



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/C
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) and C18 unsaturated acyl) derivs., hydroxides, inner salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Cocamidopropyl Betaine: 34.5% min as dry matter 28% - 31% as active substance Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	931-333-8

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1.7	N° CAS <i>CAS no.</i>	147170-44-3; 61789-40-0
1.8	Registrazioni (es. UE, USA, Giappone) - REACH <i>Registration status</i> (e.g. EU, USA, Japan) - REACH	TSCA (USA), PICCS (Philippines), ASIA-PAC (Asia-Pacific), DSL (Canada), EINECS (Europe), AICS (Australia) and ECL (Korea). 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. The product is according to the China Cosmetic Ingredient list 2014 n° 07555. REACH registration n° 01-2119489410-39-0001 None of substances listed in the “candidate” list of substances of very high concern (SVHC) are contained in the product in a relevant amount.

2.	Informazioni sulla produzione Information on production	
2.1	Origine della materia prima (vegetale, animale, sintetica) <i>Origin of starting material</i> (plant, animal, synthetic)	Vegetable, mineral and synthetic origin. Coconut fatty acids are from vegetable origin. They come from coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers). We are RSPO member (membership n° 2-0434-14-000-00). DMAPA and monochloroacetic acid are synthetic. NaOH is mineral.
2.2	La materia prima deriva da organismi geneticamente modificati (OGM)? <i>Is the starting material derived from genetically modified organisms (GMO)?</i>	No
2.3	Informazioni sul processo di produzione (descrizione generale) <i>Information on production process</i> (general description)	Reaction: Amidification of coconut fatty acid with DMAPA and further quaternization with monochloroacetic acid

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3.	Additivi <i>Additives</i>	
3.1	Conservanti <i>Preservatives</i>	Not added
3.2	Antiossidanti <i>Antioxidants</i>	Not added
3.3	Solventi <i>Solvents</i>	Water
3.4	Sbiancanti <i>Bleaching agents</i>	Not added
3.5	Altri <i>Others</i>	Not added
4.	Specifiche microbiologiche <i>Microbiological specification</i>	
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>	Not expected

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5.2	Ossido di etilene * <i>Ethylene oxide *</i>	Not expected
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 or, if used, is removed in a final step of the manufacturing process
5.4	Monomeri residui <i>Residual monomers</i>	Not expected
5.5	Ammine <i>Amines</i>	Free amidoamine: 0.5% maximum DMAPA: under detection limits (5 ppm maximum)
5.6	Nitrosammine <i>Nitrosamines</i>	Not expected
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>	20 ppm maximum as free chloroacetates
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	Not expected
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: 6% maximum Sodium glycolate: 0.5% maximum Fatty acids: 1% maximum</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>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<p>LD50 > 6.6 g/kg (from literature, protocol data 345)</p>
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<p>- 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>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>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)</p>
<p>6.6 Informazioni sull'assorbimento percutaneo</p> <p><i>Information on percutaneous permeation</i></p>	<p>Not determined</p>
<p>6.7 Altri (e.g. NOAEL)</p> <p><i>Others (e.g. NOAEL)</i></p>	<p>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</p> <p>Limits concentration > 10% active matter: H318 causes serious eye</p>

	<p>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</p>
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7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	<p>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)</p>
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fathead minnow = 3 mg/l, 96h (OECD 203) - LC50 on Zebra fish (Brachydanio rerio) = 2.0, NOEC: 1.7, 96h (IUCLID 2000) - EC50 on Daphnia magna = 5 mg/l, 48h (OECD 202) - EC50 on Daphnia magna = 6.5, NOEC: 1.6, 48h (IUCLID 2000) - EC50 on Daphnia magna = 21.7, 48h (IUCLID 2000) - EC50 on Algae (Desmodesmus subspicatus) = 15.6 mg/l, 72h (OECD 201) - EC50 on Algae (Scenedesmus subspicatus) = 1.84, 72h (IUCLID 2000) - EC50 on Algae (Scenedesmus subspicatus) = Growth rate: 0.55, NOEC: 0.09, 96h (IUCLID 200) - EC50 on Algae (Scenedesmus subspicatus) = Biomass: 30;33, NOEC: 3.2, Growth rate: 45;48, NOEC: 3.2;10, 72h (Goldschmidt 1993-1994) - EC0 on Pseudomonas sp. > 8000 mg/l, 16h (ISO 10712)
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 <i>BSE statement</i></p> <p>Dichiarazione test animali <i>Non-animal testing declaration</i></p> <p>Alcoli <i>Alcohols</i></p> <p>Glicol eteri <i>Glycol ethers</i></p> <p>Ftalati <i>Phtalates</i></p> <p>Glutine <i>Gluten</i></p> <p>Formaldeide <i>Formaldehyde (Formol)</i></p> <p>VOC <i>VOC compounds</i></p> <p>Pesticidi <i>Pesticides</i></p> <p>APEO, cloroparaffine, composti organici alogenati <i>APEOs, chloroparaffines, AOX</i></p> <p>Mercaptani <i>Mercaptanes</i></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.</p> <p>Not added and not expected</p> <p>Not added and not expected</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>Not added and not expected</p> <p>Not added and 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 composes organiques volatils (OCOV) du 12 novembre 1997".</p> <p>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</p> <p>Not added and not expected</p> <p>Not added and not expected</p>

Melamine
Melamine

Not added and not expected

Lattosio
Lactose

Not added and not expected

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

Not added and not expected

Ormoni, antibiotici e steroidi
Hormones, antibiotics and steroids

Not added and not expected

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 expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex

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)

Coloranti azoici
Azo dyes

Absent

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<p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></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. We are EFfCI GMP certified (certificate n° 20782).</p> <p>Yes</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. Store at room temperature (5°C - 30°C). In open containers, product maintains its characteristics for at least 6 months, if proper manipulated</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>Store at room temperature (15°C-25°C). At low temperature and on prolonged storage it 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>

Data / *Date* 09/02/16

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.