



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 12

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	ZETEMOL AL
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)	Emollient, thickening agent
1.4 Nome chimico <i>Chemical name</i>	Tetradecyl lactate
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Myristyl Lactate: approx. 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	215-350-1
1.7 N° CAS <i>CAS no.</i>	1323-03-1

<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), where listed as Propanic acid, 2-hydroxy-tetradecyl ester DSL (Canada), ENCS (Japan), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe) 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° 05586.</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: 01-2120747792-45-0003</p> <p>None of substances listed in the “candidate” list 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>Product is ECOCERT/COSMOS certified. ISO 16128: derived natural ingredient, 100% natural ingredient</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 (100%).</p> <p>Lactic acid is prepared by lactic acid fermentation of carbohydrates such as glucose, sucrose and lactose coming from cereals cultivated in Europe</p> <p>Myristyl alcohol comes from palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia).</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>

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2.3 Informazioni sul processo di produzione (descrizione generale) <i>Information on production process</i> (general description)	Esterification between lactic acid and myristyl alcohol
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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>	Not added and not expected
3.4 Sbiancanti <i>Bleaching agents</i>	Not added and not expected
3.5 Altri <i>Others</i>	Catalysts are fully removed after esterification process trough washing and earth filtration

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.

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 * <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 or, if used, is removed in a final step of the manufacturing process
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>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	Nitrosammine <i>Nitrosamines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
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, Random tested, Nickel was always under detection limit (0,05 ppm)
5.8	Acido monocloroacetico <i>Monochloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

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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.
5.11	Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Lactic acid: 1% maximum Myristyl alcohol: 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 not likely to be present.

6.	Tossicologia <i>Toxicology</i>	
6.1	Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	LD50 oral > 2000 mg/kg/bw (literature data, test on rats (1964), value = 10 times higher than 2000 mg/kg/bw) LD50 dermal > 2000 mg/kg /bw (literature data, OECD 402 on similar products 1996)
6.2	Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	Non irritating (literature data, OECD 404, 1971)
6.3	Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	Non irritating (literature data, rabbits, 1978)
6.4	Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Non sensitizing (literature data, in-vitro test, 1976)
6.5	Informazioni sulla genotossicità <i>Information on gene toxicity</i>	None mutagenic effect (literature data, OECD 471)

6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	<p>Toxicokinetics Interpretation of results (migrated information): no bioaccumulation potential based on study results Readily hydrolysis with high enzymatic affinity for C12-C15 lactate esters.</p> <p>Total absorption was 30.4 % at pH 3 and 9.7 % at pH 7. With the pH 3 formulation, the amount of radioactivity found in the receptor fluid, stratum corneum, viable epidermis, and dermis was 3.6, 6.3, 6.6 and 13.9%, respectively.</p>
6.7 Altri <i>Others</i>	<p>NOEL > = 500 mg/kg bw/day (literature data, rabbits, 1982)</p>

7. Ecotossicità <i>Ecotoxicity</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	<p>Readily biodegradable (from literature, Read Across data)</p>
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<p>LC50 freshwater fish: 0,26 mg/l (from literature, Read Across data) LC50 marine water fish: 0,32 mg/l (from literature, Read Across data) NOEC freshwater fish: 0,01 mg/l (from literature, Read Across data) NOEC marine water fish: 0,09 mg/l (from literature, Read Across data) EC50 freshwater invertebrates: 0,36 mg/l (from literature, Read Across data) EC50 marine water invertebrates: 0,05 mg/l (from literature, Read Across data) NOEC marine water invertebrates: 0,002 mg/l (from literature, Read Across data) NOEC freshwater invertebrates: 0,086 mg/l (from literature, Read Across data) EC50 freshwater algae: 0,09 mg/l (from literature, Read Across data) EC50 marine water algae: 0,09 mg/l (from literature, Read Across data) NOEC freshwater algae: 0,07 mg/l (from literature, Read Across data) NOEC marine water algae: 0,07 mg/l (from literature, Read Across data) NOEC for microorganisms: 40 mg/l (from literature, Read Across data)</p>

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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, DINP (diisononyl phtalate) <i>Phthalates, DINP (diisononil ftalato)</i> Glutine <i>Gluten</i> Formaldeide <i>Formaldehyde (Formol)</i> VOC <i>VOC compounds</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 for cosmetic purpose.</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 phthalates listed in EU Regulation 1223/2009 Annex II are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.</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>

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 they are not likely to be present.

Aflatossine/Micotossine

Aflatoxines/Mycotoxines

Based on information concerning the raw materials, production process and equipment used aflatoxin/mycotoxin 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 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.

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<p>Nanomateriali <i>Nanomaterials</i></p> <p>Idrocarburi Policiclici Aromatici <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></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> <p>Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons 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 (certificate n° 20782).</p> <p>Yes</p>
<p>8.1 Data di scadenza <i>Shelf life</i></p>	<p>The product, if well preserved at temperatures between 20°C and 30°C 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. ZETEMOL AL has a dual physical form. Following manufacture it is a liquid at room temperature, however over time it may crystallize to give a physical form which is solid at room temperature.</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>At temperatures lower than 20°C product can solidify. The material can be restored to its original conditions just by a light heating at 30°C. Always homogenize before using.</p>

Data / *Date* 15/05/19

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.