



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

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

<b>1. Informazioni generali</b>  <b><i>General information</i></b>	
<b>1.1 Nome commerciale</b>  <b><i>Tradename</i></b>	<b>PROTELAN 1430</b>
<b>1.2 Produttore/Fornitore</b> (indirizzo, telefono, fax, contatto)  <b><i>Manufacturer/Supplier</i></b> (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 materia prima</b> (es. tensioattivo anionico)  <b><i>Rawmaterialcategory</i></b> (e.g. anionicsurfactant)	Anionic surfactant for cosmetic and detergency field
<b>1.4 Nome chimico</b>  <b><i>Chemical name</i></b>	Sodium N-methyl-N-(1-oxotetradecyl)aminoacetate
<b>1.5 Nome INCI (CTFA) Composizione</b>  <b><i>INCI (CTFA) name Composition</i></b>	Sodium MyristoylSarcosinate: 23.5% - 28.5% Sodium Chloride: 3.5% - 5.5% (facultative) Aqua: to 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <b><i>EC (EINECS/ELINCS) no.</i></b>	250-151-3
<b>1.7 N° CAS</b>  <b><i>CAS no.</i></b>	30364-51-3

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<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), AICS (Australia), IECSC (China), TCSI (Taiwan), NZIoC (New Zealand) and PICCS (Philippines).</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 status: 01-2120782997-28-0001.</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>ISO 16128: derived natural ingredient</p> <p>% natural origin: 68.8% (on 100% molecule), average value in the solution 17.9%</p>
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<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>Vegetable (68.8%), mineral and synthetic origin (31.2%).</p> <p>Myristic acid used for myristoyl chloride comes from cleavage and further distillation of palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia).</p> <p>Sarcosine is synthetic and 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</p>

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<b>3. Additivi</b> <i>Additives</i>	
<b>3.1 Conservanti/Biocidi</b> <i>Preservatives/Biocides</i>	Not added and not expected
<b>3.2 Antiossidanti</b> <i>Antioxidants</i>	Not added and not expected
<b>3.3 Solventi</b> <i>Solvents</i>	Water
<b>3.4 Sbiancanti</b> <i>Bleaching agents</i>	Not added and not expected
<b>3.5 Altri</b> <i>Others</i>	Not added and not expected
<b>4. Specifiche microbiologiche</b> <b>Microbiological specification</b>	
<b>4.1 Contamicrobicatotale (ufc/g)</b> <i>Total viable count (colony-forming units/g)</i>	less than 10 ufc/g
<b>5. 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>	
<b>5.1 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.

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5.2	<b>Ossido di etilene *</b> <i>Ethyleneoxide *</i>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.3	<b>Solventi residui</b> <i>Residualsolvents</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>Residualmonomers</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>	See 5.11
5.6	<b>Nitrosammine</b> <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	<b>Metalli pesanti</b> <i>Heavymetals</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	<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.
<b>5.11 Altri (e.g. CMR)</b>  <i><b>Others (e.g. CMR)</b></i>	Free fatty acids: 3% maximum Free sarcosine: 1% maximum Sodium chloride: 3.5% - 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><b>Toxicology</b></i>	<b>Data based on Sodium Lauroyl Sarcosinate. No indications about a negative toxicological effect resulting from the changing of fatty chain</b>
<b>6.1 Informazioni sulla tossicità acuta</b>  <i><b>Information on acute toxicity</b></i>	- LD50 on mice = 2175 mg/kg (from literature and CESIO classification) - LD50 on rats = 5000 mg/kg (from literature and CESIO classification)
<b>6.2 Informazioni sull'irritazione cutanea</b>  <i><b>Information on skinirritation</b></i>	10% a.m. on men (20 subjects) = Not irritant (our Flex Wash Test, Pavia, 1999)
<b>6.3 Informazioni sull'irritazione oculare</b>  <i><b>Information on irritation of the mucous membrane</b></i>	- Product as it is = Irritant (CESIO data) - Product as it is = Moderately irritant (our RBC Test, protocol n° cm9011) - 5% a.m. = Not irritant (our Het Cam Test, Biolab, 1997)
<b>6.4 Informazioni sulla sensibilizzazione</b>  <i><b>Information on sensitisationpotential</b></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)
<b>6.5 Informazioni sulla genotossicità</b>  <i><b>Information on gene toxicity</b></i>	Ames test = None mutagenic effects (effectuated test, protocol n° 96/4097)

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<b>6.6 Informazioni sull'assorbimento percutaneo</b> <i>Information on percutaneous permeation</i>	Not determined
<b>6.7 Altri (e.g. NOAEL)</b> <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) <b>Limits concentration</b> > 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
<b>7. Ecotossicità</b> <i>Ecology</i>	<b>Data based on Sodium Lauroyl Sarcosinate.</b> <b>Both molecules have in fact similar chemical structure</b>
<b>7.1 Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable, 100% after 28d (our test SAM2467-3i dated 04.10.05) Anaerobic: anaerobic biodegradable (99%, Ecolabel DID List n° 2026)
<b>7.2 Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	- LC50 on Fish (96h) = 107 mg/l (literature data) - EC50 on Daphnia (48h) = 29.7 mg/l (literature data) - EC50 on Algae (72h) = 86 mg/l (literature data) - IC50 on 30% sol. (3h) > 1000 mg/l (literature data)
<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.) <b>Additional information</b> <i>(For details on specification see enclosed instruction sheet; for details on labelling and</i>	

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

<i>classification see enclosed safety data sheet.)</i>	
<b>Dichiarazione BSE</b> <b><i>BSE statement</i></b>	<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>
<b>Dichiarazione test animali</b> <b><i>Non-animaltestingdeclaration</i></b>	<p>ZSCHIMMER &amp; SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p>
<b>Glicol eteri</b> <b><i>Glycolethers</i></b>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>
<b>Ftalati, DINP (diisononylphtalate)</b> <b><i>Phtalates, DINP (diisononil ftalato)</i></b>	<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 present.</p>
<b>Glutine</b> <b><i>Gluten</i></b>	<p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p>
<b>Formaldeide</b> <b><i>Formaldehyde (Formol)</i></b>	<p>Not added. As sarcosine can be also obtained starting from formaldehyde, traces can't be excluded.</p> <p>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).</p>
<b>VOC</b> <b><i>VOC compounds</i></b>	<p>The product doesn't contain any of the substances that are classified as VOC according to "Ordonnance sur taxed'incitation sur les composes organiquesvolatils (OCOV) du 12 novembre 1997" or according to Directive 2004/42/EC.</p>
<b>Fitofarmaci</b> <b><i>Plant protection products (aldrin&amp;dieltrin, chlordan, DDT, DDE, TDE, entri, hexachlorobenzene, lindane)</i></b>	<p>Based on information concerning the raw materials, production process and equipment used plant protection products are not likely to be present.</p>



# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

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

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**  
*Aromaticamines*

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

**3-Benzilidene Canfora**  
*3-Benzylidene Camphor*

Based on information concerning the raw materials, production process and equipment used it is 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**  
*Radioactivematerial*

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



<p><b>Idrocarburi Policiclici Aromatici</b> <i>PlycyclicAromaticHydrocarbons (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>Certificazione Vegan</b> <i>Vegan statement</i></p> <p><b>Convenzione CITES</b> <i>CITES Convention</i></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>For the production and development of the product and raw materials no animal product, no animal coproduct and nor any animal derivates were used.</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 date product can still be used but it must be rechecked (microbial contamination).</p>
<p><b>8.2 Stoccaggio</b> <i>Storage recommendation</i></p>	<p>It is recommended to store the product at room temperature (20°C-25°C). Protect from frost. At temperature lower than 15°C product can become turbid, solidify and separate. The material can be restored to its original appearance by indirect heating till room temperature. A slightly heating (50°C-60°C) under stirring will accelerate this process. Homogenize before using.</p>
<p><b>8.3 Note</b> <i>Notes</i></p>	<p>Sarcosinates can have some influences on blue colour. We have seen in past that colour FD&amp;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. Colours D&amp;C Green No. 5 and D&amp;C Violet No. 2 if used in combination can produce a wide range of blues that aren't photodegradable in presence of sarcosinates. Odour and colour can be a little bit more evident due to pH reasons. When product is brought to neutral pH, they become typical</p>

# ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

	<p>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>
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Data / *Date* 01/09/2020

**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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