

GENERAL STATEMENTS

Place of issue: Gorla Maggiore, Varese (Italia)

Date of issue: January 21st, 2021

COMPANY INFORMATION

Supplier: Sinerga S.p.A.

Quality status of Company:

- ☒ UNI EN ISO 9001:2015 (Quality Management System)
- ☒ UNI CEI EN ISO 13485:2016 (Quality Management System)
- ☒ ISO 14001:2015 (Environmental Management System)
- ☒ BS OHSAS 18001:2007 (Occupational Health and Safety Management)
- ☒ ISO 22716:2007 (Good Manufacturing Practices)



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Cap. Soc. € 500.000,00 i.v.

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DIREZIONE E COORDINAMENTO
DELLA SINERGA GROUP srl

Intertek

RAW MATERIAL INFORMATION

According to our current knowledge and based on manufacturing process, Sinerga S.p.A. hereby confirms the following information for the product:

Trade Name:	Natisol
INCI name	Cocoyl proline
Allergens:	does not contain any of the 26 cosmetic allergens listed in Annex III (N. 67-92) of Cosmetics Regulation (EC) N. 1223/2009
Animal test:	has never been tested on animals for cosmetic purposes and therefore it is in accordance with article 18 of Cosmetics Regulation (EC) N. 1223/2009
BSE/TSE:	does not derive or contain animal byproducts and therefore the product is free from any BSE/TSE transmitting agents
California's Proposition 65 Inventory:	is not listed in California's Proposition 65 Inventory (last edition). Moreover, we confirm that none of the substances included in the above mentioned list is intentionally added to the product;
CITES Appendices:	starting raw materials are not listed on CITES Appendices (last edition)
CMR:	substances classified as CMR of category 1A, 1B and 2 under Part 3 of Annex VI of CLP Regulation (EC) N. 1272/2008, in compliance with the requirements of article 15 of Cosmetics Regulation (EC) N. 1223/2009 are not added nor expected
GMO:	does not derive from Genetically Modified Organisms and does not contain GMO
Nanomaterials:	does not contain any nanomaterial in conformity with article 16 of Cosmetics Regulation (EC) N. 1223/2009
Origin	<input type="checkbox"/> animal <input checked="" type="checkbox"/> vegetal <input type="checkbox"/> mineral <input type="checkbox"/> synthetic <input checked="" type="checkbox"/> other: fermentation/biotechnology/culturing cells
SVHC:	does not contain any of the substances listed in the Candidate List of Substances of Very High Concern (SVHC) published by ECHA

Impurities:

1,4-dioxane	Not expected
Artificial dyes/ colors	Not expected
Asbestos	Not expected
Camphre	Not expected
Diethylene glycol	Not expected
EDTA	Not expected
Endocrine perturbators	Not expected
Ethanol	Not expected
Ethylene oxide	Not expected
Formaldehyde donor	Not expected
Gluten	Not expected
Glycol ethers	Not expected
Methanol	Not expected
Monoethylene glycol	Not expected
Nuts, milk, eggs, fish, shellfish	Not expected
Parabens	Not expected
PEG/PPG	Not expected
Pesticides	Not expected
Phenol	Not expected
Phtalates	Not expected
Polycyclic Aromatic Hydrocarbons	Not expected
Silicone	Not expected
Sulfates	Not expected
Volatile Organic Compounds	Not expected

Heavy metals:

Ag	Not available
As	≤ 0.05 ppm
Ba	Not available
Cd	≤ 0.02 ppm
Co	Not available
Cr	Not available
Cu	Not available
Fe	Not available
Hg	< L.O.Q. (0.005 ppm)
Ni	≤ 0.15 ppm
Pb	≤ 0.01 ppm
Sb	Not available
Se	Not available
Zn	Not available

ISO 16128 STATEMENT

According to our current knowledge, Sinerga S.p.A. hereby confirms, for the following product:

NATISOL
(INCI: Cocoyl proline)

INCI Name	CAS N°	EINECS/ELINCS N°	%
Cocoyl Proline	960241-19-4	-	50-70
Aqua	7732-18-5	231-791-2	30-50

the ISO 16128 index and calculations.

ISO 16128 presents guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products, and it is divided in two parts:

Part 1: Definitions for ingredients (ISO 16128-1:2016), and

Part 2: Criteria for ingredients and products (ISO 16128-2:2017).

Here below are listed the relevant index and values:

Trade name	Index and value				
	Ingredient type	Natural origin index	Natural index	Organic origin index	Organic index
Natisol	Derived natural ^(I)	1	0.4 ^(II)	0	0

(I) Cfr. ISO 16128 Part 1, Chapter 3.1

(II) Cfr. ISO 16128 Part 1, Chapter 2.4

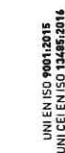
(III) Cfr. ISO 16128 Part 1, Chapter 2.1



INVENTORY POSITION

Please find below the inventory position of raw material included in the product NATISOL:

INCI Name	CAS N°	Inventory position						
		EU	USA	CHINA	JAPAN	CANADA	AUSTRALIA	KOREA
Cocoyl proline	960241-19-4	No restriction	INCI name listed on CTFA	INCI name listed on IECIC as: <i>Coconut acid</i> and <i>Proline</i>	INCI name not restricted on Standard for Cosmetics (Ministry of Health and Welfare Notification No.331 of 2000)	CAS N° listed on ICL inventory	CAS N° not listed on AICS	Listed on NCIS with the INCI names: <i>Coconut Acid</i> and <i>Proline</i>



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REACH DECLARATION

According to our current knowledge, Sinerga S.p.A. hereby declares that the product:

NATISOL
(INCI: Cocoyl proline)

is in line with the requirements of REACH Regulation 1907/2006 and subsequent amendments.

The registration number is: **01-2120831300-73-XXXX**

Maria Chiara Dominici
Regulatory Affairs
Sinerga SpA



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