ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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

INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 04

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-coco acyl derivs., hydroxides, inner salts
1.5	**Nome INCI (CTFA)** **Composizione** ***INCI (CTFA) name*** **Composition**	Cocamidopropyl Betaine: 34.5% min as dry matter 28% - 31% 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 ***Registration status*** *(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 approvation. The product is according to the China Regulatory Standard Version 2007. REACh registration n° 01-2119489410-39-0001 SVHC: absent

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 mainly from coconut oil from Cocos Nucifera (South East Asia and Philippines). 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 genetically modified organisms (GMO)?**	No
2.3	**Informazioni sul processo di produzione** (descrizione generale) **Information on production process** (general description)	Reaction: Amidification and further quaternization

3.	**Additivi** ***Additives***	
3.1	**Conservanti** ***Preservatives***	Not added

3.2	**Antiossidanti** ***Antioxidants***	Not added
3.3	**Solventi** ***Solvents***	Not added
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 Annex II della Direttiva 76/768/CEE (incl. CMR cat. I - III sostanze contrassegnate con *) deve essere dimostrata come presenza tecnicamente inevitabile lavorando in GMP e deve essere conforme all'Articolo 2 della Direttiva 76/768/CEE. ***By-products*** *The presence of traces of the substances listed in Annex II of Directive 76/768/EEC (incl. cmr cat. I – III substances marked with *) shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2 of Directive 76/768/EEC.*	
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***	Not expected

5.4	**Monomeri residui** ***Residual monomers***	Not expected
5.5	**Ammine** ***Amines***	Free amidoamine: 0.5% 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**	5 ppm maximum as sodium monochloroacetate
5.9	**Acido dicloroacetico** ***Dichloroacetic acid***	40 ppm maximum as sodium dichloroacetate
5.10	**Allergeni** **Allergens according to the 7th Amendment to the Cosmetics Directive (ppm)**	Absent
5.11	**Altri (e.g. CMR)** ***Others (e.g. CMR)***	Sodium chloride: 6% maximum Sodium glycolate: 0.5% maximum Fatty acids: 1% maximum CMR ingredients: absent

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 = 500 mg/kg bw based on forestomach finding; 1000 mg/kg bw respect to systematic toxic effect; 76.5 mg/kg x bw/d (90 die, subchronic, rats, oral)

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° 61)
7.2	**Tossicità acquatica acuta** ***Acute aquatic toxicity***	- 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) - EC50 on Daphnia magna = 6.5, NOEC: 1.6,

	48h (IUCLID 2000) - EC50 on Daphnia magna = 21.7, 48h (IUCLID 2000) - LC50 on Zebra fish (Brachydanio rerio) = 2.0, NOEC: 1.7, 96h (IUCLID 2000)
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.
Glicol eteri ***Glycol ethers***	Absent
Ftalati ***Phtalates***	Absent
Glutine ***Gluten***	Absent
Formaldeide ***Formaldehyde (Formol)***	Absent
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***	The product doesn't contain any pesticides or pollutant substances (under detection limits)

	Mercaptani ***Mercaptanes***	The product doesn't contain mercaptanes
	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***	Absent
	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
	Grado cosmetico ***Cosmetic grade***	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.
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

Data / *Date* 28/06/13

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.*