



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 07

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	AMPHOTENSID AB
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>	Betaines, C12-C14 (even numbered)- alkyldimethyl
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Coco-Betaine: 28% - 31% Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	266-368-1; 270-329-4; 616-483-1 List n° 931-700-2
1.7 N° CAS <i>CAS no.</i>	66455-29-6; 68424-94-2; 77640-81-4

<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>TSCA (USA), DSL (Canada), EINECS (Europe), ENCS (Japan), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and ECL (Korea).</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° 07527.</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: 01-2119529251-48-0012</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> <p>ISO 16128: derived natural ingredient</p> <p>% natural origin: 58.9% on the molecule at 100%, that means 17.4% on solution as it is</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>Alkyldimethylamine comes from coconut oil from Cocos Nucifera (South East Asia and Philippines) or mainly palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO supplier). Acid so obtained are transformed in fatty amines.</p> <p>We are RSPO member.</p> <p>Sodium monochloroacetate is synthetic.</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</i> (general description)</p>	<p>Reaction of alkyldimethylamine with sodium monochloroacetate in basic environment.</p>

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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>	None

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>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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 amine: 0.4% maximum
5.6	Nitrosammine <i>Nitrosamines</i>	The product doesn't contain any mono, di and tri ethanolamine. Nevertheless, being product obtained starting from amines, 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 <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, Iron (Fe) < 10 ppm, Total heavy metals (as Fe) < 10 ppm
5.8	Acido monocloroacetico <i>Monochloroacetic acid</i>	100 ppm maximum
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	100 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.
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Sodium chloride: 6.0% - 8.5% Sodium glycolate: 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 <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	LD50 > 2000 mg/kg (literature data, OECD 401)
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	- Product as it is (30% a.m.) = Irritant (literature data, OECD 404) - 16% solution = Not irritant (literature data, OECD 404)
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	> 31% concentration = Corrosive > 16% - ≤ 31% concentration = Eye damage 1 ≥ 1% - ≤ 16% concentration = Eye Irritant 2
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Not sensitizing (from all available literature data)
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	None mutagenic effects (literature data, OECD 471)
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 (systemic) = 50 mg/kg bw/day NOEL (reproduction) = 150 mg/kg bw/day

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Readily biodegradable according to CE 648/2004
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on fish = 4.44 mg/l 96h - EC50 on Daphnia = 7.76 mg/l 48h - EC50 on Algae = 9.45 mg/l 72h
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 <i>BSE statement</i>	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 <i>Non-animal testing declaration</i>	ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.
Alcoli <i>Alcohols</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
Glicol eteri <i>Glycol ethers</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
Ftalati, DINP (diisononyl phtalate) <i>Phtalates, DINP (diisononil ftalato)</i>	Based on information concerning the raw materials, production process and equipment used phtalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.

Diossina
Dioxin

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

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 they are 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 compounds

The product doesn't contain any of the substances that are classified as VOC according to "Ordonnance sur taxe d'incitation sur les composés 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

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.

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)

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).

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

Certificato Kosher <i>Kosher certificate</i> Convenzione CITES <i>CITES Convention</i>	Yes Not applicable, cultivated vegetable raw materials
8.1 Data di scadenza <i>Shelf life</i>	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.
8.2 Stoccaggio <i>Storage recommendation</i>	Protect from frost. At temperature lower than 5°C 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. Do not store over 40°C. It can have corrosive effects during storage in stainless steel tanks due to NaCl. Homogenize before using.

Data / *Date* 01.03.2018

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.