



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 PGR
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)	Emulsifier and coemulsifier, non ionic surfactant
1.4 Nome chimico <i>Chemical name</i>	1,2,3-Propanetriol, homopolymer, (9Z, 12R)-12-hydroxy-9-octadecenoate
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Polyglyceryl-3 Polyricinoleate: ~ 100% Aqua: 1% maximum
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	Absent, polymer
1.7 N° CAS <i>CAS no.</i>	68936-89-0

<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), ASIA-PAC (Asia-Pacific), NDSL (Canada) and AICS (Australia).</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 approval.</p> <p>The product is according to the China Regulatory Standard Version 2007.</p> <p>REACH registration: absent, 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>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.</p> <p>Glycerine derives through hydrolysis of coconut oil from Cocos Nucifera (South East Asia and Philippines).</p> <p>Ricinoleic acid is synthesized from castor oil or methyl ricinoleate by pyrolysis. Methyl ricinoleate is obtained from castor oil by methanolysis. Castor oil is obtained from the plant of Ricinus Communis (seeds).</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>Polyglycerol + Condensed castor oil fatty acids $\xrightarrow[\text{H}^+]{\Delta}$</p> $\text{R}-[\text{-O-CH}_2\text{-CH-CH}_2\text{-}]_n\text{-OR}$ <p style="text-align: center;"> OR</p> <p>R = H or a fatty acyl group derived from polycondensed ricinoleic acid n = degree of polymerisation of glycerol (average value = 3)</p>
<p>3. Additivi</p> <p><i>Additives</i></p>	

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3.1	Conservanti <i>Preservatives</i>	Not added
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 100 cfu/g
5.	Residui del processo di lavorazione <p>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.</p> <p><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></p>	
5.1	1,4-Diossano 1,4-Dioxane	10 ppm maximum
5.2	Ossido di etilene <i>Ethylene oxide</i>	Under detection limits (1 ppm maximum)

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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>	Absent
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	Absent
5.10	Allergeni <i>Allergens according to the 7th Amendment to the Cosmetics Directive (ppm)</i>	Absent
5.11	Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Free glycerol: 2% maximum Ricinoleic acid: 1% maximum It contains dioxane (CMR2) as impurity technically unavoidable even working in GMP (10 ppm maximum)
6.	Tossicologia <i>Toxicology</i>	
6.1	Informazioni sulla tossicità acuta	LD50 on rats > 5000 mg/kg (literature data)

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<i>Information on acute toxicity</i>	
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	Product as it is = Not irritating (literature data)
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	Product as it is = Not irritating ((literature data)
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Not sensitizing (literature data)
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>	Used also as food additive. No significant results when ingested up to 1 g/day. Recommended maximum intake 2.6 mg/kg bw/die
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: inherently biodegradable (supplier data) 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>	From its structure and according to the information on similar products, it is not dangerous for the aquatic environment.
7.3 Altri <i>Others</i>	Log Pow > 5

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<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>Additional information (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 <i>Phtalates</i></p> <p>Glutine <i>Gluten</i></p> <p>Formaldeide <i>Formaldehyde (Formol)</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>Absent</p> <p>Absent</p> <p>Absent</p> <p>Absent</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.</p>
<p>8.1 Data di scadenza <i>Shelf life</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.</p>

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Data / *Date* 02/07/13

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***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.*