



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 03

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	AMPHOTENSID DMOX
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 de lla material prima (es. tensioattivo anionico) <i>Raw material category</i> (e.g. anionic surfactant)	Amphoteric surfactant
1.4 Nome chimico <i>Chemical name</i>	Amines, C12-16-alkyldimethyl, N-oxides
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Lauramine Oxide: 29.0% - 31.0% Aqua: to 100%
1.6 N° EC (EINECS/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	287-011-6; 216-700-6; 931-292-6
1.7 N° CAS <i>CAS no.</i>	85408-49-7; 1643-20-5; 308062-28-4

<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>EINECS (Europe), PICCS (Philippines) and ASIA-PAC (Asia-Pacific).</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° 08358.</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: pre-registered (registration in 2018).</p> <p>None of substances listed in the “candidate” list (07 July 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>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 and synthetic origin.</p> <p>Fatty amines derive from fatty acids that 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>H₂O₂ 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: Treatment of fatty amines with H₂O₂</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>	Not added and not expected
4. Specifiche microbiologiche Microbiological specification	
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 information concerning the raw materials, production process and equipment used they are not likely to be present.
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: 0.5% maximum
5.6	Nitrosammine <i>Nitrosamines</i>	Not expected, but being product obtained from an amine, 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 <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, Total heavy metals (as Fe) < 10 ppm
5.8	Acido monoclوروacetico <i>Monochloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
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.

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Hydrogen peroxide: 0.2% 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>	<ul style="list-style-type: none"> - LD50 (oral) = 1680 mg/kg (literature data) - LD50 (dermal) > 2000 mg/kg (literature data) - Non toxic (Final report on the safety Lauramine Oxide and Stearamine Oxide - Journal of the American College of Toxicology, vol. 13, Number 3, 1994, Seiten 231 bis 245)
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	Product as it is = Irritating (CESIO data)
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	<ul style="list-style-type: none"> - Product as it is = Irritating (CESIO data) - 0.3% active = From no irritating to slight irritating (Final report on the safety Lauramine Oxide and Stearamine Oxide - Journal of the American College of Toxicology, vol. 13, Number 3, 1994, Seiten 231 bis 245)
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Occlusive patch on men with different concentrations = No effect (Final report on the safety Lauramine Oxide and Stearamine Oxide - Journal of the American College of Toxicology, vol. 13, Number 3, 1994, Seiten 231 bis 245)
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	Ames test = None mutagenic effects (our test n° 96/4092.1)
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 = 80 mg/kg bw/day Carcinogenicity (in vitro assay) = No effect (Final report on the safety Lauramine Oxide)

	<p>and Stearamine Oxide - Journal of the American College of Toxicology, vol. 13, Number 3, 1994, Seiten 231 bis 245)</p> <p>CIR recommended a use of Lauramine Oxide limited to 3.7% max for leave-on products.</p>
--	--

7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Readily biodegradable (literature data, listed in Ecolabel DID list n° 2203 for cosmetics and n° 62 for detergency)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fish > 2.67 mg/l/96h - EC50 on Daphnia sp. Acute Immobilisation = 3.1 mg/l/48h (OECD 202) - EC50 on Algae = 0.19 mg/l/72h (Growth Inhibition test, OECD 201) - NOEC chronic on Fish = 0.42 mg/l - NOEC chronic on Daphnia = 0.7 mg/l - NOEC chronic on Algae = 0.067 mg/l
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.)	
<p>Dichiarazione BSE <i>BSE statement</i></p> <p>Dichiarazione test animali <i>Non-animal testing declaration</i></p>	<p>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.</p> <p>ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p>

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)
Phthalates, 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)

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 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)
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)

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<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>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).</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. After this time, product can be used but it must be rechecked.</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>Store at room temperature (20°C - 30°C). Do not store at temperature higher than 40°C. At temperatures lower than 20°C physical separation is possible, particularly after prolonged periods. It is recommended to homogenize the product before use. Please take all the precautions to minimize the potential formation of nitrosamines, nitrites and other nitrosating agents.</p>

Data / *Date* 04/09/17

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.*