

# Regulatory Information Sheet (RIS)

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Product name: Azelaic acid  
Date: December, 2022  
Version: 5  
Manufacturer: CORUM Inc.

Product: Azelaic acid

December 2022, Version 5

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**01. PRODUCT IDENTIFICATION****Product Name**

Azelaic acid

**INCI Name**

PCPC Azelaic acid

IECIC list 壬二酸

表示名称 アゼライン酸

한국 INCI명/성분명 아젤라익애씨드

**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 2<sup>nd</sup> 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.
<b>COMPONENT</b>		
Azelaic acid	100%	123-99-9

**ISO16128**

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

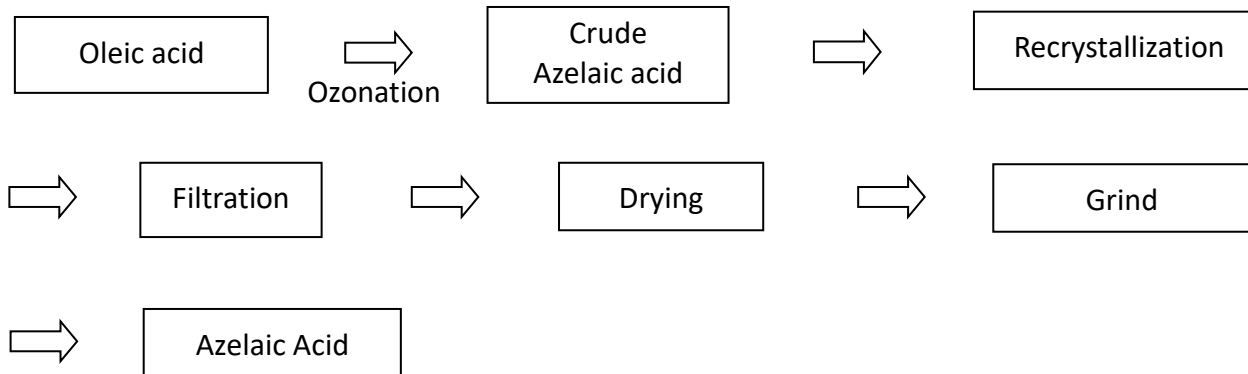
COMPONENT	Natural index	Natural origin index	Organic index	Organic origin index
Azelaic acid	0	1	0	0

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**Manufacturing Process**

The above product is synthesized by ozonation of oleic acid. The crude azelaic acid is further purified and processed via recrystallization to obtain Azelaic Acid.

**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 26 allergens listed in Annex III of the EU Cosmetic Regulation (EC) No. 1223/2009.

**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) 2022/1531, the Annex VI of Regulation (EC) No. 1272/2008 and its latest updates.

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**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.

**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. The above product does not typically support microbial growth in its anhydrous form, provided that this material is not in contact with a stagnate pool of water.

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**Nanoscale Materials**

The above product is nanoparticle free. None of the nanomaterials are used in the manufacturing process nor presented in the above product, in compliance with Article 16 of Cosmetic Regulation (EC) No. 1223/2009, Commission Recommendation 2011/696/EU, 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.

**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**

The above product is not expected to contain any plastic microbeads. 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.

**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.

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**Wheat and Gluten**

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

**03. REGULATORY STATUS****COSMOS**

The above product is certified under COSMOS standard for Natural Cosmetics in accordance with the latest version.

**California Proposition 65**

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

**Global Compliance**

ASEAN	To the best of our knowledge, the above product is banned in cosmetic use in ASEAN countries.
Australia	To the best of our knowledge, the above product is banned in cosmetic use in Australia.
Canada	The above product is restricted in cosmetics with maximum concentration of 3% in leave-on products and 10% in rinse-off 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) website with registration number: 005497-01649-2648.
European Union	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	None of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.

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South Korea	To the best of our knowledge, the above product is banned in cosmetic use in South Korea.
Taiwan	None of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
USA	The above product is restricted with maximum concentration of 15% in cosmetics.

### 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.

### RSPO (Roundtable on Sustainable Palm Oil)

The raw materials used in the above product is not derived from palm oil and palm kernel oil.



**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
Azelaic acid	Registered	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 our performance. We strive to continuously improve our corporate processes for optimal use of

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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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