.
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 (similar wording with equivalent meaning would be acceptable)

Avoid getting into the eyes.

It is assumed that instructions or use of commonplace product type names (e.g. "foam wash") 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 hand wash 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 Laureth Sulfate with a MOS value of 1900.

(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 $\mu g/cm^2$ 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 hazard identification under the CLP regulations. These levels are not exceeded in the product.

(d) Potential skin / 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 (H318), 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 8.8%.

Based on the total concentrations of such ingredients 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
An appropriate preservative challenge test has been carried out and has passed, and every batch is tested for microbial contamination.

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, PE, nylon) and the product, and this material(s) is regularly used to package similar cosmetic products in the EU. No deterioration has been seen with very similar products in the same 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 stated. 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

EF Chemical Consulting Ltd
17 Kings Crescent East, Chester, CH3 5TH, UK
Tel (+44) 01244-351644,
email: edmund@efchemicalconsulting.co.uk
web: http://www.efchemicalconsulting.co.uk
Registered in England and Wales - Registered Number 7348632

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

EF Chemical Consulting Ltd
17 Kings Crescent East, Chester, CH3 5TH, UK
Tel (+44) 01244-351644,
email: edmund@efchemicalconsulting.co.uk
web: http://www.efchemicalconsulting.co.uk
Registered in England and Wales - Registered Number 7348632