



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 13

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	PURTON CFD
1.2 Produttore/Fornitore (indirizzo, telefono, fax, contatto) <i>Manufacturer/Supplier</i> (address, phone no., fax no., contact person)	ZSCHIMMER & SCHWARZ ITALIANA Via A. Ariotto 1/C - 13038 Tricerro (VC) Italy Tel: +39 (0)161 80811 Fax: +39 (0)161 801002 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</i> <i>Composition</i>	Cocamide DEA: 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	L.n° 931-329-6
1.7 N° CAS <i>CAS no.</i>	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>TSCA (USA), DSL (Canada), REACH (Europe), AICS (Australia), KECI (Korea), TCSI (Taiwan).</p> <p>Japanes have recently changed their system, so that publication in the Japanese list of approved ingredients is no longer necessary. Any cosmetic ingredient is now allowed in Japan with no prior approval.</p> <p>The product is according to the China Cosmetic Ingredient list 2015 n° 07545.</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.</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 relevant amount.</p> <p>No substances are present in the Authorized Substance List (Reach Annex XIV)</p> <p>Please be aware that product could contains diethanolamine and n-nitrosamines. Both are listed in PO 65 (California law).</p>
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<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 (65%) and synthetic origin.</p> <p>Coconut oil is vegetable. It comes from Cocos Nucifera (South East Asia and Philippines).</p> <p>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> (general description)</p>	<p>Coconut oil plus diethanolamine, heat.</p> <p>Control = free DEA</p>

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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 * <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 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, Antimony (Sb) < 5 ppm, Barium (Ba) < 2 ppm, Chromium (Cr) III < 2 ppm, Chromium (Cr) VI < 2 ppm, Cadmium (Cd) < 2 ppm, Copper (Cu) < 2 ppm, Lead (Pb) < 1 ppm, Mercury (Hg) < 2 ppm, Scandium (Sc) < 2 ppm, Selenium (Se) < 2 ppm, Nickel (Ni) < 1 ppm, Zinc (Zn) < 2 ppm Total heavy metals (as Fe) < 10 ppm
5.8	Acido monoclороacetico <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.

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5.10 Allergeni <i>Allergens</i>	Based on information concerning the raw materials, production process and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III, No. 67-92 are not likely to be present.
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Glycerin: 10% maximum Water: 0.5% maximum Based on information concerning the raw materials, production process and equipment used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008 are not likely to be present.

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

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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 classification see enclosed safety data sheet.)	
Dichiarazione BSE <i>BSE 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 come into contact with animal origin ingredients at any stage of its production. It is therefore BSE free.

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Dichiarazione test animali

Non-animal testing declaration

Glicol eteri, glicoli, alcoli (non dichiarati nei paragrafi precedenti)

Glycol ethers, glycols, alcohols (not declared in previous paragraphs)

Metanolo

Methanol

Ftalati, DINP (diisononyl phtalate)

Phtalates, DINP (diisononil ftalato)

Glutine

Gluten

Formaldeide

Formaldehyde (Formol)

VOC

VOC compounds

Fitofarmaci

Plant protection products

APEO, cloroparaffine, composti organici alogenati

APEOs, chloroparaffines, AOX

Mercaptani

Mercaptanes

Melamine

Melamine

Lattosio

Lactose

ZSCHIMMER & SCHWARZ ITALIANA has made an animal test in 1977 on this product for evaluation of skin and eye irritation

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

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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.

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 formaldehyde is not likely to be present.

The product doesn't contain any of the substances that are classified as VOC according to "Ordonnance sur taxe d'incitation sur les composés organiques volatils (OCOV) du 12 novembre 1997".

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

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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.

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 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.

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<p>Ritardanti di fiamma <i>Flame retardants</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p> <p>Convenzione CITES <i>CITES Convention</i></p>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>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.</p> <p>Yes</p> <p>Not applicable, cultivated vegetable raw materials</p>
<p>8.1 Data di scadenza <i>Shelf life</i></p>	<p>The product, if well preserved and in its original containers, maintains its appearance and characteristics for at least one year from delivery date. After this time, product can be used but it must be rechecked.</p>
<p>8.2 Stoccaggio <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. Always homogenize before using.</p>

Data / *Date* 07/01/2020

Queste informazioni si riferiscono solo al prodotto sopramenzionato e non possono essere considerate valide per altri prodotti o in altri processi produttivi. Le informazioni sono corrette e complete secondo le nostre attuali conoscenze e sono date in buona fede ma senza garanzia. E' responsabilità dell'utilizzatore l'assicurarsi che le informazioni siano appropriate e complete per lo specifico uso del prodotto.

***This Information refers only to the above mentioned product** and does not need to be valid if used with other product(s) or in any process. The information is to our best present knowledge correct and complete and is given in good faith but without warranty. It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product.*