



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 04

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	T-OIL OE
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, solvent
1.4 Nome chimico <i>Chemical name</i>	Dioctyl Ether
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Dicaprylyl Ether
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	211-112-6
1.7 N° CAS <i>CAS no.</i>	629-82-3

<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), DSL (Canada), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe), ENCS (Japan), AICS (Australia) 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° 02200.</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 n° 01-2119485017-37-XXXX.</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.</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 (Kosher product).</p> <p>Fatty alcohol C8 is from vegetable origin. It comes from coconut oil from Cocos Nucifera (South East Asia and Philippines) or mainly palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia). Oil is then hydrolyzed and acid so obtained hydrogenated in order to obtain fatty alcohol.</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>	$2\text{CH}_3(\text{CH}_2)_6\text{-CH}_2\text{OH} \xrightarrow[\text{H}^+]{\Delta} \text{CH}_3(\text{CH}_2)_6\text{CH}_2\text{-O-CH}_2(\text{CH}_2)_6\text{CH}_3 + \text{H}_2\text{O}$ <p>Water is distilled</p>

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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>	300 ppm Tocopherol (according to Ph. Eur., USP) from natural, non OGM origin.
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>	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 <p>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.</p> <p><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></p>	
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.

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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, only water
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
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.
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>	Caprylic alcohol: 4% 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 (on rat) > 2000 mg/kg bw(OECD 401) - LD50 dermal (on rat) > 2000 mg/kg bw (OECD 402)
6.2	Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	Product as it is = Not irritant (from literature data, 1998)
6.3	Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	Product as it is = Not irritant (from literature, OECD 405, 1991)
6.4	Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Not sensitizing (from literature, OECD 406, 1991)
6.5	Informazioni sulla genotossicità <i>Information on gene toxicity</i>	None mutagenic effects (from literature, OECD 473, 2001)
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 > 1000 mg/kg bw/day (repeated dose toxicity, 90 die, rats) (OECD 408), NOAEL > 1000 mg/kg bw/day (reproductive toxicity, rats) (OECD 414)
7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Readily biodegradable: 94,2% 28d
7.2	Tossicità acquatica acuta	- LC50 on Fish = 3200 mg/l/96h (ISO 7346 (II)) - EC50 on Daphnia > 100 mg/l/48h (OECD

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<i>Acute aquatic toxicity</i>	202) - EC50 on Algae = 26,16 mg/l/72h (OECD 201) - NOEC chronic on Daphnia = 12,5 mg/l (OECD 211) - NOEC chronic on Algae = 12,5 mg/l (OECD 201)
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>Phtalates, 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 reason.</p> <p>Not added and not expected</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>Not added and not expected</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)</p>

Fitofarmaci

Plant protection products

**APEO, cloroparaffine, composti organici
alogenati**

APEOs, chloroparaffines, AOX

Mercaptani

Mercaptanes

Melamine

Melamine

Lattosio

Lactose

Aflatossine/Micotossine

Aflatoxines/Mycotoxines

Lattice

Latex

Nitrati e Nitriti

Nitrates and Nitrites

Amine aromatiche

Aromatic amines

Coloranti azoici

Azo dyes

Ormoni, antibiotici e steroidi

Hormones, antibiotics and steroids

PBT/vPvB

PBT/vPvB

Materiale radioattivo

Radioactive material

Nanomateriali

Nanomaterials

du 12 novembre 1997".

Based on information concerning the raw materials, production process and equipment used plant protection products are not likely to be present.

Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Not added and not expected

Not added and not expected

Not added and not expected

Based on information concerning the raw materials, production process and equipment used aflatoxin/mycotoxin are not likely to be present.

The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.

Not added and not expected

Based on information concerning the raw materials, production process and equipment used aromatic amines are not likely to be present.

Based on information concerning the raw materials, production process and equipment used azo dyes are not likely to be present.

Not added and not expected

Not added and not expected

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.

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

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<p>Idrocarburi Policiclici Aromatici <i>Plycyclic Aromatic Hydrocarbons (HAP)</i></p> <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>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.</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 recommendations</i></p>	<p>Store in cool and adequately ventilated premises at room temperature (15°C-25°C), maintaining the containers well sealed. Do not store at temperature higher than 30°C, protect from light and humidity.</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.