

Product Safety Assessment

Biotat Tattoo Butter

Biotat Ltd

Reference BIT002

Issue 1

Issue Date 22-Nov-22

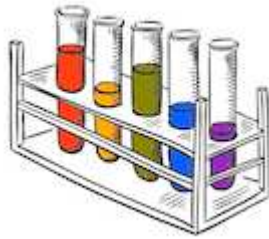
Biotat Tattoo Butter

Sponsor **Biotat Ltd**

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Butyrospermum Parkii (Shea) Butter	91080-23-8	
Glycerin	56-81-5	
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	
Eugenol	97-53-0	
Lavandula Angustifolia Herb Oil	8000-28-0	
Aloe Barbadensis Leaf Juice	85507-69-3, 94349-62-9	
Isoeugenol	97-54-1	
Linalool	78-70-6	
Geraniol	106-24-1	
Limonene	5989-27-5	
Potassium Sorbate	24634-61-5	
Sodium Benzoate	532-32-1	
Citric Acid	77-92-9, 5949-29-1	



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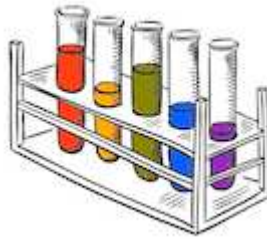
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Quantities below third decimal place not reported on this table, but have been used in calculations later in the report.

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



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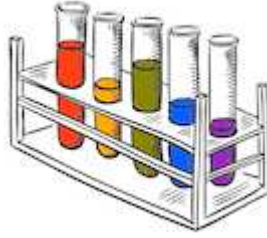
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Section 2 - Product Characteristics

Ingredient List

Butyrospermum Parkii (Shea) Butter, Glycerin, Eugenia Caryophyllus (Clove) Bud Oil, Eugenol, Lavandula Angustifolia Herb Oil, Aloe Barbadensis Leaf Juice, Isoeugenol, Linalool, Citric Acid, Potassium Sorbate, Sodium Benzoate

Frame Formulation Number Skin Care Cream Lotion, Gel 1.2
IFRA Category Body creams, oils, lotions for adults
Adult or Child Adult



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Section 3 - Microbiological Quality

This product is non-aqueous and consequently raises no microbiological issues. The reasoning behind this statement is detailed in ISO 29621 Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products.

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 7.82 g **Calculated relative daily exposure mg/kg** 130

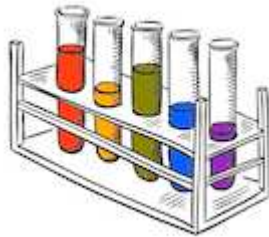
Frequency Of Use Daily

Assumed Body Weight 60 Kg

Rinse Status Leave On

Section 7 - Exposure to Ingredients

Ingredient	CAS Number	%w/w	Dose	SED	NOAEL	MoS
Butyrospermum Parkii (Shea) Butter	91080-23-8			125.22		



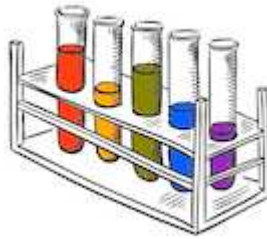
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Glycerin	56-81-5	3.00		
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	2.09		
Eugenol	97-53-0	1.81		
Lavandula Angustifolia Herb Oil	8000-28-0	0.01		
Aloe Barbadensis Leaf Juice	85507-69-3, 94349-62-9	0.01		
Isoeugenol	97-54-1	0.01	150	23977
Linalool	78-70-6	0.01	500	85251.5
Geraniol	106-24-1	0.00	1000	6975120
Limonene	5989-27-5	0.00	825	6329920
Potassium Sorbate	24634-61-5	0.00		
Sodium Benzoate	532-32-1	0.00	175	2.7E+08



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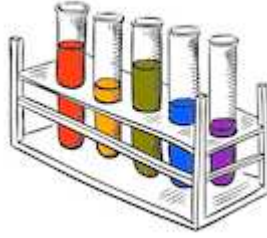
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Citric Acid	77-92-9, 5949-29-1	0.00
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The Margin of Safety (MoS) is calculated by working out the maximum feasible exposure and comparing it to the level at which no adverse effect is observed (the 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.



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Section 8 - Toxicological Profile of Ingredients

Aloe Barbadensis Leaf Juice

85507-69-3, 94349-62-9

Aloe vera has a long history of safe use in cosmetics. It has been reported to possess anti-inflammatory properties.

The Food and Drug Administration (FDA) reviewed the safety of various aloe species including *Aloe barbadensis* and *Aloe ferox* and determined that they may be used as natural flavoring substances for direct addition to food.

The Cosmetic Ingredient Review (CIR) Expert Panel has evaluated the safety of the ingredients derived from the *Aloe barbadensis* species of plant (which is commonly called Aloe vera). These are the ingredients made from aloe plants that are most often used in cosmetics. The CIR Expert Panel concluded that they were safe for use in cosmetics.

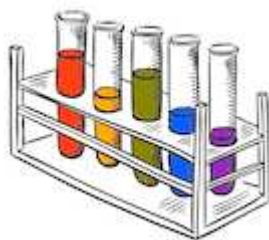
The CIR Expert Panel noted that aloe-derived ingredients may contain anthraquinones, which can be of concern if present at high levels. However, the data available for review by the CIR Expert Panel supported the conclusion that the manufacturing process is well-established and that current controls followed during production are adequate to ensure that anthraquinones remain below levels that would be of concern.

There are no restrictions on use in the EU.

Aloe vera is approved by the EMA for use in herbal remedies taken orally.

There is no NOAEL value suitable for this application, but it is nonetheless clear that this is a material that can be safely applied to the skin in small quantities.

Assessment Report on *Aloe Barbadensis* Miiller and *Aloe* (Various species, mainly *Aloe Ferox* Miller and its hybrids) European Medicines Agency Evaluation of Medicines for Human Use 2007 EMEA/HMPC/76313/2006



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Butyrospermum Parkii (Shea) Butter

91080-23-8

Butyrospermum Parkii (Shea) Butter, usually called simply Shea Butter is derived from the shea tree, *Butyrospermum parkii*, also called *Vitellaria paradoxa*. Shea Butter and the other ingredients made from the shea tree are used in many types of cosmetics and personal care products including bath products, cleansing products, eye makeup, lotions and creams, suntan products, lipstick and hair care products. In the parts of Africa where the shea tree is native, shea butter is used in cooking.

The Food and Drug Administration (FDA) includes sheanut oil on its list of direct food substances affirmed as Generally Recognized As Safe (GRAS).

The safety of *Butyrospermum Parkii* (Shea) Butter has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that these ingredients were safe for use as ingredients in cosmetics and personal care products

As with all natural products, some people are allergic to shea butter. Tree nuts including the nuts from the shea tree from which shea butter is derived do illicit an above average level of allergies compared to natural products in general. Shea butter containing products should warn about this if they are also claiming to be particularly suitable for people with sensitive skin.

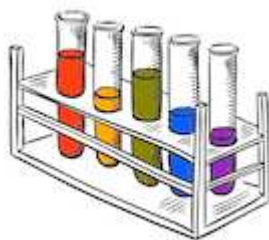
EU regulations do not limit the use of shea butter in any way.

As a foodstuff and a product that is generally regarded as safe, shea butter has never been studied in such a way that an NOAEL level can be meaningfully calculated, but its very extensive culinary use as well as its wide use in cosmetics indicate that were such a value to be determined it would be a high one and the substance's toxicity raises no concerns.

The cosmetic ingredient review included this oil in its review of fatty acid based triglyceride oils. This report found that these products, all of which have the same basic chemistry, were safe as used in cosmetics.

Given the nature of the oil in question, its lack of permeability coupled with being easily digested no NOAEL is appropriate and a margin of safety calculation is not necessary.

Cosmetic Ingredient Review Final Report Plant-Derived Fatty Acid Oils as Used in Cosmetics March 4, 2011



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Citric Acid

77-92-9, 5949-29-1

Citric Acid is an organic acid that is widely distributed in plants and animals. It is a common component of foodstuffs, both as a consciously used additive and as a naturally occurring constituent. It is an extremely widely distributed metabolite within the body. Its main use in cosmetics is as a pH regulator.

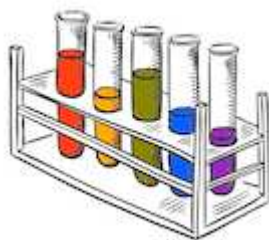
Citric acid is on the Food and Drug Administration's (FDA) list of direct food substances affirmed as Generally Recognized as Safe (GRAS).

The CIR Expert Panel evaluated scientific data and concluded that Citric Acid is safe for use in cosmetics.

The safety of Citric Acid and its Calcium, Potassium and Sodium salts has been assessed by the Joint FAO/WHO Expert Committee on Food Additives. The most recent review concluded that it was not necessary to limit the dietary intake of Citric Acid and its salts.

Given the ubiquity of this material a NOAEL is not a meaningful measure of its safety.

Cosmetic Ingredient Review Citric Acid and Its Inorganic Salts and Alkyl and Glycol Esters as Used in Cosmetics
June 9, 2011



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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% acetyleneugenol), 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.

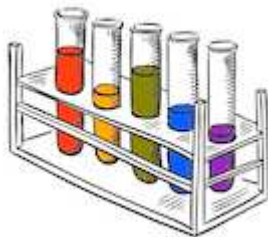
The Joint FAO/WHO Expert Committee on Food Additives determined that the acceptable daily intake for the compound eugenol is 2.5 mg/kg. This group also indicated that 250 mg/kg was the level causing no effect in the diet of rats.

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* (*Syzygium aromaticum* L. Myrtaceae): A short review. *Phytother. Res.* 21(6):501-506.



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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 absorption 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.

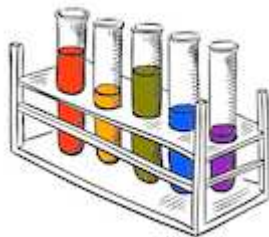
This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

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. Sipes, H. Tagami



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Glycerin

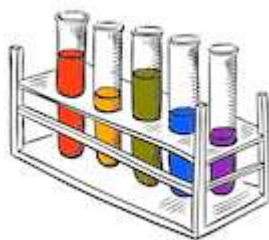
56-81-5

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 ubiquitous nature, it is inappropriate to consider a NOAEL for this material.

FDA Code of Federal Regulations 21CFR172.866



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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.

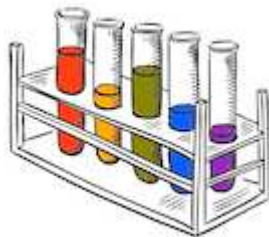
The use level in this product is well below the IFRA guideline limit for this category of product. The NOAEL is derived from a nutritional study in rats and so is questionable as to its relevance to a product used on the skin which would be a much lower hazard. But the MoS calculation even using this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

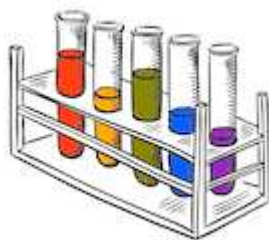
The use of lavender is so well established and its safety so well known that little justification for its use is necessary. Its use in medicine is attested to by its being listed in the Pharmacopoeia Europa. The first reference to the use of a lavender species is in Pliny, though not *angustifolia* specifically. 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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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.

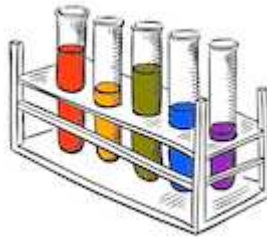
Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products. Its concentration in this product conforms to IFRA guidelines.

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.



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Linalool

78-70-6

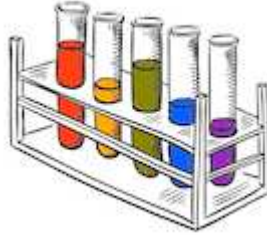
This material is not used as a direct additive to cosmetic products but sometimes occurs as a component of fragrances or essential oils. It is listed as an allergen in Annex III of the current EU cosmetic regulations.

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. Sipes, H. Tagami



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Potassium Sorbate

24634-61-5

Potassium sorbate is a widely used preservative in both cosmetics and food. In foods it goes under the label E202.

It has been registered with ECHA under the REACH regulations.

The REACH acute dermal toxicity is read across from sorbic acid which revealed an LD50 of > 2000 mg/kg bw allowing the material to be designated as practically nontoxic.

The low toxicity of the sorbates is extremely well established, with food containing up to 10% by weight showing no toxic effect. It is therefore almost impossible to come up with a suitable NOAEL level for a margin of safety calculation. It can therefore be considered to be effectively non-toxic.

The only issue with this material is that it does cause a level of allergic reactions and contact dermatitis. These effects are not frequent and are mitigated by keeping the concentration low, which is in any case required by EU regulations. It is also the case that only a low level is required to meet preservative efficacy requirements.

The maximum level of sorbate allowed under EU regulations is 0.6% which equates to 0.8% of potassium sorbate.

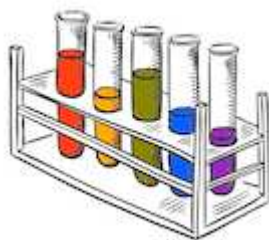
"Registration Dossier - ECHA". Echa.Europa.Eu, 2022, <https://echa.europa.eu/pt/registration-dossier/-/registered-dossier/11008>. Accessed 31 Aug 2022.

Final Report on the Safety Assessment of Sorbic Acid and Potassium Sorbate International Journal of Toxicology November/December 1988 7: 837-880

Food Addit Contam. 1990 Sep-Oct;7(5):671-6. Toxicology of sorbic acid and sorbates. Walker R.

An Bras Dermatol. 2012 Mar-Apr;87(2):263-8. Study of the frequency of allergens in cosmetics components in patients with suspected allergic contact dermatitis. Silva EA, Bosco MR, Mozer E.

Annex V Section 4 of EU Cosmetic Regulations 1223/2009



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Sodium Benzoate

532-32-1

Sodium benzoate is a widely used preservative in both foods and cosmetics. It is listed on the EU's CosIng database and is listed in the EU cosmetic regulations as an approved preservative in Annex V section 1. This limits its use level to 2.5% in rinse off products, 1.7% in oral products and 0.5% in leave on products expressed as the acid. When used in food it has the reference E211.

Benzoic and its derivatives including sodium benzoate have been reviewed by the Cosmetic Ingredient Review Panel on a number of occasions, the most recently being 2011. The conclusion was that the family including sodium benzoate were safe in present practices of use.

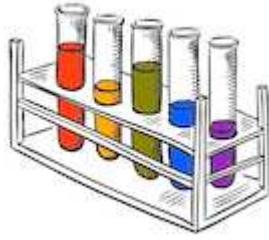
Its use level in this product comfortably meets the limits of the EU's cosmetic regulations.

The NOAEL figure used in the margin of safety calculation is the lowest and therefore the most conservative figure from an extensive toxicological study. It relates to a reproductive toxicology study in hamsters and its relevance to applying much lower levels to the skin is questionable - the true NOAEL is almost certainly much higher. Nonetheless it gives a very adequate result in the margin of safety calculation.

EU Cosmetic Regulations Annex V Section 1.

Amended Final Safety Assessment Benzyl Alcohol, and Benzoic Acid and its Salts and Benzyl Ester October 17, 2011

OECD. SIDS initial assessment report for 13th SIDS initial assessment meeting. Benzoates: benzoic acid, sodium benzoate, potassium benzoate, and benzyl alcohol.



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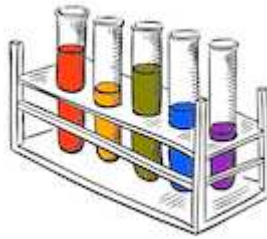
Biotat Tattoo Butter

Biotat Ltd

Reference BIT002
Issue 1
Issue Date 22-Nov-22

Section 9 - Undesirable Effects

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



Product Safety Assessment

Biotat Tattoo Butter

Biotat Ltd

Reference BIT002
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Issue Date 22-Nov-22

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.

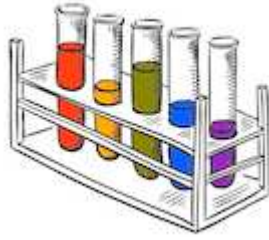
Section 2- Labels and Warnings

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.



Product Safety Assessment

Biotat Tattoo Butter

Biotat Ltd

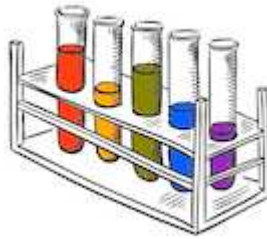
Reference BIT002
Issue 1
Issue Date 22-Nov-22

Signed

Colin Sanders

A handwritten signature in cursive script that reads "Colin Sanders". The ink is black and the signature is written in a fluid, connected style.

24/11/2022



Product Safety Assessment

Biotat Tattoo Butter

Biotat Ltd

Reference BIT002
Issue 1
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