

Product Regulatory File

Last update: 01/01/2024

1. Identity of the substance

Trade name:	Exoquat PK37
INCI name:	Cocamidopropyl Betaine
Product type:	Amphoteric surfactant
HS code:	34024900

2. Registration status

EU REACH

Registered:	Yes – see SDS section 3.2
Exempted:	Not applicable
Mixture with REACH compliant raw materials:	Not applicable

UK REACH see statement

KKDIK see statement

Global Inventories

Country	Inventory	Yes/No	
USA	TSCA	Yes	
Canada	DSL	Yes	
Australia	AIIC	Yes	
European Union	EINECS/ELINCS/NLP	Yes	
Japan	ENCS	Yes	
China	EICSC	Yes	
Korea	KECI	Yes	
New Zealand	NZIoC	Yes	
Philippines	PICCS	Yes	
Taiwan	TCSI	Yes	
Russia	Unified list of Chemicals	Yes	
Thailand	TECI	Yes	
Vietnam	NCI	Yes	



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3. Cosmetic regulation

EU Cosmetic regulation

Based on the available information EOC Surfactants (hereinafter referred to as 'the company') can confirm that the mentioned product (hereinafter referred to as 'the product') is in line with the cosmetic regulation 1223/2009 EC and its amendments.

The product contains no intentionally added substances mentioned in Annex II of the cosmetics regulation and its amendments.

Chinese cosmetic regulation

See statement.

4. Origin

Origin

The product is from synthetic and vegetable origin (palm kernel oil).

Palm source

Please find herewith the part of the product derived from a palm source:

Product	% of the product derived from a palm source ¹	Palm source	
Exoquat PK37	ca. 19	Palm kernel oil	

¹calculation based on molecular weight

GMO

In view of Regulation (EC) No 1829/2003 on genetically modified food and feed and Regulation (EC) No 1830/2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed produced from genetically modified organisms, the company can inform you as follows about the GMO status of the mentioned product.

We can hereby declare that the product does not contain genetically modified materials and is not produced by using raw materials of a genetically modified origin. At no stage during production, the product comes into contact with genetically modified organisms or with any product produced in association with genetically modified organisms.

Therefore, we also inform you that the product will not be subject to GMO labeling and traceability requirements as laid down in Regulations (EC) No 1829/2003 and 1830/2003.





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Vegan

The product does not contain any ingredients from animal* origin. The development and production of the product does not involve the use of any animal products. Intermediates and starting substances are of non-animal origin. The product is made without animal auxiliaries and cross-contamination with animal products during manufacturing is impossible.

* the word "animal" refers to the entire Animal Kingdom, that is all vertebrates and all multi-cellular invertebrates

Halal

The product does not contain ingredients from animal origin. Furthermore, it does not contain ethanol (CAS N° 64-17-5).

Kosher

The product does not contain any material that is derived from wheat, barley, soya, rice or other grain or pulse derivatives.

Furthermore, we can confirm that it does not contain any material that is derived from animals (including fish and other marine species) or that is derived from grapes or wine.

ISO 16128

The natural index, natural origin index, organic index and organic origin index of the active substance in the product are as follows:

Substance	Natural Index	Natural Origin Index*	Organic Index	Organic Origin Index
Cocamidopropyl Betaine	0	0.68	0	0

^{*}Calculation of natural origin index is based on the renewable carbon content: C of natural origin / total C

BSE/TSE

The product is produced solely from synthetic and vegetable raw materials, and no material used in the manufacture is of bovine or any animal origin (neither whole nor part). In addition, we confirm that no contact with material of animal origin can occur during the production process.

Therefore, with regard to the conditions of our production process and the raw materials used, the BSE/TSE-risk is, according to our knowledge, not to be considered as relevant.

Gluten

We do not expect the presence of gluten in the product. These substances have not been intentionally added during the manufacturing process.





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Cites

Based on the actual and available knowledge of the used raw materials, the company can inform you that the product does not contain ingredients from species listed by CITES. (https://cites.org)

These substances have not been intentionally added during the manufacturing process.

Nagoya

The product is considered to be out of the scope of the Nagoya Protocol.

5. Animal testing

The company as a producer of chemical substances fulfils all legal requirements on national as well as international level in order to protect workers, customers, users and the environment. We make every effort to provide our customers with products not only optimal for their intended purpose but also safe regarding human health and the environment.

According to Regulations (EC) 1907/2006 and (EC) 1272/2008 manufacturers of chemical substances are required, among others, to determine toxicological and ecotoxicological properties of the substances they produce. This may include animal testing if sufficient data is not already available. Relevant information, including data on animal testing, is generally provided on the Material Safety Data Sheet.

We hereby confirm that all our products or their component parts have never been the subject of animal testing or re-testing for cosmetic purposes by or on behalf of the company.

We hereby also confirm that animal experiments will only be conducted in the future for general safety requirements or if specifically requested by national and/or international regulations.

6. Allergens

Food allergens

We do not use one of the substances listed in 'Regulation (EU) Nr. 1169/2011 annex II' as raw materials to produce the product and we do not expect any contamination during the production process.

Cosmetic allergens

We do not use one fragrance allergens listed in Annex III of the cosmetic regulation EC 1223/2009 and its amendments, to produce the product and we do not expect any contamination during the production process.



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7. Nanomaterials according to EU 1223/2009

We do not expect the presence of nanomaterials in the product. These substances have not been intentionally added during the manufacturing process.

8. Microplastics

Following Regulation (EU) 2023/2055 amending Annex XVII to Regulation (EC) No 1907/2006 (REACH) and hereby adding entry 78, EOC Surfactants can inform you that the product does not contain any polymer fulfilling the definition of synthetic polymer microplastics as mentioned in entry 78.

Therefore, the REACH Annex XVII Microplastics restriction is not applicable for the product.

9. Volatile Organic Compounds (VOC)

Based on the available information the company can inform you that the product does not contain intentionally added VOC.

10. Carcinogenic, Mutagenic, Reprotoxic substances (CMR)

The product does not contain intentionally added CMR substances (cat 1A, cat 1B, cat 2) as listed in part 3 of Annex VI to Regulation (EC) No 1272/2008 and Annex II of EC 1223/2009.

11. Substances of Very High Concern (SVHC)

Based on the actual and available knowledge of the used raw materials, the company can inform you that the product does not contain SVHC's from the latest ECHA candidate list at a level of 0,1% or more.

12. California Proposition 65

To the best of our knowledge, the company can inform you that, except for the below mentioned substances, the product does not contain substances listed in the actual OEHHA Proposition 65 list.

These substances have not been intentionally added during the manufacturing process.

However, the company can inform you that the product may contain traces of Dichloroacetic acid (CAS nr 79-43-6) (see PIP section 5) and formaldehyde (CAS 50-00-0) (see PIP section 5) as impurities.

Dichloroacetic acid and formaldehyde are listed on the actual OEHHA Proposition 65 list.



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13. Persistent Organic Pollutants (POP)

We do not expect the presence of persistent organic pollutants (POP) in the product. These substances have not been intentionally added during the manufacturing process.

14.PFAS

We do not expect the presence of PFAS (Per- and polyfluoroalkyl substances) in the product. These substances have not been intentionally added during the manufacturing process.

Note: This document is also valid for the RSPO Mass Balance (MB) grade

DISCLAIMER

All recommendations for use of our products whether given by us in writing, orally, or to be implied from data or test results obtained by us, are based on the current state of our knowledge at the time such recommendations are made. When additional information is obtained, these recommendations may be updated. They may also be influenced by circumstances outside our control. Notwithstanding such recommendations, the user is responsible to determine that the product as supplied by us, is suitable for the process or purpose he intends to use it. The user of the product is solely responsible for compliance with all laws and regulations applying to the use of the product. Since we cannot control the application, use or processing of the products, we do not accept responsibility, therefore. The user shall ensure that the intended use of the products will not infringe in any party's intellectual property rights. This document replaces all previous versions.