



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

**Revisione n°**  
***Revision n° 10***

<b>1. Informazioni generali</b>  <i>General information</i>	
<b>1.1 Nome commerciale</b>  <i>Trade name</i>	<b>PROTELAN AGE</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>	L-Glutamic acid, N-coco acyl derivs., disodium salts
<b>1.5 Nome INCI (CTFA)</b> <b>Composizione</b>  <i>INCI (CTFA) name</i> <i>Composition</i>	L-Glutamic acid, N-coco acyl derivs., disodium salts (at pH lower than 7.5, INCI name is Sodium Cocoyl Glutamate): 32.6% - 38.0% as dry matter  Aqua: to 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <i>EC (EINECS/ELINCS) no.</i>	269-085-1
<b>1.7 N° CAS</b>  <i>CAS no.</i>	68187-30-4

<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>TSCA (USA), NDSL (Canada), EINECS (Europe), PICCS (Philippines), ASIA-PAC (Asia-Pacific) 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 Cosmetic Ingredient list 2015 n° 07566.</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 n° 01-2119961354-36-0001.</p> <p>At pH lower than 7.5, INCI name is Sodium Cocoyl Glutamate.</p> <p>None of substances listed in the “candidate” list (12 January 2017) of substances of very high concern (SVHC) are contained in the product in a relevant amount.</p> <p>Heavy metals are listed on PO 65 (California law).</p> <p>EFFA: not applicable.</p> <p>Organic raw material: non applicable.</p> <p>Product is ECOCERT certified.</p> <p>Product is according to the Chapter of Chemical products and substances (Rev. 08, July 2015).</p> <p>ISO 16128: derived natural ingredient</p> <p>% natural origin: 88% (on 100% molecule of disodium cocoyl glutamate)</p>
<p><b>2. Informazioni sulla produzione</b></p> <p><i>Information on production</i></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>Vegetable (88%) and mineral (12%) origin.</p> <p>Glutamic acid is obtained through fermentation of glucose/molasses or from wheat.</p> <p>Cocoyl chloride is obtained starting from fatty acid that comes from cleavage and distillation of coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</p> <p>Propanediol is vegetable; it comes from corn sugar fermentation.</p> <p>NaOH is mineral.</p>

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	Product is manufactured in Italy.
<b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b>  <b>Is the starting material derived from genetically modified organisms (GMO)?</b>	No
<b>2.3 Informazioni sul processo di produzione</b> (descrizione generale)  <b>Information on production process</b> (general description)	Schotten-Baumann reaction between cocoyl chloride and disodium glutamate

<b>3. Additivi</b>  <b>Additives</b>	
<b>3.1 Conservanti/Biocidi</b>  <b>Preservatives/Biocides</b>	Not added and not expected
<b>3.2 Antiossidanti</b>  <b>Antioxidants</b>	Not added and not expected
<b>3.3 Solventi</b>  <b>Solvents</b>	Not added and not expected
<b>3.4 Sbiancanti</b>  <b>Bleaching agents</b>	Not added and not expected
<b>3.5 Altri</b>  <b>Others</b>	4.0% - 6.0% of Propanediol

<b>4. Specifiche microbiologiche</b>  <b>Microbiological specification</b>	
<b>4.1 Conta microbica totale (ufc/g)</b>  <b>Total viable count (colony-forming units/g)</b>	less than 10 ufc/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.

***By-products***

*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.*

<b>5.1</b>	<b>1,4-Diossano *</b>  <b><i>1,4-Dioxane *</i></b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.2</b>	<b>Ossido di etilene *</b>  <b><i>Ethylene oxide *</i></b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
<b>5.3</b>	<b>Solventi residui</b>  <b><i>Residual solvents</i></b>	Based on our actual knowledge of our production process, raw materials and equipment used, no solvent is used in the manufacturing process, only water
<b>5.4</b>	<b>Monomeri residui</b>  <b><i>Residual monomers</i></b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.5</b>	<b>Ammine</b>  <b><i>Amines</i></b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
<b>5.6</b>	<b>Nitrosammine</b>  <b><i>Nitrosamines</i></b>	Not expected but as product contains residue of glutamic acid, it should not be used in cosmetic products in which N-nitroso compounds may be formed.
<b>5.7</b>	<b>Metalli pesanti</b>  <b><i>Heavy metals</i></b>	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
<b>5.8</b>	<b>Acido monocloroacetico</b>  <b><i>Monochloroacetic acid</i></b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

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<b>5.9 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.
<b>5.10 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.
<b>5.11 Altri (e.g. CMR)</b> <i>Others (e.g. CMR)</i>	Sodium glutamate: 5% maximum Coconut acid: 3% maximum Sodium chloride: 4.0% - 5.5% 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.

<b>6. Tossicologia</b> <i>Toxicology</i>	
<b>6.1 Informazioni sulla tossicità acuta</b> <i>Information on acute toxicity</i>	- LD50 oral > 2000 mg/kg (OECD 401) - LD50 dermal > 5000 mg/kg bw/d (30%-36% a.i.) (OECD 402)
<b>6.2 Informazioni sull'irritazione cutanea</b> <i>Information on skin irritation</i>	- Product as it is = Not irritant (OECD 404) - 10% a.m. = Not irritant (our Flex Wash Test n° 990354FWT)
<b>6.3 Informazioni sull'irritazione oculare</b> <i>Information on irritation of the mucous membrane</i>	- Product as it is = Irritant, Category 11 (OECD 405) - Not irritant (our test, Red Blood Cell n° cmrbc)
<b>6.4 Informazioni sulla sensibilizzazione</b> <i>Information on sensitisation potential</i>	- Product as it is = Not sensitizin (OECD 406) - Occlusive applications, 5% a.m. = The product hasn't any sensitization danger (our test n° 37/99/02 made on Sodium Lauroyl Gutamate)

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6.5	<b>Informazioni sulla genotossicità</b> <i>Information on gene toxicity</i>	<ul style="list-style-type: none"> <li>- Product as it is = Negative (OECD 407)</li> <li>- Ames test = Not mutagenic (from literature)</li> </ul>
6.6	<b>Informazioni sull'assorbimento percutaneo</b> <i>Information on percutaneous permeation</i>	Not evaluated
6.7	<b>Altri (e.g. NOAEL)</b> <i>Others (e.g. NOAEL)</i>	NOAEL = 1200 mg/kg bw/day (OECD 408)  Phototoxicity and photosensitization: 40 healthy males, 0.1%-0.5%-1%-3%-5% aqueous solutions = No abnormality was found (from literature)

7.	<b>Ecotossicità</b> <i>Ecology</i>	
7.1	<b>Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (from literature and experimental data on Sodium Lauroyl Glutamate. Both the molecules have in fact similar chemical structure) Anaerobic: anaerobic biodegradable (Fraunhofer UMSICHT, 2006)
7.2	<b>Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> <li>- LC50 on Fish = 62.4 mg/l/96h (OECD 203)</li> <li>- EC50 on Daphnia = 49 mg/l/48h (OECD 202)</li> <li>- EC50 on Algae = 32.56 mg/l/72h (OECD 201)</li> <li>- NOEC chronic on Daphnia = 0.218 mg/l (OECD 211)</li> </ul>
7.3	<b>Altri</b> <i>Others</i>	/

8.	<b>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.)	

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## **Dichiarazione BSE**

### ***BSE statement***

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.

## **Dichiarazione test animali**

### ***Non-animal testing declaration***

ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.

## **Glicol eteri**

### ***Glycol ethers***

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

## **Ftalati, DINP (diisononyl phtalate)**

### ***Phtalates, DINP (diisononil ftalato)***

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 composes organiques volatils (OCOV) du 12 novembre 1997".

## **Pesticidi**

### ***Pesticides***

Based on information concerning the raw materials, production process and equipment used pesticides are expected to conform with concentration limits of the European Pharmacopeia; Section 2.8.13 "Pesticides residues", Table 2.8.13.-1

## **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 expected to conform with the concentration limits of Regulation (EC) 1881/2006 Annex, Section 2.1.5

**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 present.

**Coloranti azoici**  
**Azo dyes**

Based on information concerning the raw materials, production process and equipment used azo dyes are not likely to be present.

**Ormoni, antibiotici e steroidi**  
**Hormones, antibiotics and steroids**

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

**PBT/vPvB**  
**PBT/vPvB**

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

**Materiale radioattivo**  
**Radioactive material**

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.

**Nanomateriali**  
**Nanomaterials**

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

**Idrocarburi Policiclici Aromatici**  
**Polycyclic Aromatic Hydrocarbons (HAP)**

Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons are expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex

Benzo[a]pyrene	≤ 1 µg/kg
Dibenz[a,h]anthracene	≤ 1 µg/kg
Cyclopenta[cd]pyrene	)
Benzofluoranthene[b+j+k]	)
Indeno[1,2,3-cd]pyrene	) Σ ≤ 5 µg/kg



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<p><b>Certificato Kosher</b> <i>Kosher certificate</i></p> <p><b>Certificazione Vegan</b> <i>Vegan statement</i></p> <p><b>Convenzione CITES</b> <i>CITES Convention</i></p>	<p>Anthanthrene ) Benzo[b]naphtho[2,1-d]thiophene ) Benz[a]anthracene ) Chrysene + Triphenylene ) <math>\Sigma \leq 20 \mu\text{g/kg}</math> Benzo[ghi]perylene )</p> <p>Yes</p> <p>For the production and development of the product and raw materials no animal product, no animal coproduct and nor any animal derivatives were used.</p> <p>Not applicable, cultivated vegetable raw materials</p>
<p><b>8.1 Data di scadenza</b> <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>
<p><b>8.2 Stoccaggio</b> <i>Storage recommendation</i></p>	<p>Store at room temperature (15°C-25°C). At low temperature and on prolonged storage it 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. Homogenize before using. Don't keep at temperature higher than 40°C for a long time, product could become yellow.</p>
<p><b>8.3 Note</b> <i>Notes</i></p>	<p>Odour and colour can be a little bit more evident due to pH reasons. When product is brought to neutral pH, they become typical again. As high pH can increase odour of product as it is, it is advisable to prepare a 10% water solution, bring it to pH 7.0 or lower and smell. Odour becomes so typical. Please remember that preservatives, perfumes and colours must be added at pH lower than 7.5.</p>

Data / *Date* 07/12/17

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**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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