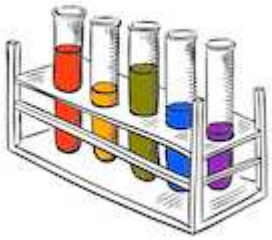

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Product Safety Assessment

Biotat Hybrid Glide

Biotat

Reference	BIT005
Issue	1
Issue Date	09-Jun-23

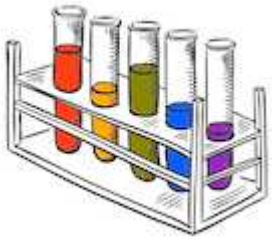
Biotat Hybrid Glide

Sponsor Biotat

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
Butyrospermum Parkii (Shea) Butter	91080-23-8	
Butyrospermum Parkii Butter	194043-92-0 - 91080-23-8	
Mineral Oil	8012-95-1, 8020-83-5, 8042-47-5	
Microcrystalline Wax	63231-60-7 64742-42-3	
Cera Microcristallina	63231-60-7 64742-42-3	
Eugenia Caryophyllus Bud Oil	8000-34-8, 8015-97-2, 84961-50-2	
Eugenol	97-53-0	
Glycerin	56-81-5	
Titanium Dioxide	13463-67-7	
Brassica Campestris Seed Oil	8002-13-9 / 90989-79-0	
Persea Gratissima Oil	8024-32-6	
Aloe Barbadensis Leaf Juice	85507-69-3, 94349-62-9	
Glycolipids	n/a	



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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.

Section 2 - Product Characteristics

Ingredient List

Butyrospermum Parkii (Shea) Butter, Butyrospermum Parkii Butter, Mineral Oil, Microcrystalline Wax, Cera Microcristallina, Eugenia Caryophyllus Bud Oil, Eugenol, Glycerin, Titanium Dioxide, Brassica Campestris Seed Oil, Persea Gratissima Oil, Aloe Barbadensis Leaf Juice, Glycolipids

Frame Formulation Number	Skin Care Cream Lotion, Gel 1.2
IFRA Category	5:Products applied to the face and body using the hands (palms), primarily leave-on
Adult or Child	Adult

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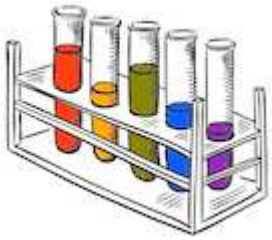

Product Safety Assessment

Biotat Hybrid Glide

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Section 3 - Microbiological Quality

The preservative efficacy of this product is likely to be confirmed if challenged by a standard efficacy test given that the levels of preservative are at a level generally found to be of an appropriate microbiological standard.

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

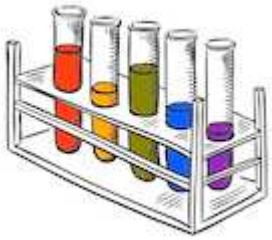
Frequency Of Use Daily

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		7.820	49.01		



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Product Safety Assessment

Biotat Hybrid Glide

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Reference BIT005
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Butyrospermum Parkii Butter	194043-92-0 - 91080-23-8	7.820	24.37
Mineral Oil	8012-95-1, 8020-83-5, 8042-47-5	7.820	21.99
Microcrystalline Wax	63231-60-7 64742-42-3	7.820	15.15
Cera Microcristallina	63231-60-7 64742-42-3	7.820	11.73
Eugenia Caryophyllus Bud Oil	8000-34-8, 8015-97-2, 84961-50-2	7.820	2.35
Eugenol	97-53-0	7.820	2.25
Glycerin	56-81-5	7.820	1.82
Titanium Dioxide	13463-67-7	7.820	1.30
Brassica Campestris Seed Oil	8002-13-9 / 90989-79-0	7.820	0.78
Persea Gratissima Oil	8024-32-6	7.820	0.78

Aloe Barbadensis Leaf Juice	85507-69-3, 94349-62-9	7.820	0.78
Glycolipids	n/a	7.820	0.26

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

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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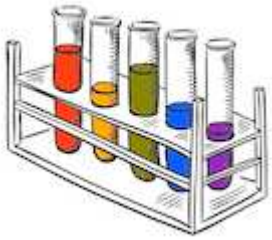

Product Safety Assessment

Biotat Hybrid Glide

Biotat

Reference BIT005
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Brassica Campestris Seed Oil 8002-13-9 / 90989-79-0

Brassica Campestris Seed Oil is the oil expressed from the seeds of the rapeseed (Cabbage), Brassica campestris L., Brassicaceae; Rape oil.

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

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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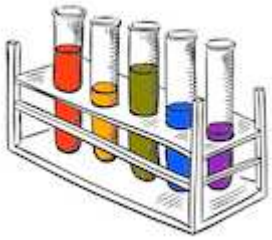

Product Safety Assessment

Biotat Hybrid Glide

Biotat

Reference BIT005
Issue 1
Issue Date 09-Jun-23

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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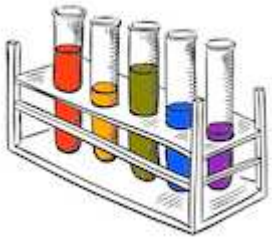

Product Safety Assessment

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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.

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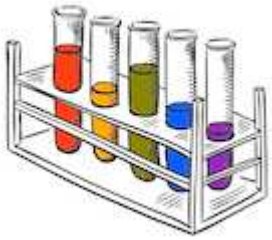

Product Safety Assessment

Biotat Hybrid Glide

Biotat

Reference	BIT005
Issue	1
Issue Date	09-Jun-23

Cera Microcristallina 63231-60-7 64742-42-3

This material is known as Microcrystalline Wax in English which is also the official name used in the United States. In Europe it is known by its latin name Cera Microcristallina. If the English name is used in Canada the French name of Cire microcrystalline is also required. It is used in pharmaceuticals. There is United States Pharmacopiea monograph for it. It is permitted as a food additive under the name E905.

It is very widely used in cosmetics, particularly in colour cosmetics. It has many benefits in these formulations, particularly the ability to hold pigments in place.

Microcrystalline Wax is a combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists of saturated straight and branched chain hydrocarbons greater than C35. As such it is composed of material of a chemically inert nature which would not be expected to give rise to toxicological concerns. The relatively high molecular weight would also suggest a material that is unlikely to be systemically absorbed in any significant quantity.

Both these assumptions are borne out by the long track record this material has of safe use, and by the lack of issues relating to safety in the literature. The Cosmetic Ingredient Review panel reviewed the scientific data on a range of fossil waxes including Microcrystalline Wax in 1984, and reaffirmed the conclusions drawn in 2005. The conclusion drawn was that this material is safe as used in cosmetics.

The European Food Standards Agency recently reviewed the safety of Microcrystalline Wax and reached the conclusion that it was safe as used in food. The current de facto Acceptable Daily Intake (ADI) is 20 mg/kg bw/day - a level that could only be achieved by deliberate ingestion of this product.

The primary route of exposure to Microcrystalline Wax and similar hydrocarbons is as a result of their indirect use in foodstuffs. It is estimated that daily exposure from this source is 0.044 mg/kg BW/day. This is equivalent to several grams per day for an adult and this clearly dwarfs any exposure from its use in products such as this one. Consequently, even though no data are available to carry out a margin of safety calculation it can be concluded that this product poses no risk to users.

JT 24(Suppl. 1):1-102, 2005 Annual Review of Cosmetic Ingredient Safety Assessments - 2002/2003

JACT 3(3):43-99, 1984 Final Report on the Safety Assessment of Fossil and Synthetic Waxes

Food Chem Toxicol. 2002 May;40(5):555-71.Dietary exposures to mineral hydrocarbons from food-use applications in the United States. Heimbach JT1, Bodor AR, Douglass JS, Barraj LM, Cohen SC, Biles RW, Faust HR.

EFSA Journal 2013;11(4):3146 [32 pp.] Scientific Opinion on the re-evaluation of microcrystalline wax (E 905) as a food additive

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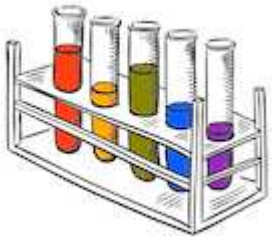

Product Safety Assessment

Biotat Hybrid Glide

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Reference BIT005
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Eugenia Caryophyllus Bud Oil 8000-34-8, 8015-97-2, 84961-50-2

Eugenia Caroyphyllus Leaf Oil is an essential oil steam-distilled from the leaves of the Clove, Eugenia caryophyllus, Myrtaceae. 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.

IFRA guidelines based on the eugenol content indicate a maximum use level of 0.6%. - a limit this product compies with.

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

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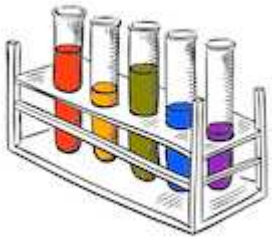

Product Safety Assessment

Biotat Hybrid Glide

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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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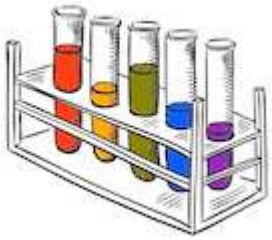

Product Safety Assessment

Biotat Hybrid Glide

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Microcrystalline Wax 63231-60-7 64742-42-3

This material is known as Microcrystalline Wax in English which is also the official name used in the United States. In Europe it is known by its latin name Cera Microcristallina. If the English name is used in Canada the French name of Cire microcrystalline is also required. It is used in pharmaceuticals. There is United States Pharmacopiea monograph for it. It is permitted as a food additive under the name E905.

It is very widely used in cosmetics, particularly in colour cosmetics. It has many benefits in these formulations, particularly the ability to hold pigments in place.

Microcrystalline Wax is a combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists of saturated straight and branched chain hydrocarbons greater than C35. As such it is composed of material of a chemically inert nature which would not be expected to give rise to toxicological concerns. The relatively high molecular weight would also suggest a material that is unlikely to be systemically absorbed in any significant quantity.

Both these assumptions are borne out by the long track record this material has of safe use, and by the lack of issues relating to safety in the literature. The Cosmetic Ingredient Review panel reviewed the scientific data on a range of fossil waxes including Microcrystalline Wax in 1984, and reaffirmed the conclusions drawn in 2005. The conclusion drawn was that this material is safe as used in cosmetics.

The European Food Standards Agency recently reviewed the safety of Microcrystalline Wax and reached the conclusion that it was safe as used in food. The current de facto Acceptable Daily Intake (ADI) is 20 mg/kg bw/day - a level that could only be achieved by deliberate ingestion of this product.

The primary route of exposure to Microcrystalline Wax and similar hydrocarbons is as a result of their indirect use in foodstuffs. It is estimated that daily exposure from this source is 0.044 mg/kg BW/day. This is equivalent to several grams per day for an adult and this clearly dwarfs any exposure from its use in products such as this one. Consequently, even though no data are available to carry out a margin of safety calculation it can be concluded that this product poses no risk to users.

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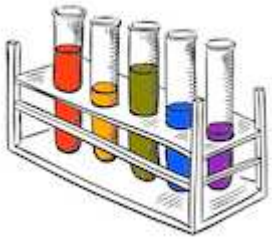

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Mineral Oil 8012-95-1, 8020-83-5, 8042-47-5

Mineral oil is a very inert material with a long track record of safe use in cosmetics in general, and has not been problematic with this product.

Paraffinum liquidum or light liquid paraffin has a long history of use in cosmetics and pharmaceuticals. It is an inert material that would not be expected to give rise to toxicity issues.

The nature of light liquid paraffin is such that it is extremely unlikely to penetrate the skin nor to cause a significant number of allergic reactions.

There are no restrictions on its use in topical products in either cosmetic or pharmaceutical regulations. There are no direct toxicity issues related to it, though excessive consumption is anticipated to lead to digestive problems. This theoretical risk has not been investigated widely, though an LD50 has been established in mice. The material is officially considered to be Generally Recognised as Safe (GRAS) in the US. There is no reason to suppose that this ingredient poses any risk of any kind.

A pharmaceutical grade is used to ensure impurities are controlled at an acceptable level.

FDA GRAS Assessment of Mineral Oil

Persea Gratissima Oil 8024-32-6

Persea Gratissima Oil is the fixed oil obtained by pressing the dehydrated sliced flesh of the avocado pear, Persea gratissima, Lauraceae. It consists principally of the glycerides of fatty acids

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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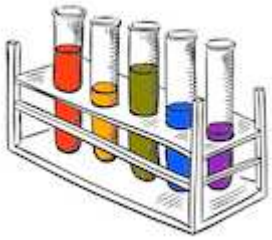

Product Safety Assessment

Biotat Hybrid Glide

Biotat

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Titanium Dioxide 13463-67-7

Titanium dioxide is a bright white reflective powder. It is dense and inert. It is the choice for most applications that require whiteness and opacity.

This material is listed on the CosIng database and has been registered on the ECHA database.

Titanium Dioxide is used in a wide range of cosmetics and personal care products including makeup, nail products, bath soaps and foot powders. Titanium Dioxide is also used in Over-the-Counter (OTC) sunscreen drug products.

The Food and Drug Administration (FDA) lists Titanium Dioxide as a color additive exempt from certification. Titanium Dioxide is safe for use in coloring products, including cosmetics and personal care products applied to the lips, and the area of the eye, provided it meets certain specifications. Titanium Dioxide is also an approved colorant for food, drugs and medical devices.

The FDA has also approved the use of Titanium Dioxide for use in OTC sunscreen drug products at concentrations up to 25%.

FDA includes Titanium Dioxide on its list of indirect food additives. For example, it may be used as a colorant in polymers used in food contact materials.

Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.

Titanium Dioxide is listed as CI 77891 in the Cosmetics Directive of the European Union (see Annex IV) and may be used without restriction as a colorant when purity requirements are fulfilled. When used as a colorant in cosmetic products in the European Union, this ingredient must be called CI 77891.

In Europe, Titanium Dioxide is also an approved UV Filter and may be used at concentrations up to 25% (see Annex VII).

The Joint FAO/WHO Expert Committee on Food Additives has determined that is it not necessary to limit the daily dietary intake for Titanium Dioxide.

Groups of 50 male and 50 female B6C3F1 mice each were fed a diet containing 2% corn oil and 25000 or 50000 ppm titanium dioxide for 103 weeks (7 days per week). A control group receiving corn oil in the diet was run concurrently. After the administration period the animals were observed for 1 additional week. The following parameters were assessed and presented: clinical signs, mortality, detailed clinical observations, body weight, and histopathology.

A NOEL (tumourogenicity; mice) of 50000 ppm (equivalent to 7500 mg/kg/day) was determined.

According to the study authors, there was no clinical sign that was judged to be related to titanium dioxide exposure, with the exception of white faeces. In male and female mice, no tumours occurred in dosed groups at incidences that were significantly higher than those for corresponding control groups. It can therefore safely be concluded that under the conditions of this bioassay, titanium dioxide was not carcinogenic by the oral route for B6C3F1 mice.

According to the harmonised classification and labelling (ATP14) approved by the European Union, this substance is suspected of causing cancer. However these concerns arise in the context of respiratory exposure in an occupational context, and have no relevance to its use in this product.

There are problems with the assignment of an NOAEL for titanium dioxide, which has been discussed in detail by the SCCS in 2000. ECHA concludes that the study does not need to be conducted because the physicochemical and toxicological properties suggest no potential for a significant rate of absorption through the skin. The oral NOAEL has been used and gives and acceptable result, even though this is based an extremely conservative assumptions.

SCCNFP/0005/98 Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products for Consumers concerning Titanium Dioxide 2000

EU List of Approved Colours Annex IV of EU1223/2009.

"Titanium Dioxide - Registration Dossier - ECHA". Echa.Europa.Eu, 2021, https://echa.europa.eu/registration-dossier/-/registered-dossier/15560. Accessed 5 July 2021.

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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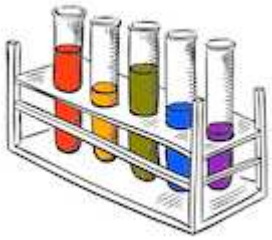
West Sussex
GU28 0AH



Product Safety Assessment

Biotat Hybrid Glide

Biotat

Reference	BIT005
Issue	1
Issue Date	09-Jun-23

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.

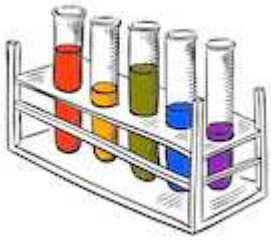
Section 2- Labels and Warnings

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 Hybrid Glide

Biotat

Reference	BIT005
Issue	1
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Signed

Colin Sanders  09/06/2023

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
Managing Director Colin's Cosmetic Consultancy 2013-