ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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

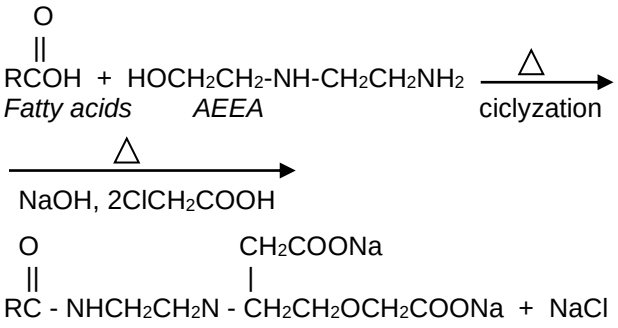
INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 15

1.	**Informazioni generali** ***General information***	
1.1	**Nome commerciale** ***Trade name***	**AMPHOTENSID GB 2009 CONC**
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***	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** ***INCI (CTFA) name*** **Composition**	Disodium Cocoamphodiacetate: average value 39% as active matter, 46% - 53% as dry matter Sodium chloride (facultative in INCI): average value 11% Aqua: to 100%
1.6	**N° EC (EINECS-/ELINCS)** ***EC (EINECS/ELINCS) no.***	List n° 931-291-0 Previous EC n° 272-043-5

1.7	**N° CAS** ***CAS no.***	68650-39-5
1.8	**Registrazioni** (es. UE, USA, Giappone) - REACh - Certificazione ***Registration status*** *(e.g. EU, USA, Japan) - REACh - Certification*	IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TCSI (Taiwan), KECI (South Korea), TSCA (USA), NZIoC (New Zealand), PICCS (Philippines), AICS (Australia) and DSL (Canada). Pre-registered in Turkey. NMPA number 103832-02176-3812. 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). Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACh registration n° 01-2119487973-19-XXXX 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%. PO 65 (California law): please check points 5.6, 5.7 and 5.9. Product is according to the Chapter of Chemical products and substances (Rev. 08, July 2015). Toxicological properties are evaluated on the full surfactant (UVCB).

2.	**Informazioni sulla produzione** **Information on production**	
2.1	**Origine della materia prima** (vegetale, animale, sintetica) **Origin of starting material** (plant, animal, synthetic)	Vegetable (44%), mineral (10%) and synthetic origin (46%). Fatty acids are from vegetable origin. They come mainly from palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia). Aminoethylethanolamine and monochloroacetic acid are synthetic (Europe). NaOH is mineral (Europe).
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)	

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

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*	
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***	Aminoethanolamine: 10 ppm maximum Amidoamine: 0.4% maximum
5.6	**Nitrosammine** ***Nitrosamines***	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.

5.7 **Metalli pesanti** ***Heavy metals***	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 (Random check, values to be considered as typical)
5.8 **Acido monocloroacetico** **Monochloroacetic acid**	600 ppm maximum as sodium monochloroacetate
5.9 **Acido dicloroacetico** ***Dichloroacetic acid***	30 ppm maximum as sodium dichloroacetate
5.10 **Allergeni** **Allergens**	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. 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.
5.11 **Altri (e.g. CMR)** ***Others (e.g. CMR)***	Sodium chloride: 9% - 12% Sodium glycolate: 1.5% maximum 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, with the exception of very small amounts of the following technically unavoidable substances even working in GMP: - aminoethylethanolamine; CAS n° 111-41-1; EC n° 203-867-5 (10 ppm max); CMR1B

6.	**Tossicologia** ***Toxicology***	In any case toxicological properties are evaluated on the full composition (UVCB substance)
6.1	**Informazioni sulla tossicità acuta** ***Information on acute toxicity***	LD50 (rats) > 5000 mg/kg (unpublished reports)
6.2	**Informazioni sull'irritazione cutanea** ***Information on skin irritation***	- 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))
6.3	**Informazioni sull'irritazione oculare** ***Information on irritation of the mucous membrane***	- 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)
6.4	**Informazioni sulla sensibilizzazione** ***Information on sensitisation potential***	- 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)
6.5	**Informazioni sulla genotossicità** ***Information on gene toxicity***	Ames test = None mutagenic effects with and without metabolic activation (J. of American College of Toxicology, Vol. 9, n° 2, 1990)
6.6	**Informazioni sull'assorbimento percutaneo** ***Information on percutaneous permeation***	Not determined
6.7	**Altri (e.g. NOAEL)** ***Others (e.g. NOAEL)***	General Population Oral DNEL = 0.39 mg/kg bw/day (repeated dose toxicity), AF = 240 (for NOAEL); General Population Inhalation DNEL = 4.06 mg/m^3 (repeated dose toxicity), AF = 60 (for NOAEC);

	General Population Dermal DNEL = 3.85 mg/kg bw/day (repeated dose toxicity), AF = 240 (for NOAEL) Photoxicity: The product doesn't induce photoallergic reactions (J. of American College of Toxicology, Vol. 9, n° 2, 1990)

7.	**Ecotossicità** ***Ecology***	
7.1	**Degradabilità/Eliminazione** ***Degradability/Elimination***	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** ***Acute aquatic toxicity***	- CL50 (fish Oncorhynchus mykiss) = 5.3 mg/l (96h) - CE50 (Daphnia magna) = 8.9 mg/l (48h) - CE50 (Algae Pseudokirchneriella subcapitata) = 16.9 mg/l (72h)
7.3	**Altri** ***Others***	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.) ***Additional information*** *(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)*	
	Dichiarazione BSE/TSE ***BSE/TSE 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 for cosmetic purpose.

Glicol eteri, glicoli, alcoli (non dichiarati nei paragrafi precedenti) ***Glycol ethers, glycols, alcohols (not declared in previous paragraphs)***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
Ftalati, DINP (diisononyl phtalate) ***Phtalates, DINP (diisononil ftalato)***	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***	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 (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 they 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, 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 1881/2019/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 not likely to be present.
Clorobenzeni/Clorofenoli ***Chlorobenzenes/Chlorophenols***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
Ritardanti di fiamma ***Flame retardants***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
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.
Certificato Kosher ***Kosher certificate***	Yes
Certificato Halal ***Halal certificate***	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.
Convenzione CITES ***CITES Convention***	Not applicable, cultivated vegetable raw materials

Protocollo di Nagoya ***Nagoya protocol***	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.
8.1 Data di Retest ***Retest date***	The product, if well preserved and in its original containers, maintains its appearance and characteristics for at least two years from delivery date. After this time, product can be used but it must be rechecked (pH and aspect).
8.2 Stoccaggio ***Storage recommendation***	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. 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. Always homogenize before using.

Data / *Date* 29/06/2023