



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 06

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	PROTELAN LS 9011/C
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>	Glycine, N-methyl-, N-coco acyl derivs., sodium salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Sodium Cocoyl Sarcosinate: 29% min as dry matter Aqua: to 100%
1.6 N° EC (EINECS/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	263-193-2
1.7 N° CAS <i>CAS no.</i>	61791-59-1

<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>TSCA (USA), DSL (Canada), EINECS (Europa), ECL (Korea), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and AICS (Australia). 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° 07569.</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 status: pre-registered (registration in 2018).</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 and nitrosamines are listed on PO 65 (California law).</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 (plant, animal, synthetic)</i></p>	<p>Vegetable (63.5%), synthetic and mineral origin.</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 from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</p> <p>Sarcosine is synthetic and 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 (general description)</i></p>	<p>Schotten-Baumann reaction</p>

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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>	Water
3.4 Sbiancanti <i>Bleaching agents</i>	Not added and not expected
3.5 Altri <i>Others</i>	Not added and not expected
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 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 1,4-Diossano * <i>1,4-Dioxane *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.

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5.2	Ossido di etilene * <i>Ethylene oxide *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
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>	See 5.11
5.6	Nitrosammine <i>Nitrosamines</i>	The product doesn't contain any mono, di and tri ethanolamine. Nevertheless, being product obtained starting from sarcosine, it should not be used in cosmetic products in which N-nitroso compounds may be formed. We evaluate nitrosamine content in a random system and till now their value has always been under detection limits (50 ppb)
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. 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>	Coconut fatty acids: 2% maximum Sodium chloride: 0.5% maximum Free sarcosine: 4% 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.

6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	- LD50 on mice = 2175 mg/kg (from literature and CESIO classification) - LD50 on rats = 5000 mg/kg (from literature and CESIO classification)
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	10% a.m. on men (20 subjects) = Not irritant (our Flex Wash Test, Pavia, 1999 made on Sodium Lauroyl Sarcosinate)
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	- Product as it is = Irritant (CESIO data) - Product as it is = Moderately irritant (our RBC Test, protocol n° cm9011 made on Sodium Lauroyl Sarcosinate) - 5% a.m. = Not irritant (our Het Cam Test, Biolab, 1997 made on Sodium Lauroyl Sarcosinate)
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	- The product hasn't any sensitization danger (H. Shelanski e altri, The Toxicology of Sodium Lauroyl Sarcosinate, unpublished data) - On guinea pigs = The product hasn't any sensitization danger (Notice to EPA, 18 September 2002)
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	Ames test = None mutagenic effects (effectuated test, protocol n° 96/4097 made on Sodium Lauroyl Sarcosinate)

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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>	NOAEL = 30 mg/kg bw/day (subchronic, rat); 1000 mg/kg bw/day (24 m, chronic, rats, oral) Subchronic toxicity (2 years study on rats): No observed effect (Notice to EPA, 18 September 2002) Limits concentration > 34.5%: Acute Tox 2 H330 (Fatal if inhaled) ≤ 34.5%: Acute Tox 4 H332 (Harmful if inhaled) > 30% H315: Skin Irritation 2, H318 Eye Damage 1 ≥ 1% - ≤ 30%: H319 Eye Irritation 2
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-3i dated 04.10.05 made on Sodium Lauroyl Sarcosinate) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2026 for cosmetics and n° 16 for detergents)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	LC50 on Fish (rainbow trout) = 56 mg/l/96h (literature data)
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.) Additional information (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 reason.

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.

Diossido di zolfo e Solfiti

Sulphur dioxide and Sulphites

100 ppm maxium as SO₂

Glutine

Gluten

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

Formaldeide

Formaldehyde (Formol)

Not added. As sarcosine can be also obtained starting from formaldehyde, traces can't be excluded.

On the other hand, it is known from the literature that formaldehyde may be formed even out of high purity polyethylene oxide surfactants, if they are stored at temperatures above 8°C and if oxygen out of the air can penetrate into the material. (M. Bergh, K. Magnusson, J. Lars G. Nilsson, A. T. Karlberg, Contact Dermatitis, 1998, 39, 14-20 and M. Donbrow in: Nonionic Surfactants, Physical Chemistry, New York Surf. Sci. Series Vol. 23/1987, p. 1011-1073).

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 (aldrin & dieldrin, chlordane, DDT, DDE, TDE, entri, hexachlorobenzene, lindane)

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

APEO, cloroparaffine, composti organici alogenati, PCB, Diossina
APEOs, chloroparaffines, AOX, PCB, Dioxin

Mercaptani
Mercaptanes

Melamine
Melamine

Lattosio
Lactose

Aflatossine/Micotossine
Aflatoxines/Mycotoxines

Lattice
Latex

Nitrati e Nitriti
Nitrates and Nitrites

Amine aromatiche
Aromatic amines

3-Benzilidene Canfora
3-Benzylidene Camphor

Ormoni, antibiotici e steroidi
Hormones, antibiotics and steroids

PBT/vPvB
PBT/vPvB

Materiale radioattivo
Radioactive material

residues", Table 2.8.13.-1

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

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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

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

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

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

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

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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.

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<p>Nanomateriali <i>Nanomaterials</i></p> <p>Idrocarburi Policiclici Aromatici <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p> <p>Certificazione Vegan <i>Vegan statement</i></p> <p>Convenzione CITES <i>CITES Convention</i></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>Benzo[a]pyrene $\leq 1 \mu\text{g/kg}$ Dibenz[a,h]anthracene $\leq 1 \mu\text{g/kg}$ Cyclopenta[cd]pyrene) Benzofluoranthene[b+j+k]) Indeno[1,2,3-cd]pyrene) $\Sigma \leq 5 \mu\text{g/kg}$ Anthanthrene) Benzo[b]naphtho[2,1-d]thiophene) Benz[a]anthracene) Chrysene + Triphenylene) $\Sigma \leq 20 \mu\text{g/kg}$ Benzo[ghi]perylene)</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 (certificate n° 20782).</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>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>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>It is recommended to store the product at temperatures higher than 10°C. When stored at less than 10°C turbidity can appear. Indirect warming with stirring will restore the product to its former appearance. Overheating should be avoided. Don't keep at temperature higher than 40°C for a long time, product could become yellow.</p>

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8.3 Note <i>Notes</i>	<p>Sarcosinates can have some influences on blue colour.</p> <p>We have seen in past that colour FD&C Blue No. 1 (Acid Blue 9, CI 42090) isn't stable on light in the presence of sarcosinates. However its aluminium lack is stable.</p> <p>Colours D&C Green No. 5 and D&C Violet No. 2 if used in combination can produce a wide range of blues that aren't photodegradable in presence of sarcosinates.</p>
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Data / *Date* 09/05/17

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.*