PART A – Cosmetic Product Safety Information

Company ("Responsible Person")
Funky Eyes Ltd

Contact person
Bob Tanda

Company address
Unit 2 Belvoir Court, Belvoir Way, Louth, Lincolnshire, LN11 0UD

Contact telephone number
01507-605777

Company Registration number
6777380

Product code

Product name
Accessor Eyes range

Category / application of product
Cosmetic eye accessories designed to change the appearance of the eye, packed in buffered saline. Kit also contains instructions, holder, and all-in-one cosmetic cleaner. Intended for occasional use only.

Our reference
HA1831

Date of report
6th December 2011

I certify that these fashion eye accessories are cosmetic in nature only and are therefore not medical devices or contact lenses / optical appliances (zero powered or otherwise) for the purposes of the Opticians Act 1989, as amended, and would instead be classed as a cosmetic product under the UK Cosmetic Products (Safety) Regulations 2008, as amended. I certify that this product is safe for use in the stated application. I also certify that the composition of the product complies with the EU Cosmetics Directive 76/768/EEC(4), the EU Cosmetics Regulation 1223/2009, and the UK Cosmetic Products (Safety) Regulations 2008, as amended, on the assessment date.

1. Physical/chemical characteristics of the product
The eye accessories are of a conic shape in order to be fitted over the eyes, and are made of a soft cosmetic-grade polymeric plastic. They consist of a polymer blank and coated on the convex side with decorative colours and patterns. They are stored in sterile sealed vials containing buffered saline. After first use they are to be transferred to the plastic holder and soaked in the cosmetic cleaner. The main polymeric component of the eye accessories contains about 55% water, which equilibrates with whatever solution they are being stored in.

2. pH
Buffered saline: pH 7.1-7.5. Cosmetic cleaner: pH 7.2-7.6

2. Results of stability testing
Funky Eyes have provided extensive data that the eye accessories have a >30 month shelf life before opening of the vials. The tests performed were: dimensions, defects, optical transmittance, sterility, and adherence of the colour coating. No significant changes were found over a 3 year period.

The all in one cosmetic cleaner solution is given a 30 month shelf life but has not specifically undergone stability testing or microbiological challenge testing. However, the recipe used is identical to one that is used in the contact lens industry that had undergone the appropriate testing. The preservative in the cosmetic cleaner has recently been changed to Polyaminopropyl Biguanide in line with that used in the contact lens industry. The concentration used is as recommended by the manufacturers of the preservative as sufficient for this type of cleaner.

The use after opening period of the eye accessories is 30 days. This is based on usual guidelines in the contact lens industry using similar polymers and cleaner solutions. The cosmetic cleaner has been given a 6 month use after opening period based on identical recipes used in the contact lens solution industry and as recommended by the preservative manufacturer. It is the main factor in deciding the disposal period for the eye accessories and there is a wide safety margin.

3. Microbiological quality

Dr E Fowles visited the site on 5th December 2011 and audited the manufacturing and sterilisation procedures. Manufacturing is carried out to Good Manufacturing Practice and is following and audited against ISO13485 “Medical Devices – Quality management systems – requirement for regulatory purposes” and ISO 9001. The manufacturing is carried out in a dedicated clean room zone fitted with US FED-STD-209E class 10000 air circulation to minimise contamination. The crimped vials are sterilised to Standard ANSI/ISO 17665 “Sterilisation of Health Care Products by Moist Heat” in an autoclave at around 121°C for 15 minutes, and the autoclave is calibrated annually in accordance with the Standard (currently by LTE Scientific Ltd). This sterilisation procedure is well-known to give a microbiological quality of <1 cfu/ml and previous tests by the company have confirmed that this is the case in their process. Previous tests have also confirmed that sterility is maintained for >3 years in the unopened vials.

Microbiological testing is not currently done routinely but the company intend in 2012 to start 3-monthly bio-burden tests on finished product vials.

The cosmetic cleaner is manufactured by a third party. Its microbiological specification is <1 cfu/ml.

4. Impurities and information about the packaging material

Eye accessories are stored in buffered saline in clinical grade glass vials, sealed with silicone rubber seal and crimped with a metal cap. The silicone rubber seals are of the same type and quality approved for the contact lens industry. The cosmetic cleaner is stored in clinical grade HDPE.

5. Normal and reasonably foreseeable use / instructions

Full instructions are enclosed in the kit. The accessories are to be placed in the eye in the same way as soft contact lenses. The coloured side may contact the mucous membranes of the eye transiently but will normally not be in contact. Instructions after opening are to soak the accessories in the cosmetic cleaner in the holder, then to dispose within 30 days of opening. The instructions on the cosmetic cleaner are to dispose within 60 days. It is expected that the majority of consumers will use once then throw away. It’s possible that some consumers might

ignore the 30 day disposal date by a few days. But the 30 day disposal date is well-known in the general population for corrective soft contact lenses stored in all-in-one lens cleaner, so non-compliance is expected to be rare.

6. Exposure estimates used in this safety report

Intended Consumer	Teenagers and adults 50kg+
Site of application	Eyes
Likely routes of exposure	Mucous membranes and dermal only
Amount of substance applied per use	Polymer pigment and binder components: practically zero. Saline or cosmetic cleaner solution: 50mg
Wash off or leave-on	Leave-on
Frequency of use	1/week (0.14/day)
Retention factor	100%
Calculated daily exposure	Polymer pigment and binder components < 1ug/kg/day, saline or cosmetic cleaner solution: 140ug/kg/day
Exposure estimates calculated by:	E Fowles, based on SCCNFP/0321/02

7. Quantitative composition of the product and compliance with EU annexes

(a) Eye accessories

Part that contacts the mucous membranes of the eye (concave side) has the tradename Methafilcon A and consists of a copolymer of Hydroxyethylmethacrylic acid and Polymethacrylic acid, cross-linked with Ethylene Glycol Dimethacrylate.

The printed convex side that is not normally in contact with the mucous membranes consists of:

70-85%: Hydroxyethylmethacrylic Acid Carbodiimide Crosspolymer
15-30%: EU Cosmetic or medical device grade pigments from the following list:

- CI 51319 (Pigment violet 23 / Carbazole Violet)
- CI 77288 (Chromium oxide greens)
- CI 74160 (Copper phthalocyanine, Pigment blue 15)
- CI 77489 / CI 77491/CI 77492/CI 7749 (Iron oxides)
- CI 77891 (Titanium dioxide)

Compliance:
All pigments listed are on Annex IV of 76/768. CI 51319 is only approved for applications involving limited exposure. This applies in this case because the pigment is present at the polymerisation stage and is chemically bound into the polymer. Also, it is not in normal contact with the membranes of the eye.

(b) Cosmetic cleaner Solution

INCI name / common name	% by weight
Pharmaceutical grade water	98.46%
Sodium chloride	0.7%

Boric acid	0.57%
Sodium Tetraborate Decahydrate	0.058%
Poloxamer 407 (Lutrol F127 from BASF)	0.15%
Hydroxypropyl methyl cellulose	0.05%
Disodium EDTA	0.01%
Polyaminopropyl Biguanide 20% solution (Cosmocil CQ from Arch)	0.0009%

Compliance:
Total borates according to Annex III of 76/768 must be <3%. The product complies.
Polyaminopropyl Biguanide is listed on Annex VI of 76/768 at maximum 0.3%. The product complies.

8. Systemic Toxicity and Margins of Safety

(a) Eye accessories
The part of the product contacting the eye is a high molecular weight ophthalmic quality polyacrylate copolymer with expected skin absorption of practically zero. It is widely used in contact lenses over many years with no reported problems. NOAEL for this material is high and estimated as 3000mg/kg/day (based on Sub-chronic (90 day) oral study of high molecular weight cross-linked polyacrylates in rats, Lindenschmidt RC, Fundamental and Applied Toxicology, vol 17, Issue 1, July 1991 p128-135.).

Margin of Safety >>1000.

Rub tests and methanol extraction tests confirm that the pigment will not be extracted from the convex side during normal use so the toxicity of the coloured side does not need to be considered. However the pigments used are all low toxicity approved cosmetic grade pigments and the polymer is a high molecular weight cross-linked polymer that will have negligible systemic absorption.

(b) Cosmetic cleaner solution
By far the most toxic components are the borate salts which have NOAEL of 9.6mg/kg/day (=9600ug/kg/day) as boron based on reproductive toxicity studies (in SCCS/1249/09).

Daily systemic exposure to borate (assuming 100% absorption) = 0.63%x140ug/kg/day = 0.88ug/kg/day

Concentration of boron in borates = 19%

Daily systemic exposure to boron = 0.88 x 19% = 0.16ug/kg/day

Margin of Safety = 9600/0.16 = 58,000

9. Local Toxicity Effects
No ocular irritation or skin sensitisation is expected from the eye accessories, the saline buffer or the cosmetic cleaner solution. The eye accessories are made of high molecular weight polymer of a type that is commonly used in contact lenses. The cosmetic cleaner solution is 98.5% water and is of a type commonly used in the contact lens industry. The only potentially irritant compound (the preservative) is present at very low concentration.

10. Human studies on the finished product

No human studies have been carried out on the finished product

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11. General Notes to the Manufacturer / Marketer (some might not be relevant for the above product)

1. This assessment applies to products manufactured, sold or marketed by the company named above as the responsible person. It cannot be transferred or sold to third parties, except with the agreement of EF Chemical Consulting Ltd.
2. This assessment applies only to the ingredients listed. A new assessment will be required if a raw material is substituted with a different INCI name, a different colour, or a different perfume or essential oil.
3. 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 recognized preservative challenge test.
6. It is assumed that cosmetic, food, or pharmaceutical grade ingredients are used wherever they are commercially available.
7. Except for the main preservatives, this assessment is valid for concentration variations of +/- 20% of the declared percentage, to allow for manufacturing variations, as long as the margin of safety for the ingredient is 120 or greater. Also, for products containing water, this assessment is valid for dilutions of the above formula with water, as long as the preservative level is maintained at the same concentration. The assessment is also valid if ingredients are reduced or taken out as long as the missing percentage is replaced by water or an edible vegetable oil (or jojoba oil) that is already listed.
8. In supplying this safety assessment EF Chemical Consulting Ltd makes no assurances that the individual substances or ingredients are registered or exempt under REACH. This is not usually an issue if the ingredient is sourced within the EU, but importers into the EU are warned that REACH notification rules apply once the annual imported quantity of a particular substance aggregated over all their products exceeds 1 TPA. Importers into the EU of products containing any botanical ingredients derived from endangered species should also make themselves aware of any CITES restrictions. We do not make these checks.

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PART B – Cosmetic Product Safety Assessment

Assessment Conclusion
The product is safe for use in the stated application, and complies with EC Regulation 1223/2009, the EU Cosmetics Directive 76/768/EEC(4), and the UK Cosmetic Products (Safety) Regulations 2008, as amended.

Required warnings and instructions for use
Full instructions for use must be included. These should detail fitting, removal, storage and cleaning, disposal after 30 days of opening, and contra-indications.

Reasoning
The polymeric body of the eye accessories is of a common type used in contact lenses over many years. The coloured side consists of a similar high molecular weight polymer and cosmetic-grade pigments, but in normal use, these will not be exposed to the mucous membranes.

The area of most concern is microbiological contamination. But Funky Eyes have robust sterilisation procedures in place and testing has confirmed that sterility is maintained. The all in one cosmetic cleaner solution provided is of a type that is commonly used in the industry to keep contact lenses safe to use for up to 30 days after opening.

Systemic toxicity and local toxicity effects are negligible. Margins of safety are much greater than 100.

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

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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