

# Regulatory Information Sheet (RIS)

Product name: Corum 5117

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Version: 5

Manufacturer: CORUM Inc.

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# **01**. PRODUCT IDENTIFICATION

## **Product Name**

Corum 5117

**INCI Name** 

PCPC Quaternium-60 (and) Propylene Glycol

IECIC list 季铵盐-60(和)丙二醇

表示名称 クオタニウム-60(2) PG

한국 INCI명/성분명 쿼터늄-60 (과) 프로필렌글라이콜

## **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		
Quaternium-60	48-52%	67633-63-0 (and) 72102-40-0
Propylene Glycol	48-52%	57-55-6



#### 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
Corum 5117	0	0	0	0

## **Manufacturing Process**

The above product is manufactured by synthetic processes.

Raw M	aterials		Amidation	Quaternization in propylene glycol
	Corum	5117		

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

## 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**

According to our knowledge and in accordance with the information received from our suppliers, propylene glycol used in this product is USP grade and contains < 0.008% of Diethylene Glycol (Diglycol). This product does not contain any glycol ether such as DEGEE, EDGME, EGBA and DEDGME.

## **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.

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#### **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 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.

## **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**. 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.
Australia	None of the ingredients contained in the above product is prohibited for use in cosmetics.
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: 123619-01649-9772.

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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.
New Zealand	None of the ingredients contained in the above product is prohibited for
	use in cosmetics.
Japan	None of the ingredients contained in the above product is prohibited for
	use in cosmetics.
South Korea	To the best of our knowledge, the above product can be applied 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	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.

## **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. We are committed to support calls for a worldwide animal testing ban on cosmetics.

## **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.

## 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**. <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	
Quaternium-60	Exempt (<1 Tonne/year)	Exempt (<1 Tonne/year)
Propylene Glycol	Exempt (<1 Tonne/year)	Exempt (<1 Tonne/year)

# **05**. <u>FAIRTRADE AND SUSTAINABILITY</u>

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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