



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

**Revisione n°**  
**Revision n° 15**

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<b>1. Informazioni generali</b> <i>General information</i>	
<b>1.1 Nome commerciale</b> <i>Trade name</i>	<b>ZETESOL LES 2/C</b>
<b>1.2 Produttore/Fornitore</b> (indirizzo, telefono, contatto) <i>Manufacturer/Supplier</i> (address, phone no., contact person)	ZSCHIMMER & SCHWARZ ITALIANA Via A. Ariotto 1/C - 13038 Tricerro (VC) Italy Tel: +39 (0)161 808111 <a href="mailto:e.merlo@zschimmer-schwarz.com">e.merlo@zschimmer-schwarz.com</a>
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico) <i>Raw material category</i> (e.g. anionic surfactant)	Anionic surfactant
<b>1.4 Nome chimico</b> <i>Chemical name</i>	Alcohols, C12-14, ethoxylated, sulfates, sodium salts 1-2.5 moles ethoxylated
<b>1.5 Nome INCI (CTFA) Composizione</b> <i>INCI (CTFA) name Composition</i>	Sodium Coceth Sulfate: 26.5% - 27.5% Aqua: to 100% INCI declaration Sodium Coceth Sulfate 27% average value
<b>1.6 N° EC (EINECS-/ELINCS)</b> <i>EC (EINECS/ELINCS) no.</i>	Absent because no longer polymer NLP n° 500-234-8
<b>1.7 N° CAS</b> <i>CAS no.</i>	68891-38-3

<p><b>1.8 Registrazioni</b> (es. UE, USA, Giappone) - REACH - Certificazione</p> <p><i>Registration status</i> (e.g. EU, USA, Japan) - REACH - Certification</p>	<p>IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TSCA (USA), NZIoC (New Zealand), TCSI (Taiwan), KECI (South Korea), PICCS (Philippines), AICS (Australia), DSL (Canada) and Vietnam. Pre-registered in Turkey.</p> <p>Notes: in Japan authorities currently do not require pre-market approval for cosmetic raw materials. This is also true for Brazil, South Korea, Philippines, USA (only for cosmetic raw materials).</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° 01-2119488639-16-0005.</p> <p>None of substances listed in the "candidate" list of substances of very high concern (SVHC) are contained in the product in a concentration <math>\geq 0.1\%</math>.</p> <p>PO 65 (California law): please check points 5.1, 5.2, 5.7 and 8 for formaldehyde (all not intentionally added).</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, mineral and synthetic origin.</p> <p>Fatty alcohol is from vegetable origin, then it is ethoxylated. It comes from palm kernel oil (Malaysia and Indonesia). Oil is then hydrolyzed and acid so obtained hydrogenated in order to obtain fatty alcohol.</p> <p>Sulfur is synthetic and NaOH is mineral.</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>S burns in presence of air giving <math>\text{SO}_2</math></p> $\text{S} + \text{O}_2 \rightarrow \text{SO}_2$ <p><math>\text{SO}_2</math> is converted in <math>\text{SO}_3</math></p> $\text{SO}_2 + \frac{1}{2} \text{O}_2 \rightarrow \text{SO}_3$ <p><math>\text{SO}_3</math> reacts with fatty alcohol ethoxylated giving</p>

	<p>an acidic intermediate that is then neutralized with NaOH</p> $\text{SO}_3 + \text{ROH} \rightarrow \text{ROSO}_3\text{H}$ <p>Control: acidity number</p> $\text{ROSO}_3\text{H} + \text{NaOH} \rightarrow \text{ROSO}_3^- \text{Na}^+ + \text{H}_2\text{O}$ <p>Control: according to specifications</p> <p>Manufacturing site: Tricerro, Italy</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.	
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<b>By-products</b> <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</b>	<b>1,4-Diossano *</b>  <b>1,4-Dioxane *</b>	17 ppm maximum (on product as it is); 60 ppm maximum (on 100% active matter)
<b>5.2</b>	<b>Ossido di etilene *</b>  <b>Ethylene oxide *</b>	Not detectable (lower than 1 ppm)
<b>5.3</b>	<b>Solventi residui</b>  <b>Residual solvents</b>	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</b>	<b>Monomeri residui</b>  <b>Residual monomers</b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.5</b>	<b>Ammine</b>  <b>Amines</b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.6</b>	<b>Nitrosammine</b>  <b>Nitrosamines</b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.7</b>	<b>Metalli pesanti</b>  <b>Heavy metals</b>	Arsenic (As) < 2 ppm, Lead (Pb) < 1 ppm, Cadmium (Cd) < 2 ppm, Mercury (Hg) < 1 ppm Heavy metals are determined with atomic adsorption in a random way.
<b>5.8</b>	<b>Acido monocloroacetico</b>  <b>Monochloroacetic acid</b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.9</b>	<b>Acido dicloroacetico</b>  <b>Dichloroacetic acid</b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.10</b>	<b>Allergeni</b>  <b>Allergens</b>	To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does

	<p>not contain substances listed under Annex II (Substances or products causing allergies or intolerances) of Regulation (EU) No. 1169/2011 on the provision of food information to consumers and its amendments.</p> <p>To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain allergens listed in Regulation (EU) No. 1223/2009 (Annex III) and its amendments.</p>
<p><b>5.11 Altri (e.g. CMR)</b></p> <p><i>Others (e.g. CMR)</i></p>	<p>Sodium sulfate: 1.0% maximum (100% a.m.) Laureth-2: 2.0% maximum (100% a.m.)</p> <p>To the best of our present knowledge, assuming the use of raw materials and manufacturing process currently employed, our product does not contain any CMR substances classified as CMR category 1A, 1B and 2 in accordance with Regulation 1272/2008 (EC) and its adaption, with the exception of very small amounts of the following technically unavoidable substances even working in GMP:</p> <ul style="list-style-type: none"> <li>- 1,4-dioxane; CAS n° 123-91-1; EC n° 204-661-8 (17 ppm max on product as it is, 60 ppm max on 100% a.m.); Annex II, Reference n° 343 (Article 17 of the Regulation (EC) No. 1223/2009)</li> <li>- Ethylene oxide; CAS n° 75-21-8; EC n° 200-849-9 (&lt; 1 ppm, not detectable); Annex II, Reference n° 182 (Article 17 of the Regulation (EC) No. 1223/2009)</li> <li>- Formaldehyde; CAS n° 50-00-0; EC n° 200-001-8 (&lt; 5 ppm, average value when product is delivered); Annex II, Reference n° 1577 (Article 17 of the Regulation (EC) No. 1223/2009)</li> </ul>
<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>- LD50 (oral) &gt; 2870 mg/kg bw (from literature, OECD 401, 1986)</li> <li>- LD50 (dermal) &gt; 2000 mg/kg bw (from literature, OECD 402, 2012)</li> </ul>
<p><b>6.2 Informazioni sull'irritazione cutanea</b></p> <p><i>Information on skin irritation</i></p>	<p>Product as it is = Irritant (from literature, OECD 404, 1994)</p>

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6.3	<b>Informazioni sull'irritazione oculare</b> <i>Information on irritation of the mucous membrane</i>	Product as it is = Irritant (from literature, OECD 405, 1980)
6.4	<b>Informazioni sulla sensibilizzazione</b> <i>Information on sensitisation potential</i>	Product as it is = Not sensitizing (from literature, OECD 406, 1986)
6.5	<b>Informazioni sulla genotossicità</b> <i>Information on gene toxicity</i>	Ames test = Negative (from literature, OECD 476, 1995)
6.6	<b>Informazioni sull'assorbimento percutaneo</b> <i>Information on percutaneous permeation</i>	0.2%-2% sol. on rats < 1% (Black, J. Soc. Cosmet. Chem. 30, 157-165, 1979)
6.7	<b>Altri (e.g. NOAEL)</b> <i>Others (e.g. NOAEL)</i>	<ul style="list-style-type: none"> <li>- NOAEL (oral) = &gt; 225 mg/kg bw/day (from literature, OECD 408, 1994)</li> <li>- NOAEL (oral) = &gt; 68 mg/kg bw/day (from literature, OECD 411, 1978)</li> </ul>

7.	<b>Ecotossicità</b> <i>Ecology</i>	
7.1	<b>Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-2i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2009)
7.2	<b>Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- LC50 on Fish = 7.1 mg/l/96h (OECD 203, literature data, 1994)</li> <li>- EC50 on Daphnia = 7.4 mg/l/48h (OECD 202, literature data, 1993)</li> <li>- EC50 on Algae = 27.7 mg/l/72h (OECD 201, literature data, 1993)</li> <li>- NOEC chronic on Fish = 0.14 mg/l, 28d (OECD 215, literature data, 1995)</li> <li>- NOEC chronic on Daphnia = 0.27 mg/l, 21d (OECD 211, literature data, 1977)</li> <li>- NOEC on Algae = 0.95 mg/l, 72h (OECD 201, literature data, 1993)</li> </ul>
7.3	<b>Altri</b> <i>Others</i>	/

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<p><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 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/TSE</b> <i>BSE/TSE statement</i></p> <p><b>Dichiarazione test animali</b> <i>Non-animal testing declaration</i></p> <p><b>Glicol eteri</b> <i>Glycol ethers</i></p> <p><b>Ftalati, DINP (diisononyl phtalate)</b> <i>Phtalates, DINP (diisononil ftalato)</i></p> <p><b>Etanolo</b> <i>Ethanol</i></p> <p><b>Glutine</b> <i>Gluten</i></p> <p><b>Formaldeide</b> <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/TSE free.</p> <p>For the purposes of the European Cosmetics regulation (EC) No. 1223/2009, no animal testing has been carried out by or on behalf of ZSCHIMMER &amp; SCHWARZ ITALIANA on the product/ingredients after 11<sup>th</sup> March 2009 and after 11<sup>th</sup> March 2013 (extended deadline for animal testing for repeated dose, reproductive toxicity or toxicokinetics).</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 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</p>



**VOC**

***VOC (volatile organic compounds)***

***Directive 2010/75/EU of 24 November 2010  
on industrial emissions (integrated  
pollution prevention and control) and  
Directive 2004/42/EC***

***Swiss VOC ordinance 814.018 (Ordinance  
on the Incentive Tax on Volatile Organic  
Compounds)***

***Fitofarmaci  
Plant protection products***

***Insetticidi/Insecticides***

***Fenolo/Phenol***

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

The VOC Directive 2010/75/EU and Directive 2004/42/EC of the European Community are complex regulations. Only based on the properties of a substance it is not possible to make a decision whether this regulation applies to the substance or not. A statement can be made only in connection with the application and the conditions of use.

As a producer of raw materials we do not have information on actual usage and conditions of use. Therefore, we can only make a statement about the volatility and the boiling point under standard conditions. You will find this information in chapter 9 of our material safety data sheet.

According to Article 2 of the SR 814.018 VOCs are liable for tax if they are listed on the positive list of substances (Annex 1) or contained in products mentioned in the positive list of products (Annex 2). According to Article 8(a) of the SR 814.018, those mixtures and products are exempted from tax in which the VOC content does not exceed 3 per cent (% by weight).

To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does not contain > 3% of the substances on the positive list of substances (annex 1) of the SR 814.018.

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 insecticides is not expected to be present and no insecticides has been used

Based on information concerning the raw materials, production process and equipment used phenol is not expected to be present and no phenol has been used.



**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**

**3-Benzilidene Canfora**

**3-Benzylidene Camphor**

**Ormoni, antibiotici, steroidi e altri ingredienti (naturali o chimici) dannosi per le funzioni del corpo umano**

**Hormones, antibiotics, steroids and other ingredients (natural or chemical) dangerous for the body functionality**

**PBT/vPvB**

**PBT/vPvB**

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

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

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

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.

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

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.

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<p><b>Materiale radioattivo</b> <i>Radioactive material</i></p> <p><b>Nanomateriali</b> <i>Nanomaterials</i></p> <p><b>Idrocarburi Policiclici Aromatici</b> <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p><b>Grado cosmetico</b> <i>Cosmetic grade</i></p> <p><b>Certificato Kosher</b> <i>Kosher certificate</i></p> <p><b>Certificato Halal</b> <i>Halal certificate</i></p> <p><b>Convenzione CITES</b> <i>CITES Convention</i></p> <p><b>Protocollo di Nagoya</b> <i>Nagoya protocol</i></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 1881/2019/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 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. We are EFfCI GMP certified.</p> <p>Yes</p> <p>Intermediates and starting materials are of non-animal origin. Product is made by a process in which only auxiliaries of non-animal origin have been used. Processing equipment is only used for products of non-animal origin. Product is made by a process in which only auxiliaries of non-ethanol origin have been used.</p> <p>Not applicable, cultivated vegetable raw materials</p> <p>The product does not fall into the scope of the Nagoya protocol. The protocol is applicable to raw materials that contain functional units of heredity. As for the primary petro- &amp; oleochemical derivatives that are used in production processes this is not the case.</p>
<p><b>8.1 Data di Retest</b> <i>Retest date</i></p>	<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 (pH and microbial count if pH is lower than 10.8) 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**

***Storage recommendation***

Store at room temperature for long periods of time (15°C - 35°C). Products come from plant at 62°C - 63°C, after that temperature decreases according to external conditions and in summer it can take several days to go below 35°C. This physiological process doesn't affect product quality. Protect from cold and prolonged heating.

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.

Data / *Date* 22/06/2023

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