



**INFORMAZIONI TOSSICOLOGICHE**  
***TOXICOLOGICAL INFORMATION***

**Revisione n°**  
***Revision n° 07***

<b>1. Informazioni generali</b>  <i>General information</i>	
<b>1.1 Nome commerciale</b>  <i>Trade name</i>	<b>PROTELAN GC</b>
<b>1.2 Produttore/Fornitore</b> (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
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico)  <i>Raw material category</i> (e.g. anionic surfactant)	Anionic surfactant, moisturizing
<b>1.4 Nome chimico</b>  <i>Chemical name</i>	Glycine, N-coco acyl derivs., sodium salts
<b>1.5 Nome INCI (CTFA) Composizione</b>  <i>INCI (CTFA) name Composition</i>	Sodium Cocoyl Glycinate: 20% - 26% Aqua: to 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <i>EC (EINECS/ELINCS) no.</i>	291-350-5
<b>1.7 N° CAS</b>  <i>CAS no.</i>	90387-74-9

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<p><b>1.8 Registrazioni</b> (es. UE, USA, Giappone) - REACH - Certificazione</p> <p><i>Registration status</i> (e.g. EU, USA, Japan) - REACH - Certification</p>	<p>IECSC (China), TCS (Taiwan), NZIoC (New Zealand), AICS (Australia) and Europe.</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>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: 01-2120762969-31-0001</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>PO 65 (California law): see points 5.6 and 5.7.</p>
<p><b>2. Informazioni sulla produzione</b></p> <p><b>Information on production</b></p>	
<p><b>2.1 Origine della materia prima</b> (vegetale, animale, sintetica)</p> <p><i>Origin of starting material</i> (plant, animal, synthetic)</p>	<p>Glycine can be found in nature (approximately 11% of the proteins in oats, 6% in sunflower, and so on). Product used is synthetic.</p> <p>Cocoyl chloride is obtained starting from fatty acids that comes from cleavage and distillation of palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia).</p> <p>NaOH is mineral.</p>
<p><b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b></p> <p><i>Is the starting material derived from genetically modified organisms (GMO)?</i></p>	<p>No</p>
<p><b>2.3 Informazioni sul processo di produzione</b> (descrizione generale)</p> <p><i>Information on production process</i> (general description)</p>	<p>Schotten-Baumann reaction from cocoyl chloride and glycine and further drying process</p>
<p><b>3. Additivi</b></p> <p><i>Additives</i></p>	

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3.1	<b>Conservanti/Biocidi</b> <i>Preservatives/Biocides</i>	Not added and not expected
3.2	<b>Antiossidanti</b> <i>Antioxidants</i>	Not added and not expected
3.3	<b>Solventi</b> <i>Solvents</i>	Water
3.4	<b>Sbiancanti</b> <i>Bleaching agents</i>	Not added and not expected
3.5	<b>Altri</b> <i>Others</i>	Not added and not expected
4.	<b>Specifiche microbiologiche</b> <b>Microbiological specification</b>	
4.1	<b>Conta microbica totale (ufc/g)</b> <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g
5.	<b>Residui del processo di lavorazione</b> 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>	
5.1	<b>1,4-Diossano *</b> <i>1,4-Dioxane *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.2	<b>Ossido di etilene *</b> <i>Ethylene oxide *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

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5.3	<b>Solventi residui</b> <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	<b>Monomeri residui</b> <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	<b>Ammine</b> <i>Amines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	<b>Nitrosammine</b> <i>Nitrosamines</i>	Not expected but as product contains residue of glycine, it should not be used in cosmetic products in which N-nitroso compounds may be formed.
5.7	<b>Metalli pesanti</b> <i>Heavy metals</i>	Arsenic (As) < 2 ppm, Antimony (Sb) < 5 ppm, Lead (Pb) < 1 ppm, Cadmium (Cd) < 2 ppm, Mercury (Hg) < 1 ppm, Nickel (Ni) < 1 ppm, Chromium (Cr) < 2 ppm, Total heavy metals (as Fe) ≤ 10 ppm
5.8	<b>Acido monocloroacetico</b> <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	<b>Acido dicloroacetico</b> <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	<b>Allergeni</b> <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. 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.

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<b>5.11 Altri (e.g. CMR)</b>  <i>Others (e.g. CMR)</i>	Fatty acids: 2% maximum Sodium chloride: 4.5% - 6.0% Glycine: 1.5% 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 are not likely to be present.
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<b>6. Tossicologia</b>  <i>Toxicology</i>	
<b>6.1 Informazioni sulla tossicità acuta</b>  <i>Information on acute toxicity</i>	- Oral LD50 on rats > 2000 mg/kg bw (from literature, OECD 425, 1997) - Dermal LD50 on rats > 2000 mg/kg bw (from literature, OECD 402, 2010)
<b>6.2 Informazioni sull'irritazione cutanea</b>  <i>Information on skin irritation</i>	Skin irritation: not irritant (from literature, OECD 404, 1998)
<b>6.3 Informazioni sull'irritazione oculare</b>  <i>Information on irritation of the mucous membrane</i>	Product as it is sold = irritant due to pH value 5% solution = mildly irritant (from literature, OECD 205, 1997)
<b>6.4 Informazioni sulla sensibilizzazione</b>  <i>Information on sensitisation potential</i>	Not sensitizing (from literature, OECD 406, 1998)
<b>6.5 Informazioni sulla genotossicità</b>  <i>Information on gene toxicity</i>	Not mutagenic (from literature, OECD 471, 1997)
<b>6.6 Informazioni sull'assorbimento percutaneo</b>  <i>Information on percutaneous permeation</i>	Not evaluated
<b>6.7 Altri (e.g. NOAEL)</b>  <i>Others (e.g. NOAEL)</i>	NOAEL = 1000 mg/kg bw/day (from literature, OECD 421, 2013)

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<b>7. Ecotossicità</b> <i>Ecology</i>	
<b>7.1 Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Readily biodegradable according to CE 648/2004 (from literature)
<b>7.2 Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- LC50 on Danio rerio (zebra fish) &gt; 100 mg/l 96h (literature data, similar OECD 203, 2008)</li> <li>- EC50 on Daphnia magna (water flea) &gt; 100 mg/l 48h (literature data, Read Across, OECD 202, 2013)</li> <li>- EC50 on Algae (Scenedesmus subspicatus) = 15.4 mg/l 72h (literature data, Read Across, OECD 201, 2013)</li> </ul>
<b>7.3 Altri</b> <i>Others</i>	/

<b>8. Informazioni aggiuntive</b> (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.)	
<b>Dichiarazione BSE/TSE</b> <i>BSE/TSE statement</i>  <b>Dichiarazione test animali</b> <i>Non-animal testing declaration</i>  <b>Glicol eteri</b> <i>Glycol ethers</i>  <b>Ftalati, DINP (diisononyl phtalate)</b> <i>Phtalates, DINP (diisononil ftalato)</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/TSE free.</p> <p>ZSCHIMMER &amp; SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>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</p>

**Glutine**  
**Gluten**

present.

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 but please be aware this is an upiquitarius product.

**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 composes 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 it is 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**

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

<p><b>Coloranti azoici</b> <i>Azo dyes</i></p> <p><b>3-Benzilidene Canfora</b> <i>3-Benzylidene Camphor</i></p> <p><b>Ormoni, antibiotici e steroidi</b> <i>Hormones, antibiotics and steroids</i></p> <p><b>PBT/vPvB</b> <i>PBT/vPvB</i></p> <p><b>Materiale radioattivo</b> <i>Radioactive material</i></p> <p><b>Nanomateriali</b> <i>Nanomaterials</i></p> <p><b>Idrocarburi Policiclici Aromatici</b> <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p><b>Grado cosmetico</b> <i>Cosmetic grade</i></p> <p><b>Certificato Kosher</b> <i>Kosher certificate</i></p> <p><b>Convenzione CITES</b> <i>CITES Convention</i></p>	<p>present.</p> <p>Based on information concerning the raw materials, production process and equipment used azo dyes are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</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 any nanotechnology is used to produce it</p> <p>Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons 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>Yes</p> <p>Not applicable, cultivated vegetable raw materials</p>
<p><b>8.1 Data di retest</b> <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 (pH).</p>



**8.2 Stoccaggio**

***Storage recommendation***

At room temperature (20°-25°C), it is a clear to light turbid liquid, which may form a slight precipitate on storage. Protect from exposure to cold during transport and storage.

At temperature lower than 15°C product can become turbid/viscosize/frozen. 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.

Always homogenize before using.

Data / *Date* 15/01/2021

**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.

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