



Safety Assessment

GZ 4371/13

DATE OF APPROVAL: October 29, 2013

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DATE OF ASSIGNMENT: October 24th, 2013

RECEIPT OF SAMPLE: October 2013

CLIENT (DISTRIBUTOR): Österreichischer Imkerbund, Georg Cochplatz 3/11a, 1010 Wien

TEST SAMPLE: Base recipe "Propolis Crème Drescher" including manufacturing process

PLACE OF ASSESSMENT: Belan Ziviltechniker-GmbH, Durisolstraße 7, A-4600 Wels (PSID 278 gemäß Akkreditierungsgesetz mit Bescheid GZ BMWA-92.714/0077-I/12/2009)

Introduction

In accordance with Regulation (EC) No 1223/2009 the distributor/ manufacturer of cosmetic products has to provide a safety assessment for all ingredients of a specific product including a basic toxicological profile.

The client has contracted the preparation of the safety assessment with Dipl.-Ing. Dr. Thomas Eidenberger (CV see Attachment 1). Dipl.-Ing. Dr. Thomas Eidenberger fulfils the criteria set out in BGBl. 168/1996 § 1(1), 2e idgF and was authorized according to § 73 Food Safety and Consumer Protection Law to assess the safety of cosmetics (BGBl. 13/2006 from January 20th, 2006 idjgF).



Strategy for Safety Assessment

Amongst others following sources are consulted for the assessment:

National and European regulations for the use of ingredients in cosmetic products (positive lists, prohibition and restricted use listings)

The Data Base CosIng (<http://ec.europa.eu/consumers/cosmetics/cosing/>) describing ingredients to be used in cosmetic products in the European Union

Entries in the Hazardous Substances Data Bank (HSDB) and Toxline (<http://toxnet.nlm.nih.gov>) both operated by the National Library of Medicine (USA).

Material Safety Data Sheets

PubMed (<http://www.ncbi.nih.gov/>) literature survey focused on contact dermatitis and allergy.

Opinions of the Federal Institute for Risk Assessment, Germany

Amendments to 96/335/EG of the commission (2006/257/EG, L97/1, 5.4. 2006)

Opinions on Cosmetic Products and Non-Food Products for Consumers (http://ec.europa.eu/health/ph_risk/committees/sccp/sccp_opinions_en.htm)

Cosmetic Ingredient Reviews (<http://cir-safety.org>)

The International Fragrance Association (<http://ifraorg.org>)

Publications of the RIFM (flavour components).

The evaluation respects the SCCP's Note of Guidance for the testing of cosmetic ingredients and their Safety Evaluation (8th Revision).

Abbreviations

ADI	Acceptable daily intake
CIR	Cosmetic Ingredient Review
COSING	Cosmetic Ingredient Inventory
FDA	Food and Drug Administration
HSDB	Hazard Substances Data Bank
LD	Lethal Dose
MOS	Margin of Safety (NOAEL/SED)
NOAEL	No adverse effect level ($ADI \times f = NOAEL$)
SCCP	Scientific Committee for Cosmetic Products
SED	Systemic exposure dose

Expert Opinion

The ingredients of "Propolis Crème Drescher" are listed and characterized in Table 1. All ingredients are listed in the CosIng Inventory. For none of the ingredients used restrictions are given in the CosIng Inventory; hence the product composition is permitted under the regulations for cosmetic products.

The evaluation of the entries in the Hazardous Substances Data Bank (HSDB), Toxline and published Cosmetic Ingredient Reviews does not contradict a safe use of the ingredients in cosmetic products.

The evaluation of relevant literature retrieved for the allergic potential after topical use of the main ingredients does not provide substantial evidence to question the safety of the product.

The toxicological evaluation provides –where applicable- Margins of Safeties >100 (see Attachment 2).

The evaluation of the Systemic Exposure Dosage presented on Table 1 does not add a substantial risk for the safe use of the product at hand.

The manufacturing process should comply with the rules governing the Good Manufacturing Practice (GMP).

Based on the information presented the ingredients of "Propolis Crème Drescher" exhibit low sensitization and negligible toxic potentials when used in topical cosmetic products. No synergistic effects for the particular composition of the product could be retrieved from the literature.

Summary and Conclusion

All ingredients of "Propolis Crème Drescher" are permitted in cosmetic products and are used in accordance with the applicable restrictions.

The assessment of exposure to the product, of the individual ingredients and the manufacturing process yields an adequate safety profile for "Propolis Crème Drescher" especially if the intended use as cosmetic product in accordance with the recommendations of the manufacturer is taking into consideration.

Responsible for the Assessment



Dipl.-Ing. Dr. Thomas Eidenberger

Table 1

Mass %	INCI	SED
18.33	Cetearyl Alcohol (Cetearyl Alcohol) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
18.33	Petrolatum (Petrolatum) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
18.33	Peanut Oil (Arachis Hypogaea Oil) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
18.33	Hydrogenated Peanut Oil (Peanut oil, hydrogenated) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
18.33	Paraffin (Paraffinum) Basunguent (no quantitative composition available, estimate <25 %))	1.34E-03
18.33	Mineral Oil (Paraffinum Liquidum) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
18.33	Lanolin Alcohol (Lanolin Alcohol) Basunguent (no quantitative composition available, estimate <25 %)	1.34E-03
0.73	BHT (BHT) Basunguent (no quantitative composition available, estimate <1 %)	2.15E-06
7.33	Cera Microcristallina (Cera Microcristallina) Basunguent (no quantitative composition available, estimate <10 %)	2.15E-04
18.67	Olivenöl (Olea Europaea Fruit Oil)	1.39E-03
5.00	Propolis cera (Propolis cera)	1.00E-04
5.00	Alcohol (Alcohol)	1.00E-04
3.00	Bienenwachs (Cera Alba)	3.60E-05



Pharma & Lebensmittel

● Beratung - Entwicklung – Laboranalytik

● Eidenberger & Mittelbach

Attachment 1

BELAN Ziviltechniker-GmbH
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Curriculum Vitae

Name: Dipl.Ing. Dr. Thomas Eidenberger

Date/Place of Birth: 20. October 1963/Vienna

Address: Gartenweg, 4400 St. Ulrich/Steyr
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Civil status: Married since 29. June 1991
Wife Mag. Margit , 4. October 1965/Vienna
Profession Physiotherapist
Son Lukas, 02. August 1992/ Steyr
Son Lorenz, 16.February 1997/ Steyr

Parents: Father Dipl.Ing. Karl Eidenberger, + 2013
Mother Helga Eidenberger, + 1991

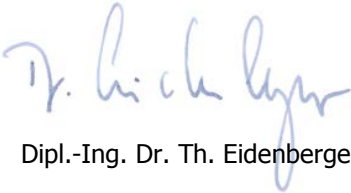
Education: 1969 - 1973 Grammar School in Vienna
1973 - 1981 High School in Vienna, High School Diploma
1981 - 1990 University of Agriculture, Food- and Biotechnology
1990 Diploma degree (Dipl.-Ing.)
1994 Doctors degree (Dr.rer.nat.techn.)
1996 Public Certificate Consulting Engineer
Public Certificate Legal Expert
1997 Authorization acc. § 50 LMG 1975 (Authorised to
test and certify food and cosmetics)
2008 Authorization acc. § 73 LMSVG 2006 (Authorised
to test and certify food and cosmetics)

Professional Career: 1988 - 1990 Co-Worker within funded research projects at
the University of Agriculture (Plant genetics)
1990 - 1991 Assistant at Technical University Vienna
1991 - 1996 Research Scientist, at Nycomed Pharma, Linz

Professional Career:

- 1997 - Manager of BELAN Ziviltechniker-GmbH
- 2002 - Head of study course Bio- and Environmental Engineering at the University of Applied Sciences in Upper Austria
- 2004 - 2006 Dean of the faculty for technical and environmental sciences
- 2008 - Head of the accredited laboratory (ISO-17025) Belan ZT-GmbH

Wels, 2013-09-29



Dipl.-Ing. Dr. Th. Eidenberger

Attachment 2

Detailed description of the ingredients, toxicological evaluation and calculation of the margin of safety

(6 pages)

Attachment 2

INCI	Mass %	COSING-Function	CAS-No	Restriction/Others	HSDB No
Cetearyl Alcohol Basunguent (no quantitative composition available, estimate <25 %)	18.33	Emollient, Emulsifying, Emulsion Stabilising, Foam Boosting, Opacifying, Surfactant, Viscosity Controlling	67762-27-0 8005-44-5	CIR concluded that Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol are safe as cosmetic ingredients in the present practices of use (J AM Coll Tox 1988 7, 3)	-
Petrolatum Basunguent (no quantitative composition available, estimate <25 %)	18.33	Antistatic, Emollient	8009-03-8	II/904 (except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen) 0474/01 - Opinion concerning Chemical Ingredients in Cosmetic Products classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to the Chemicals Directive 67/548/EEC 0825/04 - Opinion concerning Chemical Ingredients in Cosmetic Products classified as Carcinogenic, Mutagenic or Toxic to Reproduction according to the Chemicals Directive 67/548/EEC	1138
Peanut Oil (Arachis Hypogaea Oil) Basunguent (no quantitative composition available, estimate <25 %)	18.33	Emollient, Solvent	8002-03-7	CIR: Final report on the safety assessment of Peanut (Arachis hypogaea) Oil, Hydrogenated Peanut Oil, Peanut Acid, Peanut Glycerides, and Peanut (Arachis hypogaea) Flour. Int J Toxicol. 2001;20 Suppl 2:65-77.	5152
Hydrogenated Peanut Oil (Peanut oil, hydrogenated) Basunguent (no quantitative composition available, estimate <25 %)	18.33	Emollient, Emulsifying, Skin Conditioning, Viscosity Controlling	68425-36-5	CIR: Final report on the safety assessment of Peanut (Arachis hypogaea) Oil, Hydrogenated Peanut Oil, Peanut Acid, Peanut Glycerides, and Peanut (Arachis hypogaea) Flour. Int J Toxicol. 2001;20 Suppl 2:65-77.	-
Paraffin (Paraffinum) Basunguent (no quantitative composition available, estimate <25 %)	18.33	Emollient, Antistatic, Skin protecting, Solvent	8012-95-1 8042-47-5	CIR 2012: safe as used (< 50 %)	1922

Attachment 2

INCI	Mass %	COSING-Function	CAS-No	Restriction/Others	HSDB No
Mineral Oil (Paraffinum Liquidum) Basunguent (no quantitative composition available, estimate <25 %)	18.33	Antistatic, Emollient, Skin protecting, Solvent	8012-95-1 8042-47-5	CIR 2012: safe as used (< 50 %)	1922
Lanolin Alcohol (Lanolin Alcohol) BBasunguent (no quantitative composition available, estimate <25 %)	18.33	Antistatic, Binding, Emollient, Emulsifying, Hair conditioning, Viscosity controlling	8027-33-6	CIR states a safe, topical use in current cosmetic practice	1817
BHT (BHT) Basunguent (no quantitative composition available, estimate <1 %)	0.73	Antioxidant, Masking	128-37-0		1147
Cera Microcristallina (Cera Microcristallina) Basunguent (no quantitative composition available, estimate <10 %)	7.33	Binding, Emulsion Stabilising, Opacifying, Viscosity Controlling	63231-60-7 64742-42-3		-
Olivendi (Olea Europaea Fruit Oil)	18.67	Emollient, Perfuming, Solvent	8001-25-0	CIR: Essentially olive oil is considered safe in the present practices of use and concentration in cosmetics (2010)	5151
Propolis cera (Propolis cera)	5.00	Antiseborrhoeic, Moisturing, Smoothing	85665-41-4	Rajpara S; Wilkinson MS; King CM; Gawkrödger DJ; English JS; Statham BN; reen C; Sansom JE; Chowdhury MM; Horne HL; Ormerod AD. Contact Dermatitis. 2009, Nov; 61(5):287-90.	-
Alcohol (Alcohol)	5.00	Antifoaming, Antimicrobial, Astringent, Masking, Solvent, Viscosity Controlling	64-17-5		82

Attachment 2

INCI	Mass %	COSING-Function	CAS-No	Restriction/Others	HSDB No
Bienenwachs (Cera Alba)	3.00	Emollient, Emulsifying, Film forming, Perfuming	8012-89-3	Jensen CD, Andersen KE. Allergic contact dermatitis from cera alba (purified propolis) in a lip balm and candy. Contact Dermatitis. 2006 Nov;55(5):312-3 Koster FB. Drug Cosmet. Ind.; VOL 129 ISS Nov 1981	

Propoliscreme nach "Drescher"	
Stoffbezeichnung	Gewicht in Gramm
Basunguent (Salbengrundlage)	220
Olivenöl (Oleum olivae)	56
Propolistropfen (Propolis cera, Alcohol)	15
Bienenwachs (Apis cera)	9
Total	300

Attachment 2

INCI	NOAEL or supporting information g/kg BW/day	SED g/kg BW/day	Base for MOS calculation g/kg BW	MOS
Cetearyl Alcohol Basunguent (no quantitative composition available, estimate ≤25 %)	CIR states a safe use up to 25 % (JACT 7(3):359-413, 1988 confirmed 12/05).	1.34E-03		CIR: safe as used (MOS>100)
Petrolatum Basunguent (no quantitative composition available, estimate ≤25 %)	NOAEL of 2 g/kg/day (EPA, 1996; MRID 413688-22) edible ADI: 0.0-2.0 x 10 ⁻² g/kg/day CIR 2012: safe as used (< 50 %)	1.34E-03		CIR: safe as used (MOS>100)
Peanut Oil (Arachis Hypogaea Oil) Basunguent (no quantitative composition available, estimate ≤25 %)	CIR states safe as used. edible Ring J, Möhrenschrager M. Allergy to peanut oil--clinically relevant? J Eur Acad Dermatol Venereol. 2007 21(4):452-5. Yunginger JW, Calobrisi SD. Investigation of the allergenicity of a refined peanut oil-containing topical dermatologic agent in persons who are sensitive to peanuts. Cutis. 2001 68(2):153-5.	1.34E-03		CIR: safe as used (MOS>100)
Hydrogenated Peanut Oil (Peanut oil, hydrogenated) Basunguent (no quantitative composition available, estimate ≤25 %)	CIR states safe as used. edible	1.34E-03		CIR: safe as used (MOS>100)
Paraffin (Paraffinum) Basunguent (no quantitative composition available, estimate <25 %))	MSDS: LD50 (rat) oral > 2 g/kg LD50 (rabbit) dermal > 3 g/kg NOAEL 2 g/kg/day (EPA, 1996; MRID 413688-22) edible ADI:0.0-1.0 x 10 ⁻² g/kg	1.34E-03		CIR: safe as used (MOS>100)

Attachment 2

INCI	NOAEL or supporting information g/kg BW/day	SED g/kg BW/day	Base for MOS calculation g/kg BW	MOS
Mineral Oil (Paraffinum Liquidum) Basunguent (no quantitative composition available, estimate <25 %)	MSDS: LD50 (rat) oral > 2 g/kg LD50 (rabbit) dermal > 3 g/kg NOAEL 2 g/kg/day (EPA, 1996; MRID 413688-22) edible ADI:0.0-1.0 x 10 ⁻² g/kg	1.34E-03		CIR: safe as used (MOS>100)
Lanolin Alcohol (Lanolin Alcohol) BBasunguent (no quantitative composition available, estimate <25 %)	edible, LD50 oral>5 g/kg BW	1.34E-03		CIR: safe as used (MOS>100)
BHT (BHT) Basunguent (no quantitative composition available, estimate <1 %)	edible, LD50 oral 1-5 g/kg BW NOAEL (oral, chronic): 4.17x10 ⁻⁴ g/kg/day	2.15E-06	4.17E-04	1.94E+02
Cera Microcristallina (Cera Microcristallina) Basunguent (no quantitative composition available, estimate <10 %)	NOAEL rats 1.10 g/kg bw/day (sub-chronic) U.S. EPA September, 2011	2.15E-04	0.1	4.65E+02
Olivendi (Olea Europaea Fruit Oil)	edible, no safety concerns, > 1 g/kg bw considered safe	1.39E-03	1	7.17E+02
Propolis cera (Propolis cera)	edible NOAEL: 1.4 g/kg (oral 90 day treatment) Burdock GA. Review of the biological properties and toxicity of bee propolis (propolis). Food Chem Toxicol. 1998 Apr;36(4):347-63 usual daily recommendation in dietary supplements: 0.25-0.50 g/day Shaw D, Leon C, Kolev S, Murray V. Traditional remedies and food supplements. A 5-year toxicological study (1991-1995). Drug Saf. 1997 Nov; 17(5): 342-56.	1.00E-04	0.1	1.00E+03
Alcohol (Alcohol)	0.5 g/kg does not affect the behaviour of man LD50 Rat (oral): 7.06 g/kg LD50 Rat (iv): 1.44 g/kg LD50 Mouse (oral): 3.45 g/kg LD50 Mouse (iv): 1.97 g/kg	1.00E-04		considered safe (MOS>100)

Attachment 2

INCI	NOAEL or supporting information g/kg BW/day	SED g/kg BW/day	Base for MOS calculation g/kg BW	MOS
Bienenwachs (Cera Alba)	edible (E901) estimated human intake: 0.40-0.65 g/day EFSA cannot calculate ADI but concludes that E901 has a low if any toxicological potential. LD50 Rat (oral): >5.00 g/kg FAO and WHO working groups WHO Food Additives Series Vol:30 (1993) pp 231-4: non-toxic, but allergy upon intake possible JACT 3(3):1-41, 1984 confirmed 06/03 IJT 24(51):48-52, 2005: safe as used in cosmetics (<56 %)	3.60E-05	0.5	1.39E+04