



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 08

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	AMPHOTENSID GB 2009 CONC
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>	Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-,2-(C7-C17 odd-numbered, C17- unsatd. alkyl) derivs. and sodium hydroxide and chloroacetic acid
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Disodium Cocoamphodiacetate: 46% - 53% as dry matter Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	931-291-0 (previous 272-043-5)
1.7 N° CAS <i>CAS no.</i>	68650-39-5

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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>TSCA (USA), DSL (Canada), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe), AICS (Australia) 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° 07584.</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 status: pre-registered.</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 (point 5.7) are listed on PO 65 (California law).</p> <p>Product is ECOCERT and COSMOS certified.</p> <p>Product is according to the Chapter of Chemical products and substances (Rev. 08, July 2015).</p> <p>ISS code: AUT-10</p> <p>Toxicological properties are evaluated on the full surfactant (UVCB).</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 (plant, animal, synthetic)</i></p>	<p>Vegetable (44%), mineral and synthetic origin.</p> <p>Fatty acids are from vegetable origin. They come from coconut oil from Cocos Nucifera (South East Asia and Philippines) or mainly palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</p> <p>Aminoethylethanolamine 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>

<p>2.3 Informazioni sul processo di produzione (descrizione generale)</p> <p>Information on production process (general description)</p>	$ \begin{array}{c} \text{O} \\ \\ \text{RCOH} + \text{HOCH}_2\text{CH}_2\text{-NH-CH}_2\text{CH}_2\text{NH}_2 \xrightarrow[\text{ciclyzation}]{\Delta} \\ \text{Fatty acids} \quad \text{AEEA} \\ \xrightarrow[\text{NaOH, 2ClCH}_2\text{COOH}]{\Delta} \\ \begin{array}{c} \text{O} \qquad \qquad \text{CH}_2\text{COONa} \\ \qquad \qquad \\ \text{RC - NHCH}_2\text{CH}_2\text{N - CH}_2\text{CH}_2\text{OCH}_2\text{COONa} + \text{NaCl} \end{array} \end{array} $
<p>3. Additivi</p> <p>Additives</p>	
<p>3.1 Conservanti/Biocidi</p> <p>Preservatives/Biocides</p>	Not added and not expected
<p>3.2 Antiossidanti</p> <p>Antioxidants</p>	Not added and not expected
<p>3.3 Solventi</p> <p>Solvents</p>	Water
<p>3.4 Sbiancanti</p> <p>Bleaching agents</p>	Not added and not expected
<p>3.5 Altri</p> <p>Others</p>	Not added and not expected
<p>4. Specifiche microbiologiche</p> <p>Microbiological specification</p>	
<p>4.1 Conta microbica totale (ufc/g)</p> <p>Total viable count (colony-forming units/g)</p>	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*

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.
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>	Aminoethanolamine: 10 ppm maximum Amidoamine: 0.4% maximum
5.6	Nitrosammine <i>Nitrosamines</i>	Not expected, but because amino groups are present, please avoid to use it with substances able to originate nitrosoamines, that means nitrosating agents (e.g. 2-Bromo-2-Nitropropan-1,3-Diol, NO ₃ ⁻ , NO ₂ ⁻) and use proper packaging. In the raw materials (aminoethylethanolamine) and in the product itself, N-Nitrosoamine are below 50 ppb. They are not checked for every batch but in a random way and till now they have always been under detection limits (20 ppb). The product is according to European Cosmetic Legislation. To be preserved in a nitrite-free container.

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5.7	Metalli pesanti <i>Heavy metals</i>	Lead (Pb) < 0.25 ppm, Arsenic (As) < 0.25 ppm, Cadmium (Cd) < 0.25 ppm, Chromium (Cr) < 0.50 ppm, Nickel (Ni) < 0.25 ppm, Mercury (Hg) < 0.25 ppm
5.8	Acido monoclороacetico <i>Monochloroacetic acid</i>	600 ppm maximum as sodium monochloroacetate
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	30 ppm maximum as sodium dichloroacetate
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: 9% - 12% Sodium glycolate: 7% maximum Sodium diglycolate: 1.5% 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: aminoethylethanolamine (CMR1B) as impurity technically unavoidable even working in GMP (10 ppm maximum)
6.	Tossicologia <i>Toxicology</i>	In any case toxicological properties are evaluated on the full composition (UVCB substance)
6.1	Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	LD50 (rats) > 5000 mg/kg (unpublished reports)

<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<ul style="list-style-type: none"> - From 10% to 12% of active matter on health skin and on skin with lesions = From non irritating to strict irritating (J. of American College of Toxicology, Vol. 9, n° 2, 1990) - 1% active matter, SIDI test = Non irritating (J. of American College of Toxicology, Vol. 9, n° 2, 1990) - 3% in water on health skin and on skin with lesions = Non irritating (Our test n° 1-3-171/3-75 (1975))
<p>6.3 Informazioni sull'irritazione oculare</p> <p><i>Information on irritation of the mucous membrane</i></p>	<ul style="list-style-type: none"> - Draize test, from 10% to 12% of active matter without rinsing = From light to strict irritant (J. of American College of Toxicology, Vol. 9, n° 2, 1990) - Draize test, from 10% to 12% of active matter with rinsing = From non irritating to slight irritant (J. of American College of Toxicology, Vol. 9, n° 2, 1990)
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<ul style="list-style-type: none"> - RIPT semiocclusive test, 0.4% in active matter = Not sensitizing (J. of American College of Toxicology, Vol. 9, n° 2, 1990) - RIPT occlusive test, 0.7% in active matter = Not sensitizing (J. of American College of Toxicology, Vol. 9, n° 2, 1990)
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<p>Ames test = None mutagenic effects with and without metabolic activation (J. of American College of Toxicology, Vol. 9, n° 2, 1990)</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>General Population Oral DNEL = 0.39 mg/kg bw/day (repeated dose toxicity), AF = 240 (for NOAEL);</p> <p>General Population Inhalation DNEL = 4.06 mg/m³ (repeated dose toxicity), AF = 60 (for NOAEC);</p> <p>General Population Dermal DNEL = 3.85 mg/kg bw/day (repeated dose toxicity), AF = 240 (for NOAEL)</p> <p>Phototoxicity: The product doesn't induce photoallergic reactions (J. of American College of Toxicology, Vol. 9, n° 2, 1990)</p>

7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic biodegradability: rapidly biodegradable 84% after 28 d (OECD 301A), 72% after 27 d (OECD 301E), 72% after 28 d (OECD 301F) Anaerobic biodegradability: biodegradable 100% after 28 d (OECD 311)
7.2	Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- CL50 (fish <i>Oncorhynchus mykiss</i>) = 5.3 mg/l (96h) - CE50 (<i>Daphnia magna</i>) = 8.9 mg/l (48h) - CE50 (Algae <i>Pseudokirchneriella subcapitata</i>) = 16.9 mg/l (72h)
7.3	Altri <i>Others</i>	NOEC: 66 mg/l

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> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri, glicoli, alcoli (non dichiarati nei paragrafi precedenti) <i>Glycol ethers, glycols, alcohols (not declared in previous paragraphs)</i> Ftalati, DINP (diisononyl phtalate) <i>Phtalates, DINP (diisononil ftalato)</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 free. ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose. Based on information concerning the raw materials, production process and equipment used they are not likely to be present. 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

Parabeni
Parabens

present.

Based on information concerning the raw materials, production process and equipment used they are 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 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 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

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, steroidi e altri ingredienti (naturali o chimici) dannosi per le funzioni del corpo umano

Hormones, antibiotics, steroids and other ingredients (natural or chemical) dangerous for the body functionality

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

Pork free

Pork free

Based on information concerning the raw materials, production process and equipment used it is 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 $\leq 1 \mu\text{g/kg}$

Dibenz[a,h]anthracene $\leq 1 \mu\text{g/kg}$

Cyclopenta[cd]pyrene)

Benzofluoranthene[b+j+k])

Indeno[1,2,3-cd]pyrene) $\Sigma \leq 5 \mu\text{g/kg}$

Anthanthrene)

Benzo[b]naphtho[2,1-d]thiophene)

Benz[a]anthracene)

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<p>Clorobenzeni/Clorofenoli <i>Chlorobenzenes/Chlorophenols</i></p> <p>Ritardanti di fiamma <i>Flame retardants</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p> <p>Convenzione CITES <i>CITES Convention</i></p>	<p>Chrysene + Triphenylene) $\Sigma \leq 20 \mu\text{g/kg}$ Benzo[ghi]perylene)</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>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>Not applicable, cultivated vegetable raw materials</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.</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>Store at room temperature (15°C-25°C). Protect from frost. At low temperature and on prolonged storage turbidity and stratification phenomena can appear. Indirect warming with stirring will restore the product to its former appearance. This doesn't affect the quality of the product.</p> <p>The viscosity of the product can increase if the storage is higher than 20°C for a long time. Due to its high salt content it can have a corrosive effect during storage in stainless steel tanks.</p>

Data / *Date* 06/06/17

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.