ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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

INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 03

1.	**Informazioni generali** ***General information***	
1.1	**Nome commerciale** ***Trade name***	**AMPHOTENSID 9M**
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)*	Blend of amphoteric and anionic surfactants in water
1.4	**Nome chimico** ***Chemical name***	Water (and) 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 (and) Sodium Laureth Sulfate (and) Sodium Chloride
1.5	**Nome INCI (CTFA)** **Composizione** ***INCI (CTFA) name*** **Composition**	Aqua: to 100% Disodium Cocoamphodiacetate: 10% - 25% Sodium Laureth Sulfate: 10% - 25% Sodium Chloride: 7% max
1.6	**N° EC (EINECS-/ELINCS)** ***EC (EINECS/ELINCS) no.***	231-791-2 (and) 931-291-0 (previous 272-043-5) (and) absent because polymer (and) 231-598-3

1.7	**N° CAS** ***CAS no.***	7732-18-5 (and) 68650-39-5 (and) 9004-82-4 (and) 7647-14-5
1.8	**Registrazioni** (es. UE, USA, Giappone) - REACh ***Registration status*** *(e.g. EU, USA, Japan) - REACh*	TSCA (USA), DSL (Canada), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe), AICS (Australia) and ECL (Korea) for Disodium Cocoamphodiacetate. TSCA (USA), ENCS (Europe), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and DSL (Canada) for Sodium Laureth Sulfate. 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 products are according to the China Cosmetic Ingredient list 2015 (n° 07584 for Disodium Cocoamphodiacetate and n° 08336 for Sodium Laureth Sulfate). REACh status: pre-registered for Disodium Cocoamphodiacetate and absent because polymer for Sodium Laureth Sulfate. 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. Dioxane and heavy metals are listed on PO 65 (California law).

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. For Disodium Cocoamphodiacetate, coconut oil comes from Cocos Nucifera (South East Asia and Philippines) or palm/palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers). Aminoethylethanolamine and monochloroacetic acid are synthetic. NaOH is mineral. For Sodium Laureth Sulfate, fatty alcohol is from vegetable origin, then it is ethoxylated. Origin from fatty alcohol: coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm/palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers). Sulfur is synthetic and NaOH is

		mineral. We are RSPO member.
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)	Simple mixing and adjusting pH and dry matter of the following ingredients: Disodium Cocoamphodiacetate, Sodium Laureth Sulfate, water and sodium chloride

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***	Not added and not expected
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 in good manufacturing practice and that it conforms with Article 17 of Regulation No. 1223/2009.*	
5.1	**1,4-Diossano *** ***1,4-Dioxane **	50 ppm maximum
5.2	**Ossido di etilene *** ***Ethylene oxide **	Not detectable (lower than 1 ppm)
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: under detection limits (5 ppm maximum) Amidoamine: 0.2% 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.
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**	250 ppm maximum as sodium monochloroacetate

5.9	**Acido dicloroacetico** ***Dichloroacetic acid***	20 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 sulfate: 1% maximum Laureth-3: 1% maximum Sodium diglycolate: 1% maximum Sodium chloride: 7% 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: dioxane (CMR2) as impurity technically unavoidable even working in GMP (50 ppm maximum)

6.	**Tossicologia** ***Toxicology***	
6.1	**Informazioni sulla tossicità acuta** ***Information on acute toxicity***	1) Disodium Cocoamphodiacetate LD50 (rats) > 5000 mg/kg (unpublished reports) 2) Sodium Laureth Sulfate - LD50 (on rats) > 2000 mg/kg bw (OECD 402) - LD50 > 540 mg/kg bw (active ingredient) (OECD 401)
6.2	**Informazioni sull'irritazione cutanea** ***Information on skin irritation***	1) Disodium Cocoamphodiacetate - 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)) 2) Sodium Laureth Sulfate - Product as it is = Irritant (OECD 404) - 30%-60% on rabbit = Stark irritant (Avon, CTFA, 1972) - 25% on rabbit = Stark irritant (CPTC 1977, FDRL 1976) - 6%-10% on rabbit = Slightly irritant (Avon, 1970, IBTL 1975) - 5%-5.6% on rabbit = None irritation (Leberco Labs, 1977) - 18% on man = Slighly irritant (Avon, 1972) - 0.5% on man = Nearly none irritation (Hill Top Research, 1973)
6.3 Informazioni sull'irritazione oculare ***Information on irritation of the mucous membrane***	1) Disodium Cocoamphodiacetate - 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) 2) Sodium Laureth Sulfate - Product as it is = Irritant (OECD 405) - Draize test = From none to stark irritation (J. of the American College of Toxicology, 2,5,15, 1983)
6.4 Informazioni sulla sensibilizzazione ***Information on sensitisation potential***	1) Disodium Cocoamphodiacetate - 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) 2) Sodium Laureth Sulfate - Product as it is = Not sensitizing (OECD 406) - 0.07%-0.19% on Guinea pigs = The product hasn't any sensitization danger (Avon, 1977 - 1978) - 14.3% sol. on man = The product hasn't any sensitization danger (CTFA, 1980)
6.5 Informazioni sulla genotossicità ***Information on gene toxicity***	1) Disodium Cocoamphodiacetate Ames test = None mutagenic effects with and without metabolic activation (J. of American College of Toxicology, Vol. 9, n° 2, 1990) 2) Sodium Laureth Sulfate - Ames test = None mutagenic effect (our test

	n° 96-4086.1) - Negative (OECD 475)
6.6 Informazioni sull'assorbimento percutaneo ***Information on percutaneous permeation***	1) Disodium Cocoamphodiacetate Not determined 2) Sodium Laureth Sulfate 0.2%-2% sol. on rats < 1% (Black, J. Soc. Cosmet. Chem. 30, 157-165, 1979)
6.7 Altri (e.g. NOAEL) ***Others (e.g. NOAEL)***	1) Disodium Cocoamphodiacetate NOAL consumer systemic effect (oral): 0.39 mg/kg DNEL consumer systematic effect (dermic): 3.85 mg/kg (long term) 2) Sodium Laureth Sulfate NOAEL (oral, human) = 300 mg/kg bw/day DNEL (dermal route) = 1650 mg/kg bw/day (repeated dose toxicity), AF = 20

7. Ecotossicità ***Ecology***	
7.1 Degradabilità/Eliminazione ***Degradability/Elimination***	1) Disodium Cocoamphodiacetate 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) 2) Sodium Laureth Sulfate Aerobic: readily biodegradable (our test SAM2467-9i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List)
7.2 Tossicità acquatica acuta ***Acute aquatic toxicity***	1) Disodium Cocoamphodiacetate - 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) 2) Sodium Laureth Sulfate - LC50 on Fish = 1 - 10 mg/l, 96h (literature data) - EC50 on Daphnia = 7.2 mg/l, 48h (literature data) - EC50 on Algae = 7.5 mg/l, 72h (literature data) - EC10 on Pseudomonas putida = 100 mg/l (literature data)

	- NOEC chronic on Fish = 1 mg/l, 45d (literature data) - NOEC chronic on Daphnia = 0.18 mg/l, 21d (OECD 211, literature data)
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 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 ***Glycol ethers***	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.
Glutine ***Gluten***	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
Formaldeide ***Formaldehyde (Formol)***	Not added, but in general one has to accept that formaldehyde can be present in lower concentrations in ethoxylated products. Our random tests show values lower than 5 ppm. On the other hand, it is known from the literature that formaldehyde may be formed even out of high purity polyethylene oxide surfactants, if they are stored at temperatures

	above 8°C and if oxygen out of the air can penetrate into the material. (M. Bergh, K. Magnusson, J. Lars G. Nilsson, A. T. Karlberg, Contact Dermatitis, 1998, 39, 14-20 and M. Donbrow in: Nonionic Surfactants, Physical Chemistry, New York Surf. Sci. Series Vol. 23/1987, p. 1011-1073).
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 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***	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.
3-Benzilidene Canfora ***3-Benzylidene Camphor***	Based on information concerning the raw materials, production process and equipment used it is 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 ***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
Convenzione CITES ***CITES Convention***	Not applicable, cultivated vegetable raw materials

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. When opened, product lasts 6 months. After this date, it can be used but it must be rechecked. Depending on the temperature, the pH value may decrease during storage. However the product quality is not negatively influenced above a pH value of 4.0.
8.2 Stoccaggio ***Storage recommendation***	Protect from frost. At temperature lower than 15°C it can become turbid or viscous or it can separate. 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. Always homogenize before using.

Data / *Date* 13/02/17

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.*