# Regulatory Information Sheet (RIS)

Product name:Corum 5089Date:March, 2024Version:7Manufacturer:CORUM Inc.

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## **Inspire to Discover New Efficacy**

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Product: Corum 5089

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# **01**. <u>PRODUCT IDENTIFICATION</u>

# **Product Name**

	Corum 5089
INCI Name	
PCPC	Cholesteryl Hydroxystearate
IECIC list	胆甾醇羟基硬脂酸酯
表示名称	ヒドロキシステアリン酸コレステリル
한국 INCI명/성분명	콜레스테릴하이드록시스테아레이트

# 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.
COMPONENT		
Cholesteryl Hydroxystearate	100%	40445-72-5

# 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	Natural	Organic	Organic
	index	origin index	index	origin index
Corum 5089	0	1	0	0



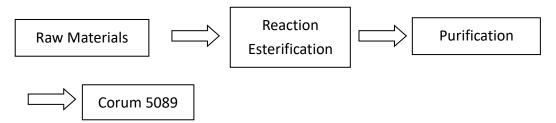
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## **Manufacturing Process**

The above product is manufactured by synthetic processes.



# **02.** <u>STATEMENTS ABOUT INGREDIENTS</u>

# 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 hydroxylanisole) and BHT (butylated hydroxytoluene) during the manufacturing process, and we confirm that it does not have any appreciable trace of BHA/BHT.

### **BSE/TSE**

The above product is free from the risk of all BSE and TSE. It is also not derived from specific-risk materials as defined in European Commission Decision 97/534/EC. While some of the materials may contain chemicals produced from animal material substances, they are not considered a TSE/BSE risk based on their source (sourcing takes into consideration animal species, tissue and country of origin) and/or exposure to processing conditions known to inactivate infectious agents associated with TSE/BSE diseases.

# 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 Cosmetic Regulation (EC) No.1223/2009 and its latest updates.

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# **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.

# 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.



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## **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 above product does not typically support microbial growth in its anhydrous form which provides that those materials are not in contact with a stagnant pool of water. We do not run and report pathogenic microbial content of the above product. If we were to run microbial content on the above product, we would expect the result always be zero.

### **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.

#### **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.



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#### **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.

# **03**. <u>REGULATORY STATUS</u>

### **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 Compli	ance
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.

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Australia	None of the ingredients contained in the above product is prohibited for use in cosmetics.
Brazil	None of the ingredients contained in the above products are listed in the RDC N <sup>o</sup> 529, DE 4 DE AGOSTO DE 2021 and RDC N <sup>o</sup> 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) website with registration number: 001830-01649-6555.
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	None of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
South Korea	None of the ingredients contained in the above product is prohibited or restricted for use in cosmetics.
Taiwan	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.

# NATRUE

The type of ingredients, the processing methods and the overall composition of the above product is authenticated 100% natural in complied with the NATRUE Standard.

### **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 purposes by or on behalf of CORUM Inc.

# **Cruelty-free**

We do not support any practice of animal cruelty which causes suffering to animals, including mulesing. We confirm that our raw material supplier supports the good animal husbandry and The Five Animal Freedoms described in the OIE Terrestrial Animal Health Code, including:

- 1) Freedom from hunger and thirst
- 2) Freedom from discomfort
- 3) Freedom from pain, injury or disease
- 4) Freedom to express normal behavior
- 5) Freedom from fear and distress

# NOAEL (No Observed Adverse Effect Level)

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

# 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**. <u>EU/UK REACH STATUS</u>

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
Cholesteryl Hydroxystearate	Exempt (<1 Tonne/year)	Exempt (<1 Tonne/year)

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# 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 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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