



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 08

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	ZETESOL LES 2/C
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)	Anionic surfactant
1.4 Nome chimico <i>Chemical name</i>	Alcohols, C12-14, ethoxylated, sulfates, sodium salts 1-2,5 moles ethoxylated
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Sodium Coceth Sulfate: 26.5% - 27.5% Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	NLP n° 500-234-8
1.7 N° CAS <i>CAS no.</i>	68891-38-3

<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), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific), NLP (Europe) and ECL (Korea). 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. The product is according to the China Cosmetic Ingredient list 2015 n° 08336. Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACH registration n° 01-2119488639-16-0005. None of substances listed in the “candidate” list of substances of very high concern (SVHC) are contained in the product in a relevant amount. Dioxane and heavy metals are listed on PO 65 (California law). ISO 16128: derived natural ingredient % natural origin: 51.1% on the molecule at 100%, that means 13.8% on solution as it is</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, mineral and synthetic origin. Fatty alcohol is from vegetable origin, then it is ethoxylated. Origin from fatty alcohol: coconut oil from Cocos Nucifera (South East Asia and Philippines) or mainly palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers). We are RSPO member. Sulfur is synthetic and NaOH is mineral.</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></p>	<p>Phase 1: fatty alcohol 2 OE plus SO₃. Control: acidity number Phase 2: neutralization with NaOH solution. Control: see specification</p>

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(general description)	
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>	Water
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 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 *	60 ppm maximum (on 100% active matter); 17 ppm maximum (on product as it is)

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	1,4-Dioxane *	
5.2	Ossido di etilene * <i>Ethylene oxide *</i>	Not detectable (lower than 1 ppm)
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. 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)</p> <p><i>Others (e.g. CMR)</i></p>	<p>Sodium sulfate: 1% maximum (100% a.m.) Laureth-2: 2% maximum (100% a.m.)</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: dioxane (CMR2) as impurity technically unavoidable even working in GMP (60 ppm maximum on 100% a.m.)</p>
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<p>6. Tossicologia</p> <p><i>Toxicology</i></p>	
<p>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<ul style="list-style-type: none"> - LD50 (on rats) > 2000 mg/kg bw (OECD 402) - LD50 > 540 mg/kg bw (active ingredient) (OECD 401)
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<ul style="list-style-type: none"> - Product as it is = Irritant (OECD 404) - 30%-60% on rabbit = Stark irritant (Avon, CTFA, 1972) - 25% on rabbit = Stark irritant (CPTC 1977, FDRL 1976) - 6%-10% on rabbit = Slightly irritant (Avon, 1970, IBTL 1975) - 5%-5.6% on rabbit = None irritation (Leberco Labs, 1977) - 18% on man = Slightly irritant (Avon, 1972) - 0.5% on man = Nearly none irritation (Hill Top Research, 1973)
<p>6.3 Informazioni sull'irritazione oculare</p> <p><i>Information on irritation of the mucous membrane</i></p>	<ul style="list-style-type: none"> - Product as it is = Irritant (OECD 405) - Draize test = From none to stark irritation (J. of the American College of Toxicology, 2,5,15, 1983)
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<ul style="list-style-type: none"> - Product as it is = Not sensitizing (OECD 406) - 0.07%-0.19% on Guinea pigs = The product hasn't any sensitization danger (Avon, 1977 - 1978) - 14.3% sol. on man = The product hasn't any sensitization danger (CTFA, 1980)
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<ul style="list-style-type: none"> - Ames test = None mutagenic effect (our test n° 96-4086.1) - Negative (OECD 475)

6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	0.2%-2% sol. on rats < 1% (Black, J. Soc. Cosmet. Chem. 30, 157-165, 1979)
6.7 Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i>	NOAEL (oral, human) = 300 mg/kg bw/day DNEL (dermal route) = 1650 mg/kg bw/day (repeated dose toxicity), AF = 20 Vaginal mucous membrane irritation: - 0.28% on beagles = None irritation (Tusing Toxicol. Appl. Pharmacol., 1962, 4,402-9) - 28% on beagles = Slightly irritant (Tusing Toxicol. Appl. Pharmacol., 1962, 4,402-9) - 0.07% on beagles for 3 weeks = None irritation (CTFA, 1980) Photoirritation on man: - 0.07% (RIPT + UV) = 4 light reactions on 153 subjects (CTFA, 1980) - 0.07% (RIPT + UV) = 2 light reaction on 56 subjects (CTFA, 1980) Chronic toxicity: - Oral = Till 100 mg/kg bw/d no adverse effects (OECD 408) - Dermal = No systemic toxicity (OECD 411, 0.9% a.1.)
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-2i dated 04.10.05 made on Sodium Laureth Sulfate) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2009 for cosmetic products and n° 2009 for detergents)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Fish = 1 - 10 mg/l, 96h (literature data) - EC50 on Daphnia = 7.2 mg/l, 48h (literature data) - EC50 on Algae = 7.5 mg/l, 72h (literature data) - EC10 on Pseudomonas putida = 100 mg/l (literature data) - NOEC chronic on Fish = 1 mg/l, 45d (literature data) - NOEC chronic on Daphnia = 0.18 mg/l, 21d (OECD 211, literature data)

<p>7.3 Altri <i>Others</i></p>	<p>/</p>
<p>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.)</p> <p><i>Additional information</i> (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</p>	
<p>Dichiarazione BSE <i>BSE statement</i></p> <p>Dichiarazione test animali <i>Non-animal testing declaration</i></p> <p>Glicol eteri <i>Glycol ethers</i></p> <p>Ftalati, DINP (diisononyl phtalate) <i>Phthalates, DINP (diisononil ftalato)</i></p> <p>Glutine <i>Gluten</i></p> <p>Formaldeide <i>Formaldehyde (Formol)</i></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 & 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>Not added, but in general one has to accept that formaldehyde can be present in lower concentrations in ethoxylated products. Our random tests show values lower than 5 ppm. On the other hand, it is known from the literature that formaldehyde may be formed even out of high purity polyethylene oxide surfactants, if they are stored at temperatures above 8°C and if oxygen out of the air can penetrate into the material. (M. Bergh, K. Magnusson, J. Lars G. Nilsson, A. T. Karlberg, Contact Dermatitis, 1998, 39, 14-20 and M. Donbrow in: Nonionic Surfactants, Physical</p>

VOC

VOC compounds

Chemistry, New York Surf. Sci. Series Vol. 23/1987, p. 1011-1073).

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

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.

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3-Benzilidene Canfora
3-Benzylidene Camphor

Based on information concerning the raw materials, production process and equipment used it is 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

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)
Benzo[a]anthracene)
Chrysene + Triphenylene) Σ ≤ 20 µg/kg
Benzo[ghi]perylene)

Grado cosmetico
Cosmetic grade

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).

Certificato Kosher
Kosher certificate

Yes

Convenzione CITES
CITES Convention

Not applicable, cultivated vegetable raw materials

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8.1 Data di scadenza <i>Shelf life</i>	<p>The product, if well preserved and in its original sealed 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>Depending on the temperature, the pH value may decrease during storage. However the product quality is not negatively influenced above a pH value of 4.0. Nevertheless below pH 10.8 the addition of a preservative is advisable.</p>
8.2 Stoccaggio <i>Storage recommendation</i>	<p>Store at room temperature (15°C-25°C). Protect from cold and heat.</p> <p>At temperatures below 10°C and on prolonged storage it can become turbid. The material can be restored to its original appearance by indirect heating and stirring. This doesn't affect the quality of the product. Avoid overheating. Homogenize before using.</p>

Data / *Date* 06/07/18

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.