



## Safety Assessment

GZ 4370/13

DATE OF APPROVAL: October 29, 2013

NUMBER OF PAGES: 7 (+ 4 pages Attachment 2)

DATE OF ASSIGNMENT: October 24<sup>th</sup>, 2013

RECEIPT OF SAMPLE: October 2013

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

TEST SAMPLE: Base recipe "Propolis Crème Zangerl" 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](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 (8<sup>th</sup> 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 Zangerl" 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 Zangerl" 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 Zangerl" 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 Zangerl" 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
38.43	Vaseline ( <b>Petrolatum</b> )	5.91E-03
38.43	Lanolin ( <b>Lanolin</b> )	5.91E-03
5.76	Bienenhonig ( <b>Mel</b> )	1.33E-04
13.45	Propolis cera ( <b>Propolis cera</b> )	7.24E-04
3.84	Alcohol ( <b>Alcohol</b> )	5.91E-05
3.84	Lärchenterpentin ( <b>Turpentine oil</b> )	5.91E-05
0.08	Latschenkiefernöl ( <b>Pinus Mugo Twig Oil</b> )	2.36E-08



Pharma & Lebensmittel

● Beratung - Entwicklung – Laboranalytik

● Eidenberger & Mittelbach

## Attachment 1

BELAN Ziviltechniker-GmbH  
akkreditierte Prüfstelle gemäß  
ÖNORM EN ISO/IEC 17025

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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  
Telephone: +43(0)725247842

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

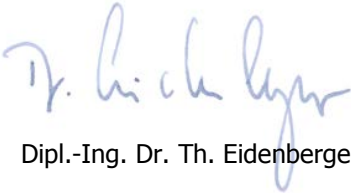
Education: 1969 - 1973 Grammar School in Vienna  
1973 - 1981 High School in Vienna, High School Diploma  
1981 - 1990 University of Agriculture, Food- and Biotechnology  
1990 Diploma degree (Dipl.-Ing.)  
1994 Doctors degree (Dr.rer.nat.techn.)  
1996 Public Certificate Consulting Engineer  
Public 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

(4 pages)

Attachment 2

INCI	Mass %	COSING-Function	CAS-No	Restriction/Others	HSDB No
Vaseline (Petrolatum)	38.43	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 CIR 2012: safe as used (< 50 %)  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
Lanolin (Lanolin)	38.43	Antistatic, Binding, Emollient, Emulsifying, Hair conditioning, Viscosity controlling	8027-33-6	CIR states a safe, topical use in current cosmetic practice (Final report of the safety assessment of acetylated lanolin alcohol and related compounds prepared by the Expert Panel of the Cosmetic Ingredient Review, 9 November 1979).	1817
Bienenhonig (Mel)	5.76	Emollient, Humectant, Moisturising	8028-66-8	-	-
Propolis cera (Propolis cera)	13.45	Antiseborrhoeic, Moisturing, Smoothing	85665-41-4	Rajpara S; Wilkinson MS; King CM; Gawkrödger DJ; English JS; Statham BN; ree C; Sansom JE; Chowdhury MM; Horne HL; Ormerod AD. Contact Dermatitis. 2009, Nov; 61(5):287-90.	-
Alcohol (Alcohol)	3.84	Antifoaming, Antimicrobial, Astringent, Masking, Solvent, Viscosity Controlling	64-17-5	-	82



Attachment 2

INCI	Mass %	COSING-Function	CAS-No	Restriction/Others	HSDB No
Lärchenterpentin (Turpentine oil)	3.84	Perfuming	8006-64-2	III/125: Peroxide value less than 10 mmoles/L SCCS opinions: 0392/00 - An Initial List of Perfumery Materials which must not form part of Cosmetic products except subject to the restrictions and conditions laid down SCCS OPINION on Fragrance allergens in cosmetic products, 2011: Clinical tests were performed 21CFR172.510: May be added to human nutrition as flavoring	204
Latschenkiefernöl (Pinus Mugo Twig Oil)	0.08	Perfuming	90082-72-7	III/109 : Peroxide value less than 10 mmoles/L SCCS opinions: 0392/00 - An Initial List of Perfumery Materials which must not form part of Cosmetic products except subject to the restrictions and conditions laid down SCCS OPINION on Fragrance allergens in cosmetic products, 2011: Clinical tests were performed 21CFR172.510: May be added to human nutrition as flavoring	-

Propoliscreme nach "Zangerl"	
Stoffbezeichnung	Gewicht in Gramm
Vaseline (Petrolatum)	100
Lanolin (Lanolin Cera)	100
Propolis (Propolis Cera + Propolis Cera in Lösung)	25
Bienenhonig (Mel)	15
Propolislösung (Propolis cera, Alcohol)	10
Lärchenterpentin (Larix Decidua)	10
Latschenkiefernöl (Pinus Mugo Turr.)	0.2
Total	260.2

Attachment 2

INCI	NOAEL or supporting information g/kg BW/day	SED g/kg BW/day	Base for MOS calculation g/kg BW	MOS
Vaseline (Petrolatum)	NOAEL of 2 g/kg/day (EPA, 1996; MRID 413688-22) edible ADI: 0.0-2.0 x 10 <sup>-2</sup> g/kg/day	5.91E-03	2	3.39E+02
Lanolin (Lanolin)	edible, LD50 oral >5.0 g/kg BW considered safe in topical formulations	5.91E-03		- CIR: safe as used (MOS>100)
Bienenhonig (Mel)	edible, no safety concerns, > 1 g/kg bw considered safe	1.33E-04	1	7.52E+03
Propolis cera (Propolis cera)	edible NOAEL: 1.4 g/kg bw (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.	7.24E-04	0.5	6.91E+02
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	5.91E-05		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
Lärchenterpentin (Turpentine oil )	LD50 Rat (oral): 5.76 g/kg LD50 Mouse (iv): 1.18 g/kg LC50 Mouse (inhalation): 29 g/m <sup>3</sup> /2 hr Estimated Lowest Lethal Dose Human (oral): 0.5 g/kg  Only single cases of contact allergy reported, mainly for painters using it as solvent.	5.91E-05		considered safe (MOS>100)
Latschenkiefernöl (Pinus Mugo Twig Oil)		2.36E-08		considered safe (MOS>100)