



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 02

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	ALCOOL CETILSTEARILICO 50
1.2 Fornitore (indirizzo, telefono, fax, contatto) <i>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)	Viscosity enhancer, coemulsifier, opacifier, consistency factor
1.4 Nome chimico <i>Chemical name</i>	Alcohols, C16-18
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Cetyl Alcohol: 45% - 55% Stearyl Alcohol: 45% - 55%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	Alcohols, C16-18: 267-008-6 Cetyl Alcohol: 253-149-0 Stearyl Alcohol: 204-017-6
1.7 N° CAS <i>CAS no.</i>	Alcohols, C16-18: 67762-27-0 Cetyl Alcohol: 36653-82-4 Stearyl Alcohol: 112-92-5

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<p>1.8 Registrazioni (es. UE, USA, Giappone) - REACH</p> <p><i>Registration status (e.g. EU, USA, Japan) - REACH</i></p>	<p>TSCA (USA), DSL (Canada), ENCS (Japan), AICS (Australia), ECL (Korea), SWISS (Switzerland), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and EINECS (Europe) for both Cetyl Alcohol and Stearyl Alcohol.</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 for Cetyl Alcohol and n° 07972 for Stearyl Alcohol).</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 registrations: n° 01-21199485905-24-xxxx for Cetyl Alcohol and 01-21199485907-20-xxxx for Stearyl Alcohol</p> <p>None of substances listed in the “candidate” list (20 June 2016) 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>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.</p> <p>Fatty alcohols C16 and C18 come from coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO supplier).</p> <p>We are RSPO member (membership n° 2-0434-14-000-00).</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>Information on production process (general description)</p>	$ \begin{array}{ccc} \begin{array}{c} \text{CH}_2\text{-O-R}_1 \\ \\ \text{CH-O-R}_2 \\ \\ \text{CH}_2\text{-O-R}_3 \end{array} & \xrightarrow[\text{transesterification}]{\text{CH}_3\text{OH } \Delta} & \begin{array}{c} \text{CH}_2\text{-OH} \\ \\ \text{CH-OH} \\ \\ \text{CH}_2\text{-OH} \end{array} \\ & & \begin{array}{c} \text{O} \qquad \qquad \text{O} \qquad \qquad \text{O} \\ \qquad \qquad \quad \qquad \qquad \quad \\ + \text{R}_1\text{-C-OCH}_3 + \text{R}_2\text{-C-OCH}_3 + \text{R}_3\text{-C-OCH}_3 \end{array} \\ & \xrightarrow[\Delta]{\text{H}_2 \text{ (Hydrogenation)}} & \text{R}_1\text{-OH} + \text{R}_2\text{-OH} + \text{R}_3\text{-OH} \\ & \xrightarrow{\text{distillation}} & \text{CH}_3(\text{CH}_2)_{14}\text{CH}_2\text{OH} + \\ & & \text{CH}_3(\text{CH}_2)_{16}\text{CH}_2\text{OH} \end{array} $
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<p>3. Additivi</p> <p><i>Additives</i></p>	
<p>3.1 Conservanti/Biocidi</p> <p><i>Preservatives/Biocides</i></p>	Not added and not expected
<p>3.2 Antiossidanti</p> <p><i>Antioxidants</i></p>	Not added and not expected
<p>3.3 Solventi</p> <p><i>Solvents</i></p>	Not added and not expected
<p>3.4 Sbiancanti</p> <p><i>Bleaching agents</i></p>	Not added and not expected
<p>3.5 Altri</p> <p><i>Others</i></p>	Not added and not expected

<p>4. Specifiche microbiologiche</p> <p>Microbiological specification</p>	
<p>4.1 Conta microbica totale (ufc/g)</p> <p><i>Total viable count (colony-forming units/g)</i></p>	less than 10 cfu/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. <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>	
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>	Methanol: 100 ppm maximum
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>	<p>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.</p> <p>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>
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	<p>Methanol: 100 ppm maximum Hydrocarbons: 0.5% maximum</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>

6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	<ul style="list-style-type: none"> - LD50 (oral, rat) > 5000 mg/kg (OECD 401) - LD50 (dermal, rabbit) > 5000 mg/kg (OECD 402) - LC50 (inhalation, rat) > 0,375 mg/l (OECD 403)
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	<p>Not irritant (from literature data)</p>
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	<p>Irritant (from literature data)</p>
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	<p>Not sensitizing (from literature data and our knowledge on the product)</p>
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	<p>Ames test on bacteria = Negative (literature data)</p>

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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 x bw/d (rat, repeated dose); NOAEL for reproduction = 2000 mg/kg (rat, OECD 422); NOAEL for growth = 2000 mg/kg (rat, OECD 422)
7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (Ecolabel DID List n° 34) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 34)
7.2	Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- CL50 on Fish > 0,4 mg/l/96h (OECD 203) - CE50 on Daphnia > 70 mg/l/48h (OECD 202) - CE50 on Algae = 250 mg/l/72h (OECD 201) - NOEC (long term) (Daphnia) > 0,98 mg/l (OECD 202)
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>	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.

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Dichiarazione test animali

Non-animal testing declaration

ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product.

Glicol eteri

Glycol ethers

Not added and not expected

Ftalati, DINP (diisononyl phthalate)

Phthalates, DINP (diisononil ftalato)

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.

Glutine

Gluten

Not added and not expected

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 composes 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

Not added and not expected

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

PBT/vPvB

PBT/vPvB

Not added and not expected

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

Idrocarburi Policiclici Aromatici

Polycyclic Aromatic Hydrocarbons (HAP)

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

Benzo[a]pyrene	≤ 1 µg/kg
Dibenz[a,h]anthracene	≤ 1 µg/kg
Cyclopenta[cd]pyrene)
Benzo[fluoranthene][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)

Clorobenzeni/Clorofenoli

Chlorobenzenes/Chlorophenols

Not added and not expected

Ritardanti di fiamma

Flame retardants

Not expected

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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 Regulation 1223/2009, its annexes and its further amendments. We are EFfCI GMP certified (certificate n° 20782).
8.1 Data di scadenza <i>Shelf life</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.
8.2 Stoccaggio <i>Storage recommendation</i>	Store at room temperature (15°C-25°C). Do not store at temperature higher than 40°C. Protect from heat and humidity.

Data / *Date* 21/09/16

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.