

# Technical Data File

RADICARE®-GOLD

RAHN  
COSMETIC  
ACTIVES

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## 1. General Information

<b>INCI-EU</b>	Crambe Abyssinica Seed Oil, Beta-Carotene, Xanthophylls, Tocopherol, Helianthus Annuus Seed Oil, Rosmarinus Officinalis Leaf Extract			
<b>INCI-PCPC/JAPAN</b>	Crambe Abyssinica Seed Oil, Beta-Carotene, Xanthophylls, Tocopherol, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract			
<b>INCI-CHINA</b>	Crambe Abyssinica Seed Oil, Beta-Carotene, Xanthophylls, Tocopherol, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract			
<b>NMPA Submission Code</b>	118859-03337-3877			
<b>INCI alternative</b>	None			
<b>Details of Contents</b>	<b>INCI-PCPC</b>	<b>Content in %</b>	<b>CAS-No.</b>	<b>EINECS-No.</b>
	Crambe Abyssinica Seed Oil	90 - 100	2245025-38-9	273-313-5
	Beta-Carotene	0.1 - 1	7235-40-7	230-636-6
	Xanthophylls	0.1 - 1	127-40-2	n.a.
	Tocopherol	0.1 - 1	54-28-4	200-201-5
	Helianthus Annuus (Sunflower) Seed Oil	< 0.1	8001-21-6	232-273-9
	Rosmarinus Officinalis (Rosemary) Leaf Extract	< 0.1	84604-14-8	283-291-9
<b>Preservatives</b>	None			
<b>Customs Tariff No.</b>	382499 (harmonised system)			
<b>EU Cosmetic Regulation</b>	The product is in compliance with Regulation (EC) No. 1223/2009 and its amendments.			
<b>Country of Origin</b>	DE			

## 2. Nagoya & Access Benefit Sharing

INCI-PCPC	CAS-No.	Status
Crambe Abyssinica Seed Oil	2245025-38-9	Exempted <sup>1</sup>
Beta-Carotene	7235-40-7	Compliant <sup>2</sup>
Xanthophylls	127-40-2	Compliant <sup>2</sup>
Tocopherol	54-28-4	Exempted <sup>1</sup>
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	Exempted <sup>1</sup>
Rosmarinus Officinalis (Rosemary) Leaf Extract	84604-14-8	Compliant <sup>2</sup>

<sup>1</sup> No ABS requirement: The ingredient either is not derived from a genetic resource or is a commodity without utilization in the sense of the Protocol.

<sup>2</sup> The resource was accessed before October 12th 2014 and is not a matter of the Nagoya Protocol. Certificates of Compliance are only available for products that originate from genetic resources accessed after October 12th 2014.

<sup>3</sup> All obligations are met. However, a Certificate of Compliance can only be sent if the provider country has setup a corresponding service. Numerous states currently do not regulate the access of their genetic resources and thus do not provide any documents of compliance.

<sup>4</sup> All obligations are met. Internationally Recognized Certificate of Compliance available.

## 3. Natural Cosmetics

Cosmos	Conform/listed	
Ecocert	Accepted according to self-assessment	
NaTrue	Conform/listed	
ISO 16128	<b>Origin</b>	<b>Content in %</b>
	Natural	100.000
	Natural origin	100.000
	Organic	0.000
	Organic origin	0.000

### 4. Sourcing Ingredients

INCI-PCPC	Continent of Origin	Sourcing Country
Crambe Abyssinica Seed Oil	Worldwide	
Beta-Carotene	Europe	Germany
Xanthophylls	Europe	Germany
Tocopherol	America, Asia, Europe	
Helianthus Annuus (Sunflower) Seed Oil	Europe	Switzerland
Rosmarinus Officinalis (Rosemary) Leaf Extract	Africa, Europe	

If precisely known, the sourcing countries refer to the countries of origin of the active substances. However, RAHN reserves the right to source in other countries in case of shortage or quality deviations. Water is obtained from production site.

## 5. Chemical Registration

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### Registration

To the best of our knowledge as of today there is no restriction. This does not release the customer from the obligation to verify for himself that the import and use is permitted in the country of destination.

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### Europe

#### REACH 1907/2006

The product is in compliance with Regulation (EC) No. 1907/2006 and is free of SVHC's according to the SVHC Candidate List. (Due to our active monitoring, this statement also applies if the date of this data sheet is older than the publication date of the latest SVHC list).

INCI-PCPC	CAS-No.	Status	Reg. No.	Total tonnage band (p.a)
Crambe Abyssinica Seed Oil	2245025-38-9	Exempted <sup>3</sup>		
Beta-Carotene	7235-40-7	Exempted <sup>3</sup>		
Xanthophylls	127-40-2	Exempted <sup>3</sup>		
Tocopherol	54-28-4	Exempted <sup>1</sup>		
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	Exempted <sup>3</sup>		
Rosmarinus Officinalis (Rosemary) Leaf Extract	84604-14-8	Exempted <sup>1</sup>		

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<sup>1</sup> Volume annually below 1 ton

<sup>2</sup> Exempted according Annex IV

<sup>3</sup> Exempted according Annex V

<sup>4</sup> Exempted because polymer

<sup>5</sup> Registered, in compliance with REACH legislation 1907/2006

### China

#### IECSC

INCI-CHINA	CAS-No.	Status
Crambe Abyssinica Seed Oil	2245025-38-9	Exempted <sup>3</sup>
Beta-Carotene	7235-40-7	Compliant <sup>2</sup>
Xanthophylls	127-40-2	Exempted <sup>3</sup>
Tocopherol	54-28-4	Compliant <sup>2</sup>
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	Compliant <sup>2</sup>
Rosmarinus Officinalis (Rosemary) Leaf Extract	84604-14-8	Compliant <sup>2</sup>

<sup>1</sup> Subject to other existing laws and regulations

<sup>2</sup> IECSC 2013 and updates / hidden registration

<sup>3</sup> Exempted (natural substance / compliant extraction method)

<sup>4</sup> Not registered

### Australia

#### Australian Industrial Chemicals Introduction Scheme (AICIS)

INCI-PCPC	CAS-No.	Status
Crambe Abyssinica Seed Oil	2245025-38-9	Not listed <sup>3</sup>
Beta-Carotene	7235-40-7	Listed <sup>1</sup>
Xanthophylls	127-40-2	Listed <sup>1</sup>
Tocopherol	54-28-4	Listed <sup>1</sup>
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	Listed <sup>1</sup>
Rosmarinus Officinalis (Rosemary) Leaf Extract	84604-14-8	Listed <sup>1</sup>

<sup>1</sup> Listed on Australian Inventory of Industrial Chemicals (AIIC)

<sup>2</sup> Listed, yet not publicly available.

<sup>3</sup> Not listed, can be imported as reported, may require assessment. Ask your importer for detailed information.

<sup>4</sup> Naturally occurring substances are defined as an unprocessed chemical occurring in a natural environment; or a chemical occurring in a natural environment that is extracted without chemical change by: manual, mechanical or gravitational means; or dissolution in water; or flotation; or a process of heating for the sole purpose of removing uncombined water; or any other process prescribed by the rules.

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## Canada

### Canada Domestic Substances List (DSL) In Commerce List of Food and Drugs Act Substances (R-ICL)

INCI-PCPC	CAS-No.	Status
Crambe Abyssinica Seed Oil	2245025-38-9	Not listed <sup>3</sup>
Beta-Carotene	7235-40-7	Listed <sup>1</sup>
Xanthophylls	127-40-2	Listed <sup>1</sup>
Tocopherol	54-28-4	Listed <sup>1</sup>
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	Listed <sup>1</sup>
Rosmarinus Officinalis (Rosemary) Leaf Extract	84604-14-8	Listed <sup>1</sup>

<sup>1</sup> Listed on Canada Domestic Substances List (DSL).

<sup>2</sup> Listed on In Commerce List of Food and Drugs Act Substances (R-ICL).

<sup>3</sup> Not listed, limited quantity applies, ask your importer for detailed information.

<sup>4</sup> Naturally occurring substances are defined as either unprocessed or processed only by manual, mechanical or gravitational means; by dissolution in water; by flotation; by heating solely to remove water; extracted from air by any means.

## 6. Safety Assessment

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<b>Safety Assessment (Annex I of Regulation (EC) No. 1223/2009)</b>	Exposure assessment (based on a conservative exposure scenario: i.e. body lotion containing maximal use level of 5 %).	Evaluation of the toxicological profile of the ingredients with emphasis on MoS calculation (based on NOAEL) by independent, qualified safety assessor.	All ingredients, and consequently the product, can be considered as safe for designated use in finished cosmetic products, provided the recommended use levels are respected. Detailed report available upon request.
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The safety assessment is part of the TOX-Package (separate document)

The safety assessment was conducted in accordance with the "SCCS Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation". The Margin of Safety includes use by pregnant women and babies. On this basis, this cosmetic ingredient can also be used in products for pregnant women and babies.

## 7. Toxicology

	Test Point	Method	Result
<b>Toxicology</b>	Toxicity	Bibliographical References	Not toxic
	Dermal Irritation	Rep. Human Patch Test, undiluted, on 50 people	Not irritating
	Eye Irritation	OECD No. 437: BCOP-Test, undiluted	Not irritating
	Sensitisation	Rep. Human Patch Test, undiluted, on 50 people	Not sensitising
	Phototoxicity	Photo Patch Test, undiluted, on 30 people	Not phototoxic
	Mutagenicity	OECD No. 471: Bacterial Reverse Mutation Test (AMES) in 5 S. typhimurium strains	Not mutagenic
<b>Ecotoxicology</b>	Daphnia Toxicity	OECD No. 202: Daphnia sp. Acute Immobilisation Test (Limit Test; 100 mg/l, 48 h)	Not toxic
	Biodegradability	OECD No. 301F: Ready Biodegradability	Readily biodegradable
	Water Hazard	Self-categorisation according to AwSV (Germany only)	Water hazard class 1

Detailed information and original study reports can be found in the TOX-Package (separate document)

## 8. Toxicity

<b>INCI-PCPC</b>	Crambe Abyssinica Seed Oil
<b>CAS</b>	2245025-38-9
<b>Toxicological assessment</b>	Crambe Abyssinica Seed Oil is well known in the cosmetic industry and considered as safe as judged by the CIR [1].
<b>References</b>	1 Cosmetic Ingredient Review Expert Panel: Plant-Derived Edible Oils, and Other Derivatives as Used in Cosmetics. Cosmetic Ingredient Review 2011.
<b>INCI-PCPC</b>	Beta-Carotene
<b>CAS</b>	7235-40-7
<b>Toxicological assessment</b>	Content of Tetradesmus obliquus extract. Evaluation of Tetradesmus obliquus (Synonyms = Scenedesmus obliquus; Acutodesmus obliquus) as an edible alga revealed good tolerability. 5g daily for children and 10 g daily for adults were very well tolerated with no adverse events [1, 2].
<b>References</b>	1 Ishaq AG, Matias-Peralta HM, Basri H. Bioactive Compounds from Green Microalga - Scenedesmus and its Potential Applications: A Brief Review. Pertanika J. Trop. Agric. Sci 2016, 39: 1-16. 2 Barka A, Blecker C. Microalgae as a potential source of single-cell proteins. A review. Biotechnol. Agron. Soc. Environ. 2016, 20: 427-436.
<b>INCI-PCPC</b>	Xanthophylls
<b>CAS</b>	127-40-2
<b>Toxicological assessment</b>	Content of Tetradesmus obliquus extract as Lutein. Evaluation of Tetradesmus obliquus (Synonyms = Scenedesmus obliquus; Acutodesmus obliquus) as an edible alga revealed good tolerability. 5 g extract daily for children and 10 g daily for adults were very well tolerated with no adverse events [1, 2].
<b>References</b>	1 Ishaq AG, Matias-Peralta HM, Basri H. Bioactive Compounds from Green Microalga - Scenedesmus and its Potential Applications: A Brief Review. Pertanika J. Trop. Agric. Sci 2016, 39: 1-16. 2 Barka A, Blecker C. Microalgae as a potential source of single-cell proteins. A review. Biotechnol. Agron. Soc. Environ. 2016, 20: 427-436.
<b>INCI-PCPC</b>	Tocopherol
<b>CAS</b>	54-28-4
<b>Toxicological assessment</b>	Tocopherol is safe as used in cosmetic formulations (i.e. up to 5%) [1].
<b>References</b>	1 Zondlo Fiume M. Final report on the safety assessment of Tocopherol, Tocopheryl Acetate, Tocopheryl Linoleate, Tocopheryl Linoleate/Oleate, Tocopheryl Nicotinate, Tocopheryl Succinate, Dioleoyl Tocopheryl Methylsilanol, Potassium Ascorbyl Tocopheryl Phosphate, and Tocophersolan. Int J Toxicol 2002, 21 Suppl 3: 51-116.
<b>INCI-PCPC</b>	Helianthus Annuus (Sunflower) Seed Oil
<b>CAS</b>	8001-21-6
<b>Toxicological assessment</b>	The CIR Expert Panel has found a general lack of clinical adverse effects for edible oils including Helianthus Annuus Seed Oil (i.e. up to 96%) [1].
<b>References</b>	1 Cosmetic Ingredient Review Expert Panel: Plant-Derived Edible Oils, and Other Derivatives as Used in Cosmetics. Cosmetic Ingredient Review 2011.

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<b>INCI-PCPC</b>	Rosmarinus Officinalis (Rosemary) Leaf Extract
<b>CAS</b>	84604-14-8
<b>Toxicological assessment</b>	NOAEL = 180 mg/kg/d [1]. LD50 rat > 2000 mg/kg bw [2]. Rosemary is well tolerated with only few documented cases of adverse events [3].
<b>References</b>	<p>1 Aguilar F. Use of rosemary extracts as a food additive - Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food. The EFSA Journal 2008, 721: 1-29.</p> <p>2 Anadon A, Martinez-Larranaga MR, Martinez MA, Ares I, Garcia-Risco MR, Senorans FJ, et al. Acute oral safety study of rosemary extracts in rats. J Food Prot 2008, 71: 790-795.</p> <p>3 Ulbricht C, Abrams TR, Brigham A, Ceurvels J, Clubb J, Curtiss W, et al. An evidence-based systematic review of rosemary (Rosmarinus officinalis) by the Natural Standard Research Collaboration. J Diet Suppl 2010, 7: 351-413.</p>

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## 9. Manufacturing

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The product is obtained by CO2 Extraction of microalgae, followed by addition and mixing of remaining constituents.

## 10. Raw Material Constituent Information

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INCI-PCPC	Description
Crambe Abyssinica Seed Oil	Crambe Abyssinica Seed Oil is of plant origin, obtained by pressing of crambe seeds.
Beta-Carotene	Beta-Carotene is of plant origin, obtained by CO2 Extraction of micro algae.
Xanthophylls	Xanthophylls are of plant origin, obtained by CO2 Extraction from micro algae.
Tocopherol	Tocopherol is of plant origin, obtained of non-GMO soybean oil by different distillation steps.
Helianthus Annuus (Sunflower) Seed Oil	Helianthus Annuus Seed Oil is of plant origin, obtained by pressing of sunflower seeds, Organic Quality.
Rosmarinus Officinalis (Rosemary) Leaf Extract	Rosmarinus Officinalis Leaf Extract is of plant origin, obtained by CO2 extraction of rosemary leaves.

## 11. Various Statements in alphabetical order

<b>Animal Tests</b>	Neither the product nor its ingredients have been tested on animals.
<b>BSE</b>	The product is free from substances of bovine origin.
<b>CITES</b>	The product is composed of ingredients that are not derived from protected species and are therefore compliant with CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) provisions.
<b>CMR</b>	The product is free from substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008.
<b>CO2 Footprint</b>	Cradle-to-customer plus waste approach, based on Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard (GHG Protocol) was applied. CO2 emissions from cultivation to the delivery to the customer's factory gates as well as disposal of its packaging. Detailed information see Product Brochur.
<b>Gluten</b>	The product can be considered as gluten-free as it does not contain ingredients derived from grain (e.g. wheat, rye or barley) or does not contain detectable levels of Gluten (< 5 ppm Gluten, measured as Gliadin).
<b>GMO</b>	The product neither contains genetically modified organisms nor ingredients which are produced from genetically modified organisms.
<b>Halal</b>	Certified
<b>Irradiation</b>	Neither the product nor its ingredients were treated with ionising radiation during or after the manufacturing process.
<b>Kosher</b>	Accepted according self-assessment
<b>Nanomaterial</b>	The product is free from substances defined as nanomaterial under Article 2 Paragraph 1 (k) of Regulation (EC) No. 1223/2009.
<b>Microplastic</b>	The product does not contain any Microplastic according to Annex XVII to REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and its amendments.
<b>Mineral Oil</b>	No mineral oils were used in manufacture.
<b>Palm Oil</b>	The product does not contain palm oil, palm kernel oil or palm (kernel) oil derivatives
<b>Production</b>	The manufacturing of the product is in accordance to Cosmetic GMP, i.e. ISO 22716 or equivalent guidelines
<b>Proposition List 65</b>	The product does not contain any of the substances listed on California's Proposition 65 List, latest release

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<b>Vegan</b>	To the best of our knowledge, neither the product nor the constituents or components used in the manufacture of the product contain any material, which is derived from animal / bird / insect or marine animal origin. From this, we conclude that the product is suitable for vegan cosmetics.
<b>VOC</b>	0 %

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## 12. Impurities

	<b>Method</b>	<b>Result</b>
<b>Allergens</b>	GC/MS (reporting level > 20 ppm)	Contains none of the allergens listed in Annex III of the Regulation (EC) No. 1223/2009 and its amendments.
<b>Heavy Metal</b>	DIN EN ISO 11885 / DIN EN ISO 17249 (Al, Cd, Cu, As, Ni, Pb) / DIN EN 13806 (Hg)	Heavy metal content was below detection limit.
<b>Pesticides</b>	§64 LFGB L00.00-115 (QuEChERS) / §35 LMBG L00.00-34 (DFG S-19)	Pesticide content was below detection limit.
<b>Residual Solvents</b>	ICH Guideline for Residual Solvents Q3C(R6), Appendix 1	Does not contain any (residual) solvents.
<b>Iodine</b>	IPC-MS / detection limit < 0.1 ppm	Iodine content was below detection limit.

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**Prohibited substances  
Annex II and restricted  
substances Annex III of  
Cosmetic Regulation  
1223/2009/EC**

Due to the manufacturing process and origin of the starting materials, the presence of substances listed in Annex II and III of the Cosmetic Regulation 1223/2009/EC is not to be expected in the product, and, therefore, is not part of our monitoring process for contaminants and residues. Any traces of impurities (if any) are technically unavoidable in good manufacturing practice.

**Food Allergens**

Does not contain any food Allergens listed to Annex II of the Regulation (EU) No. 1169/2011.

**Further impurities in  
alphabetical order**

Due to the manufacturing process and origin of the starting materials, the presence of the substances listed below is not to be expected in the product, and, therefore, is not part of our monitoring process for contaminants and residues. Any traces of impurities (if any) are technically unavoidable in good manufacturing practice.

Aflatoxins  
Aldehydes  
BHA  
BHT  
Conflict minerals  
Cortisol, hydro-cortisol  
Diethylene Glycol (DEG)  
EDTA  
Endocrine disruptors  
Ethanol  
Ethylene glycol  
Free Amines  
Glycol ethers  
Halogen organic compounds  
Latex  
Mycotoxine  
Nonylphenol ethoxylate  
Parabens  
Petrochemical ingredients  
Polycyclic aromatic hydrocarbons (PAH)  
Polyethylene glycol (PEG)  
Siloxanes  
Sulphates  
Terpenes

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