



**INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION**

Revisione n°
Revision n° 01

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	SETACIN 103 SPEZIAL
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>	Poly(oxy-1,2-ethanediyl), a-(3-carboxy-1-oxo-3-sulfopropyl)-w-(dodecyloxy)-, disodium salt
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Disodium Laureth Sulfosuccinate: 268 min as Hyamine number (29.7% min as active matter) Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	Absent because polymer
1.7 N° CAS <i>CAS no.</i>	39354-45-5 (generic)

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<p>1.8 Registrazioni (es. UE, USA, Giappone) - REACH</p> <p><i>Registration status</i> (e.g. EU, USA, Japan) - REACH</p>	<p>TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and ASIA-PAC (Asia-Pacific).</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 approvation. Anyway SETACIN 103 SPEZIAL is officially listed in JCIC as Disodium laurethsulfosuccinate.</p> <p>The product is not listed into the China Regulatory Standard Version 2007.</p> <p>REACH registration: absent because polymer</p> <p>None of substances listed in the “candidate” list of substances of very high concern (SVHC) are contained in the product in a relevant amount.</p> <p>Dioxane is 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, mineral and synthetic origin.</p> <p>Fatty alcohol is vegetable (then it is ethoxylated 3EO). Origin of fatty alcohol: coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (South East Asia).</p> <p>NaOH is mineral.</p> <p>Maleic Anhydride and Sodium Sulfite are synthetic.</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> (general description)</p>	<p>1 phase: Fatty alcohol 3EO plus maleic anhydride, heat. Control: acidity number</p> <p>2 phase: Ester from the first phase added with water, sodium sulfite and sodium hydroxide; heat. Control: see specification</p>

<p>3. Additivi</p> <p><i>Additives</i></p>	
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3.1	Conservanti <i>Preservatives</i>	200 - 250 ppm of Formaldehyde
3.2	Antiossidanti <i>Antioxidants</i>	Not added
3.3	Solventi <i>Solvents</i>	Not added
3.4	Sbiancanti <i>Bleaching agents</i>	Not added
3.5	Altri <i>Others</i>	Not added
4.	Specifiche microbiologiche Microbiological specification	
4.1	Conta microbica totale (ufc/g) <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g
5.	Residui del processo di lavorazione La presenza di tracce delle sostanze elencate in Annex II della Direttiva 76/768/CEE (incl. CMR cat. I - III sostanze contrassegnate con *) deve essere dimostrata come presenza tecnicamente inevitabile lavorando in GMP e deve essere conforme all'Articolo 2 della Direttiva 76/768/CEE. <i>By-products</i> <i>The presence of traces of the substances listed in Annex II of Directive 76/768/EEC (incl. cmr cat. I – III substances marked with *) shall be allowed provided that such presence is technically unavoidable in good manufacturing practice and that it conforms with Article 2 of Directive 76/768/EEC.</i>	
5.1	1,4-Diossano <i>1,4-Dioxane</i>	5 ppm maximum
5.2	Ossido di etilene <i>Ethylene oxide</i>	Not detectable (lower than 1 ppm)

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5.3	Solventi residui <i>Residual solvents</i>	Not expected
5.4	Monomeri residui <i>Residual monomers</i>	Not expected
5.5	Ammine <i>Amines</i>	Not expected
5.6	Nitrosammine <i>Nitrosamines</i>	Not expected
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>	Not expected
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	Not expected
5.10	Allergeni <i>Allergens according to the Cosmetics Directive and its amendments (ppm)</i>	Not expected
5.11	Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Laureth-3: 10% maximum Polyethylene glycol: 0.5% maximum Maleic acid (as sulphitated maleic acid Na ⁺ salt) = 6% maximum Sodium sulphite as SO ₂ = 50 ppm maximum It contains formaldehyde (CMR2) as preservative (200 - 250 ppm) and dioxane (CMR2) as impurity technically unavoidable even working in GMP (5 ppm maximum)

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6.	Tossicologia <i>Toxicology</i>	
6.1	Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	LD50 ~ 30 g/kg (Journal of the American College of Toxicology, Part B 1:107, 1990)
6.2	Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	- It isn't irritant (CESIO data) - 3% solution = It isn't irritant (test n° 1-3-557/2, 1976)
6.3	Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	3% solution on rabbit = It isn't irritant (test n° 1-3-557/1, 1976)
6.4	Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	2% active matter in challenge test = The product hasn't any sensitization danger (test from literature: IBR / 10/87)
6.5	Informazioni sulla genotossicità <i>Information on gene toxicity</i>	Ames test = None mutagenic effects (test n° 96-4084)
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>	NOEL = 250 mg/kg x bw/d (repeated oral dose, rats); NOAEL = 300 mg/kg x bw/d (repeated oral dose, rats)
7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-1i dated 04.10.05) Anaerobic: from its structure and according to the information on similar products it can be regarded as biodegradable in anaerobic way
7.2	Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Fish > 1 mg/l (literature data) - EC50 on Daphnia > 1 mg/l (literature data) - EC50 on Algae > 1 mg/l (literature data)

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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> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</i> Ftalati <i>Phtalates</i> Glutine <i>Gluten</i> Formaldeide <i>Formaldehyde (Formol)</i> VOC <i>VOC compounds</i> Pesticidi <i>Pesticides</i> Melamine <i>Melamine</i> Lattosio <i>Lactose</i>	<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 tested the product on 1976 for evaluation of its skin and eye irritation and skin sensitization.</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>200 - 250 ppm of formaldehyde</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>The product doesn't contain any pesticides or pollutant substances (under detection limits).</p> <p>Not expected</p> <p>Not expected</p>

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<p>Aflatossine/Micotossine <i>Aflatoxines/Mycotoxines</i></p> <p>Lattice <i>Latex</i></p> <p>Nanomateriali <i>Nanomaterials</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p>	<p>Not expected</p> <p>The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.</p> <p>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</p> <p>The product is of cosmetic grade and it can be used in cosmetic products. It is according to Directive 76/768/EC and Regulation 1223/2009 and its amendments.</p> <p>Yes</p>
<p>8.1 Data di scadenza e stoccaggio <i>Shelf life and storage recommendation</i></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. Store at room temperature (15°C-25°C). At low temperature and on prolonged storage product 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. Overheating should be avoided. 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.</p>

Data / *Date* 20/08/2013

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.