



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 00

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| 1. Informazioni generali <i>General information</i> | |
| 1.1 Nome commerciale <i>Trade name</i> | AMPHOTENSID DMOX/24 |
| 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> | Amides, C12-16-alkyldimethyl, N-oxides |
| 1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i> | Lauramine Oxide: 23.5% - 24.5% Aqua: to 100% |
| 1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i> | 287-011-6; 216-700-6 |
| 1.7 N° CAS <i>CAS no.</i> | 85408-49-7; 1643-20-5 |

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| 1.8 Registrazioni (es. UE, USA, Giappone) - REACH <i>Registration status</i> (e.g. EU, USA, Japan) - REACH | EINECS (Europe), PICCS (Philippines) and ASIA-PAC (Asia-Pacific). 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. The product is not listed into the China Regulatory Standard Version 2007. REACH registration: pre-registered (registration 31.05.2018). SVHC: absent |
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| 2. Informazioni sulla produzione Information on production | |
| 2.1 Origine della materia prima (vegetale, animale, sintetica) <i>Origin of starting material</i> (plant, animal, synthetic) | Vegetable and synthetic origin. Fatty amines derive from fatty acids that come from coconut or palm kernel oil (South East Asia and Philippines) (RSPO supplier). H ₂ O ₂ is synthetic. |
| 2.2 La materia prima deriva da organismi geneticamente modificati (OGM)? <i>Is the starting material derived from genetically modified organisms (GMO)?</i> | No |
| 2.3 Informazioni sul processo di produzione (descrizione generale) <i>Information on production process</i> (general description) | Reaction: Treatment of fatty amines with H ₂ O ₂ |

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| 3. Additivi <i>Additives</i> | |
| 3.1 Conservanti <i>Preservatives</i> | Not added |
| 3.2 Antiossidanti <i>Antioxidants</i> | Not added |

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| 3.3 | Solventi <i>Solvents</i> | Water |
| 3.4 | Sbiancanti <i>Bleaching agents</i> | Not added |
| 3.5 | Altri <i>Others</i> | Not added |
| 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. I - III 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. I – III 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> | Not expected |
| 5.2 | Ossido di etilene * <i>Ethylene oxide *</i> | Not expected |
| 5.3 | Solventi residui <i>Residual solvents</i> | Not expected |
| 5.4 | Monomeri residui <i>Residual monomers</i> | Not expected |

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| 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 monocloroacetico <i>Monochloroacetic acid</i> | Not expected |
| 5.9 | Acido dicloroacetico <i>Dichloroacetic acid</i> | Not expected |
| 5.10 | Allergeni Allergens according to the Cosmetics Regulation 1223/2009/EC and its further amendments (ppm) | Not expected |
| 5.11 | Altri (e.g. CMR) <i>Others (e.g. CMR)</i> | Hydrogen peroxide: 0.2% maximum CMR ingredients: absent |
| 6. | Tossicologia <i>Toxicology</i> | |
| 6.1 | Informazioni sulla tossicità acuta <i>Information on acute toxicity</i> | 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) |

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| 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 and Stearamine Oxide - Journal of the American College of Toxicology, vol. 13, Number 3, 1994, Seiten 231 bis 245) CIR recommended a use of Lauramine Oxide limited to 3.7% max for leave-on products. |
| 7. Ecotossicità <i>Ecology</i> | |
| 7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i> | Readily biodegradable (literature data, listed in Ecolabel DID list n° 62) |
| 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 Algae = 0.19 mg/l (72h) (Growth Inhibition test, OECD 201) - EC50 on Daphnia sp. Acute Immobilisation = 3.1 mg/l (48h) (OECD 202) |

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| 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> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</i> Ftalati <i>Phtalates</i> Glutine <i>Gluten</i> Formaldeide <i>Formaldehyde (Formol)</i> VOC <i>VOC compounds</i> Pesticidi <i>Pesticides</i> Nanomateriali <i>Nanomaterials</i> | <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.</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>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".</p> <p>The product doesn't contain any pesticides or pollutant substances (under detection limits)</p> <p>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</p> |

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| Grado cosmetico <i>Cosmetic grade</i> | The product is of cosmetic grade and it can be used in cosmetic products. It is according to Directive 76/768/EC and Regulation 1223/2009, its annexes and its amendments. |
| 8.1 Data di scadenza e stoccaggio <i>Shelf life and storage recommendation</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. 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. |

Data / *Date* 05/02/14

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.