



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 00

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	AMPHOTENSID B4/CONC-I MC PKO
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 808111 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)	Amphoteric surfactant
1.4 Nome chimico <i>Chemical name</i>	1-Propanaminium, 3-amino-N-(carboxymethyl)- N,N-dimethyl-,N-C8-18(even numbered) acyl derivs., hydroxides, inner salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Cocamidopropyl Betaine: 44.0% - 48.0% as dry matter Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	308-107-7 (new assigned EC number: 931- 296-8)
1.7 N° CAS <i>CAS no.</i>	97862-59-4

<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>EINECS (Europe).</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° 07555.</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 in 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).</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 (plant, animal, synthetic)</i></p>	<p>Vegetable, mineral and synthetic origin.</p> <p>Palm kernel oil is vegetable. It comes from Elaeis Guineensis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</p> <p>DMAPA and monochloroacetic acid are synthetic.</p> <p>NaOH is mineral.</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 (general description)</i></p>	<p>Reaction: Amidification and further quaternization</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
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.

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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 amidoamine: 0.09% maximum DMAPA: 15 ppm maximum
5.6	Nitrosammine <i>Nitrosamines</i>	Lower than detection limits (50 ppb)
5.7	Metalli pesanti <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	Acido monocloroacetico <i>Monochloroacetic acid</i>	5 ppm maximum
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	30 ppm maximum
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. 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.

<p>5.11 Altri (e.g. CMR)</p> <p><i>Others (e.g. CMR)</i></p>	<p>Sodium chloride: 5% - 7% Sodium glycolate: 1% maximum Fatty acids: 1% maximum Glycerol: 2% - 4%</p> <p>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.</p>
<p>6. Tossicologia</p> <p><i>Toxicology</i></p>	<p>All data are based on EC n° 931-333-8</p>
<p>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<p>- LD50 oral > 1960 mg a.i./kg bw (OECD 401) - LD50 dermal > 2000 mg/kg (OECD 402)</p>
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<p>- Sol. 30% in water (rabbit) = Not irritant (OECD 404) - Patch test on volunteers at different concentrations = Non irritating (CIR: CTFA 3-15-11, 1983; CIR: CTFA 1988) - Product as it is = Non irritating (CESIO 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 (rabbit) = Risk of serious damage to eyes, Category 1 (OECD 405) - From irritating to practically non irritating depending on concentration and type of product (rinse/non rinse) (CIR: FDRL 1982, CTFA 3-15-13; CIR: Leberco 1965; CIR: Stillmeadow Inc. 1980; CIR: CTFA 1983)</p>
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<p>- Product as it is = Not sensitizing in the maximum-dose test on guinea pigs (OECD 406) - Test on volunteers at different concentrations = Not sensitizing (CIR: CTFA 1980; CIR: CTFA 1984)</p>
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<p>- Ames test = None mutagenic effects (test effectuated on 10/05/1996, protocol PR. 1-05) - No experimental evidence on genotoxicity in vitro/vivo</p>

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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>	NOAEL = 76.5 mg/kg x bw/d (90 die, subchronic, rats, oral) DNEL (dermal route) = 7.5 mg/kg bw/day (repeated dose toxicity), AF = 40 Limits concentration > 10% active matter: H318 causes serious eye damage (R41) Signal word: danger Symbol: GHS05 4-10% active matter: H319 causes serious eye irritation (R36) Signal word: warning Symbol: GHS07 < 4% active matter: no classification
7. Ecotossicità <i>Ecology</i>	All data are based on EC n° 931-333-8
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-6i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2202 for cosmetics and n° 61 for detergents)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Fish = 15 mg/l, 96h (OECD 203) - EC50 on Daphnia = 1,1 mg a.i./l, 24h (OECD 202) - EC50 on Algae = 4,66 mg a.i./l, 72h (OECD 201) - EC0 on Pseudomonas sp. > 8000 mg/l, 16h (ISO 10712) - NOEC chronic on Fish = 0,135 mg a.i./l, 100d (OECD 210) - NOEC chronic on Daphnia = 0,32 mg a.i./l, 21d (OECD 211)
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)	

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<p>allegata.)</p> <p>Additional information (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</p>	
<p>Dichiarazione BSE BSE statement</p> <p>Dichiarazione test animali Non-animal testing declaration</p> <p>Alcoli Alcohols</p> <p>Glicol eteri Glycol ethers</p> <p>Ftalati, DINP (diisononyl phtalate) Phtalates, DINP (diisononil ftalato)</p> <p>Parabeni Parabens</p> <p>Siliconi Silicons</p> <p>Glutine Gluten</p> <p>Formaldeide Formaldehyde (Formol)</p> <p>VOC VOC compounds</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/TSE free.</p> <p>ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <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> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.</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 composes organiques volatils (OCOV) du 12 novembre 1997".</p>

Pesticidi
Pesticides

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 e steroidi
Hormones, antibiotics and steroids

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

PBT/vPvB
PBT/vPvB

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

<p>Materiale radioattivo <i>Radioactive material</i></p> <p>Nanomateriali <i>Nanomaterials</i></p> <p>Idrocarburi Policiclici Aromatici <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p>	<p>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.</p> <p>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</p> <p>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</p> <table border="0"> <tr> <td>Benzo[a]pyrene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Dibenz[a,h]anthracene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Cyclopenta[cd]pyrene</td> <td>)</td> </tr> <tr> <td>Benzo[fluoranthene[b+j+k]</td> <td>)</td> </tr> <tr> <td>Indeno[1,2,3-cd]pyrene</td> <td>) Σ ≤ 5 µg/kg</td> </tr> <tr> <td>Anthanthrene</td> <td>)</td> </tr> <tr> <td>Benzo[b]naphtho[2,1-d]thiophene</td> <td>)</td> </tr> <tr> <td>Benz[a]anthracene</td> <td>)</td> </tr> <tr> <td>Chrysene + Triphenylene</td> <td>) Σ ≤ 20 µg/kg</td> </tr> <tr> <td>Benzo[ghi]perylene</td> <td>)</td> </tr> </table> <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. We are EFfCI GMP certified (certificate n° 20782).</p> <p>Yes</p>	Benzo[a]pyrene	≤ 1 µg/kg	Dibenz[a,h]anthracene	≤ 1 µg/kg	Cyclopenta[cd]pyrene)	Benzo[fluoranthene[b+j+k])	Indeno[1,2,3-cd]pyrene) Σ ≤ 5 µg/kg	Anthanthrene)	Benzo[b]naphtho[2,1-d]thiophene)	Benz[a]anthracene)	Chrysene + Triphenylene) Σ ≤ 20 µg/kg	Benzo[ghi]perylene)
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Chrysene + Triphenylene) Σ ≤ 20 µg/kg																				
Benzo[ghi]perylene)																				
<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</i></p>	<p>Store at room temperature (15°C-25°C). At low temperature and on prolonged storage product can become turbid. The material can be restored to its original appearance by indirect heating and stirring. This doesn't affect the quality of the product. Overheating should be avoided.</p>																				

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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.

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