

Regulatory Information Sheet (RIS)

Product name: Azeclair®
Date: March, 2024
Version: 7
Manufacturer: CORUM Inc.

Product: Azeclair®

March 2024, Version 7

TABLE OF CONTENTS

01. <u>PRODUCT IDENTIFICATION</u>	3-4	Wheat and Gluten	7
Product Name	3	03. <u>REGULATORY STATUS</u>	8-10
INCI Name	3	California Proposition 65	8
Country of Origin	3	Global Compliance	8
Cosmetic Grade Ingredient	3	Halal Certificate	9
Composition	3	Kosher	9
ISO16128	4	Non-Animal Origin/Vegan	9
Manufacturing Process	4	Non-Animal Testing	9
02. <u>STATEMENTS ABOUT INGREDIENTS</u>	4-7	NOAEL	9
Allergens/Fragrance Allergens	4	SVHC	10
BHA/BHT	4	04. <u>EU/UK REACH STATUS</u>	10
BSE/TSE	5	05. <u>FAIRTRADE AND SUSTAINABILITY</u>	10-11
CMR	5		
Conflict Minerals	5		
Cumene	5		
1,4-Dioxane	5		
Diethylene Glycol/Glycol Ethers	5		
Formaldehyde	6		
GMO	6		
Heavy Metal	6		
Hormones, Phthalates, Phenols and Bisphenols	6		
Latex	6		
Microbial Content	6		
Nanoscale Materials	6		
Non-Irradiation	6		
Paraben and Sulphates	7		
Paraffin	7		
Pesticide	7		
Plastic Microbeads and Synthetic Polymer Microparticle	7		
PAH	7		
PFAS	7		
Silicone	7		
VOC	7		

Product: Azeclair®

March 2024, Version 7

01. PRODUCT IDENTIFICATION**Product Name**

Azeclair®

INCI Name

PCPC Potassium Azeloyl Diglycinate

IECIC list 壬二酰二甘氨酸钾

表示名称 アゼロイルジグリシンK

한국 INCI명/성분명 포타슘아젤로일다이글라이시네이트

Country of Origin

The undersigned CORUM Inc. at FL 6, No. 360, Ruei Guang Rd., Neihu District, Taipei, Taiwan declares that the above product is the product of Taiwan. The manufacturing site is at No.10, Cheng Kung 2nd St., Min-Hsiung Industrial Park, Chiayi, Taiwan.

Cosmetic Grade Ingredient

The above product with its assigned INCI name, is currently published in Cosmetic Ingredient Dictionary and Handbook by the Personal Care Products Council.

Composition

The above product complies the following component:

	Amount	CAS No.
COMPONENT		
Water	68-72%	7732-18-5
Potassium Azeloyl Diglycinate	28-30%	477773-67-4
PRESERVATIVE		
1,2 Hexanediol	0.1-1%	6920-22-5
Phenoxyethanol	0.1-1%	122-99-6
Ethylhexylglycerin	<0.1%	70445-33-9

Product: Azeclair®

March 2024, Version 7

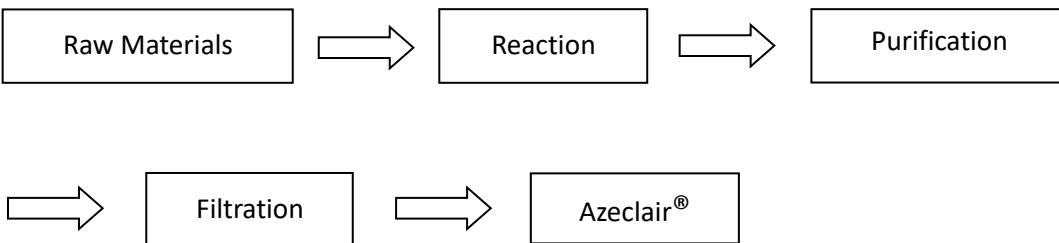
ISO16128

According to the ISO standard criteria and calculating rules, we provide the information on the degree of natural origin for the above product.

PRODUCT	Natural index	Natural origin index	Organic index	Organic origin index
Azeclair®	0.7	0.835	0	0

Manufacturing Process

The above product is manufactured by synthetic processes.



02. STATEMENTS ABOUT INGREDIENTS

Allergens/Fragrance Allergens

The above product is not expected to contain wood, paper, soy, nut, beef or any of their derivatives. When reviewed against the lists of US FDA and EU EFSA allergens, the above product is considered as allergen free. No allergen is intentionally added or introduced throughout the manufacturing processes. Based on the information provided by our raw material suppliers and to the best of our knowledge of our product chemistry, we confirm that the above product is not expected to contain any of the allergens listed in Annex III of the EU Cosmetic Regulation (EC) No. 1223/2009 and its latest updates.

BHA/BHT

The above product does not contain any BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene) during the manufacturing process, and we confirm that it does not have any appreciable trace of BHA/BHT.

Product: Azeclair®

March 2024, Version 7

BSE/TSE

The above product is free from the risk of all BSE and TSE. We hereby confirm that the raw materials of the above product are not expected to contain any animal or cell culture derived products or additives.

CMR (Carcinogenic, Mutagenic, Reprotoxic Substances)

None of the ingredients contained in this product is classified as carcinogenic, mutagenic or toxic for reproduction in accordance with the CMR Omnibus Regulation (EU), the Annex VI of Regulation (EC) No. 1272/2008 and its latest updates.

Conflict Minerals

Conflict minerals are four particular metals (Tin, Tantalum, Tungsten or Gold), which when sourced from the Democratic Republic of the Congo (DRC) and/or surrounding countries have a high risk of funding rebel groups or terrorist activity. We herewith confirm the component and manufacturing process of the above product is free of conflict minerals because it is not part of the manufacturing process nor is intentionally added.

Cumene

The above product is not expected to contain any cumene. Cumene usually comes from solvents, such as Naphtha and BTX. (Benzene, Toluene, Xylene). We do not use these solvents in the manufacturing process, and we would not expect to find cumene present. We do not intentionally run and report cumene content of the above product. If we did, the result would always be in compliance with the 18th Adaptation to Technical Progress (18th ATP) to Regulation (EC) 1272/2008 on the classification, labelling, and packaging of substances and mixtures.

1,4-Dioxane

The above product is not expected to contain any 1,4-dioxane and ethylene oxide. Neither 1,4-dioxane nor ethylene oxide related derivatives are used in the manufacturing process and we would not expect to find 1,4-dioxane and ethylene oxide present.

Diethylene Glycol/Glycol Ethers

The above product is not expected to contain diethylene glycol and any glycol ethers as they are not part of the manufacturing process nor are intentionally added.

Product: Azeclair®

March 2024, Version 7

Formaldehyde

The above product is not expected to contain formalin, free formaldehyde or chemicals containing formaldehyde donors. Formaldehyde-releasing preservatives and packaging materials are also not used in the manufacturing process of the above product, and so the release of formaldehyde during storage and use is not expected.

GMO (Genetically Modified Organisms)

None of the raw materials used in the production is from genetically modified origins. The above product is not produced using GMO.

Heavy Metal

The above product is expected to be free from heavy metals because heavy metals are not part of the manufacture nor are intentionally added.

Hormones, Phthalates, Phenols and Bisphenols

The above product is not expected to contain hormones, phthalates, phenols and bisphenols as they are not used in the manufacture.

Latex

The above product is not expected to contain latex as it is not used in the manufacture.

Microbial Content

The total aerobic microbial count (TAMC) and the total yeast/mold count (TYMC) of the above product are both less than 100 cfu/g that meet the standard of total microbial count for general cosmetic raw material.

Nanoscale Materials

The above product is not considered as nanomaterials and is in compliance with Article 16 of Cosmetic Regulation (EC) No. 1223/2009, Commission Recommendation 2022/C 229/01, and The French decree No. 2012-232.

Non-Irradiation

The raw materials of the above product have not been radioactively contaminated, and the irradiation is not used in the manufacturing process.

Product: Azeclair®

March 2024, Version 7

Paraben and Sulphates

The above product is not expected to contain paraben and sulphates, as they are not used in the manufacture.

Paraffin

The above product is not expected to contain paraffin as it is not used in the manufacture.

Pesticide

The above product is not intended to add any pesticides including triclosan during the manufacturing process, and we do not expect to have any appreciable trace of pesticide.

Plastic Microbeads and Synthetic Polymer Microparticle

The above product is not expected to contain any plastic microbeads and synthetic polymer microparticle. Plastic microbeads defined by restricted proposals of ECHA are not part of the raw materials, nor are intentionally added in the manufacturing process. Therefore, they are not expected to be present. In addition, the above product is not considered as synthetic polymer microparticles and is compliance with Regulation (EC) No 1907/2006 and its latest updates.

PAH (Polycyclic Aromatic Hydrocarbons)

The above product is expected to be free of PAH because they are not part of the manufacturing process nor are intentionally added.

PFAS (Per- and polyfluoroalkyl substances)

The above product is not expected to contain PFAS as it is not part of the manufacturing process nor is intentionally added.

Silicone

The above product is not expected to contain silicone as it is not used in the manufacture.

VOC (Volatile Organic Compound)

According to European Commission Directive 99/13/EC, the ingredients of this product are not classified as VOC.

Wheat and Gluten

The above product is not expected to contain wheat or gluten that may cause sensitization by inhalation and skin contact.

Product: Azeclair®

March 2024, Version 7

03. REGULATORY STATUS

California Proposition 65

The ingredients contained in this product are not listed by the State of California as substances that may cause cancer or other reproductive harm.

Global Compliance

ASEAN	None of the ingredients contained in the above product is listed in the Annex II Part 1 and Annex III Part 1 of Annexes of the ASEAN cosmetic directive. However, Phenoxyethanol (CAS: 122-99-6) is restricted with maximum concentration of 1% as preservatives in cosmetics.
Australia	Other than Phenoxyethanol (CAS: 122-99-6) is restricted with maximum concentration of 1% in cosmetic use, none of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
Brazil	None of the ingredients contained in the above products are listed in the RDC Nº 529, DE 4 DE AGOSTO DE 2021 and RDC Nº 530, DE 4 DE AGOSTO DE 2021 of prohibited and restricted ingredients for use in cosmetic products.
Canada	None of the ingredients contained in the above product is listed in the Cosmetic Ingredient Hotlist (2022) of prohibited and restricted ingredients for use in cosmetic products.
China	All the ingredients contained in the above product are listed in the latest version of IECIC list (2021), please refer to the IECIC name(s) in section 1. In addition, the above product is compliant with the Cosmetic Supervision and Administration Regulation (CSAR) implemented on January 1 ,2021 and it is listed on the National Medical Product Administration (NMPA) with registration number: 185759-01649-2627.
European Union and UK	The above product is tested for its safety profile and intended for use in the cosmetic products. The manufacturing process of the above product does not use any substances in the List of Substances Prohibited in Cosmetic Products, as specified in the Regulation (EC) No. 1223/2009 with its amendments listed in Commission Regulation (EU) 2019/831.
Japan	None of the ingredients contained in the above product is prohibited for use in cosmetics.
New Zealand	Other than Phenoxyethanol (CAS: 122-99-6) is restricted with maximum

Product: Azeclair®

March 2024, Version 7

	concentration of 1% in cosmetics, none of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
South Korea	To the best of our knowledge, Potassium Azeloyl Diglycinate (CAS: 477773-67-4) in the above product is restricted in cosmetics in South Korea due to its chemical definition as a derivative of azelaic acid.
Taiwan	Other than Phenoxyethanol (CAS: 122-99-6) is restricted with maximum concentration of 1% in cosmetics, none of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
UAE	None of the ingredients contained are the above product are prohibited nor restricted by GSO 1943/2016.
USA	None of the ingredients contained in the above product is prohibited nor restricted by FDA regulations.

Halal Certificate

This product complies with the Halal standards and has been reviewed and approved by the Taiwan Halal Integrity Development Association (THIDA) for Halal certification.

Kosher

The above product is not expected to contain any animal, milk, or animal derived ingredients.

Non-Animal Origin/Vegan

All the materials involved in the above product contain no substances which are completely or partially of animal origin, nor involved the use of any animal product, by product or derivatives. We also declare that our process to produce the above product is vegan compliant. The word "animal" refers to the entire Animal Kingdom, that is all vertebrates and all multi-cellular invertebrates.

Non-Animal Testing

From individual ingredients to final formulation, we always try our best to use the most up-to-date, innovative, scientific, non-animal cosmetic testing evaluations to demonstrate safety. The above product has not been the subject of animal testing for any purpose by or on behalf of CORUM Inc. We are committed to support calls for a worldwide animal testing ban on cosmetics.

NOAEL (No Observed Adverse Effect Level)

We are committed to enforcing our No Animal Testing Policy, no data on NOAEL is available.

Product: Azeclair®

March 2024, Version 7

SVHC (Substances of Very High Concerns)

The above product is not expected to contain any substance classified as SVHC under REACH, Article 57 and not in the candidate List of SVHC published by ECHA according to REACH, Article 59(10).

04. EU/UK REACH STATUS

The above product complies with EU and UK legislation in EC Regulation No. 1907/2006 (REACH) and its latest adaptations. The following table shows registration status (REACH) of components in this product:

INCI	EU Status	UK Status
Water	Exempt (Annex IV/V)	Exempt (Annex IV/V)
Potassium Azeloyl Diglycinate	Exempt (<1 Tonne/year)	Exempt (<1 Tonne/year)

05. FAIRTRADE AND SUSTAINABILITY

The product has been developed following our CSR policy and green chemistry principles to minimize the environmental impact of the activities and manage resources sustainability and responsibility. The raw materials in our manufacturing process do not belong to the Brazilian Access to Genetic Resources and Associated Traditional Knowledge, according to the Biodiversity Law, 13, 123/2015, and are sourced in countries with Access and Benefit Sharing (ABS) regulations in place including the Nagoya Protocol and Convention on International Trade of Endangered Species (CITES) to promote fair sharing of benefits arising from the utilization of genetic resources.

Our core aims align closely with several of the UN SDGs, which provide us with a framework for assessing how we can align environmental and social outcomes more effectively, rather than looking at each issue on a standalone basis. On people, we have the code of conduct policy to support gender equality, anti-discrimination, anti-child worker, anti-forced labor, workplace safety, freedom of association, the rights to collective bargaining, good health and well-being. On prosperity, we make targeted investments in infrastructure and energy projects, integrating SDGs at each stage to achieve positive and measurable social and environmental outcomes. On planet, we positively report to CDP climate change and EcoVadis agencies to manage risks and minimize the environmental impact, as well as to create maximum benefits for local communities.

We are certified with ISO 9001 (Quality), ISO 14001 (Environmental), and ISO 45001 (occupational health and safety) management systems, which enable us to efficiently control risks and improve

Product: Azeclair®

March 2024, Version 7

our performance. We strive to continuously improve our corporate processes for optimal use of precious natural resources, to actively provide a working environment that encourages the workplace safety, health and well-being of our employees, and to create and support a sustainable, socially equitable economy.

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