

Company ("Responsible Person")
The Aftercare Company

Contact person
Shirley Jaffrey

Company address
No2 Moorcroft Mews, High St, Saltney, Chester, CH4 8SH

Contact telephone number
01244-678766

Country of origin and manufacturer if outside EEA

Product code
THC02

Product name
BPA Body Piercing Aftercare

Category / application of product
Oil for use following piercing – not
for use on tongue or genitals

Our reference
HA714

Date of assessment
11th October 2010

I certify that the formulation referred to above, with the composition as given below, is safe for use in the stated application, and complies with the EU Cosmetics Directive 76/768/EEC(4) and the UK Cosmetic Products (Safety) Regulations 2008, as amended.



Dr Edmund Hartley Fowles, BA, CChem, MRSC

INCI name / common name	% by weight	EFC safety code
Helianthus Annuus Seed Oil	Max 100%	F1
Tocopheryl Acetate	Max 2%	C1
Essential oils: any combination of the following up to a total maximum of 2.0%		
Lavandula Angustifolia oil		IFR-1
Melaleuca Viridiflora Leaf oil		IFR-1
Melaleuca Alternifolia Leaf oil		IFR-1

Notes:

1. This assessment applies to products 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. This formulation has not been assessed for children under 3.
4. 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.
5. The safety of a cosmetic product is also dependent on its microbiological quality and it's up to the manufacturer / Responsible Person to have systems in place to control it. EU guidelines from COLIPA are that the maximum number of organisms is <1000cfu/g, and <100cfu/g for products used in the vicinity of the eyes. Also, the following organisms should be absent in a 0.1g sample (0.5g sample for products used around the eyes): Pseudomonas Aeruginosa, Staphylococcus Aureus, Candida Albicans. For products containing water it is strongly recommended that the product pass a preservative challenge test.
6. It is assumed that cosmetic, food, or pharmaceutical grade ingredients are used wherever they are commercially available.
7. Except where a maximum percentage is specifically stated, or where a maximum – minimum range is given, this assessment is valid for concentration variations of +/- 20% 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 water, as long as the preservative level is maintained at the correct concentration.

How this assessment was made

This assessment was made taking into account the safety profile of each individual ingredient, its concentration, and the intended use of the finished product, especially whether it is intended to be left on the skin or rinsed off. Particular credit is given to ingredients which are in current widespread use and have a long history of being used in cosmetics without safety concerns. Ingredients are considered based on literature and structural chemistry for their potential to be irritants, skin sensitisers or photo-sensitisers, and they are also considered for their potential systemic and oral toxicity. The potential for skin absorption is also considered. Summaries of the safety profile of each ingredient and any limitations of use prescribed by the EU Cosmetics Directive, IFRA or other national regulatory authorities outside the EU are held on EF Chemical Consulting Ltd's databases.

Safety codes

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.

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

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.

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. Avoid use around eyes and lips.

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 be 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 be 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.

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 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 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.

Ann: Listed in either Annex 5, 6, or 7 of the EU Cosmetic Safety Regulations 76/768/EEC, and used in line with the stated limits

Sp: Special comment – see below:

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

- 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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