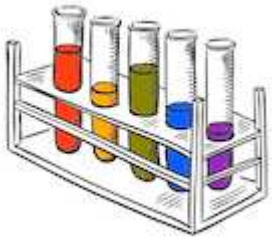


Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH

Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

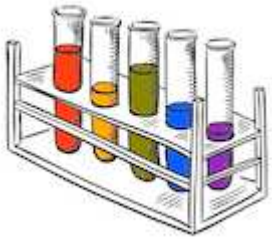
Pink Tattoo Glide

Sponsor Biotat Ltd

Part A

Section 1 - Quantitative and Qualitative Composition

Ingredient	CAS Number	%w/w
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	
Glycerin	56-81-5	
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	
Eugenol	97-53-0	
Glycolipids	n/a	
CI 77019 (Mica)	12001-26-2	
CI 77891 (Titanium Dioxide)	13463-67-7	
Lavandula Angustifolia Herb Oil	8000-28-0	
Isoeugenol	97-54-1	
Tin Oxide	18282-10-5	
CI 77491 (Iron Oxides)	1309-37-1, 1317-61-9, 1345-25-1, 1345-27-3, 52357-70-7	



Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH

Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference	BIT004
Issue	1
Issue Date	11-May-23

Linalool	78-70-6
Geraniol	106-24-1
Limonene	5989-27-5

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.

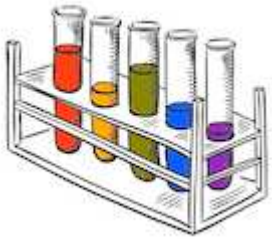
Section 2 - Product Characteristics

Ingredient List

Mineral Oil, Microcrystalline Wax, Cera Microcristallina, Glycerin, Eugenia Caryophyllus (Clove) Bud Oil, Eugenol, Glycolipids, Lavandula Angustifolia Herb Oil, Isoeugenol, Tin Oxide, Linalool, CI 77019 (Mica), CI 77891 (Titanium Dioxide), CI 77491 (Iron Oxides)

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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
Mineral Oil	8012-95-1, 8020-83-5, 8042-47-5		7.820	54.39		

Microcrystalline Wax	63231-60-7 64742-42-3	7.820	36.69		
Cera Microcristallina	63231-60-7 64742-42-3	7.820	27.52		
Glycerin	56-81-5	7.820	6.52		
Eugenia Caryophyllus (Clove) Bud Oil	84961-50-2	7.820	3.91		
Eugenol	97-53-0	7.820	3.40		
Glycolipids	n/a	7.820	0.64		
CI 77019 (Mica)	12001-26-2	7.820	0.44		
CI 77891 (Titanium Dioxide)	13463-67-7	7.820	0.20	7500	37125.6
Lavandula Angustifolia Herb Oil	8000-28-0	7.820	0.01		
Isoeugenol	97-54-1	7.820	0.01	150	12787.7
Tin Oxide	18282-10-5	7.820	0.01	2000	306905

CI 77491 (Iron Oxides)	1309-37-1, 1317-61-9, 1345-25-1, 1345-27-3, 52357-70-7	7.820	0.01		
Linalool	78-70-6	7.820	0.01	500	85251.5
Geraniol	106-24-1	7.820	0.00	1000	6975120
Limonene	5989-27-5	7.820	0.00	825	6329920

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

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

CI 77019 (Mica) 12001-26-2

Mica is a naturally occurring group of silicate minerals. In cosmetics and personal care products, Mica, from muscovite mica is used in the formulation of a wide variety of product types, including makeup, nail products and skin care products. Like most silicates it is chemically unreactive and unlikely to penetrate the skin.

The Food and Drug Administration (FDA) lists Mica as a color additive exempt from certification. Mica, is safe for use in coloring products, including cosmetics and personal care products applied to the lips, and the area of the eye.

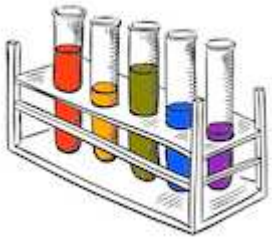
FDA also includes aluminum and potassium silicate (Mica) on the list of indirect food additives and permits its use as a colorant for polymers with incidental contact with food.

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

Its inert nature and low absorbtion makes a MoS calculation uneccessary. A toxicology study on rats using titanium dioxide coated mica is of questionable relevance but did use exceptionally high levels without any adverse effects.

Journal of Toxicology and Environmental Health 02/1990; 29(4):417-29. Toxicology and carcinogenesis studies of dietary titanium dioxide-coated mica in male and female Fischer 344 rats. B K Bernard, M R Osheroff, A Hofmann, J H Mennear

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference	BIT004
Issue	1
Issue Date	11-May-23

CI 77491 (Iron oxides) 1309-37-1, 1317-61-9, 1345-25-1, 1345

Iron Oxides used in cosmetic products is an inorganic compound consisting of any one or combinations of synthetically prepared iron oxides that includes hydrated forms of iron oxides. In cosmetics and personal care products, Iron Oxides are used in the formulation of a wide variety of product types, including makeup and skin care preparations. They are insoluble in water and are presented as insoluble particles that remain on the surface of the skin and do not interact with other formulation ingredients.

The Food and Drug Administration (FDA) lists Iron Oxides as a color additive exempt from certification. Iron Oxides are safe for use in coloring products, including cosmetics and personal care products applied to the lips, and the area of the eye, provided they meet certain specifications.

The FDA also includes Iron Oxides on its list of indirect food additives considered Generally Recognized As Safe (GRAS).

An extensive review of the role of metals including iron in the International Journal of Cosmetic Scientists failed to discover any serious toxicological issues relating to the use of iron in cosmetics.

This colourant is on the EU's approved list in Annex IV of the cosmetic regulations, subject to the condition that it also meets the purity criteria as set out in Commission Directive 95/45/EC.

The inert nature of iron oxide, its long history of safe use and lack of permeability to the skin makes the establishment of an NOAEL not especially meaningful. Recently a study has been carried out on iron oxide nanoparticles. The studies themselves are not relevant but have indicated that toxicity is a function of particle size and that relatively large particles are effectively non-toxic.

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

CI 77891 (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.

"Substance Information - ECHA". Echa.Europa.Eu, 2022, https://echa.europa.eu/et/substance-information/-/substanceinfo/100.033.327. Accessed 2 Mar 2022.

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.

The IFRA guidelines for clove bud oil are

Category 1-0.55%
Category 2-0.17%
Category 3-1.71%
Category 4-3.05%
Category 5A-0.78%
Category 5B-0.78%
Category 5C-0.78%
Category 5D-0.26%
Category 6-0.78%
Category 7B-1.71%
Category 8-0.26%
Category 9-5.98%
Category 10A-5.98%
Category 10B-21.95%
Category 11A-0.26%
Category 11B-0.26%

All these levels assume continual use of the product. Higher levels can be justified for products that are used episodically.

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.

IFRA Standards 50th Amendment 2022

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

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

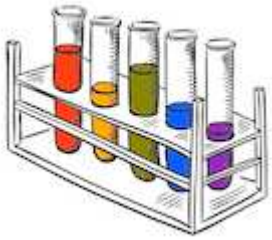
Glycolipids n/a

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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.

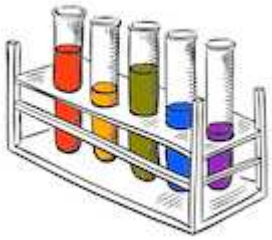
IFRA Standard

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)

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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).

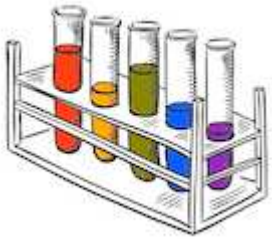
Its traditional usage has not precluded medical research into its properties, with no previously unsuspected risks coming to light. Some of the terpenes that comprise lavender oil are listed as allergens in the EU legislation, but despite this allergic reactions to lavender are extremely low. Only 1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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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.

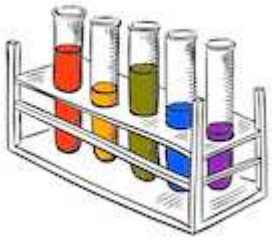
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) . Scientific Opinion on Flavouring Group Evaluation 25, Revision 2 (FGE.25Rev2): Aliphatic and aromatic hydrocarbons from chemical group 31 . EFSA Journal 2011; 9(6):2177. [126 pp.]. doi:10.2903/j.efsa.2011.2177. Available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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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.

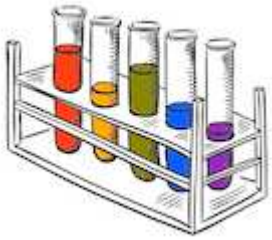
Its presence must be indicated in the list of ingredients when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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.

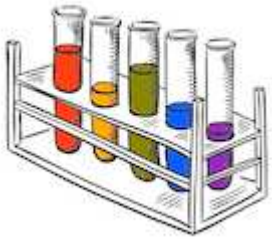
The primary route of exposure to Microcrystalline Wax and similar hydrocarbons is as a result of their indirect use in foodstuffs. It is estimated that daily exposure from this source is 0.044 mg/kg BW/day. This is equivalent to several grams per day for an adult and this clearly dwarfs any exposure 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.

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

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.

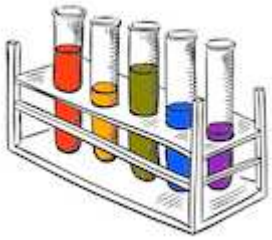
The nature of light liquid paraffin is such that it is extremely unlikely to penetrate the skin nor to cause a significant number of allergic reactions.

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference BIT004
Issue 1
Issue Date 11-May-23

Tin Oxide 18282-10-5

Tin dioxide is used as a colourant in cosmetic products and is listed on the EU's CosIng database with no restrictions on its use. Its colour index number is CI 77861, and although the official name is Tin Oxide this is not consistent with most colourant monographs. It would be defendable to label it as CI 77861, and it might be anticipated that at some point in the future the official name will be changed to this to bring it into line with the standard practice.

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.

Tin is a common element and was one of the first metals to be used, its use dating back to before historic times. Consequently its risks are well known. The oxide is a very inert form and is not associated with the toxic effects of tin, although there is a condition called Stannosis which is the result of long term occupational exposure to the inhalation of tin oxide dust. This is not relevant to this product.

The scientific data on tin oxide was considered by the Cosmetic Ingredient Review Panel in 2013. The CIR Expert Panel concluded that tin(IV) oxide is safe in the present practices of use and concentration in cosmetics, practices which this product follows.

There is no publised NOAEL for tin oxide, but the dermal toxicity value of tin itself has been used.

A group of five male and five female Wistar rats was topically treated with 2000 mg/kg bw of tin metal powder (prepared to provide a particle size in the range 2 -11 µm) in a GLP compliant study conducted to current internationally accepted guidelines (OECD 402 and EU Method B.3). No evidence was found for dermal toxicity at the limit dose level.

This is a conservative approach as it exagerrates the quantity of tin, and because tin in tin oxide will be less bioavailable - and the testing has not even been titrated to the maximum level. Nonetheless it gives an acceptable level of safety in the margin of safety calculation.

Final Report on the Safety Assessment of Tin(IV) Oxide as Used in Cosmetics December 2013

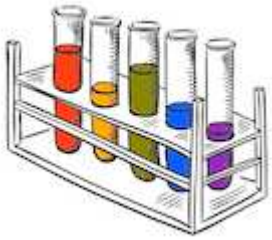
Health effects assessment for Tin and compounds Environmental Protection Agency Vol:EPA/600/8-88/055 (1987) 41 p

"Registration Dossier - ECHA". Echa.Europa.Eu, 2021, https://echa.europa.eu/et/registration-dossier/-/registered-dossier/14736/2/3. Accessed 26 Sept 2021.

Section 9 - Undesirable Effects

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

Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH



Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference	BIT004
Issue	1
Issue Date	11-May-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.

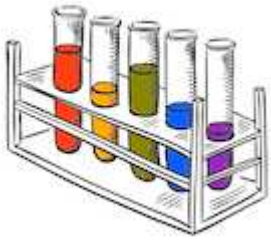
Section 2- Labels and Warnings

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.



Colin's Cosmetic Consultancy Ltd
1 Market Square
Petworth
West Sussex
GU28 0AH

Product Safety Assessment

Pink Tattoo Glide

Biotat Ltd

Reference	BIT004
Issue	1
Issue Date	11-May-23

Signed

Colin Sanders  12/05/2023

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-