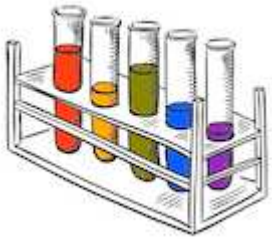

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Product Safety Assessment

Biotat Green Soap

Biotat Ltd

Reference BIT001
Issue 1
Issue Date 22-Nov-22

Biotat Green Soap

Sponsor Biotat Ltd

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Aqua	7732-18-5	
Potassium Cocoate	61789-30-8	
Alcohol denat.	64-17-5	
Glycerin	56-81-5	
Sucrose	57-50-1	
Potassium Castorate	8013-05-6	
Potassium Palmate	n/a	
Glycolipids	n/a	
Lavandula Angustifolia Herb Oil	8000-28-0	
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	
Eugenol	97-53-0	
Linalool	78-70-6	
Geraniol	106-24-1	
Limonene	5989-27-5	

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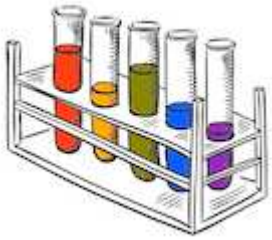

Product Safety Assessment

Biotat Green Soap

Biotat Ltd

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Isoeugenol	97-54-1

Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.

Fragrance allergens are quoted as additional items so percentages may not add up to 100.

Section 2 - Product Characteristics

Ingredient List

Aqua, Potassium Cocoate, Alcohol Denat., Glycerin, Sucrose, Potassium Castorate, Potassium Palmate, Glycolipids, Lavandula Angustifolia Herb Oil, Eugenia Caryophyllus (Clove) Bud Oil, Eugenol, Linalool

Frame Formulation Number	Liquid Soap 2.9
IFRA Category	Liquid soap
Adult or Child	Adult

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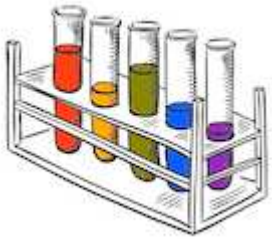

Product Safety Assessment

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Section 3 - Microbiological Quality

Liquid soap is self preserving and has been made for many centuries without problems. It is probably explained by a combination of the high pH, high osmotic pressure and the presence of free fatty acids.

Section 4 - Impurities and packaging

This formulation does not contain any ingredients with toxicologically relevant impurities.

There are no known or likely interactions with the pack that have any safety implications.

Section 5 - Normal and Foreseeable Use

This product is intended for topical application to a limited body area in small quantities.

Section 6 - Exposure

Where Used This product is applied to the skin

Estimated Daily Amount Used 20 g

Calculated relative daily exposure mg/kg 333

Frequency Of Use Daily

Assumed Body Weight 60 Kg

Rinse Status Rinse Off

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Aqua	7732-18-5			208.60		
Potassium Cocoate	61789-30-8			35.23		

Alcohol denat.	64-17-5	24.02	24000	999.306
Glycerin	56-81-5	21.67		
Sucrose	57-50-1	17.38		
Potassium Castorate	8013-05-6	14.75		
Potassium Palmate	n/a	9.68		
Glycolipids	n/a	1.33		
Lavandula Angustifolia Herb Oil	8000-28-0	0.33		
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	0.33		
Eugenol	97-53-0	0.29		
Linalool	78-70-6	0.15	500	3333.33
Geraniol	106-24-1	0.00	1000	272727
Limonene	5989-27-5	0.00	825	247500

Isoeugenol	97-54-1	0.00	150	150000

The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed (the NOAEL). If the MoS is 100 then the use level is one hundredth the level at which any effect is observed. Any level above 100 is considered to be acceptable.

Section 8 - Toxicological Profile of Ingredients

Alcohol Denat. 64-17-5

Alcohol (ethanol) is a very familiar product with an well known toxicity profile when consumed as a drink. Alcohol denat has a bitter tasting chemical added to make it unpalatable and therefore prevent inappropriate ingestion. Given its biological effects the NOAEL is of questionable relevance to topical application, and topical application would not be expected to contribute to systemic exposure.

The Food and Drug Administration (FDA) includes Alcohol on its list of direct food substances considered Generally Recognized as Safe (GRAS). Alcohol may also be used as an indirect food additive. For example, it may be used as a component of adhesives in contact with food. The FDA has also approved Alcohol for use in Over-the-Counter (OTC) antimicrobial drug products.

The margin of safety calculation is of questionable relevance in the case of this material, but nonetheless the result is acceptable.

Int J Toxicol. 2008;27 Suppl 1:1-43. doi: 10.1080/10915810802032388.
Final report of the safety assessment of Alcohol Denat., including SD Alcohol 3-A, SD Alcohol 30, SD Alcohol 39, SD Alcohol 39-B, SD Alcohol 39-C, SD Alcohol 40, SD Alcohol 40-B, and SD Alcohol 40-C, and the denaturants, Quassin, Brucine Sulfate/Brucine, and Denatonium Benzoate.

Aqua 7732-18-5

Water raises no toxicological issues.

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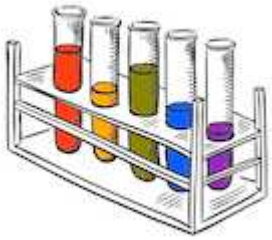

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Eugenia Caryophyllus (Clove) Bud Oil 84961-50-2

"Clove Oil". Eugenia Caryophyllus Bud Oil is an essential oil steam-distilled from the dried flower buds of the Clove, Syzygium aromaticum, syn. Eugenia caryophyllus, Myrtaceae. It contains eugenol (82-87% including about 10% acetyleugenol), caryophyllene. There are a number of variations on the name in the botanical literature including Eugenia caryophyllata.

It is listed on the EU's CosIng database without any restrictions on its use. It has been registered with ECHA under the REACH regulations.

The LD50 of clove essential oil orally administered in rats is reported as 2.65 and 3.72 g/kg. The dermal LD50 for clove essential oil is 5 g/kg.

The oral LD50 of the compound eugenol is 3 g/kg in mice, 1.9 or 2.7 g/kg in rats, and 2.1 g/kg in guinea pigs. Clove essential oil is approximately 90% eugenol.

The Joint FAO/WHO Expert Committee on Food Additives determined that the acceptable daily intake for the compound eugenol is 2.5 mg/kg. This group also indicated that 250 mg/kg was the level causing no effect in the diet of rats.

There is no data available to carry out a margin of safety calculation, but given the low level of exposure from this product it is possible to conclude that this material is safe as used in this product.

Opdyke, D.L.J. 1979. Monographs on fragrance raw materials. New York: Pergamon.

JECFA. 1982. Eugenol. WHO Food Additives Series 17: FAO/ WHO Joint Expert Committee on Food Additives.

Chaieb, K., H. Hajlaoui, T. Zmantar, et al. 2007. The chemical composition and biological activity of clove essential oil, Eugenia caryophyllata (Syzigium aromaticum L. Myrtaceae): A short review. Phytother. Res. 21(6):501-506.

Eugenol 97-53-0

Eugenol's name derives from the latin name for cloves, and it is the main constituent of clove oil. It is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

Eugenol both as a flavouring agent itself and as a constituent in clove oil is used in cooking and consequently is widely ingested. Despite this it does have some toxic effects. Adverse effects from ingestion have been reported, but at levels considerably in excess of any foreseeable absorbtion across the skin even from the neat oil, indeed the FDA classify eugenol as Generally Recognised As Safe (GRAS). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake for Eugenol of up to 2.5 mg/kg body weight when used as a flavoring agent. No NOAEL is appropriate.

The use level in this formulation is well below the limit stipulated in the IFRA standard for this category of product.

IFRA Standards 48th Amendment

Geraniol 106-24-1

Geraniol is pale-yellow oil with a rose odour.

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

The use level is well within the IFRA guideline for this material in this class of product, IFRA's main concern being to limit the risk of sensitisation.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin,A.E. Rogers , J.H. Saurat , I.G. Sipesi, H. Tagami

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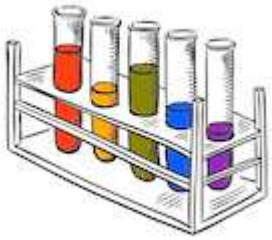

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Glycerin 56-81-5

Glycerin is a common ingredient in both cosmetics and food and as a very widespread metabolite in the body. It represents no risk to consumers in cosmetic products.

The Food and Drug Administration (FDA) includes Glycerin on its list of direct food additives considered Generally Recognized As Safe (GRAS), and on its list of approved indirect food additives. Glycerin is also an FDA approved active ingredient in Over-the-Counter (OTC) skin protectant drug products, ear drying products and it an approved demulcent for the eyes.

Given its ubiquous nature, it is inappropriate to consider a NOAEL for this material.

FDA Code of Federal Regulations 21CFR172.866

Glycolipids n/a

Glycolipids are mixed substances which contain carbohydrates covalently attached to a lipid.

It is listed on the EU's CosIng database without any restrictions on its use.

These subtances are regular components of the body's biochemistry. They raise no toxicological issues

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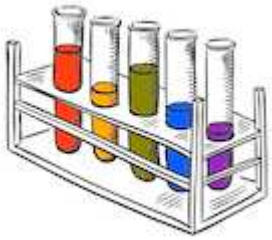

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Isoeugenol 97-54-1

Isoeugenol is a pale yellow liquid which smells something like carnation.

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The use level in this product is well below the IFRA guideline limit for this category of product. The NOAEL is derived from a nutritional study in rats and so is questionable as to its relevence to a product used on the skin which would be a much lower hazard. But the MoS calculation even using this very conservative data is still perfectly acceptable.

IFRA Standard

EFSA Journal 2012;10(1):2532 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species.

EFSA Journal 2012;10(1):2532 EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP); Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species. EFSA Journal 2012;10(1):2532. [15 pp.] doi:10.2903/j.efsa.2012.2532. Available online: © European Food Safety Authority, 2012 Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) (www.efsa.europa.eu/efsajournal)

Scientific Opinion on the safety and efficacy of propenylhydroxybenzenes (chemical group 17) when used as flavourings for all animal species EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

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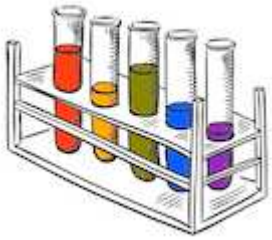

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Lavandula Angustifolia Herb Oil 8000-28-0

Lavandula Angustifolia Herb Oil is an essential oil distilled from the flowering herbs of the lavender, Lavandula angustifolia, Labiatae. ISO 8902:2009.

The use of lavender is so well established and its safety so well known that little justification for its use is necessary. Its use in medicine is attested to by its being listed in the Pharmacopiea Europa. The first reference to the use of a lavender species is in Pliny, though not angustifolia specifically. It is listed by the FDA as Generally Recognised As Safe (GRAS).

Its traditional usage has not precluded medical research into its properties, with no previously unsuspected risks coming to light. Some of the terpenes that comprise lavender oil are listed as allergens in the EU legislation, but despite this allergic reactions to lavender are extremely low. Only 1 case of photoallergy has ever been recorded in the scientific literature.

Lavender is used as a food ingredient and so no margin of safety is considered to be necessary. Calculations have been done on the individual ingredients.

Tisserand, Robert; Young, Rodney (2013-12-02). Essential Oil Safety: A Guide for Health Care Professionals. Elsevier Health Sciences UK.

FDA Code of Federal Regulations Title 21, Substances Generally Recognised As Safe Volume 3 Subpart A--General Provisions Sec. 182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) 21CFR182.20 Revised as of April 1, 2013

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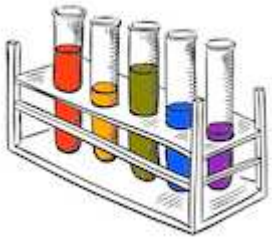

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Limonene 5989-27-5

Limonene is a terpene that is found in citrus fruits and consequently is commonly ingested. As such it is listed by the FDA as generally recognised as safe (GRAS). Given this, a NOAEL is not particularly relevant to the assessment of its safety. A review of flavouring ingredients by EFSA confirmed this assumption. Even so a value has been assigned to it by ECHA and when an MoS is calculated it is acceptable.

This material is not often used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

In an acute dermal toxicity study, 10 rabbits were administered a single dermal dose of l-limonene at 5000 mg/kg bw. Animals were then observed for mortality and clinical signs of toxicity for 14 days. No deaths and clinical signs of toxicity occurred during the observation period. Dermal reactions noted were moderate redness (3/10 rabbits) and moderate edema (6/10 rabbits) at the site of application.

The dermal LD50 for l-limonene is higher than 5000 mg/kg bw in rabbits therefore it is not classified according to Directive 67/548/EEC and CLP Regulation (EC) No 1272/2008.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products. Its concentration in this product conforms to IFRA guidelines.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) . Scientific Opinion on Flavouring Group Evaluation 25, Revision 2 (FGE.25Rev2): Aliphatic and aromatic hydrocarbons from chemical group 31 . EFSA Journal 2011; 9(6):2177. [126 pp.]. doi:10.2903/j.efsa.2011.2177. Available online: www.efsa.europa.eu/efsajournal

J Toxicol Environ Health B Crit Rev. 2013;16(1):17-38. doi: 10.1080/10937404.2013.769418. Safety evaluation and risk assessment of d-Limonene. Kim YW, Kim MJ, Chung BY, Bang du Y, Lim SK, Choi SM, Lim DS, Cho MC, Yoon K, Kim HS, Kim KB, Kim YS, Kwack SJ, Lee BM.

IFRA Standards 20

"(R)-P-Mentha-1,8-Diene - Registration Dossier - ECHA". Echa.Europa.Eu, 2020, https://echa.europa.eu/registration-dossier/-/registered-dossier/15256/7/3/4. Accessed 30 Aug 2020.

Linalool 78-70-6

This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

The MoS calculation despite its very conservative assumptions does not lead to any toxicological concerns.

Int J Toxicol. 2008 Mar-Apr;27(2):183-8 Evaluation of the developmental toxicity of linalool in rats. Politano VT, Lewis EM, Hoberman AM, Christian MS, Diener RM, Api AM.

Food and Chemical Toxicology Volume 46, Supplement 11, November 2008 Toxicologic and Dermatologic Assessment of Cyclic and Non-Cyclic Terpene Alcohols The RIFM EXPERT Panel, D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin,A.E. Rogers , J.H. Saurat , I.G. Sipesi, H. Tagami

Potassium Castorate 8013-05-6

Potassium Castorate is the potassium soap of castor oil.

It is listed on the EU's CosIng database without any restrictions on its use.

It has been registered with ECHA under the REACH regulations.

"Substance Information - ECHA". Echa.Europa.Eu, 2022, https://echa.europa.eu/substance-information/-/substanceinfo/100.029.442. Accessed 22 Nov 2022.

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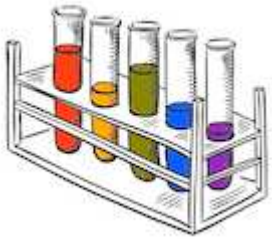

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Potassium Cocoate 61789-30-8

The saponificaton of vegetable oils to produce the sodium salts of their constituent fatty acids, commonly known as soap, is one of the oldest if not the oldest chemical processes in the personal care industry. It dates back at least to the time of the Roman Empire and has been practised continually since that time. The replacement of sodium hydroxide with potassium hydroxide gives rise to potassium soaps of which potassium cocoate is a typical example. Although not as ubiquitous as sodium soaps, potassium soaps are still used in a wide spread of products including shaving soaps and marine soaps.

It would be surprising if any new toxicological concerns were to arise on so widely spread and well established a technology. A review by the CIR of the oils used in this process and their derivatives drew the expected conclusion that these materials are safe as used in personal care products.

Given their similarity to common food ingredients and the ease with which the body metabolises them, these ingredients cannot be easily assigned an NOAEL and it would be difficult to interpret exactly what one would mean for this kind of material.

Int J Toxicol. 2011 May;30(3 Suppl):5S-16S. doi: 10.1177/1091581811400636. Final report on the safety assessment of Cocos nucifera (coconut) oil and related ingredients. Burnett CL, Bergfeld WF, Belsito DV, Klaassen CD, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, Andersen FA.

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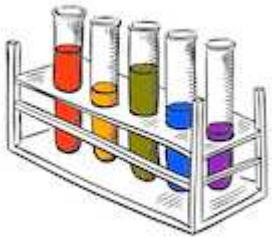

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Potassium Palmate n/a

Potassium palmate is the potassium soap formed by the reaction of potassium hydroxide and palmititic acid. It is therefore a close analogy to the much more widely used sodium palmate. The differences between the two are fairly minor, with the potassium soap having a higher solubility in ionic media making it possible to use in specialist soaps such as those intended for use in salt water and for modifying the foaming characteristics of more conventional soaps.

It is listed on the EU's CosIng database with no restrictions on its use.

The safety of this material is best considered by comparison with the better known sodium palmate.

The saponificaton of vegetable oils to produce the sodium salts of their constituent fatty acids, commonly known as soap, is one of the oldest if not the oldest chemical processes in the personal care industry. It dates back at least to the time of the Roman Empire and has been practised continually since that time.

It would be surprising if any new toxicological concerns were to arise on so widely spread and well established a technology. A review by the CIR of the oils used in this process and their derivatives drew the expected conclusion that these materials are safe as used in personal care products.

Given their similarity to common food ingredients and the ease with which the body metabolises them, these ingredients cannot be easily assigned an NOAEL and it would be difficult to interpret exactly what one would mean for this kind of material.

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Sucrose 57-50-1

As a common and familiar everyday food ingredient sucrose, commonly known as sugar, raises no toxicological concerns.

Section 9 - Undesirable Effects

No undesirable effects are foreseen with this product when used under conditions of normal and foreseeable use.

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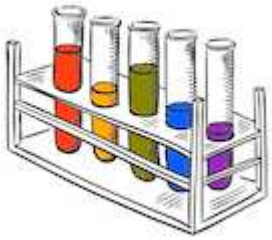

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Part B

Section 1- Assessment Conclusion

This product has been assessed and found to comply with the requirements of current EU,UK and US cosmetic regulations. The ingredients selected have been reviewed and are used at levels suitable to ensure that the end user will experience the level of safety they can reasonably expect for this kind of product when used in accordance with the manufacturers instructions, and when manufactured following a suitable cosmetic GMP procedure.

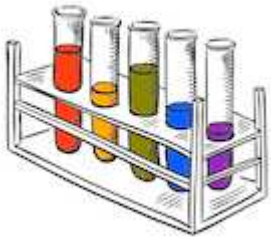
Section 2- Labels and Warnings

This product does not require any specific warnings over and above those customary in this category.

Period After Opening 12 Months

Section 3- Reasoning

This is a standard product using conventional ingredients at normal levels. This category of products has a good track record of safe use and so can be presumed to be safe under normal and foreseeable conditions of use. Interactions between ingredients are unlikely to be problematic in this kind of product.



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Product Safety Assessment

Biotat Green Soap

Biotat Ltd

Reference	BIT001
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Signed

Colin Sanders  24/11/2022

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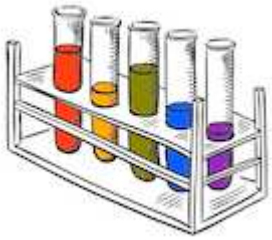

Product Safety Assessment

Biotat Green Soap

Biotat Ltd

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Issue Date	22-Nov-22

Appendix - Credentials of Assessor

Colin Sanders Bsc(Hons) FRSB Dip SCS
Date of Birth 19.5.1960

Academic Qualifications

Bachelor of Science in Environmental Science from Leicester Polytechnic, lower second with honours awarded in 1983.

Diploma in Cosmetic Science awarded by the Society of Cosmetic Science awarded in 1985

Membership of Professional Bodies

Society of Cosmetic Scientists

Fellow of the Royal Society of Biology

Experience

Development Chemist at Intergen Cosmetics 1983-1987
Quality Assurance W.M.Stills 1987-1990
Formulation Scientist/Formulation Laboratory Manager Stiefel Laboratories 1990-2004
Head of Product Formulation Medex/Montagne Jeunesse 2004-2013