



**INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION**

**Revisione n°
Revision n° 13**

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1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	PURTON CFD
1.2 Produttore/Fornitore (indirizzo, telefono, contatto) <i>Manufacturer/Supplier</i> (address, phone no., contact person)	ZSCHIMMER & SCHWARZ ITALIANA Via A. Ariotto 1/C - 13038 Tricerro (VC) Italy Tel: +39 (0)161 80811 e.merlo@zschimmer-schwarz.com
1.3 Categoria della material prima (es. tensioattivo anionico) <i>Raw material category</i> (e.g. anionic surfactant)	Non ionic surfactant, thickener
1.4 Nome chimico <i>Chemical name</i>	Amides, C8-18 (even numbered) and C18-unsatd., N,N-bis(hydroxyethyl)
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Cocamide DEA: 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	271-657-0; 263-163-9; 931-329-6
1.7 N° CAS <i>CAS no.</i>	68603-42-9; 61791-31-9; 68155-07-7

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<p>1.8 Registrazioni (es. UE, USA, Giappone) - REACH - Certificazione</p> <p><i>Registration status (e.g. EU, USA, Japan) - REACH - Certification</i></p>	<p>For CAS 68155-07-7: TSCA (USA), IECSC (China), IECIC (China, Cosmetic Ingredient), DSL (Canada), REACH (Europe), AICS (Australia), KECI (South Korea), TCSI (Taiwan) and Vietnam. Pre-registered in Turkey.</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>This substance is identified by SDA Substance Name: C8-18 and C18 unsatd. alkyl carboxylic acid amide diethanol and SDA Reporting Number: 01-024-00.</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° 01-2119490100-53-0001.</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>No substances are present in the Authorized Substance List (Reach Annex XIV).</p> <p>PO 65 (California law): please check points 5.6 and 5.7 (all not intentionally added).</p>
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<p>2. Informazioni sulla produzione</p> <p><i>Information on production</i></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 (65%) and synthetic origin. Coconut oil is vegetable. It comes from Cocos Nucifera (South East Asia and Philippines). Diethanolamine 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></p>	<p>Coconut oil plus diethanolamine, heat. Control = free DEA</p> <p>Manufacturing site: Tricerro, Italy</p>

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(general description)	
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 cfu/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 *	Based on information concerning the raw materials, production process and equipment

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	1,4-Dioxane *	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 DEA: 3% maximum (average value 2% - 3%)
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, Cadmium (Cd) < 2 ppm, Lead (Pb) < 1 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

	<p>(Substances or products causing allergies or intolerances) of Regulation (EU) No. 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.</p>
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	<p>Glycerin: 10% 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>

6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	<p>- LD50 (oral) > 2000 mg/kg bw (from literature OECD 401, 1996) - LD50 (dermal) > 2000 mg/kg bw (from literature data, 1976)</p>
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	<p>Product as it is = irritating (from literature OECD 404, 1986)</p>
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	<p>Product as it is = highly irritant (from literature OECD 405, 1987)</p>
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	<p>Product as it is = Not sensitizing (from literature OECD 406, 1990)</p>
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	<p>Product as it is = Not mutagenic (from literature data, 1999)</p>

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6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	1.92%, shave cream, 5 days/week topic appl., 500 mg/kg/days, rabbit = moderate erythema, wrinkling up and dryness skin, irritation both in health and lesioned skin, none systematic toxicity caused by the treatment (CIR: CTFA 2-32-89, 1975)
6.7 Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i>	NOAEL (oral) > 750 mg/kg bw/day 28d, (from literature OECD 407, 1983) NOAEL (dermal) = 50 mg/kg bw/day from literature data, 2001)
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-5i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2140 for cosmetics and n° 52 for detergents)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fish > 2,4 mg/l, 96h (from literature OECD 203, 1996) - EC50 on Daphnia = 3,2 mg/l, 48h (from literature OECD 202, 1994) - EC50 on Algae 3,9 mg/l, 72h (from literature OECD 201, 2001) - NOEC chronic on Fish = 0,32 mg/l (from literature OECD 204, 1995) - NOEC chronic on Daphnia = 0,07 mg/l, 21d (from literature OECD 202, 1995) - NOEC chronic on Algae = 0,3 mg/l, 72h (from literature OECD 201, 2001)
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	

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<i>classification see enclosed safety data sheet.)</i>	
Dichiarazione BSE/TSE <i>BSE/TSE statement</i>	<p>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 come into contact with animal origin ingredients at any stage of its production. It is therefore BSE/TSE free.</p>
Dichiarazione test animali <i>Non-animal testing declaration</i>	<p>ZSCHIMMER & SCHWARZ ITALIANA has made an animal test in 1977 on this product for evaluation of skin and eye irritation</p>
Glicol eteri, glicoli, alcoli (non dichiarati nei paragrafi precedenti) <i>Glycol ethers, glycols, alcohols (not declared in previous paragraphs)</i>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>
Metanolo <i>Methanol</i>	<p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p>
Ftalati, DINP (diisononyl phthalate) <i>Phthalates, DINP (diisononil ftalato)</i>	<p>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.</p>
Glutine <i>Gluten</i>	<p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p>
Formaldeide <i>Formaldehyde (Formol)</i>	<p>Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.</p>
VOC <i>VOC (volatile organic compounds)</i> <i>Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) and Directive 2004/42/EC</i>	<p>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.</p> <p>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.</p>

**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 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.

**Fitofarmaci
Plant protection products**

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

**APEO, cloroparaffine, composti organici
alogenati
APEOs, chloroparaffines, AOX**

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

**Mercaptani
Mercaptanes**

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

**Melamine
Melamine**

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

**Lattosio
Lactose**

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

**Aflatossine/Micotossine
Aflatoxines/Mycotoxines**

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

**Lattice
Latex**

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

**Nitrati e Nitriti
Nitrates and Nitrites**

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

**Amine aromatiche
Aromatic amines**

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

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Coloranti azoici

Azo dyes

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

Ormoni, antibiotici, steroidi e altri ingredienti (naturali o chimici) dannosi per le funzioni del corpo umano

Hormones, antibiotics, steroids and other ingredients (natural or chemical) dangerous for the body functionality

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.

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.

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.

We are EFfCI GMP certified.

Certificato Kosher

Kosher certificate

Yes

Certificato Halal

Halal certificate

Intermediates and starting materials 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.

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<p>Convenzione CITES <i>CITES Convention</i></p> <p>Protocollo di Nagoya <i>Nagoya protocol</i></p>	<p>Product is made by a process in which only auxiliaries of non-ethanol origin have been used.</p> <p>Not applicable, cultivated vegetable raw materials</p> <p>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.</p>
<p>8.1 Data di retest</p> <p><i>Retest date</i></p>	<p>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).</p>
<p>8.2 Stoccaggio</p> <p><i>Storage recommendation</i></p>	<p>Store the product at room temperature (15°C-30°C). However it is recommended to store the product at temperatures higher than 5°C because low temperatures can cause turbidity and/or product separation and/or viscosity increasing; in this case it is necessary to heat the product. at 40°C-50°C.</p> <p>Always homogenize before using.</p>

Data / *Date* 06/07/2023

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