



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 25

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 and C18 unsatd. acyl) derivs., inner salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Cocamidopropyl Betaine: 34.5% min as dry matter 28.5% - 32.0% as active substance Sodium Chloride: 6.0% max Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	931-333-8 (List n°)
1.7 N° CAS <i>CAS no.</i>	147170-44-3; 61789-40-0

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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>For CAS 147170-44-3: IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TSCA (USA), TCSI (Taiwan), PICCS (Philippines) and NDSL (Canada).</p> <p>For CAS: 61789-40-0: IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TSCA (USA), NZIoC (New Zealand), TCSI (Taiwan), KECI (South Korea), PICCS (Philippines), AICS (Australia) and DSL (Canada).</p> <p>Pre-registered in Turkey. NMPA number 107208-02176-7308.</p> <p>Notes: in Japan authorities currently do not require pre-market approval for cosmetic raw materials. This is also true for Brazil, South Korea, Philippines, USA (only for cosmetic raw materials).</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 n° 01-2119489410-39-0001.</p> <p>None of substances listed in the “candidate” list of substances of very high concern (SVHC) are contained in the product in a concentration > 0.1%.</p> <p>Product doesn't contain any PBT/vPvB substances.</p> <p>PO 65 (California law): please check points 5.5, 5.6, 5.7 and 5.9.</p>
<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, mineral and synthetic origin.</p> <p>% vegetable on molecule (100%) = 57%.</p> <p>Fatty acids are mainly from palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia).</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>

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2.3 Informazioni sul processo di produzione (descrizione generale) Information on production process (general description)	Reaction: Amidification of fatty acids with DMAPA and further quaternization with monochloroacetic acid Manufacturing site: Tricerro, Italy
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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 <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.</i>	
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1223/2009.	
5.1 1,4-Diossano * 1,4-Dioxane *	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.2 Ossido di etilene * Ethylene oxide *	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.3 Solventi residui Residual solvents	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 Residual monomers	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5 Ammine Amines	Free amidoamine: 0.5% maximum DMAPA: under detection limits (5 ppm maximum)
5.6 Nitrosammine Nitrosamines	The product doesn't contain any mono, di and tri ethanolamine. Nevertheless, being product obtained starting from DMAPA, it should not be used in cosmetic products in which N-nitroso compounds may be formed. We evaluate nitrosamine content in a random system and till now their value has always been under detection limits (50 ppb).
5.7 Metalli pesanti Heavy metals	Arsenic (As) < 2 ppm, Antimony (Sb) < 5 ppm, Lead (Pb) < 1 ppm, Cadmium (Cd) < 2 ppm, Mercury (Hg) < 2 ppm, Nickel (Ni) < 1 ppm, Cobalt (Co) < 1 ppm, Chromium (Cr) < 2 ppm, Total heavy metals (as Fe) < 10 ppm (Random check, values to be considered as typical)
5.8 Acido monocloroacetico Monochloroacetic acid	5 ppm maximum as sodium monochloroacetate

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5.9 Acido dicloroacetico <i>Dichloroacetic acid</i>	40 ppm maximum as sodium dichloroacetate
5.10 Allergeni <i>Allergens</i>	<p>To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain substances listed under Annex II (Substances or products causing allergies or intolerances) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers and its amendments.</p> <p>To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain allergens listed in Regulation (EU) No. 1223/2009 (Annex III) and its amendments.</p>
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	<p>Sodium chloride: 6% maximum Sodium glycolate: 0.5% maximum Fatty acids: 1% maximum</p> <p>To the best of our present knowledge, assuming the use of raw materials and manufacturing process currently employed, our product does not contain any CMR substances classified as CMR category 1A, 1B and 2 in accordance with Regulation 1272/2008 (EC) and its adaption.</p>
6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	<ul style="list-style-type: none"> - LD50 oral = 2335 mg/kg bw (OECD 401, from literature 1977) - LD50 dermal > 2000 mg/kg (OECD 402, from literature, 1987)
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	<ul style="list-style-type: none"> - Sol. 30% in water (rabbit) = Not irritant (OECD 404, from literature, 1992) - 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 classification)

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6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	<ul style="list-style-type: none"> - 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) - Product as it: irritant, H318 (from literature, OECD 405,1986)
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	<ul style="list-style-type: none"> - Product as it is = Not sensitizing in the maximum-dose test on guinea pigs (OECD 406, from literature,1990) - Test on volunteers at different concentrations = Not sensitizing (CIR: CTFA 1980; CIR: CTFA 1984)
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	<ul style="list-style-type: none"> - Ames test = None mutagenic effect (test effectuated on 10/05/1996, protocol PR. 1-05) - No experimental evidence on genotoxicity in vitro/vivo
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>	<ul style="list-style-type: none"> - 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
7. Ecotossicità <i>Ecology</i>	
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>	<ul style="list-style-type: none"> - 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)

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	- 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 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/TSE <i>BSE/TSE statement</i> Dichiarazione test animali <i>Non-animal testing declaration</i> Alcoli <i>Alcohols</i> Glicol eteri <i>Glycol ethers</i> Metanolo <i>Methanol</i> Ftalati, DINP (diisononyl phtalate) <i>Phtalates, DINP (diisononil ftalato)</i> 2-Fenilfenolo <i>2-Phenylphenol</i> Parabeni <i>Parabens</i>	<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 it is 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 it is 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>

Siliconi
Silicons

Based on information concerning the raw materials, production process and equipment used they 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 (volatile organic compounds)

**Directive 2010/75/EU of 24 November 2010
on industrial emissions (integrated
pollution prevention and control) and
Directive 2004/42/EC**

The VOC Directive 2010/75/EU and Directive 2004/42/EC of the European Community are complex regulations. Only based on the properties of a substance it is not possible to make a decision whether this regulation applies to the substance or not. A statement can be made only in connection with the application and the conditions of use.

As a producer of raw materials we do not have information on actual usage and conditions of use. Therefore, we can only make a statement about the volatility and the boiling point under standard conditions. You will find this information in chapter 9 of our material safety data sheet.

**Swiss VOC ordinance 814.018 (Ordinance
on the Incentive Tax on Volatile Organic
Compounds)**

According to Article 2 of the SR 814.018 VOCs are liable for tax if they are listed on the positive list of substances (Annex 1) or contained in products mentioned in the positive list of products (Annex 2). According to Article 8(a) of the SR 814.018, those mixtures and products are exempted from tax in which the VOC content does not exceed 3 per cent (% by weight).

To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain > 3% of the substances on the positive list of substances (annex 1) of the SR 814.018.

Fitofarmaci
Plant protection products

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

**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 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 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.

POP (inquinanti organici persistenti)
POP

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 1881/2019/EC and any nanotechnology is used to produce it

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<p>Idrocarburi Policiclici Aromatici <i>Plycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p> <p>Certificato Halal <i>Halal certificate</i></p> <p>Convenzione CITES <i>CITES Convention</i></p> <p>Protocollo di Nagoya <i>Nagoya protocol</i></p> <p>Peso molecolare <i>Molecular weight</i></p>	<p>Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons 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. We are EFfCI GMP certified.</p> <p>Yes</p> <p>Intermediates and starting materials are of non-animal origin. Product is made by a process in which only auxiliaries of non-animal origin have been used. Processing equipment is only used for products of non-animal origin. Product is made by a process in which only auxiliaries of non-ethanol origin have been used.</p> <p>Not applicable, cultivated vegetable raw materials</p> <p>The product does not fall into the scope of the Nagoya protocol. The protocol is applicable to raw materials that contain functional units of heredity. As for the primary petro- & oleochemical derivatives that are used in production processes this is not the case.</p> <p>MW = 362</p>
<p>8.1 Data di retest <i>Retest date</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 (aspect and pH). 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>

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8.3 Altro <i>Other</i>	<p>Radiations are not used. Microplastic are not added and not present. Alcohols as Ethyl, Methyl, Isopropyl are not added and not used in any stage on production. SLES and SLS are not contained.</p> <p>Specific Limits concentration for health > 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</p>
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Data / *Date* 16/11/2022

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