ZSCHIMMER & SCHWARZ ITALIANA S.p.A.

Zschimmer & Schwarz Italiana – 13038 – Tricerro (VC) / ITALY

INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 00

1.	**Informazioni generali** ***General information***	
1.1	**Nome commerciale** ***Trade name***	**PROTELAN LS 9011/SL**
1.2	**Produttore/Fornitore** (indirizzo, telefono, fax, contatto) ***Manufacturer/Supplier*** *(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) ***Raw material category*** *(e.g. anionic surfactant)*	Anionic surfactant, moisturizing
1.4	**Nome chimico** ***Chemical name***	Sodium N-lauroylsarcosinate in aqueous solution (lower than 30%)
1.5	**Nome INCI (CTFA)** **Composizione** ***INCI (CTFA) name*** **Composition**	Sodium Lauroyl Sarcosinate: 29% min as dry matter Aqua: to 100%
1.6	**N° EC (EINECS-/ELINCS)** ***EC (EINECS/ELINCS) no.***	205-281-5
1.7	**N° CAS** ***CAS no.***	137-16-6

1.8	**Registrazioni** (es. UE, USA, Giappone) - REACh ***Registration status*** *(e.g. EU, USA, Japan) - REACh*	TSCA (USA), DSL (Canada), ENCS (Japan), AICS (Australia), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe) and ECL (Korea). 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 approvation. The product is according to the China Cosmetic Ingredient list 2014 n° 08413. REACh registration n° 01-2119527780-39-0001. None of substances listed in the "candidate" list of substances of very high concern (SVHC) are contained in the product in a relevant amount.

2.	**Informazioni sulla produzione** **Information on production**	
2.1	**Origine della materia prima** (vegetale, animale, sintetica) **Origin of starting material** (plant, animal, synthetic)	Vegetable (62.5%), synthetic and mineral origin. Lauroyl chloride is obtained starting from lauric acid that comes from cleavage and distillation of coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil for Elaeis Guineenis (South East Asia). Palm oil is from RSPO suppliers. Sarcosine is synthetic and NaOH is mineral.
2.2	**La materia prima deriva da organismi geneticamente modificati (OGM)?** **Is the starting material derived from genetically modified organisms (GMO)?**	No
2.3	**Informazioni sul processo di produzione** (descrizione generale) **Information on production process** (general description)	Schotten-Baumann reaction

3.	**Additivi** ***Additives***	

3.1	**Conservanti** ***Preservatives***	Not added and not expected
3.2	**Antiossidanti** ***Antioxidants***	Not added and not expected
3.3	**Solventi** ***Solvents***	Water
3.4	**Sbiancanti** ***Bleaching agents***	Not added and not expected
3.5	**Altri** ***Others***	Not added and not expected

4.	**Specifiche microbiologiche** **Microbiological specification**	
4.1	**Conta microbica totale (ufc/g)** ***Total viable count (colony-forming units/g)***	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.*

5.1	**1,4-Diossano *** ***1,4-Dioxane **	Not expected
5.2	**Ossido di etilene *** ***Ethylene oxide **	Not expected

5.3	**Solventi residui** ***Residual solvents***	Not expected
5.4	**Monomeri residui** ***Residual monomers***	Not expected
5.5	**Ammine** ***Amines***	See 5.11
5.6	**Nitrosammine** ***Nitrosamines***	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** ***Heavy metals***	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** **Monochloroacetic acid**	Not expected
5.9	**Acido dicloroacetico** ***Dichloroacetic acid***	Not expected
5.10	**Allergeni** **Allergens according to the Cosmetics Regulation 1223/2009/EC and its further amendments (ppm)** **(cereals containing gluten and products thereof, crustaceans and products thereof, eggs and products thereof, fish and products thereof, peanuts and products thereof, soybeans and products thereof, milk and dairy products (including lactose), nuts and nut products, celery and products thereof, mustard and products thereof,**	Not expected

	sesame seeds and products thereof, lupine, molluscs, maize and products thereof)	
5.11	**Altri (e.g. CMR)** ***Others (e.g. CMR)***	Lauric acid: 2% maximum Sodium chloride: 0.5% maximum Free sarcosine: 1% maximum CMR ingredients: absent

6.	**Tossicologia** ***Toxicology***	
6.1	**Informazioni sulla tossicità acuta** ***Information on acute toxicity***	- 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** ***Information on skin irritation***	10% a.m. on men (20 subjects) = Not irritant (our Flex Wash Test, Pavia, 1999)
6.3	**Informazioni sull'irritazione oculare** ***Information on irritation of the mucous membrane***	- 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)
6.4	**Informazioni sulla sensibilizzazione** ***Information on sensitisation potential***	- 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** ***Information on gene toxicity***	Ames test = None mutagenic effects (effectuated test, protocol n° 96/4097)
6.6	**Informazioni sull'assorbimento percutaneo** ***Information on percutaneous permeation***	Not determined
6.7	**Altri (e.g. NOAEL)** ***Others (e.g. NOAEL)***	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** ***Ecology***	
7.1	**Degradabilità/Eliminazione** ***Degradability/Elimination***	Aerobic: readily biodegradable, 100 % after 28d (our test SAM2467-3i dated 04.10.05) Anaerobic: anaerobic biodegradable (99%, Ecolabel DID List n° 16)
7.2	**Tossicità acquatica acuta** ***Acute aquatic toxicity***	- 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)
7.3	**Altri** ***Others***	/

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.)*	
	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.
Glicol eteri ***Glycol ethers***	Not added and not expected
Ftalati ***Phtalates***	Not added and not expected
Diossido di zolfo e Solfiti ***Sulphur dioxide and Sulphites***	100 ppm maxium as SO_2
Glutine ***Gluten***	Not added and not expected
Lattosio ***Lactose***	Not added and not expected
Formaldeide ***Formaldehyde (Formol)***	Not added. As sarcosine can be also obtained starting from formaldehyde, traces can't be excluded
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)***	The product doesn't contain any pesticides or pollutant substances (under detection limits).
APEO, cloroparaffine, composti organici alogenati, PCB, Diossina ***APEOs, chloroparaffines, AOX, PCB, Dioxin***	Not added and not expected
Mercaptani ***Mercaptanes***	The product doesn't contain mercaptanes
Melamine ***Melamine***	Not added and not expected
Lattosio ***Lactose***	Not added and not expected
Aflatossine/Micotossine ***Aflatoxines/Mycotoxines***	Not added and not expected
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***	Not added and not expected
3-Benzilidene Canfora ***3-Benzylidene Camphor***	Not added and not expected
Ormoni, antibiotici, steroidi e altri ingredienti (naturali o chimici) dannosi per le funzioni del corpo umano ***Hormones, antibiotics, steroids and other ingredients (natural or chemical) dangerous for the body functionality***	Not added and not expected
Irragiamento/Irradiamento ***Ionization/Radiation***	The product hasn't been treated by ionization and/or radiation
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 ***Plycyclic Aromatic Hydrocarbons (HAP)***	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 Anthanthrene) Benzo[b]naphtho[2,1-d]thiophene) Benz[a]anthracene) Chrysene + Triphenylene) Σ ≤ 20 μg/kg Benzo[ghi]perylene)
Coloranti azoici ***Azo dyes***	Not added and not expected
Minerali quali colombite-tantalite (coltan) e il suo derivato tantalio; cassiterite e il suo derivato stagno; wolframite e il suo derivato tungsteno; oro ***Minerals/ores such as columbite-tantalite (coltan) and its derivative tantalum; cassiterite and its derivative tin; wolframite and its derivative tungsten; gold***	Not added and not expected
Grado cosmetico ***Cosmetic grade***	The product is of cosmetic grade and it can be used in cosmetic products. It is according to Regulation 1223/2009, its annexes and its amendments. We are EFfCI GMP certified (certificate n° 20782)
Certificato Kosher ***Kosher certificate***	Yes

8.1 Data di scadenza ***Shelf life***	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.
8.2 Stoccaggio ***Storage recommendation***	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.
8.3 Note ***Notes***	Sarcosinates can have some influences on blue colour. 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. 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. 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.

Data / *Date* 05/10/15

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.*