ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

Zschimmer & Schwarz Italiana – 13038 – Tricerro (VC) / ITALY

INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 09

1.	**Informazioni generali** ***General information***	
1.1	**Nome commerciale** ***Trade name***	**ZETESOL LES 3/SL**
1.2	**Produttore/Fornitore** (indirizzo, telefono, fax, contatto) ***Manufacturer/Supplier*** *(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) ***Raw material category*** *(e.g. anionic surfactant)*	Anionic surfactant
1.4	**Nome chimico** ***Chemical name***	Alcohols, C12-14, ethoxylated, sulfates, sodium salts 3 moles ethoxylated
1.5	**Nome INCI (CTFA)** **Composizione** ***INCI (CTFA) name*** **Composition**	Sodium Laureth Sulfate: 26.5% - 27.5% Aqua: to 100%
1.6	**N° EC (EINECS-/ELINCS)** ***EC (EINECS/ELINCS) no.***	Absent because polymer
1.7	**N° CAS** ***CAS no.***	9004-82-4

1.8	**Registrazioni** (es. UE, USA, Giappone) - REACh - Certificazione ***Registration status*** *(e.g. EU, USA, Japan) - REACh - Certification*	ENCS (Europe), IECSC (China, Chemical), IECIC (China, Cosmetic Ingredient), TSCA (USA), NZIoC (New Zealand), KECI (South Korea), PICCS (Philippines), AICS (Australia), DSL (Canada) and Vietnam. Pre-registered in Turkey. 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). Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACh registration: absent because polymer. None of substances listed in the "candidate" list of substances of very high concern (SVHC) are contained in the product in a concentration > 0.1%. PO 65 (California law): see points 5.1, 5.2, 5.7 and 8 for formaldehyde.

2.	**Informazioni sulla produzione** **Information on production**	
2.1	**Origine della materia prima** (vegetale, animale, sintetica) **Origin of starting material** (plant, animal, synthetic)	Vegetable, mineral and synthetic origin. Fatty alcohol is from vegetable origin, then it is ethoxylated with 3EO (polymer). Monomer units are EO (ethylene oxide) that is not detectable in finished product and fatty alcohol. Origin from fatty alcohol: mainly palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia). MW of fatty alcohol ethoxylated is 327. KOH/NaOH are used as catalysts. Fatty alcohol ethoxylated is stable with time. Sulfur is synthetic and NaOH is mineral.
2.2	**La materia prima deriva da organismi geneticamente modificati (OGM)?** **Is the starting material derived from genetically modified organisms (GMO)?**	No
2.3	**Informazioni sul processo di produzione** (descrizione generale) **Information on production process** (general description)	S burns in presence of air giving SO_2 $S + O_2 \rightarrow SO_2$ SO_2 is converted in SO_3 trough a fix-bed catalyst (V_2O_5)

	$SO_2 + ½ O_2 \rightarrow SO_3$ SO_3 reacts with fatty alcohol ethoxylated giving an acidic intermediate that is then neutralized with NaOH $SO_3 + ROH \rightarrow ROSO_3H$ Control: acidity number $ROSO_3H + NaOH \rightarrow ROSO_3^- Na^+ + H_2O$ Control: according to specifications

3.	**Additivi** ***Additives***	
3.1	**Conservanti/Biocidi** ***Preservatives/Biocides***	Not added and not expected
3.2	**Antiossidanti** ***Antioxidants***	Not added and not expected
3.3	**Solventi** ***Solvents***	Water
3.4	**Sbiancanti** ***Bleaching agents***	Not added and not expected
3.5	**Altri** ***Others***	Not added and not expected

4.	**Specifiche microbiologiche** **Microbiological specification**	
4.1	**Conta microbica totale (ufc/g)** ***Total viable count (colony-forming units/g)***	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. ***By-products*** *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.*	
5.1	**1,4-Diossano *** ***1,4-Dioxane **	120 ppm maximum (100% active matter)
5.2	**Ossido di etilene *** ***Ethylene oxide **	Not detectable (lower than 1 ppm)
5.3	**Solventi residui** ***Residual solvents***	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** ***Residual monomers***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5	**Ammine** ***Amines***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	**Nitrosammine** ***Nitrosamines***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.7	**Metalli pesanti** ***Heavy metals***	Arsenic (As) < 2 ppm, Antimony (Sb) < 2 ppm, Lead (Pb) < 2 ppm, Cadmium (Cd)< 2 ppm, Cobalt (co) < 1 ppm, Mercury (Hg) < 1 ppm, Nickel (Ni) < 1 ppm, Chromium (Cr) < 1 ppm, Total heavy metals (as Fe) < 5 ppm (Random check, values to be considered as typical)
5.8	**Acido monocloroacetico** **Monochloroacetic acid**	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

5.9 Acido dicloroacetico ***Dichloroacetic acid***	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.10 Allergeni **Allergens**	To the best of our knowledge, assuming the use of the raw materials and manufacturing process currently employed, the product does 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. 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.
5.11 Altri (e.g. CMR) ***Others (e.g. CMR)***	Sodium sulfate: 0.5% maximum Laureth-3: 1.0% maximum 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: - 1,4-dioxane; CAS n° 123-91-1; EC n° 204-661-8 (120 ppm max on 100% a.m.); Annex II, Reference n° 343 (Article 17 of the Regulation (EC) No. 1223/2009) - Ethylene oxide; CAS n° 75-21-8; EC n° 200-849-9 (< 1 ppm, not detectable); Annex II, Reference n° 182 (Article 17 of the Regulation (EC) No. 1223/2009) - Formaldehyde; CAS n° 50-00-0; EC n° 200-001-8 (< 5 ppm, average value when product is delivered); Annex II, Reference n° 1577 (Article 17 of the Regulation (EC) No. 1223/2009)

6. Tossicologia ***Toxicology***	
6.1 Informazioni sulla tossicità acuta	- LD50 (on rats) > 2000 mg/kg bw (OECD 402)

	Information on acute toxicity	- LD50 > 540 mg/kg bw (active ingredient) (OECD 401)
6.2	**Informazioni sull'irritazione cutanea** *Information on skin irritation*	- 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 = Slighly irritant (Avon, 1972) - 0.5% on man = Nearly none irritation (Hill Top Research, 1973)
6.3	**Informazioni sull'irritazione oculare** *Information on irritation of the mucous membrane*	- 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)
6.4	**Informazioni sulla sensibilizzazione** *Information on sensitisation potential*	- 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)
6.5	**Informazioni sulla genotossicità** *Information on gene toxicity*	- Ames test = None mutagenic effect (our test n° 96-4086.1) - Negative (OECD 475)
6.6	**Informazioni sull'assorbimento percutaneo** *Information on percutaneous permeation*	0.2%-2% sol. on rats < 1% (Black, J. Soc. Cosmet. Chem. 30, 157-165, 1979)
6.7	**Altri (e.g. NOAEL)** *Others (e.g. NOAEL)*	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** ***Ecology***	
7.1	**Degradabilità/Eliminazione** ***Degradability/Elimination***	Aerobic: readily biodegradable (our test SAM2467-2i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List)
7.2	**Tossicità acquatica acuta** ***Acute aquatic toxicity***	- 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)
7.3	**Altri** ***Others***	/

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.) ***Additional information*** *(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)*	
	Dichiarazione BSE/TSE ***BSE/TSE statement***	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.
Dichiarazione test animali ***Non-animal testing declaration***	ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.
Glicol eteri ***Glycol ethers***	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
Ftalati, DINP (diisononyl phtalate) ***Phtalates, 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***	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
Formaldeide ***Formaldehyde (Formol)***	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 Chemistry, New York Surf. Sci. Series Vol. 23/1987, p. 1011-1073).
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	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.

Swiss VOC ordinance 814.018 (Ordinance on the Incentive Tax on Volatile Organic Compounds)	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.
Fitofarmaci ***Plant protection products***	Based on information concerning the raw materials, production process and equipment used plant protection products are not likely to be present.
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 aflotoxin/mycotoxin are not likely to be present
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 1881/2019/EC and any nanotechnology is used to produce it
Idrocarburi Policiclici Aromatici ***Plycyclic Aromatic Hydrocarbons (HAP)***	Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons are not likely to be present
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.
Certificato Kosher ***Kosher certificate***	Yes
Certificato Halal ***Halal certificate***	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.
Convenzione CITES ***CITES Convention***	Not applicable, cultivated vegetable raw materials
Protocollo di Nagoya ***Nagoya protocol***	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- & oleochemical derivatives that are used in production processes this is not the case.

8.1 Data retest ***Retest date***	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 (pH and microbial contamination). 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. As product is preservative free, if pH goes under 10.8 the addition of a preservative is necessary.
8.2 Stoccaggio ***Storage recommendation***	Store at room temperature (15°C-25°C). Protect from cold and heat. At temperatures lower than 10°C it can become turbid. The material can be restored to its original appearance by indirect heating at 30°C-40°C and stirring. This doesn't affect the quality of the product. Avoid overheating. Homogenize before using.
8.3 Altro ***Other***	**Specific Limits concentration for health** GHS05 - Corrosive H315, H318, H412 ≥ 10%: Eye Damage 1 H318, Skin irrit. 2 H315 ≥ 5% - < 10%: Eye Irritation 2 H319 < 5%: no label

Data / *Date* 20/10/2022