



ANDREA GALLO DI LUIGI S.r.l.u.

Azienda fondata nel 1892

Via Erzelli 9, 16152 Genova, Italy Tel. +39 (0)10 6502941
info@andreagallo.it www.andreagallo.it p.iva00270850100

INFORMAZIONI TOSSICOLOGICHE *TOXICOLOGICAL INFORMATION*

Revisione n°

Revision n° 11

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	Cocamide MEA
1.2 Fornitore (indirizzo, telefono, contatto) <i>Manufacturer/Supplier</i> (address, phone no., contact person)	Andrea Gallo di Luigi Srlu via Erzelli 9, 16152 - Genova Italy tel. 010 6502941 mail: regulatory@andreagallo.it
1.3 Categoria della material prima (es. tensioattivo anionico) <i>Raw material category</i> (e.g. anionic surfactant)	Non ionic surfactant
1.4 Nome chimico <i>Chemical name</i>	Amides, C8-18 (even numbered) and C18-unsatd., N-(hydroxyethyl)
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Cocamide MEA: 84.5% min
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	List n° 931-330-1 Alternative: 273-927-3 (268-770-2 old one)
1.7 N° CAS <i>CAS no.</i>	Alternative: 69227-24-3 (68140-00-1 old one)



<p>1.8 Registrazioni (es. UE, USA, Giappone) - REACH - Certificazione</p> <p><i>Registration status</i> (e.g. EU, USA, Japan) - REACH - Certification</p>	<p>For CAS 69227-24-3: IECIC (China, Cosmetic Ingredient), TCSI (Taiwan), ENCS (Japan), TECI (Thailand), TSCA (USA) and DSL (Canada). Pre-registered in Turkey.</p> <p>For CAS 68140-00-1: IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TCSI (Taiwan), ENCS (Japan), TECI (Thailand), TSCA (USA) and DSL (Canada). Pre-registered in Turkey.</p> <p>NMPA number 007545-02176-8163.</p> <p>Notes: in Japan authorities currently do not require pre-market approval for cosmetic raw materials. This is also true for Brazil, South Korea, Philippines, USA (only for cosmetic raw materials).</p> <p>Product is not a biocidal according to Regulation 528/2012.</p> <p>The product is not a phytosanitary according to Regulation 1107/2009.</p> <p>REACH registration n° 01-2119490101-51-0007.</p> <p>None of substances listed in the "candidate" list of substances of very high concern (SVHC) are contained in the product in a concentration $\geq 0.1\%$.</p> <p>PO 65 (California law): please check points 5.6 and 5.7 (all not intentionally added).</p>
<p>2. Informazioni sulla produzione</p> <p>Information on production</p>	
<p>2.1 Origine della materia prima (vegetale, animale, sintetica)</p> <p><i>Origin of starting material</i> (plant, animal, synthetic)</p>	<p>Vegetable (76.7%) and synthetic (23.3%) origin.</p> <p>Coconut oil is vegetable. It comes from Cocos Nucifera (South East Asia and Philippines).</p> <p>Monoethanolamine is synthetic.</p>
<p>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</p> <p><i>Is the starting material derived from genetically modified organisms (GMO)?</i></p>	<p>No</p>
<p>2.3 Informazioni sul processo di produzione (descrizione generale)</p> <p><i>Information on production process</i> (general description)</p>	<p>Coconut oil plus monoethanolamine, heat.</p> <p>Control = free MEA</p> <p>Manufacturing site: Tricerro, Italy</p>



3. Additivi <i>Additives</i>	
3.1 Conservanti/Biocidi <i>Preservatives/Biocides</i>	Not added and not expected
3.2 Antiossidanti <i>Antioxidants</i>	Not added and not expected
3.3 Solventi <i>Solvents</i>	Water: 0.5% maximum
3.4 Sbiancanti <i>Bleaching agents</i>	Not added and not expected
3.5 Altri <i>Others</i>	Not added and not expected
4. Specifiche microbiologiche Microbiological specification	
4.1 Conta microbica totale (ufc/g) <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g
5. Residui del processo di lavorazione La presenza di tracce delle sostanze elencate in Allegato II del Regolamento No. 1223/2009 (che sostituisce la Direttiva 76/768/CEE) (incl. CMR cat. 1A, 1B e 2 sostanze contrassegnate con *) deve essere dimostrata come presenza tecnicamente inevitabile lavorando in GMP e deve essere conforme all'Articolo 17 del Regolamento No. 1223/2009. <i>By-products</i> <i>The presence of traces of the substances listed in Annex II of Regulation No. 1223/2009 (replaced Directive 76/768/EEC) (incl. cmr cat. 1A, 1B and 2 substances marked with *) shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 17 of Regulation No. 1223/2009.</i>	
5.1 1,4-Diossano * <i>1,4-Dioxane *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.



5.2 Ossido di etilene * <i>Ethylene oxide *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.3 Solventi residui <i>Residual solvents</i>	Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process, only water
5.4 Monomeri residui <i>Residual monomers</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5 Ammine <i>Amines</i>	Free MEA: 5% maximum (average value 3% maximum) (MEA purity 99% minimum); with secondary amine content 0.5% maximum
5.6 Nitrosammine <i>Nitrosamines</i>	N-Nitrosoamine are below 50 ppb. They are not checked for every batch but in a random way and till now they have always been under detection limits (20 ppb). The product is according to European Cosmetic Legislation. Please remind not to use it with substances able to originate nitrosoamines, that means nitrosating agents (e.g. 2-Bromo-2-Nitropropan-1,3-Diol). To be preserved in a nitrite-free container.
5.7 Metalli pesanti <i>Heavy metals</i>	Arsenic (As) < 2 ppm, Lead (Pb) < 1 ppm, Cadmium (Cd) < 2 ppm, Mercury (Hg) < 1 ppm (Random check, values to be considered as typical)
5.8 Acido monocloroacetico <i>Monochloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.9 Acido dicloroacetico <i>Dichloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.10 Allergeni <i>Allergens</i>	To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain substances listed under Annex II (Substances or products causing allergies or intolerances) of Regulation (EU) No.



	<p>1169/2011 on the provision of food information to consumers and its amendments.</p> <p>To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain allergens listed in Regulation (EU) No. 1223/2009 (Annex III) and its amendments (e.g. Regulation 1545/2023).</p>
<p>5.11 Altri (e.g. CMR)</p> <p><i>Others (e.g. CMR)</i></p>	<p>Glycerin: 10% maximum Monoethanolamine: 5% maximum (average value: 3% maximum) Water: 0.5% maximum</p> <p>To the best of our present knowledge, assuming the use of raw materials and manufacturing process currently employed, our product does not contain any CMR substances classified as CMR category 1A, 1B and 2 in accordance with Regulation 1272/2008 (EC) and its adaption.</p>

<p>6. Tossicologia</p> <p><i>Toxicology</i></p>	
<p>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<p>- LD50 oral > 2000 mg/kg (OECD 401, rat, literature data) - LD50 dermal > 2000 mg/kg (rabbit, literature data)</p>
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<p>Product as it is = Not irritating (OECD 404, rabbit, literature data)</p>
<p>6.3 Informazioni sull'irritazione oculare</p> <p><i>Information on irritation of the mucous membrane</i></p>	<p>Product as it is = Irritating (OECD 405, rabbit, literature data)</p>
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<p>Not sensitizing (OECD 406, Guinea pig, literature data)</p>
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<p>None mutagenic effect (OECD 471, literature data)</p>



6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	Not determined
6.7 Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i>	Reproductive toxicity: no effects observed (OECD 422, rat, literature data). Note: Cocamide MEA can be considered as SAFE at every concentration in rinse off products and SAFE till 10% in leave on products.
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (from literature data) Anaerobic: anaerobic biodegradable (from literature data)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fish = 3 mg/l/96h (OECD 203) - EC50 on Daphnia = 3 mg/l/48h (OECD 202) - EC50 on Algae = 8,7 mg/l/72h (OECD 201) - NOEC chronic on Fish = 0,32 mg/l 28d (OECD 204) - NOEC chronic on Daphnia = 2,2 mg/l 21d (OECD 211) - NOEC chronic on Algae = 0,3 mg/l (OECD 201)
7.3 Altri <i>Others</i>	/
8. Informazioni aggiuntive (Per i dettagli sulle specifiche vedere il bollettino tecnico allegato; per i dettagli sull'etichettatura e la classificazione vedere la scheda di sicurezza allegata.) <i>Additional information</i> (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)	
Dichiarazione BSE/TSE <i>BSE/TSE statement</i>	The product is not from animal origin. Furthermore it doesn't contain any ingredient of animal origin, it is not produced using ingredients of animal origins and it doesn't



Dichiarazione test animali

Non-animal testing declaration

come into contact with animal origin ingredients at any stage of its production. It is therefore BSE/TSE free.

For the purposes of the European Cosmetics regulation (EC) No. 1223/2009, no animal testing has been carried out by or on behalf of the producer on the product/ingredients after 11th March 2009 and after 11th March 2013 (extended deadline for animal testing for repeated dose, reproductive toxicity or toxicokinetics).

Glicol eteri

Glycol ethers

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Ftalati, DINP (diisononyl phtalate)

Phtalates, DINP (diisononil ftalato)

Based on information concerning the raw materials, production process and equipment used phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

Glutine

Gluten

Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

Formaldeide

Formaldehyde (Formol)

Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.

VOC

VOC (volatile organic compounds)

Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Directive 2004/42/EC

The VOC Directive 2010/75/EU and Directive 2004/42/EC of the European Community are complex regulations. Only based on the properties of a substance it is not possible to make a decision whether this regulation applies to the substance or not. A statement can be made only in connection with the application and the conditions of use.

As a producer of raw materials we do not have information on actual usage and conditions of use. Therefore, we can only make a statement about the volatility and the boiling point under standard conditions. You will find this information in chapter 9 of our material safety data sheet.

Swiss VOC ordinance 814.018 (Ordinance on the Incentive Tax on Volatile Organic Compounds)

According to Article 2 of the SR 814.018 VOCs are liable for tax if they are listed on the positive list of substances (Annex 1) or contained in products mentioned in the positive list of products (Annex 2). According to Article 8(a) of the SR 814.018, those mixtures and



Fitofarmaci

Plant protection products

APEO, cloroparaffine, composti organici alogenati

APEOs, chloroparaffines, AOX

Mercaptani

Mercaptanes

Melamine

Melamine

Lattosio

Lactose

Aflatossine/Micotossine

Aflatoxines/Mycotoxines

Lattice

Latex

Nitrati e Nitriti

Nitrates and Nitrites

Amine aromatiche

Aromatic amines

Coloranti azoici

Azo dyes

Ormoni, antibiotici e steroidi

Hormones, antibiotics and steroids

products are exempted from tax in which the VOC content does not exceed 3 per cent (% by weight).

To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain > 3% of the substances on the positive list of substances (annex 1) of the SR 814.018.

Based on information concerning the raw materials, production process and equipment used plant protection products are not likely to be present.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

Based on information concerning the raw materials, production process and equipment used aflatoxin/mycotoxin are not likely to be present

The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Based on information concerning the raw materials, production process and equipment used aromatic amines are not likely to be present.

Based on information concerning the raw materials, production process and equipment used azo dyes are not likely to be present.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.



Pork free
Pork free

Yes, absent

PBT/vPvB
PBT/vPvB

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

PFAS
PFAS

Based on information concerning the raw materials, production process and equipment used (no analytical controls done) there are no added PFASs in the manufacturing process and there have been no manufacturing process changes that would have introduced PFASs.

Materiale radioattivo
Radioactive material

Based on information concerning the raw materials, production process and equipment used radioactive material is not expected to be present and no irradiation has been used.

Microplastiche
Microplastics

Substance is not and doesn't contain any polymer and therefore it is not a microplastic according to Regulation 2023/2055.

Nanomateriali
Nanomaterials

The product doesn't contain any nanomaterials according to the new European Cosmetic Regulation 1223/2009/EC and 1881/2019/EC and any nanotechnology is used to produce it.

Idrocarburi Policiclici Aromatici
Polycyclic Aromatic Hydrocarbons (HAP)

Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons are not likely to be present.

Clorobenzeni/Clorofenoli
Chlorobenzenes/Chlorophenols

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Ritardanti di fiamma
Flame retardants

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Grado cosmetico
Cosmetic grade

The product is of cosmetic grade and it can be used in cosmetic products.
It is according Regulation 1223/2009, its annexes and its further amendments.

Certificato Kosher
Kosher certificate

Product is produced under rabbinical supervision, a Kosher Certificate is available. Kosher in terms of Passover-Items: OK.



Certificato Halal <i>Halal certificate</i>	Product is not produced under muslimic supervision. Intermediates and starting material are of non-animal origin. Product is made by a process in which only auxiliaries of non-animal origin have been used. Processing equipment is only used for products of non-animal origin. Product is made by a process in which only auxiliaries of non-ethanol origin have been used.
Convenzione CITES <i>CITES Convention</i>	Not applicable, cultivated vegetable raw materials.
Protocollo di Nagoya <i>Nagoya protocol</i>	The product does not fall into the scope of the Nagoya protocol. The protocol is applicable to raw materials that contain functional units of heredity. As for the primary petro- & oleochemical derivatives that are used in production processes this is not the case.
Peso molecolare <i>Molecular weight</i>	256
8.1 Data di retest <i>Retest date</i>	The product, if well preserved and in its original containers, maintains its appearance and characteristics for at least two years from delivery date. After this time, product can be used but it must be rechecked (aspect).
8.2 Stoccaggio <i>Storage recommendation</i>	It is recommended to store the product at temperatures between 5°C and 25°C in well ventilated premises. Protect from hot temperatures.

Data / *Date* 18/02/2025

Le informazioni fornite in questo documento sono corrette al meglio delle nostre conoscenze, informazioni e convinzioni alla data della sua pubblicazione. Le informazioni si riferiscono solo al materiale specifico designato e potrebbero non essere valide per tale materiale utilizzato in combinazione con qualsiasi altro materiale o in altro processo, a meno che non sia specificato nel testo.

Le informazioni si basano sulla nostra attuale conoscenza ed esperienza.

Ci riserviamo il diritto di apportare modifiche a seguito di processi tecnologici o sviluppi. Queste informazioni non implicano alcuna responsabilità o altra responsabilità legale da parte nostra, anche per quanto riguarda i diritti di brevetto di terzi esistenti. In particolare, non è implicita alcuna garanzia o garanzia di proprietà in senso giuridico.

Il cliente non è esonerato dall'obbligo di effettuare un'attenta ispezione e controllo della merce in entrata.

Questo documento viene stampato automaticamente e pertanto non è firmato.

The information provided in this document is correct to the best of our knowledge, information and belief at the date of its publication. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

The information is based on our present knowledge and experience.



ANDREA GALLO DI LUIGI S.r.l.u.

Azienda fondata nel 1892

Via Erzelli 9, 16152 Genova, Italy Tel. +39 (0)10 6502941
info@andreagallo.it www.andreagallo.it p.iva00270850100

*We reserve the right to make any changes as a result of technological process or developments. This information implies no liability or other legal responsibility on our part, including with regard to existing third party patent rights. In particular, no guarantees or warranty of properties in the legal sense is implied.
The customer is not exempted from the obligation to conduct careful inspection and testing of incoming goods.
This document is automatically printed and therefore not signed.*