

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

INFORMAZIONI TOSSICOLOGICHE TOXICOLOGICAL INFORMATION

Revisione n° Revision n° 01

1.	Informazioni generali General information						
1.1	Nome commerciale Trade name	ALCOOL C14/98					
1.2	Fornitore (indirizzo, telefono, fax, contatto) 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)	Non ionic surfactant					
1.4	Nome chimico Chemical name	1-Tetradecanol					
1.5	Nome INCI (CTFA) Composizione INCI (CTFA) name Composition	Myristyl Alcohol: > 98% Aqua: 0.1% maximum					
1.6	N° EC (EINECS-/ELINCS) EC (EINECS/ELINCS) no.	204-000-3					
1.7	N° CAS CAS no.	112-72-1					

1.8	Registrazioni (es. UE, USA, Giappone) - REACh Registration status (e.g. EU, USA, Japan) - REACh	TSCA (USA), DSL (Canada), ENCS (Japan), AICS (Australia), ECL (Korea), SWISS (Switzerland), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and EINECS (Europe). 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 2015 n° 05576. Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACh status: pre-registered. None of substances listed in the "candidate"
		Regulation 1107/2009. REACh status: pre-registered.

2.	Informazioni sulla produzione Information on production	
2.1	Origine della materia prima (vegetale, animale, sintetica) Origin of starting material (plant, animal, synthetic)	Vegetable origin. Fatty alcohol C14 is from vegetable origin. It comes from coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers). We are RSPO member (membership n° 2-0434-14-000-00)
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)	Trans-esterification, hydrogenation and distillation

3.	Additivi							
	Additives							
3.1	Conservanti/Biocidi	Not added and not expected						
	Preservatives/Biocides							
3.2	Antiossidanti	Not added and not expected						
	Antioxidants							
3.3	Solventi	Not added and not expected						
	Solvents							
3.4	Sbiancanti	Not added and not expected						
	Bleaching agents							
3.5	Altri	Not added and not expected						
	Others							
		<u> </u>						
4.	Specifiche microbiologiche							
4.	Specifiche microbiologiche Microbiological specification							
4.		less than 10 cfu/g						
	Microbiological specification	less than 10 cfu/g						
	Microbiological specification Conta microbica totale (ufc/g) Total viable count (colony-forming units/g) Residui del processo di lavorazione La presenza di tracce delle sostanze elencate in Allegato Direttiva 76/768/CEE) (incl. CMR cat. 1A, 1B e 2 sostanze presenza tecnicamente inevitabile lavorando in GMP e de 1223/2009. By-products The presence of traces of the substances listed in Annex	II del Regolamento No. 1223/2009 (che sostituisce la e contrassegnate con *) deve essere dimostrata come ve essere conforme all'Articolo 17 del Regolamento No. II of Regulation No. 1223/2009 (replaced Directive ked with *) shall be allowed provided that such presence is						
4.1	Microbiological specification Conta microbica totale (ufc/g) Total viable count (colony-forming units/g) Residui del processo di lavorazione La presenza di tracce delle sostanze elencate in Allegato Direttiva 76/768/CEE) (incl. CMR cat. 1A, 1B e 2 sostanze presenza tecnicamente inevitabile lavorando in GMP e de 1223/2009. By-products The presence of traces of the substances listed in Annex 76/768/EEC) (incl. cmr cat. 1A, 1B and 2 substances man technically unavoidable in good manufacturing practice ar	II del Regolamento No. 1223/2009 (che sostituisce la e contrassegnate con *) deve essere dimostrata come ve essere conforme all'Articolo 17 del Regolamento No. II of Regulation No. 1223/2009 (replaced Directive ked with *) shall be allowed provided that such presence is						

5.2	Ossido di etilene * Ethylene oxide *	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.3	Solventi residui Residual solvents	Hydrocarbons: 0.4% maximum Methanol: 100 ppm maximum
5.4	Monomeri residui Residual monomers	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5	Ammine Amines	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	Nitrosammine Nitrosamines	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
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	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.9	Acido dicloroacetico Dichloroacetic acid	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.10	Allergens	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)	Based on information concerning the raw materials, production process and equipment
	Others (e.g. CMR)	used CMR substances according to Annex VI of the CLP Regulation (EC) 1272/2008 are not
		likely to be present.

6.	Tossicologia Toxicology				
6.1	Informazioni sulla tossicità acuta Information on acute toxicity	Oral LD50 (rats, 0.8% in lotion) > 5 kg (CIR: CTFA 1980)			
6.2	Informazioni sull'irritazione cutanea Information on skin irritation	- Product as it is = Not irritant (CESIO labell indication) - 50% solution on rabbit = Irritant (Fettalkoh publication) - 25% solution on men = Not irrit (Fettalkohole publication) - 0.8% lotion, 4 weeks, 53 subjects = lirritant (CIR: CTFA 1981) - 0.8% lotion, patch 24h, 0.5 ml, lesioned a health skin, rabbit = Not irritant (CIR: CT 1981)			
6.3	Informazioni sull'irritazione oculare Information on irritation of the mucous membrane	- Product as it is = Not irritant (CESIO data) - 0.8% lotion, 0.1 ml, rabbit = Not irritant (CIR CTFA, 1981) - 3% antiperspirable formula, 0.1 ml with and without irrigation, rabbit = Light irritation in rinsed eye and moderate irritation in non rinsed eye (CIR: CTFA 1963)			
6.4	Informazioni sulla sensibilizzazione Information on sensitisation potential	0.1% lotion, Schwartz-Peck, patch 24h + challenge 24h, 106 subjects = Not sensitizing (CIR: CTFA 1981)			
6.5	Informazioni sulla genotossicità Information on gene toxicity	Ames test = Not mutagenic (literature data extrapolation and our knowledge on the product)			
6.6	Informazioni sull'assorbimento percutaneo Information on percutaneous permeation	Not determined			

6.7	Altri (e.g. NOAEL) Others (e.g. NOAEL)	Photo sensitization (0.10% in lotion, volunteers = Not photosensitizing (CIR, CT 1981) CIR Note: safe till 5%			
7.	Ecotossicità				
	Ecology				
7.1	Degradabilità/Eliminazione	Readily biodegradable (> 60%)			
	Degradability/Elimination				
7.2	Tossicità acquatica acuta	- LC50 on Fish (Carassius Auratus) > 10 mg/l			
	Acute aquatic toxicity	96h (literature data) - EC50 on Daphnia > 10 mg/l 48h (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 for cosmetic reasons.			
	Glicol eteri Glycol ethers	Not added and not expected			

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 Not added and not expected

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 Not added and not expected

Melamine Melamine Not added and not expected

Lattosio Lactose Not added and not expected

Aflatossine/Micotossine Aflatoxines/Mycotoxines Based on information concerning the raw materials, production process and equipment used aflotoxin/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 Not added and not expected

	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	Not added and not expected
	PBT/vPvB PBT/vPvB	Not added and not expected
	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 Plycyclic 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 $\leq 1~\mu g/kg$ Dibenz[a,h]anthracene $\leq 1~\mu g/kg$ Cyclopenta[cd]pyrene) Benzofluoranthene[b+j+k]) Indeno[1,2,3-cd]pyrene) $\Sigma \leq 5~\mu g/kg$ Anthanthrene) Benzo[b]naphtho[2,1-d]thiophene) Benz[a]anthracene) Chrysene + Triphenylene) $\Sigma \leq 20~\mu g/kg$ Benzo[ghi]perylene)
	Grado cosmetico Cosmetic grade	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).
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				•	place.	Protect	from	high
	Storage recommendation	tempe	ratu	res	•				

Data / Date 19/10/16

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.