



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 00

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	ZETEMULS RT 141
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)	Emulsifier, solubilizing agent
1.4 Nome chimico <i>Chemical name</i>	Sorbitan monolaurate, ethoxylated; Sorbitan, monododecanoate, poly(oxy-1,2-ethandiyl) derivs.
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Polysorbate 20: 97% min Aqua: 3% max
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	Absent, polymer
1.7 N° CAS <i>CAS no.</i>	9005-64-5

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1.8 Registrazioni (es. UE, USA, Giappone) - REACH <i>Registration status</i> (e.g. EU, USA, Japan) - REACH	TSCA (USA), DSL (Canada), ENCS (Japan), SWISS (Switzerland), PICCS (Philippines), ASIA-PAC (Asia-Pacific), NLP (Europe), AICS (Australia) 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 Regulatory Standard Version 2007. REACH registration: absent because polymer
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2. Informazioni sulla produzione Information on production	
2.1 Origine della materia prima (vegetale, animale, sintetica) <i>Origin of starting material</i> (plant, animal, synthetic)	Vegetable and synthetic. Sorbitol and lauric acid are vegetable. Ethylene oxide is synthetic.
2.2 La materia prima deriva da organismi geneticamente modificati (OGM)? <i>Is the starting material derived from genetically modified organisms (GMO)?</i>	No
2.3 Informazioni sul processo di produzione (descrizione generale) <i>Information on production process</i> (general description)	Esterification of 1,4 sorbitan (obtained from sorbitol less water) with lauric acid and further ethoxylation.

3. Additivi <i>Additives</i>	
3.1 Conservanti <i>Preservatives</i>	Not added
3.2 Antiossidanti <i>Antioxidants</i>	Not added

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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 cfu/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>	10 ppm maximum
5.2	Ossido di etilene <i>Ethylene oxide</i>	Not detectable (lower than 1 ppm)
5.3	Solventi residui <i>Residual solvents</i>	Not expected
5.4	Monomeri residui <i>Residual monomers</i>	Not expected

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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 7th Amendment to the Cosmetics Directive (ppm)</i>	Not expected
5.11	Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Ashes: 0.25% maximum Peroxide value: 10 meq/kg It contains dioxane (CMR2) as impurity technically unavoidable even working in GMP (10 ppm maximum, average value: 1-2 ppm)
6.	Tossicologia <i>Toxicology</i>	
6.1	Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	- LD50 (oral, rats) > 4.6 g/kg (CIR, Eagle et al., Food Res. 348-61, 1956) - LD50 (oral, mouse) > 25 g/kg (CIR, Hopper et al., J. Am. Phar. Assoc. Sci. Ed. 38(8)428-32, 1949)
6.2	Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	- Product as it is (rabbit) = Not irritant (CIR, Atlas Tox. Lab. 1970 - 71) - Sol. 40% (24h patch test, human) = Not irritant (CIR, CTFA 1974)

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6.3	Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	Product as it is (Draize test) = Not irritant (CIR, Atlas Tox. Lab. 1970 - 71)
6.4	Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Product as it is = Not sensitizing (CIR, JACT 3(5)1-82, 1984)
6.5	Informazioni sulla genotossicità <i>Information on gene toxicity</i>	Ames test = Not mutagenic (literature data)
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 (3 m, chronic, rats, oral)
7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable
7.2	Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Carassius Auratus (96h) = 1 - 10 mg/l - EC50 on Daphnia (48h) = 1 - 10 mg/l
7.3	Altri <i>Others</i>	COD value: 2100 mg O2/g
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)	

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<i>instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</i>	
<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 <i>Phtalates</i></p> <p>Glutine <i>Gluten</i></p> <p>Formaldeide <i>Formaldehyde (Formol)</i></p> <p>VOC <i>VOC compounds</i></p> <p>Pesticidi <i>Pesticides</i></p> <p>Nanomateriali <i>Nanomaterials</i></p> <p>Grado cosmetico <i>Cosmetic grade</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.</p> <p>Not added and not expected</p> <p>Not added and not expected</p> <p>Not added and not expected</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 1 ppm (under detection limits)</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>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>8.1 Data di scadenza <i>Shelf life</i></p>	<p>The product, if stored at temperatures between 0°C and 30°C 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</p>

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	rechecked.
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Data / *Date* 07/11/13

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.*