ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

Zschimmer & Schwarz Italiana – 13038 – Tricerro (VC) / ITALY

INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 02

1.	**Informazioni generali** ***General information***	
1.1	**Nome commerciale** ***Trade name***	**AMPHOTENSID B4/C**
1.2	**Produttore/Fornitore** (indirizzo, telefono, fax, contatto) ***Manufacturer/Supplier*** *(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) ***Raw material category*** *(e.g. anionic surfactant)*	Amphoteric surfactant
1.4	**Nome chimico** ***Chemical name***	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** ***INCI (CTFA) name*** **Composition**	Cocamidopropyl Betaine: 34.5% min as dry matter 29.0% min as active substance Aqua: to 100%
1.6	**N° EC (EINECS-/ELINCS)** ***EC (EINECS/ELINCS) no.***	931-333-8

1.7	**N° CAS** ***CAS no.***	147170-44-3; 61789-40-0
1.8	**Registrazioni** (es. UE, USA, Giappone) - REACh - Certificazione ***Registration status*** *(e.g. EU, USA, Japan) - REACh - Certification*	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 approvation. The product is according to the China Cosmetic Ingredient list 2015 n° 07555. Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACh registration n° 01-2119489410-39-0001. None of substances listed in the "candidate" list (17th December 2015) of substances of very high concern (SVHC) are contained in the product in a relevant amount. Heavy metals are listed on PO 65 (California law). Product is according to the Chapter of Chemical products and substances (Rev. 08, July 2015).

2.	**Informazioni sulla produzione** **Information on production**	
2.1	**Origine della materia prima** (vegetale, animale, sintetica) **Origin of starting material** (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)?** **Is the starting material derived from**	No

	genetically modified organisms (GMO)?	
2.3	**Informazioni sul processo di produzione** (descrizione generale) **Information on production process** (general description)	Reaction: Amidification of coconut fatty acid with DMAPA and further quaternization with monochloroacetic acid

3.	**Additivi** ***Additives***	
3.1	**Conservanti/Biocidi** ***Preservatives/Biocides***	Not added
3.2	**Antiossidanti** ***Antioxidants***	Not added
3.3	**Solventi** ***Solvents***	Water
3.4	**Sbiancanti** ***Bleaching agents***	Not added
3.5	**Altri** ***Others***	Not added

4.	**Specifiche microbiologiche** ***Microbiological specification***	
4.1	**Conta microbica totale (ufc/g)** ***Total viable count (colony-forming units/g)***	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. ***By-products***

	*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.*	
5.1	**1,4-Diossano *** ***1,4-Dioxane **	Not expected
5.2	**Ossido di etilene *** ***Ethylene oxide **	Not expected
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***	Not expected
5.5	**Ammine** ***Amines***	Free amidoamine: 0.3% maximum DMAPA: under detection limits (5 ppm maximum)
5.6	**Nitrosammine** ***Nitrosamines***	Not expected
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, Chromium (Cr) < 2 ppm, Total heavy metals (as Fe) < 10 ppm
5.8	**Acido monocloroacetico** **Monochloroacetic acid**	50 ppm maximum as sodium monochloroacetate
5.9	**Acido dicloroacetico** ***Dichloroacetic acid***	40 ppm maximum as sodium dichloroacetate
5.10	**Allergeni** **Allergens**	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.
5.11 Altri (e.g. CMR) ***Others (e.g. CMR)***	Sodium chloride: 6% maximum Sodium glycolate: 0.5% maximum Fatty acids: 1% 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.

6. Tossicologia ***Toxicology***	
6.1 Informazioni sulla tossicità acuta ***Information on acute toxicity***	LD50 > 6.6 g/kg (from literature, protocol data 345)
6.2 Informazioni sull'irritazione cutanea ***Information on skin irritation***	- 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)
6.3 Informazioni sull'irritazione oculare ***Information on irritation of the mucous membrane***	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)
6.4 Informazioni sulla sensibilizzazione ***Information on sensitisation potential***	Test on volunteers at different concentrations = Not sensitizing (CIR: CTFA 1980; CIR: CTFA 1984)
6.5 Informazioni sulla genotossicità ***Information on gene toxicity***	Ames test = None mutagenic effects (test effectuated on 10/05/1996, protocol PR. 1-05)
6.6 Informazioni sull'assorbimento percutaneo ***Information on percutaneous permeation***	Not determined

6.7	**Altri (e.g. NOAEL)** ***Others (e.g. NOAEL)***	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** ***Ecology***	
7.1	**Degradabilità/Eliminazione** ***Degradability/Elimination***	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** ***Acute aquatic toxicity***	- 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 subspicauts) = 1.84, 72h (IUCLID 2000) - EC50 on Algae (Scenedesmus subspicauts) = Growth rate: 0.55, NOEC: 0.09, 96h (IUCLID 200) - EC50 on Algae (Scenedesmus subspicauts) = 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** ***Others***	/

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/TSE free.
	Dichiarazione test animali ***Non-animal testing declaration***	ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product.
	Alcoli ***Alcohols***	Not added and not expected
	Glicol eteri ***Glycol ethers***	Not added and not expected
	Ftalati ***Phtalates***	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.
	Parabeni ***Parabens***	Not added and not expected
	Siliconi ***Silicons***	Not added and not expected
	Glutine ***Gluten***	Not added and not expected
	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) du 12 novembre 1997".
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***	Not added and not expected
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 aflotoxin/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
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***	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 ***Plycyclic 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) Benzofluoranthene[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)
	Grado cosmetico ***Cosmetic grade***	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).
	Certificato Kosher ***Kosher certificate***	Yes
8.1	**Data di scadenza** ***Shelf life***	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
8.2	**Stoccaggio** ***Storage recommendation***	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.

Data / *Date* 29.01.2018

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.*