



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 07

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	SEBUMOL PGPR
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>	Polyglycerin polyricinoleate
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Polyglyceryl-3 Polyricinoleate: ~ 100%
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 CAS numbers 29894-35-7 and 235783-76-3 can be also used

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<p>1.8 Registrazioni (es. UE, USA, Giappone) - REACH - Certificazione</p> <p><i>Registration status (e.g. EU, USA, Japan) - REACH - Certification</i></p>	<p>For CAS 68936-89-0: IECSC (China, Chemicals), TCSI (Taiwan), TSCA (USA), NZIoC (New Zealand), AICS (Australia) and NDSL (Canada).</p> <p>For CAS 29894-35-7: IECSC (China, Chemicals), TCSI (Taiwan), NZIoC (New Zealand), PICCS (Philippines) and AICS (Australia).</p> <p>For CAS 235783-76-3: not listed.</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: 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 concentration > 0.1%.</p> <p>PO 65 (California law): see point 5.7.</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 (plant, animal, synthetic)</i></p>	<p>Vegetable.</p> <p>Origin: palm/palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia) or other vegetable oils for glycerol.</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 (general description)</i></p>	<p>Polyglycerol + Condensed castor oil fatty acids $\xrightarrow[\text{H}^+]{\Delta}$</p> $\text{R}-\left[\text{O}-\underset{\text{OR}}{\text{CH}_2}-\underset{\text{n}}{\text{CH}}-\text{CH}_2\right]-\text{OR}$

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	R = H or a fatty acyl group derived from polycondensed ricinoleic acid n = degree of polymerisation of glycerol (average value = 3)
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3. Additivi <i>Additives</i>	
3.1 Conservanti/Biocidi <i>Preservatives/Biocides</i>	Not added and not expected
3.2 Antiossidanti <i>Antioxidants</i>	Not added and not expected
3.3 Solventi <i>Solvents</i>	Not added and not expected
3.4 Sbiancanti <i>Bleaching agents</i>	Not added and not expected
3.5 Altri <i>Others</i>	Catalysts are fully removed after esterification process through basic water washing and earth filtration

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 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. <i>By-products</i> <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>	
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5.1	1,4-Diossano * <i>1,4-Dioxane *</i>	Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process, only water
5.2	Ossido di etilene * <i>Ethylene oxide *</i>	Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process, only water
5.3	Solventi residui <i>Residual solvents</i>	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 <i>Residual monomers</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5	Ammine <i>Amines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	Nitrosammine <i>Nitrosamines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
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>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.9	Acido dicloroacetico <i>Dichloroacetic acid</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.10	Allergeni <i>Allergens</i>	Based on information concerning the raw materials, production process and equipment used fragrance allergens as of EU Regulation 1223/2009 Annex III, No. 67-92 are not likely to be present.

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	Based on information concerning the raw materials, production process and equipment used food allergens as of EU Directive 2000/13/EC (as amended), Annex IIIa and Regulation (EU) 1169/2011, Annex II are not likely to be present.
5.11 Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Water: 1% maximum Free glycerol: 2% maximum Ricinoleic acid: 1% maximum Based on information concerning the raw materials, production process and equipment used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008 and (EC) 2019/831 are not likely to be present.

6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	LD50 on rats > 5000 mg/kg (literature data)
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

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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 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
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/TSE <i>BSE/TSE statement</i> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</i>	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. ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product. Based on information concerning the raw materials, production process and equipment used they are not likely to be present.

Ftalati
Phthalates

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)

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

VOC
VOC compounds

The product doesn't contain any of the substances that are classified as VOC according to "Ordonnance sur taxe d'incitation sur les composés organiques volatils (OCOV) du 12 novembre 1997" or according to Directive 2004/42/EC.

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 they are not likely to be present.

Aflatossine/Micotossine
Aflatoxines/Mycotoxines

Based on information concerning the raw materials, production process and equipment used aflatoxin/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

The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.

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<p>Irraggiamento/Ionizzazione <i>Radiation/Ionization</i></p> <p>Nanomateriali <i>Nanomaterials</i></p> <p>Idrocarburi Policiclici Aromatici <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Coloranti azoici <i>Azo dyes</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Convenzione CITES <i>CITES Convention</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>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>Based on information concerning the raw materials, production process and equipment used azo dyes 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>Not applicable, cultivated vegetable raw materials</p>
<p>8.1 Data di retest <i>Retest date</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 (acidity number).</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>Store at room temperature (15°C-25°C) in clean and aerated premises. Keep packaging unopened and undamaged.</p>

Data / *Date* 11/11/2021

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.