



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 02

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	PROTELAN AGE
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)	Anionic surfactant, moisturizing
1.4 Nome chimico <i>Chemical name</i>	L-Glutamic acid, N-coco acyl derivs., disodium salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name 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%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	269-085-1
1.7 N° CAS <i>CAS no.</i>	68187-30-4

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<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), 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 Regulatory Standard Version 2007.</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>SVHC: absent</p>
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<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 and mineral origin.</p> <p>Glutamic acid is obtained through fermentation of glucose/molasses or from wheat.</p> <p>Cocoyl chloride is obtained starting from coconut acid that comes from cleavage and distillation of coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil for Elaeis Guineensis (South East Asia). Palm oil is RSPO.</p> <p>Propanediol (Zemea™) is from vegetable origin. NaOH is mineral.</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>Schotten-Baumann reaction for cocoyl chloride and disodium glutamate</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>	4.0% - 6.0% of Propanediol (Zemea™)

4.	Specifiche microbiologiche Microbiological specification	
4.1	Conta microbica totale (ufc/g) <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/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>	Not expected
5.2	Ossido di etilene <i>Ethylene oxide</i>	Not expected

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5.3	Solventi residui <i>Residual solvents</i>	4.0% - 6.0% of Propanediol (Zemea™)
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 but as product contains residue of glutamic acid, it should not be used in cosmetic products in which N-nitroso compounds may be formed.
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 Cosmetics Directive and its amendments (ppm)</i>	Not expected
5.11	Altri (e.g. CMR) <i>Others (e.g. CMR)</i>	Sodium glutamate: 5% maximum Coconut acid: 3% maximum Sodium chloride: 3.5% - 5.5% CMR ingredients: absent
6.	Tossicologia <i>Toxicology</i>	
6.1	Informazioni sulla tossicità acuta	LD50 on mice (male) = 5.5/kg (from literature)

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	<i>Information on acute toxicity</i>	
6.2	Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	10% a.m. = Not irritant (our Flex Wash Test n° 990354FWT)
6.3	Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	Not irritant (our test, Red Blood Cell n° cmrbc)
6.4	Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Occlusive applications, 5% a.m. = The product hasn't any sensitization danger (our test n° 37/99/02)
6.5	Informazioni sulla genotossicità <i>Information on gene toxicity</i>	Ames test = Not mutagenic (from literature)
6.6	Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	Not evaluated
6.7	Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i>	NOAEL = 1200 mg/kg bw/day Phototoxicity and photosensitization: 40 healthy males, 0.1%-0.5%-1%-3%-5% aqueous solutions = No abnormality was found (from literature) Further information on MSDS

7.	Ecotossicità <i>Ecology</i>	
7.1	Degradabilità/Eliminazione <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	Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Zebra fish = 1940 mg/l 96h (OECD 203) (experimental data on Sodium Lauroyl Glutamate. Both the molecules have in fact similar chemical structure) - EC50 on Daphnia magna = 246 mg/l 48h (OECD 202) (experimental data on Sodium

	Lauroyl Glutamate. Both the molecules have in fact similar chemical structure) - EC50 on Algae > 1000 mg/l (OECD 209) (experimental data on Sodium Lauroyl Glutamate. Both the molecules have in fact similar chemical structure)
7.3 Altri <i>Others</i>	/

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 <i>BSE statement</i> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</i> Ftalati <i>Phtalates</i> Glutine <i>Gluten</i> Formaldeide <i>Formaldehyde (Formol)</i> VOC <i>VOC compounds</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 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 and not expected</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>

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Pesticidi <i>Pesticides</i> Nanomateriali <i>Nanomaterials</i> Grado cosmetico <i>Cosmetic grade</i> Radiazioni <i>Radiations</i>	Not expected from raw materials used 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 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. No radiations
8.1 Data di scadenza <i>Shelf life</i>	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. Homogenize before using.

Data / *Date* 23/10/13

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.