



**INFORMAZIONI TOSSICOLOGICHE**  
***TOXICOLOGICAL INFORMATION***

**Revisione n°**  
***Revision n° 09***

<b>1. Informazioni generali</b>  <b><i>General information</i></b>	
<b>1.1 Nome commerciale</b>  <b><i>Trade name</i></b>	<b>PURTON CFD</b>
<b>1.2 Produttore/Fornitore</b> (indirizzo, telefono, fax, contatto)  <b><i>Manufacturer/Supplier</i></b> (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
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico)  <b><i>Raw material category</i></b> (e.g. anionic surfactant)	Non ionic surfactant, thickener
<b>1.4 Nome chimico</b>  <b><i>Chemical name</i></b>	Amides, C8-18 (even numbered) and C18-unsatd., N,N-bis(hydroxyethyl)
<b>1.5 Nome INCI (CTFA)</b> <b>Composizione</b>  <b><i>INCI (CTFA) name</i></b> <b><i>Composition</i></b>	Cocamide DEA: 84.5% min
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <b><i>EC (EINECS/ELINCS) no.</i></b>	271-657-0; 263-163-9; 931-329-6
<b>1.7 N° CAS</b>  <b><i>CAS no.</i></b>	68603-42-9; 61791-31-9; 68155-07-7

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<p><b>1.8 Registrazioni</b> (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), PICCS (Philippines), ASIA-PAC (Asia-Pacific), ENCS (Japan) and ECL (Korea).</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 (12 January 2017) of substances of very high concern (SVHC) are contained in the product in a relevant amount.</p> <p>Please be aware that product could contain n-nitrosamines. Nitrosamines are listed in PO 65 (California law). Heavy metals are listed on PO 65 (California law).</p>
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<p><b>2. Informazioni sulla produzione</b></p> <p><b>Information on production</b></p>	
<p><b>2.1 Origine della materia prima</b> (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><b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b></p> <p><i>Is the starting material derived from genetically modified organisms (GMO)?</i></p>	<p>No</p>
<p><b>2.3 Informazioni sul processo di produzione</b> (descrizione generale)</p> <p><i>Information on production process</i> (general description)</p>	<p>Coconut oil plus diethanolamine, heat. Control = free DEA</p>

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<b>3. Additivi</b> <i>Additives</i>	
<b>3.1 Conservanti/Biocidi</b> <i>Preservatives/Biocides</i>	Not added and not expected
<b>3.2 Antiossidanti</b> <i>Antioxidants</i>	Not added and not expected
<b>3.3 Solventi</b> <i>Solvents</i>	Water: 0.5% maximum
<b>3.4 Sbiancanti</b> <i>Bleaching agents</i>	Not added and not expected
<b>3.5 Altri</b> <i>Others</i>	Not added and not expected
<b>4. Specifiche microbiologiche</b> <b>Microbiological specification</b>	
<b>4.1 Conta microbica totale (ufc/g)</b> <i>Total viable count (colony-forming units/g)</i>	less than 10 cfu/g
<b>5. Residui del processo di lavorazione</b> 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>	
<b>5.1 1,4-Diossano *</b> <i>1,4-Dioxane *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

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5.2	<b>Ossido di etilene *</b> <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	<b>Solventi residui</b> <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	<b>Monomeri residui</b> <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	<b>Ammine</b> <i>Amines</i>	Free DEA: 5% maximum (average value 2% - 3%)
5.6	<b>Nitrosammine</b> <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	<b>Metalli pesanti</b> <i>Heavy metals</i>	Arsenic (As) < 2 ppm, Antimony (Sb) < 5 ppm, Lead (Pb) < 1 ppm, Cadmium (Cd) < 2 ppm, Mercury (Hg) < 2 ppm, Nickel (Ni) < 1 ppm, Chromium (Cr) < 2 ppm, Total heavy metals (as Fe) < 10 ppm
5.8	<b>Acido monocloroacetico</b> <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	<b>Acido dicloroacetico</b> <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	<b>Allergeni</b> <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.

	Based on information concerning the raw materials, production process and equipment used food allergens as of EU Directive 2000/13/EC (as amended), Annex IIIa and Regulation (EU) 1169/2011, Annex II are not likely to be present.
<b>5.11 Altri (e.g. CMR)</b>  <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.

<b>6. Tossicologia</b>  <i>Toxicology</i>	
<b>6.1 Informazioni sulla tossicità acuta</b>  <i>Information on acute toxicity</i>	- LD50 oral > 5000 mg/kg bw (OECD 401) - LD50 dermal > 2000 mg/kg bw
<b>6.2 Informazioni sull'irritazione cutanea</b>  <i>Information on skin irritation</i>	- Product as it is = strongly irritant (OECD 404) - 3% solution on rabbit = It isn't irritant (our test n° 1-3-195/2-77) - 30% in propylene glycol, 0.3 ml, health and lesioned skin, 23h patch, rabbit = moderate irritation (CIR: CTFA 1976, 2-32-123)
<b>6.3 Informazioni sull'irritazione oculare</b>  <i>Information on irritation of the mucous membrane</i>	- Product as it is = strongly irritant (OECD 405) - 3% aqueous solution on rabbit = It isn't irritant (our test n° 1-3-195/3-77) - 30% in propylene glycol, 0.1 ml, rabbit = light irritant (CIR: CTFA 1984, 2-32-124)
<b>6.4 Informazioni sulla sensibilizzazione</b>  <i>Information on sensitisation potential</i>	- Product as it is = Not sensitizing (OECD 406) - Kligman e Magnusson Test on 10% active matter = The product hasn't any sensitization danger (Cosmetic Ingredient Review) - Test on 104 women, 2% shampoo, 3 occlusive patches, 87 usage days, challenge 10 days after final use = on the starting patch 8 subjects with light erythema, 1 with strong erythema and 2 with erythema + oedema; 30 subjects with challenge reaction (1+, 2+, 3+) = irritant but not sensitizing (International Research Service, CTFA, 1983)

<b>6.5 Informazioni sulla genotossicità</b> <i>Information on gene toxicity</i>	<ul style="list-style-type: none"> <li>- Product as it is = Not mutagenic (OECD 471)</li> <li>- Ames test = None mutagenic effect (our test n° 96-4095 dated 10/5/96)</li> </ul>
<b>6.6 Informazioni sull'assorbimento percutaneo</b> <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)
<b>6.7 Altri (e.g. NOAEL)</b> <i>Others (e.g. NOAEL)</i>	NOAEL (oral route) > 750 mg/kg bw/day (28d, OECD 407) NOAEL (dermal route) = 50 mg/kg bw/day NOAEL = 1000 mg/kg x bw/d (9 die, reproductive toxicity, rats, oral) NOEL = 50 mg/kg bw/day (oral, rats, male-female, 90 days)  Note: CIR: SAFE at use concentrations in rinse off products, < 10% in leave on (do not use in cosmetics that can produce nitrous compounds)
<b>7. Ecotossicità</b> <i>Ecology</i>	
<b>7.1 Degradabilità/Eliminazione</b> <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)
<b>7.2 Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- LC50 on Fish &gt; 2 mg/l, 96h (OECD 203)</li> <li>- EC50 on Daphnia = 3,2 mg/l, 48h (OECD 202)</li> <li>- EC50 on Algae &gt; 2,1 mg/l, 72h (OECD 201)</li> <li>- EC50 on Pseudomonas putida = 6 g/l, 72h (DIN 38412 L8)</li> <li>- NOEC chronic on Fish = 0,32 mg/l (OECD 204)</li> <li>- NOEC chronic on Daphnia = 0,07 mg/l, 21d (OECD 211)</li> <li>- NOEC chronic on Algae = 0,3 mg/l, 72h (OECD 201)</li> </ul>

**7.3 Altri**  
***Others***

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**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.)

***Additional information***

*(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)*

**Dichiarazione BSE**

***BSE statement***

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.

**Dichiarazione test animali**

***Non-animal testing declaration***

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

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

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

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

**Metanolo**

***Methanol***

Based on information concerning the raw materials, production process and equipment used it is 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 compounds***

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



**Pesticidi**  
**Pesticides**

du 12 novembre 1997”.

Based on information concerning the raw materials, production process and equipment used pesticides are expected to conform with concentration limits of the European Pharmacopeia; Section 2.8.13 “Pesticides residues”, Table 2.8.13.-1

**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 expected to conform with the concentration limits of Regulation (EC) 1881/2006 Annex, Section 2.1.5

**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**

**PBT/vPvB**

**PBT/vPvB**

**Materiale radioattivo**

**Radioactive material**

**Nanomateriali**

**Nanomaterials**

**Idrocarburi Policiclici Aromatici**

**Polycyclic Aromatic Hydrocarbons (HAP)**

**Clorobenzeni/Clorofenoli**

**Chlorobenzenes/Chlorophenols**

**Ritardanti di fiamma**

**Flame retardants**

**Grado cosmetico**

**Cosmetic grade**

**Certificato Kosher**

**Kosher certificate**

**Convenzione CITES**

**CITES Convention**

Yes, absent

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 radioactive material is not expected to be present and no irradiation has been used.

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

Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons are expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex

Benzo[a]pyrene  $\leq 1 \mu\text{g/kg}$

Dibenz[a,h]anthracene  $\leq 1 \mu\text{g/kg}$

Cyclopenta[cd]pyrene )

Benzo[fluoranthene[b+j+k] )

Indeno[1,2,3-cd]pyrene )  $\Sigma \leq 5 \mu\text{g/kg}$

Anthanthrene )

Benzo[b]naphtho[2,1-d]thiophene )

Benz[a]anthracene )

Chrysene + Triphenylene )  $\Sigma \leq 20 \mu\text{g/kg}$

Benzo[ghi]perylene )

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.

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 (certificate n° 20782).

Yes

Not applicable, cultivated vegetable raw materials

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<b>8.1 Data di scadenza</b> <i>Shelf life</i>	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.
<b>8.2 Stoccaggio</b> <i>Storage recommendation</i>	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.

Data / *Date* 21/04/17

**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.*