Research & Management Consultancy

Partners: M. C. Perry B.Sc.(Hons), C.Biol., MSB., M.T.O.P.R.A. R. G. Perry

Consultants to the Pharmaceutical, Chemical and Allied Industries

R & M Consultancy
Sterling House
3A New Street
Ledbury
Herefordshire
HR8 2DX UK

Telephone +44 (0)1531 635008
Facsimile +44 (0)1531 634844

E-mail: enquiries@rm-consult.co.uk
Web site: www.rm-consult.co.uk

Shampoo safety assessment

This Safety Assessment is for a GK Hair Taming System with Juvexin silver shampoo cosmetic product formulation dated 6 March 2013.

Part A

Cosmetic Product Safety Information

1 Quantitative and Qualitative composition

INCI	CAS	EINECS	Function	%
Aqua	7732-18-5	231-791-2	Solvent	75-100
Sodium C14-16 olefin sulfonate	68439-57-6	270-407-8	Surfactant	10-25
Cocamidopropyl hydroxysultaine	68139-30-0	268-761-3	Antistatic/ foam boost	1-5
Disodium cocoamphodiacetate	-	931-291-0	Surfactant/ foam boost	1-5
Methyl gluceth-20	68239-42-9	-	Humectant	0.1-1
Parfum	-	-	Fragrance	0.3
Polyquaternium-7	26590-05-6	-	Antistatic	0.1-1
Glycol distearate	627-83-8	203-886-9	Emollient/ emulsifier	0.1-1
Polyquaternium-10	81859-24-7	617-262-2	Antistatic	≤0.1
PEG-150 pentaerythrityl tetrastearate	-	-	Emulsifier	≤0.1
PEG-6 caprylic/capric glycerides	-	-	Emulsifier	≤0.1
Panthenol	81-13-0	201-327-3	Antistatic	≤0.1
CI 60725	81-48-1	201-353-5	Colourant	≤0.1
Keratin	68238-35-7	269-409-1	Hair Conditioner/ Humectant	≤0.1
Citric acid	77-92-9	201-069-1	Buffer	≤0.1
Guar Hydroxypropyltrimonium Chloride	65497-29-2	-	Antistatic/ film former/ viscosity controller	≤0.1
Disodium ETDA	139-33-3	205-358-3	Chelator	≤0.1
Methylchloroisothiazolinone	26172-55-4	247-500-7	Preservative	0.001125
Methylisothiazolinone	2682-20-4	220-239-6	Preservative	0.000375
Benzyl benzoate	120-51-4	204-402-9	Preservative	≤0.1

2 Physical/chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of substances or mixtures.

The individual ingredients are purchased against an agreed specification and are supplied with a certificate of conformity to that specification. The physical/chemical specification of the ingredients are well known and commonly used in similar products. Their inclusions in the finished product at the specified concentrations do not give rise to any concerns.

There are no nanomaterials present in the finished cosmetic product either by design or as accidental byproducts of the manufacturing processes.

2.2 Physical/chemical characteristics of finished cosmetic product

The physical/chemical characteristics of the finished cosmetic product are confirmed against an in-house specification. There are no novel characteristics and the finished product is similar to other cosmetic products currently marketed

2.3 Stability of cosmetic product
Stability studies where colour, odour, appearance, pH and viscosity were recorded at various times up to 3 months on samples stored at room temperature or 45°C/75%RH support a shelf life of 24 months and a Period After Opening of 24 months.

3 Microbiological quality

3.3.1 Microbiological quality of substances or mixtures
The microbiological quality of the ingredients conforms to the agreed specification and stated on the certificate of conformity.

3.2 Microbiological quality of finished cosmetic product
The finished product meets or exceeds the requirements of microbial testing (USP 29) .

4 Impurities, traces, package information

4.1 Purity of substances or mixtures
A statement has been provided by the bulk manufacturer that verifies that the cosmetic product does conform with the cosmetic Directive 76/768/ EC and any presence of traces of substances is within the allowed limits.

The ingredients in the formulation do not indicate any potential interactions that may result in unintended impurities being present in the finished cosmetic product.

4.2 Evidence of technical unavoidability of traces of prohibited substances
There is no evidence of traces of prohibitive substances and none would be expected to be present in this formulation. All finished cosmetic products are manufactured according to Good Manufacturing Practice (GMP) with GMP certificates on file.

4.3 Relevant characteristics of package information
The product is presented as a 300ml polyphenylene oxide bottle and polypropylene cap.

The immediate packaging used for the finished cosmetic product has been previously used for similar formulation without any reported problems.

5 Normal and reasonable foreseeable use

The finished cosmetic product is intended for use as a shampoo. It is therefore expected to be applied to the skin.

6 Exposure to the cosmetic product

SCCS Notes of Guidance 7th Revision [SCCS/1416/11] quotes an estimated daily amount of shampoo applied to be 10.46g. With a retention factor of 0.01 (ie rinse off) the calculated daily exposure is 0.105g /day and the calculated relative daily exposure is 1.74mg/kg bodyweight/day based on a human bodyweight of 60kg.

7 Exposure to the substances

As stated above, based on the assumption that 0.105g of shampoo is applied daily, the table below gives the equivalent daily application values for each ingredient both as mg/day and mg/kg bodyweight/day.

INCI	%	Equiv daily application *	
		(mg)	(mg/kg bodyweight/day)
Aqua	75-100	105	1.7500
Sodium C14-16 olefin sulfonate	10-25	26.25	0.4375
Cocamidopropyl hydroxysultaine	1-5	5.25	0.0875
Disodium cocoamphodiacetate	1-5	5.25	0.0875
Methyl gluceth-20	0.1-1	1.05	0.0175
Parfum	0.3	0.315	0.0053
Polyquaternium-7	0.1-1	1.05	0.0175
Glycol distearate	0.1-1	1.05	0.0175
Polyquaternium-10	≤0.1	0.105	0.0018
PEG-150 pentaerythrityl tetrastearate	≤0.1	0.105	0.0018
PEG-6 caprylic/capric glycerides	≤0.1	0.105	0.0018
Panthenol	≤0.1	0.105	0.0018
CI 60725	≤0.1	0.105	0.0018
Keratin	≤0.1	0.105	0.0018
Citric acid	≤0.1	0.105	0.0018
Guar Hydroxypropyltrimonium Chloride	≤0.1	0.105	0.0018
Disodium ETDA	≤0.1	0.105	0.0018
Methylchloroisothiazolinone	0.001125	0.0012	0.0001
Methylisothiazolinone	0.000375	0.0004	0.0001
Benzyl benzoate	≤0.1	0.105	0.0018

* based on the top range value

Several of the ingredients have restrictions on their maximum concentration in the final product:-

Ingredient	% in final product	Max permitted	Complies
Methylchloroisothiazolinone	0.001125	0.0015	Yes
Methylisothiazolinone	0.000375	0.0005	Yes
Benzyl benzoate	≤0.1	0.5 (as acid)	Yes

The body's exposure to the remaining ingredients can be calculated based on the estimated daily application of 0.105g of shampoo. In the absence of absorption data the assumption is made that 100% is absorbed, representing a worst-case scenario.

8 Toxicological profile of the substances

8.1 General considerations on Toxicological Profile as part of the Safety Assessment

The exposure to the ingredients has been discussed in section 5, 6 and 7 above.

The toxicological profile of this formulation is similar to many cosmetic products with well-known ingredients and none of the ingredients are novel.

There are specific restrictions on the concentration of some of the ingredients as listed in 7 above.

8.2 Toxicological profile of substances for all the relevant toxicological endpoints

There are no toxicological concerns with the ingredients and their presence.

8.3 Consideration of all the significant routes of absorption

As the product is applied to the skin, the main route of absorption will be dermal.

No other routes apply when used as intended.

8.4 Consideration of systemic effects and calculation of the margin of Safety

INCI Name	Conc (%)	Dermal absorption (%)	SED (mg/kg bodyweight/day)	MoS
Aqua	75-100	100	1.7500	nc
Sodium C14-16 olefin sulfonate	10-25	100	0.4375	2,285
Cocamidopropyl hydroxysultaine	1-5	100	0.0875	nc
Disodium cocoamphodiacetate	1-5	100	0.0875	nc
Methyl gluceth-20	0.1-1	100	0.0175	285,714
Parfum	0.3	100	0.0053	Within IFRA statement limits
Polyquaternium-7	0.1-1	100	0.0175	57,142
Glycol distearate	0.1-1	100	0.0175	571,428
Polyquaternium-10	≤0.1	100	0.0018	277,777
PEG-150 pentaerythrityl tetrastearate	≤0.1	100	0.0018	nc
PEG-6 caprylic/capric glycerides	≤0.1	100	0.0018	nc
Panthenol	≤0.1	100	0.0018	555555
CI 60725	≤0.1	100	0.0018	nc
Keratin	≤0.1	100	0.0018	nc
Citric acid	≤0.1	100	0.0018	1,666,666
Guar Hydroxypropyltrimonium Chloride	≤0.1	100	0.0018	5,555,555
Disodium ETDA	≤0.1	100	0.0018	555,555
Methylchloroisothiazolinone	0.001125	100	0.0001	Within SCCP max permitted concentration
Methylisothiazolinone	0.000375	100	0.0001	Within SCCP max permitted concentration
Benzyl benzoate	≤0.1	100	0.0018	Within SCCP max permitted concentration

nc Not calculated

The margin of safety (MoS) is calculated as:-

$MoS = \frac{NOAEL}{SED}$	Where MoS - margin of safety NOAEL - No observable adverse effect level SED Systemic Exposure Dosage

A MoS of 100 or more indicates a reasonable margin on safety for each ingredient.

All MoSs, where calculable, were in excess of 100

It is therefore considered unlikely that there would be any systemic effects for the product user.

8.5 Impact on the toxicological profile of certain characteristics of the substances or the product

The impurity profile of the ingredients is well documented, the ingredients are well-known and have been extensively used in a range cosmetic products for several years.

It is therefore considered that the toxicological impact of the ingredients or the finished product is negligible.

8.6 Use of read-across should be substantiated and justified

In previous years similar formulations have been marketed using the same or very similar product formulation. The formulations are sufficiently similar to allow “read-across” of safety data.

8.7 Identification of the sources of information

Safety data has been obtained from SCCS opinions, the use of European Commission database, CosIng, internet-based databases such as PubMed, TOXLINE, MEDLINE, RTECS and from data supplied by ingredient and product manufacturers.

9 Undesirable effects and serious undesirable effects

Systems are in place to record and collate any and all reports of adverse events. These will be listed and supplied to the safety assessor in a regular manner and this safety assessment may be revised in the light of these adverse event reports.

No adverse events have been reported for similar formulations over the last 12 months.

10 Other information on the cosmetic product

No other information could be found relating to the safety of the ingredients or the finished cosmetic product.

Annex 1 - Part B Cosmetic product safety assessment

This Safety Assessment is for a GK Hair Taming System with Juvexin silver shampoo cosmetic product formulation dated 6 March 2013.

1 Assessment Conclusion

This safety assessment for human health is based upon the information available at this date. Reviews of this assessment will be made as and when new information becomes available. If significant adverse reactions are reported by consumers, a new evaluation will be made and any appropriate action taken.

It is recommended that reviews of the supporting data are conducted every 2 years.

Based on the information provided and reviewed, it is considered that the formulations listed above complies with Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 cosmetic product (Official Journal L 342, 22/12/2009 P. 0059-0209)

2 Labelled warnings and instructions for use

The proposed label for this cosmetic product presentation is acceptable and no additions are required.

3 Reasoning

3.1 Safety Evaluation of substances and/or mixtures

All ingredients have a well-known toxicological profile. They have been freely used in similar products for many years without adverse health effects.

The information provided is sufficient to provide an informed safety evaluation of the selection of the ingredients and therefore it is considered that no additional data needs to be generated to support this evaluation.

3.2 Safety Evaluation of the Cosmetic Product

The assessment of the ingredients, the finished cosmetic product, immediate packaging, intended use and product label has confirmed that the shampoo cosmetic product complies with Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 cosmetic product (Official Journal L 342, 22/12/2009 P. 0059-0209).

Copies of all the supporting documentation are held by Van Tibolli Beauty Ltd (Ireland).

4 Assessors Credentials and approval of part B

It is concluded that the above formulations conform to Regulation No 1223/2009 and can therefore be marketed in the EU.

The qualifications and experience of the assessor is provided below.

.....

M C Perry B.Sc., C.Biol., MSB., MTOPRA

Dated 27 June 2013

INFORMATION ON THE AUTHOR

Name: Martin Cyril Perry

Qualifications: B.Sc. (Hons.), C.Biol., MSB, M.T.O.P.R.A.
UK registered toxicologist (Listed by Institute of Biology/British Toxicology Society)
European registered toxicologist (Listed by Eurotox)

Membership of Learned Societies

British Toxicology Society
European Society of Toxicology
The Organisation for Professionals in Regulatory Affairs
Society of Biology

Summary of Career

R & M Consultancy, Ledbury, Herefordshire. Consultant.	1989-date
Cph (UK) Ltd., Malvern, Worcestershire. Technical manager.	1988-89
Toxicol Laboratories Ltd., Ledbury, Herefordshire. Head of General Toxicology.	1977-88
Life Science Research, Stock, Essex Toxicology supervisor, general toxicology.	1973-77
Fisons Agrochemical Division, Saffron Walden, Essex. Research scientist, toxicology department.	1972-73
Sandoz, Basle, Switzerland. Research technician, pharmacology department.	1972
Lister Institute for Preventative Medicine, London. Research assistant, biochemistry department.	1970-71
Pfizer, Sandwich, Kent. Animal technician, toxicology department.	1967