



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

**Revisione n°**  
***Revision n° 01***

<b>1. Informazioni generali</b>  <b><i>General information</i></b>	
<b>1.1 Nome commerciale</b>  <b><i>Trade name</i></b>	<b>ALCOL CETILICO C16</b>  <b>CETYL ALCOHOL C16</b>
<b>1.2 Fornitore</b> (indirizzo, telefono, fax, contatto)  <b><i>Supplier</i></b> (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)  <b><i>Raw material category</i></b> (e.g. anionic surfactant)	Non ionic surfactant
<b>1.4 Nome chimico</b>  <b><i>Chemical name</i></b>	Hexadecan-1-ol
<b>1.5 Nome INCI (CTFA)</b> <b>Composizione</b>  <b><i>INCI (CTFA) name</i></b> <b><i>Composition</i></b>	Cetyl Alcohol: 97% - 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <b><i>EC (EINECS/ELINCS) no.</i></b>	253-149-0
<b>1.7 N° CAS</b>  <b><i>CAS no.</i></b>	36653-82-4

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<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), ENCS (Japan), AICS (Australia), ECL (Korea), SWISS (Switzerland), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and EINECS (Europe).</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° 03526.</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.</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>
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<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 origin.</p> <p>Fatty alcohol C16 is from vegetable origin. It comes from coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</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>	<p>Trans-esterification, hydrogenation and further distillation</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>	Not added and not expected
<b>3.3 Solventi</b> <i>Solvents</i>	Water
<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 cfu/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.

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5.2	<b>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.
5.3	<b>Solventi residui</b> <i>Residual solvents</i>	Hydrocarbons: 0.5% maximum Methanol: 100 ppm maximum
5.4	<b>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.
5.5	<b>Ammine</b> <i>Amines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	<b>Nitrosammine</b> <i>Nitrosamines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.7	<b>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
5.8	<b>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.
5.9	<b>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.
5.10	<b>Allergeni</b> <i>Allergens according to the 7<sup>th</sup> Amendment to the Cosmetics Directive (ppm)</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.

<p><b>5.11 Altri (e.g. CMR)</b></p> <p><i>Others (e.g. CMR)</i></p>	<p>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.</p>
<p><b>6. Tossicologia</b></p> <p><i>Toxicology</i></p>	
<p><b>6.1 Informazioni sulla tossicità acuta</b></p> <p><i>Information on acute toxicity</i></p>	<ul style="list-style-type: none"> <li>- Oral LD50 (rats) = 5 kg (CIR: CTFA 1980)</li> <li>- Dermal LD50, product as it is &gt; 2.6 g/kg (CIR: Am. Ind. Hyg. Assoc. J. 34 (II) 493, 1973)</li> <li>- Dermal LD50 in formulation, lipstick, on rabbit &gt; 2 g/kg (CIR: CTFA, 1980)</li> <li>- For inhalation, rat, guinea pig, 10 min vapours exposition, 9.6 ml/L after 30 min for 4 h = None effect (CIR: The Franklin Institute Research Laboratories, Philadelphia, 37, 1978)</li> </ul>
<p><b>6.2 Informazioni sull'irritazione cutanea</b></p> <p><i>Information on skin irritation</i></p>	<ul style="list-style-type: none"> <li>- Product as it is = Not irritant (CESIO labelling indication)</li> <li>- 20% in petrolatum, 0.1 ml, 24 h occlusive patch on rabbits, evaluation after 24 and 72 h = Minimum/light irritant (CIR: CTFA, 1972)</li> <li>- 4%, formulations with 0.5 ml and 0.5 g, lesioned and health skin on rabbits = From light to well defined erythema and light desquamation in the first study; none irritation after 24 h patch test in the second study (CIR: CTFA 1979; CIR: CTFA 1980)</li> <li>- 2%, 2 different form. on rabbits, 1 time/day for 4 days = From light to well defined erythema, or well defined erythema and bland oedema (CIR: CTFA 1978)</li> <li>- 3.25% formulation, lesioned and health skin, 1 h occlusive dressing = Light erythema and oedema (CIR: Consumer Product Testing Company, Inc. 1981)</li> <li>- On men, 100%, 24-48 h in occlusion, 20 subjects = None irritation (CIR: CTFA 1972, 1973)</li> </ul>
<p><b>6.3 Informazioni sull'irritazione oculare</b></p> <p><i>Information on irritation of the mucous membrane</i></p>	<ul style="list-style-type: none"> <li>- Product as it is = Not irritant (CESIO data)</li> <li>- 100%, 0.1 ml, rabbit = Not irritant (CIR: CTFA, 1972)</li> <li>- 2.7% and 3.6% formulations, irrigations into the two rabbits eyes = Not irritant (CIR: JACT 7(3), 1988)</li> </ul>

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<b>6.4 Informazioni sulla sensibilizzazione</b> <i>Information on sensitisation potential</i>	<ul style="list-style-type: none"> <li>- Product as it is = Not sensitizing (CIR: CTFA 1980)</li> <li>- On men, 5% formulation, 5 induction patches, 48 h, 1 challenge after 48 h = Not sensitizing (CIR: Ivy Research Laboratories, Inc. 1984)</li> </ul>
<b>6.5 Informazioni sulla genotossicità</b> <i>Information on gene toxicity</i>	Ames test, Salmonella typhimurium LT2 = Not mutagenic (CIR: J. Environ. Sci. Health Part A, 17, 217-39, 1973)
<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 x bw/d (oral, rats) Subacute/subchronic toxicity, 2% on rabbits, for 3 months = Bland inflammation on the application site, normal hematological and clinical-physical values (CIR: CTFA, 1981) Photo sensitization = Not photosensitizing (CIR, CTFA 1981)
<b>7. Ecotossicità</b> <i>Ecology</i>	
<b>7.1 Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (Ecolabel DID List n° 34) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2530)
<b>7.2 Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- Pimephales promelas = none deaths, concentration 500 mg/l, time 5 g (from manufacturers data)</li> <li>- Lepomis Macrochirus = concentration 1000 mg/l (LC 50), time 96 h (from manufacturers data)</li> </ul>
<b>7.3 Altri</b> <i>Others</i>	/
<b>8. 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)	

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<p>allegata.)</p> <p><b>Additional information</b> (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</p>	
<p><b>Dichiarazione BSE</b> <b>BSE statement</b></p> <p><b>Dichiarazione test animali</b> <b>Non-animal testing declaration</b></p> <p><b>Glicol eteri</b> <b>Glycol ethers</b></p> <p><b>Ftalati, DINP (diisononyl phtalate)</b> <b>Phtalates, DINP (diisononil ftalato)</b></p> <p><b>Glutine</b> <b>Gluten</b></p> <p><b>Formaldeide</b> <b>Formaldehyde (Formol)</b></p> <p><b>VOC</b> <b>VOC compounds</b></p> <p><b>Pesticidi</b> <b>Pesticides</b></p> <p><b>APEO, cloroparaffine, composti organici alogenati</b> <b>APEOs, chloroparaffines, AOX</b></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 &amp; 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> <p>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</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>

***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



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<p><b>Idrocarburi Policiclici Aromatici</b></p> <p><b>Plycyclic Aromatic Hydrocarbons (HAP)</b></p>  <p><b>Grado cosmetico</b></p> <p><b>Cosmetic grade</b></p>  <p><b>Certificato Kosher</b></p> <p><b>Kosher certificate</b></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"> <tbody> <tr> <td>Benzo[a]pyrene</td> <td style="text-align: right;">≤ 1 µg/kg</td> </tr> <tr> <td>Dibenz[<i>a,h</i>]anthracene</td> <td style="text-align: right;">≤ 1 µg/kg</td> </tr> <tr> <td>Cyclopenta[<i>cd</i>]pyrene</td> <td style="text-align: right;">)</td> </tr> <tr> <td>Benzofluoranthene[<i>b+j+k</i>]</td> <td style="text-align: right;">)</td> </tr> <tr> <td>Indeno[1,2,3-<i>cd</i>]pyrene</td> <td style="text-align: right;">) Σ ≤ 5 µg/kg</td> </tr> <tr> <td>Anthanthrene</td> <td style="text-align: right;">)</td> </tr> <tr> <td>Benzo[<i>b</i>]naphtho[2,1-<i>d</i>]thiophene</td> <td style="text-align: right;">)</td> </tr> <tr> <td>Benz[<i>a</i>]anthracene</td> <td style="text-align: right;">)</td> </tr> <tr> <td>Chrysene + Triphenylene</td> <td style="text-align: right;">) Σ ≤ 20 µg/kg</td> </tr> <tr> <td>Benzo[<i>ghi</i>]perylene</td> <td style="text-align: right;">)</td> </tr> </tbody> </table> <p>The product is of cosmetic grade and it can be used in cosmetic products.</p> <p>It is according Regulation 1223/2009, its annexes and its further amendments.</p> <p>We are EFfCI GMP certified (certificate n° 20782).</p> <p>Yes</p>	Benzo[a]pyrene	≤ 1 µg/kg	Dibenz[ <i>a,h</i> ]anthracene	≤ 1 µg/kg	Cyclopenta[ <i>cd</i> ]pyrene	)	Benzofluoranthene[ <i>b+j+k</i> ]	)	Indeno[1,2,3- <i>cd</i> ]pyrene	) Σ ≤ 5 µg/kg	Anthanthrene	)	Benzo[ <i>b</i> ]naphtho[2,1- <i>d</i> ]thiophene	)	Benz[ <i>a</i> ]anthracene	)	Chrysene + Triphenylene	) Σ ≤ 20 µg/kg	Benzo[ <i>ghi</i> ]perylene	)
Benzo[a]pyrene	≤ 1 µg/kg																				
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Benzo[ <i>ghi</i> ]perylene	)																				
<p><b>8.1 Data di scadenza</b></p> <p><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></p> <p><b>Storage recommendation</b></p>	<p>Store at room temperature (15°C-25°C). Do not store at temperature higher than 40°C. Protect from heat and humidity.</p>																				

Data / *Date* 17/02/17

**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.***