

GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

 Review date:
 Version:

 19.05.2023
 8.0

93646-COCAMIDOPROPYL BETAINE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: Cocamidopropyl betaine

Bulk code: 93646 Internal code: 405035

1.2 Synonyms.

Tego betaine L

2. DESCRIPTION

Appearance (25°C): Liquid (free of foreign matter).

Colour: Clear.

Odour: Characteristic

Origin: The product is derived from fatty acids from coconut (cocos nucifera) and/or palm

oil, synthetic sources and minerals.

Geographical origin: Spain, France, Italy, United States.

3. COMPOSITION/INFORMATION ON COMPONENTS.

CAS No: 61789-40-0

INCI: Cocamidopropyl betaine.

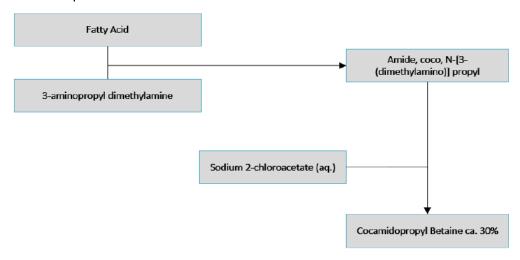
INCI for labelling: Aqua, Cocamidopropyl Betaine, Sodium Benzoate.

General composition:

PRODUCT	%	
Aqua	60-64	
Cocamidopropyl betaine	30-32	
Sodium chloride	4-6	
Sodium glycolate	≤0.7	
Cocamidopropyl dimethylamine	<3	
Fatty acid	<0.5	
Sodium benzoate	Ca. 0.5	
3-aminopropyldimethylamine	< 0.002	
Sodium monochloroacetate	<0.002	



Method of production:



The fatty acid is of plant origin (coconut or palm), the DMAPA is synthetic (petrochemical origin), as is the monochloroacetic acid, and the sodium hydroxide used to neutralise it is of mineral origin.

4. PHYSICO-CHEMICAL DATA.

For more information see the analysis report.

Solubility: The product is soluble in water and alcohol.

5. PROPERTIES/USES.

Cosmetic use.

Surfactant.

Aqueous cocamidopropyl betaine solution for cosmetic formulations.

This product is an amphoteric surfactant used to produce cosmetics. It is compatible with anionic, non-ionic, cationic and other amphoteric surfactants and it can provide formulation and performance benefits in terms of an abundant stable foam, superior foaming and cleansing in the presence of soap and hard water. Cocamidopropyl betaine (CAPB) is often used together with primary anionic surfactants, such as sodium laureth sulfate, where it helps to improve smoothness and increase the viscosity and characteristics of the formulation's foam. A ratio of 3: 1 anionic: CAPB is typically used, although in levels up to 1: 1 it improves performance. It can also be used to help solubilise cationic conditioning agents, such as those in 2-in-1 formulations.



6. DOSAGE.

No information available.

7. REMARKS.

STORAGE:

It is recommended the product is stored below 40°C. At lower temperatures (<20°C) there may be a physical separation, especially after extended periods of time and, in this case, it should be homogenised before use. The colour may deteriorate over time if stored above 40°C.

This product contains a significant amount of chloride, which may be slightly corrosive to common metals.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

This product is not derived from sources of animal origin and no animals or materials derived from animals are used at any point in the manufacturing process. For this reason, it is free of BSE/TSE with regards to its origins.

GMOs:

The product is not made using any substance containing genetically modified organisms.

CMR:

No substance classed as carcinogenic, mutagenic or reprotoxic in categories 1A, 1B or 2 in Appendix VI of the CLP Regulation is present in the product in amounts greater than 0.1%. Any trace or impurity that may be present is technically inevitable under conditions of good manufacturing practice.

SVHC:

The product does contain any of the SVHC detailed in the list of the latest candidates for REACH (1907/2006/EC) in concentrations exceeding 0.1%.

NANOPARTICLES:

Neither the starting materials nor their ingredients are considered nanomaterials in accordance with the definitions provided in Regulation 1223/2009, Recommendation 2011/696/EU or French Decree 2012-232.



VOCs:

The level of VOCs according to Directives 2004/42/EC and 1999/13/EC are estimated to be in amounts lower than 1%.

The level of VOCs according to 2010/75/EU are estimated to be in amounts lower than 1%. The product contains <3% VOCs according to the definition given in Swiss Ordinance 814.018.

RADIATION:

Irradiation is not used at any point in the product manufacturing or handling process.

PESTICIDES:

Although the product is not a plant extract, when the product may be derived from raw materials of natural origin there are extensive chemical and physical processes involved in converting the raw material into the finished product, so no pesticide residues are expected to be present.

PRESERVATIVES:

The product contains sodium benzoate in amounts of 0.5%.

RESIDUAL SOLVENTS:

No class 1, 2 or 3 residual solvent of those listed in USP <467> or in the ICHQ3C Guides is used to manufacture the product.

CONTAMINANTS/IMPURITIES:

- Nitrosamines: According to the raw materials' chemical composition and knowledge of the manufacturing process, nitrosamines are not formed when the main reagents react. However, some by-products present in the raw materials, such as impurities, could eventually, and under certain conditions, form nitrosamines. The manufacturer has performed tests on apparent total n-nitroso compounds (ATNC) in representative batches of the product and the results obtained were: ATNC as NNO (nitrous oxide) <15 ppb (μg/kg) (LoD = 15 ppb LoQ = 50 ppb)
- 3-Aminopropyldimethylamine < 20 ppm
- Microplastics: The product is not considered a microplastic or microsphere.
- Endocrine disruptors: The product does not intentionally contain any of the 66 endocrine disruptors identified in Appendix 15 of the European Commission DG ENIV
- PFAS (perfluoroalkyl or polyfluoroalkyl substances) or by-product substances are not added intentionally during the manufacturing process.
- Based on the starting materials and the production process, the following (products not tested) are not expected to be present:
 - o 1.4-Dioxane
 - o Diethylene glycol



- o Glycol ethers
- o Latex
- o Phthalates

The product is compliant with Regulation (EC) 1223/2009 on cosmetic products and may be legally marked in line with EU cosmetics regulations. Any technically inevitable impurity is listed in the following table, if applicable.

*Technically unavoidable, if applicable.

Chemical Name	CAS RN	Concentration (% or ppm)	Annex / Ref #	Name on List	Additional Comments
Sodium Benzoate	65-85-0	ca. 0.5%	V/1	Benzoic acid and its sodium salts	n/a
3- aminopropyldimethylam ine	109-55-7	<20 ppm	III/62	Trialkylamines, trialkanolamines and their salts	Refer to Annex III/62 for additional restrictions; Maximum secondary amine content: 0.5% (applies to raw materials

HEAVY METALS:

ANALYTE	RESULT	LIMIT OF DETECTION
Arsenic	Not detected	1 mg/kg
Cadmium	Not detected	0.1 mg/kg
Chromium	Not detected	1 mg/kg
Cobalt	Not detected	1 mg/kg
Copper	Not detected	1 mg/kg
Lead	Not detected	1 mg/kg
Mercury	Not detected	0.1 mg/kg
Nickel	Not detected	1 mg/kg
Selenium	Not detected	1 mg/kg
Silver	Not detected	Not tested, not expected

CALIFORNIA PROPOSITION 65:

The product does not contain any substance recognised by the State of California as a cause of cancer or reproductive toxicity at levels that require a declaration in line with this standard.

NAGOYA PROTOCOL:

The product falls outside the scope of the Nagoya Protocol.



ALLERGENS:

- Food allergens: The product does not contain any of the allergens listed in the FALCPA 2204. The product does not contain any of the allergens listed in Regulation 1169/2011 or their derivatives. The product is gluten free.
- Cosmetic allergens: The product is not expected to contain any of the 26 allergens, as defined in Appendix III of Regulation (EC) 1223/2009.

VEGAN/VEGETARIAN:

The product does not contain any animal products or derivatives that include meat, bones, milk or products thereof, eggs or products thereof, honey or products thereof, silk or dyes from insects, hair, leather, wool or down.

HALAL:

The product has not been officially certified Halal or by the Islamic Council, but the manufacturer believes the product is permitted in line with Muslim standards as the product is made synthetically from materials that have no animal origins or derivatives, and it does not contain pork or enzymes. Ethyl alcohol and alcoholic drinks are not used during the manufacturing process, and the material is made and stored in a facility free from pork and animals.

KOSHER:

The product is free of ethanol and animal derivatives.

The product has not been officially certified as Kosher, but the manufacturer believes the product is permitted in line with Jewish framework standards given the information offered by raw material suppliers and the manufacturing process.

TESTED ON ANIMALS:

Neither the product nor any of its components have been tested on animals.

RSPO:

The manufacturer is committed to using sustainable palm oil, palm kernel oil and derivatives. The manufacturer has been an ordinary member of the "Round Table on Sustainable Palm Oil" since 2013. All manufacturing processes in which palm oil is used as a raw material have a mass balance (MB) RSPO certified supply chain.

CITES:

Given the product's origin, it falls outside the scope of CITES. No known component from species included in the CITES appendix is used in the manufacturing process.

ECOCERT:

The product is Ecocert certified.



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ISO 16128:

The product contains more than 50% renewable carbons and, therefore, it complies with the ISO 16128: 2017-2 Standard for natural and organic cosmetic products and ingredients. The product has a renewable carbon index (RCI) of 66%.

Natural index: 0

Natural origin index: 0.66

Organic index: 0

Organic origin index: 0

Final category of ingredients: Natural derivative.

REACH:

01-2119513359-38

CSAR:

126813-02077-1791