



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

**Revisione n°**  
***Revision n° 02***

<b>1. Informazioni generali</b>  <i>General information</i>	
<b>1.1 Nome commerciale</b>  <i>Trade name</i>	<b>AMPHOTENSID COX/MC</b>
<b>1.2 Produttore/Fornitore</b> (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 808111 Fax: +39 (0)161 801002 e.merlo@zschimmer-schwarz.com
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico)  <i>Raw material category</i> (e.g. anionic surfactant)	Amphoteric surfactant
<b>1.4 Nome chimico</b>  <i>Chemical name</i>	3-C12-18-(even numbered)-alkylamido-N,N-dimethylpropan-1-amino oxide
<b>1.5 Nome INCI (CTFA) Composizione</b>  <i>INCI (CTFA) name Composition</i>	Cocamidopropylamine Oxide: 36% - 38%  Aqua: to 100%
<b>1.6 N° EC (EINECS/ELINCS)</b>  <i>EC (EINECS/ELINCS) no.</i>	Old EC number: 268-938-5 List no° 939-581-9
<b>1.7 N° CAS</b>  <i>CAS no.</i>	Old CAS number: 68155-09-9

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<p><b>1.8 Registrazioni</b> (es. UE, USA, Giappone) - REACH</p> <p><i>Registration status (e.g. EU, USA, Japan) - REACH</i></p>	<p>TSCA (USA), DLS (Canada), EINECS (Europe), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and ECL (Korea).</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: pre-registered (registration 31.05.2018).</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>Heavy metals are listed on PO 65 (California law). Ecolabel DID List 2016: n° 2205</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 and synthetic origin.</p> <p>Hydrogenated coconut oil comes from coconut oil from Cocos Nucifera (South East Asia and Philippines), than it is hydrogenated.</p> <p>DMAPA and H<sub>2</sub>O<sub>2</sub> are 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>Reaction: Amidification and further reaction with H<sub>2</sub>O<sub>2</sub></p>

<p><b>3. Additivi</b></p> <p><i>Additives</i></p>	
<p><b>3.1 Conservanti</b></p> <p><i>Preservatives</i></p>	<p>Not added</p>

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3.2	<b>Antiossidanti</b> <i>Antioxidants</i>	Not added
3.3	<b>Solventi</b> <i>Solvents</i>	Water
3.4	<b>Sbiancanti</b> <i>Bleaching agents</i>	Not added
3.5	<b>Altri</b> <i>Others</i>	2.0% - 3.0% of Glycerine

4.	<b>Specifiche microbiologiche</b> <b>Microbiological specification</b>	
4.1	<b>Conta microbica totale (ufc/g)</b> <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g

5.	<b>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>	
5.1	<b>1,4-Diossano *</b> <i>1,4-Dioxane *</i>	Not expected
5.2	<b>Ossido di etilene *</b> <i>Ethylene oxide *</i>	Not expected
5.3	<b>Solventi residui</b> <i>Residual solvents</i>	Not expected

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5.4	<b>Monomeri residui</b> <i>Residual monomers</i>	Not expected
5.5	<b>Ammine</b> <i>Amines</i>	Free amidoamine: 0.3% maximum DMAPA: not detectable
5.6	<b>Nitrosammine</b> <i>Nitrosamines</i>	<p>The product doesn't contain any mono, di and tri ethanolamine.</p> <p>Nevertheless, being product obtained starting from DMAPA, it should not be used in cosmetic products in which N-nitroso compounds may be formed.</p> <p>We evaluate nitrosamine content in a random system and till now their value has always been under detection limits (50 ppb).</p>
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>	Not expected
5.9	<b>Acido dicloroacetico</b> <i>Dichloroacetic acid</i>	Not expected
5.10	<b>Allergeni</b> <b>Allergens according to the Cosmetics Regulation 1223/2009/EC and its further amendments (ppm)</b>	Not expected
5.11	<b>Altri (e.g. CMR)</b> <i>Others (e.g. CMR)</i>	Fatty acids: 1% maximum Hydrogen peroxide: 0.17% maximum CMR ingredients: absent
6.	<b>Tossicologia</b> <i>Toxicology</i>	

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<b>6.1</b>	<b>Informazioni sulla tossicità acuta</b> <i>Information on acute toxicity</i>	LD50 (Orale) > 500 (OECD 423, literature data OECD 404)
<b>6.2</b>	<b>Informazioni sull'irritazione cutanea</b> <i>Information on skin irritation</i>	Product as it is = Irritating (literature data OECD 405)
<b>6.3</b>	<b>Informazioni sull'irritazione oculare</b> <i>Information on irritation of the mucous membrane</i>	Product as it is = Irritating (literature data OECD 405)
<b>6.4</b>	<b>Informazioni sulla sensibilizzazione</b> <i>Information on sensitisation potential</i>	Not sensitizing (literature data, OECD 406)
<b>6.5</b>	<b>Informazioni sulla genotossicità</b> <i>Information on gene toxicity</i>	Ames test = None mutagenic effects (our test n° 96/4092.1)
<b>6.6</b>	<b>Informazioni sull'assorbimento percutaneo</b> <i>Information on percutaneous permeation</i>	10% Absorption rate, no bioaccumulation potential (literature data)
<b>6.7</b>	<b>Altri (e.g. NOAEL)</b> <i>Others (e.g. NOAEL)</i>	NOAEL = 15 mg/kg x bw/d (dilution factor 81.5, 28 g test, subacute, rats, oral, literature data)
<b>7.</b>	<b>Ecotossicità</b> <i>Ecology</i>	
<b>7.1</b>	<b>Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (but failing 10 day window) (OECD 301 B, literature data)
<b>7.2</b>	<b>Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	LC50 on Fish = 0,68 mg/l/96h (100% a.i.), EC50 on Daphnia = 19,9 mg/l/48h (100% a.i.), EC50 on Algae = 0,705 mg/l/72h (100% a.i.), NOEC chronic on Fish = 0,42 mg/l 302 d (100% a.i.), NOEC chronic on Daphnia = 0,7 mg/l 21 d (100% a.i.)
<b>7.3</b>	<b>Altri</b> <i>Others</i>	/

<p><b>8. Informazioni aggiuntive</b> (Per i dettagli sulle specifiche vedere il bollettino tecnico allegato; per i dettagli sull'etichettatura e la classificazione vedere la scheda di sicurezza allegata.)</p> <p><b>Additional information</b> (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</p>	
<p><b>Dichiarazione BSE</b> <b>BSE statement</b></p> <p><b>Dichiarazione test animali</b> <b>Non-animal testing declaration</b></p> <p><b>Glicol eteri</b> <b>Glycol ethers</b></p> <p><b>Ftalati</b> <b>Phthalates</b></p> <p><b>Glutine</b> <b>Gluten</b></p> <p><b>Formaldeide</b> <b>Formaldehyde (Formol)</b></p> <p><b>VOC</b> <b>VOC compounds</b></p> <p><b>Pesticidi</b> <b>Pesticides</b></p> <p><b>APEO, cloroparaffine, composti organici alogenati</b> <b>APEOs, chloroparaffines, AOX</b></p> <p><b>Mercaptani</b> <b>Mercaptanes</b></p>	<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 free.</p> <p>ZSCHIMMER &amp; SCHWARZ ITALIANA has never made or commissioned animal tests on this product.</p> <p>Not expected</p> <p>Not expected</p> <p>Not expected</p> <p>Not added, not expected</p> <p>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".</p> <p>The product doesn't contain any pesticides or pollutant substances (under detection limits).  materials, production process and equipment used they are not likely to be present.</p> <p>Not added and not expected</p> <p>The product doesn't contain mercaptanes</p>

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<b>Melamine</b> <b>Melamine</b>	Not expected
<b>Lattosio</b> <b>Lactose</b>	Not expected
<b>Aflatossine/Micotossine</b> <b>Aflatoxines/Mycotoxines</b>	Not expected
<b>Lattice</b> <b>Latex</b>	The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.
<b>Nitrati e Nitriti</b> <b>Nitrates and Nitrites</b>	Not expected
<b>Idrocarburi Policiclici Aromatici</b> <b>Plycyclic Aromatic Hydrocarbons (HAP)</b>	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 )
<b>Coloranti azoici</b> <b>Azo dyes</b>	Absent
<b>Grado cosmetico</b> <b>Cosmetic grade</b>	The product is of cosmetic grade and it can be used in cosmetic products. It is according to Directive 76/768/EC and Regulation 1223/2009, its annexes and its amendments.
<b>Certificato Kosher</b> <b>Kosher certificate</b>	Yes
<b>8.1 Data di scadenza</b> <b>Shelf life</b>	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 at room temperature (15°C-25°C) and in any case higher than 5°C. Protect from frost. When stored at low temperature turbidity can appear. Indirect warming will restore the product to its former appearance.
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Data / *Date* 21/03/18

**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.*