



**INFORMAZIONI TOSSICOLOGICHE**  
***TOXICOLOGICAL INFORMATION***

**Revisione n°**  
***Revision n° 02***

<b>1. Informazioni generali</b>  <i>General information</i>	
<b>1.1 Nome commerciale</b>  <i>Trade name</i>	<b>T-OIL OE</b>
<b>1.2 Produttore/Fornitore</b> (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
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico)  <i>Raw material category</i> (e.g. anionic surfactant)	Emollient, solvent
<b>1.4 Nome chimico</b>  <i>Chemical name</i>	Dioctyl Ether
<b>1.5 Nome INCI (CTFA)</b> <b>Composizione</b>  <i>INCI (CTFA) name</i> <i>Composition</i>	Dicaprylyl Ether: 96% minimum Aqua: to 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <i>EC (EINECS/ELINCS) no.</i>	211-112-6
<b>1.7 N° CAS</b>  <i>CAS no.</i>	629-82-3

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<p><b>1.8 Registrazioni</b> (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 (12 January 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>Product is ECOCERT/COSMOS certified.</p>
<p><b>2. Informazioni sulla produzione</b></p> <p><b>Information on production</b></p>	
<p><b>2.1 Origine della materia prima</b> (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 palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia) (RSPO suppliers). Coconut oil is then hydrolyzed and acid so obtained hydrogenated in order to obtain fatty alcohol.</p>
<p><b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b></p> <p><i>Is the starting material derived from genetically modified organisms (GMO)?</i></p>	<p>No</p>
<p><b>2.3 Informazioni sul processo di produzione</b> (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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<b>3. Additivi</b> <i>Additives</i>	
<b>3.1 Conservanti/Biocidi</b> <i>Preservatives/Biocides</i>	Not added and not expected
<b>3.2 Antiossidanti</b> <i>Antioxidants</i>	300 ppm Tocopherol (according to Ph. Eur., USP) from natural, non OGM origin.
<b>3.3 Solventi</b> <i>Solvents</i>	Not added and not expected
<b>3.4 Sbiancanti</b> <i>Bleaching agents</i>	Not added and not expected
<b>3.5 Altri</b> <i>Others</i>	Not added and not expected
<b>4. Specifiche microbiologiche</b> <b>Microbiological specification</b>	
<b>4.1 Conta microbica totale (ufc/g)</b> <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g
<b>5. Residui del processo di lavorazione</b> 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>	
<b>5.1 1,4-Diossano *</b> <i>1,4-Dioxane *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

<b>5.2 Ossido di etilene *</b>  <i>Ethylene oxide *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.3 Solventi residui</b>  <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
<b>5.4 Monomeri residui</b>  <i>Residual monomers</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.5 Ammine</b>  <i>Amines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.6 Nitrosammine</b>  <i>Nitrosamines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.7 Metalli pesanti</b>  <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
<b>5.8 Acido monocloroacetico</b>  <i>Monochloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.9 Acido dicloroacetico</b>  <i>Dichloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.10 Allergeni</b>  <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.

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<b>5.11 Altri (e.g. CMR)</b>  <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.
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<b>6. Tossicologia</b>  <i>Toxicology</i>	
<b>6.1 Informazioni sulla tossicità acuta</b>  <i>Information on acute toxicity</i>	- LD50 oral (on rat) > 2000 mg/kg (OECD 401) - LD50 dermal (on rat) > 2000 mg/kg (OECD 402)
<b>6.2 Informazioni sull'irritazione cutanea</b>  <i>Information on skin irritation</i>	Product as it is = Not irritant (literature data and our knowledge on the product)
<b>6.3 Informazioni sull'irritazione oculare</b>  <i>Information on irritation of the mucous membrane</i>	Product as it is = Not irritant (literature data and our knowledge on the product)
<b>6.4 Informazioni sulla sensibilizzazione</b>  <i>Information on sensitisation potential</i>	Not sensitizing (literature data and our knowledge on the product)
<b>6.5 Informazioni sulla genotossicità</b>  <i>Information on gene toxicity</i>	None mutagenic effects (literature data and our knowledge on the product)
<b>6.6 Informazioni sull'assorbimento percutaneo</b>  <i>Information on percutaneous permeation</i>	Not determined
<b>6.7 Altri (e.g. NOAEL)</b>  <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)

<b>7. Ecotossicità</b>  <i>Ecology</i>	
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<b>7.1</b>	<b>Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Readily biodegradable (from literature data)
<b>7.2</b>	<b>Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- LC50 on Fish = 3200 mg/l/96h (ISO 7346 (II))</li> <li>- EC50 on Daphnia &gt; 100 mg/l/48h (OECD 202)</li> <li>- EC50 on Algae = 18 mg/l/72h (OECD 201)</li> <li>- NOEC chronic on Daphnia = 12,5 mg/l (OECD 211)</li> <li>- NOEC chronic on Algae = 12,5 mg/l (OECD 201)</li> </ul>
<b>7.3</b>	<b>Altri</b> <i>Others</i>	/

<b>8.</b>	<b>Informazioni aggiuntive</b> (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.)	
	<b>Dichiarazione BSE</b> <i>BSE statement</i>  <b>Dichiarazione test animali</b> <i>Non-animal testing declaration</i>  <b>Glicol eteri</b> <i>Glycol ethers</i>  <b>Ftalati, DINP (diisononyl phthalate)</b> <i>Phthalates, DINP (diisononil ftalato)</i>  <b>Glutine</b> <i>Gluten</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 &amp; 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>

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## **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 composés 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**

Not added and not expected

## **Melamine**

**Melamine**

Not added and not expected

## **Lattosio**

**Lactose**

Not added and not expected

## **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**

Not added and not expected

## **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**

Not added and not expected

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<p><b>PBT/vPvB</b> <b>PBT/vPvB</b></p> <p><b>Materiale radioattivo</b> <b>Radioactive material</b></p> <p><b>Nanomateriali</b> <b>Nanomaterials</b></p> <p><b>Idrocarburi Policiclici Aromatici</b> <b>Polycyclic Aromatic Hydrocarbons (HAP)</b></p> <p><b>Grado cosmetico</b> <b>Cosmetic grade</b></p> <p><b>Certificato Kosher</b> <b>Kosher certificate</b></p> <p><b>Convenzione CITES</b> <b>CITES Convention</b></p>	<p>Not added and not expected</p> <p>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.</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 expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex</p> <table border="0"> <tr> <td>Benzo[a]pyrene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Dibenz[a,h]anthracene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Cyclopenta[cd]pyrene</td> <td>)</td> </tr> <tr> <td>Benzofluoranthene[b+j+k]</td> <td>)</td> </tr> <tr> <td>Indeno[1,2,3-cd]pyrene</td> <td>) Σ ≤ 5 µg/kg</td> </tr> <tr> <td>Anthanthrene</td> <td>)</td> </tr> <tr> <td>Benzo[b]naphtho[2,1-d]thiophene</td> <td>)</td> </tr> <tr> <td>Benz[a]anthracene</td> <td>)</td> </tr> <tr> <td>Chrysene + Triphenylene</td> <td>) Σ ≤ 20 µg/kg</td> </tr> <tr> <td>Benzo[ghi]perylene</td> <td>)</td> </tr> </table> <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>	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	)
Benzo[a]pyrene	≤ 1 µg/kg																				
Dibenz[a,h]anthracene	≤ 1 µg/kg																				
Cyclopenta[cd]pyrene	)																				
Benzofluoranthene[b+j+k]	)																				
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Chrysene + Triphenylene	) Σ ≤ 20 µg/kg																				
Benzo[ghi]perylene	)																				
<p><b>8.1 Data di scadenza</b> <b>Shelf life</b></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><b>8.2 Stoccaggio</b> <b>Storage recommendations</b></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>																				



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Data / *Date* 19/01/17

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