



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 04

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	T-QUAT CTA CONC
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)	Cationic surfactant, conditioning agent
1.4 Nome chimico <i>Chemical name</i>	Cetrimonium chloride in water solution
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Cetrimonium Chloride: 27% - 30% Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	203-928-6 (and) 231-791-2
1.7 N° CAS <i>CAS no.</i>	112-02-7 (and) 7732-18-5

<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), ENCS (Japan), AICS (Australia), SWISS (Switzerland), PICCS (Philippines), ASIA-PAC (Asia-Pacific), EINECS (Europe), ECL (Korea), IECSC (China) and NZIoC (New Zealand).</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 Cosmetic Ingredient list 2015 n° 06886.</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: per-registered.</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>Methyl Chloride (point 5.11) and heavy metals are listed in PO65 (California law).</p> <p>Listed at n° 44 Annex VI of Cosmetic Regulation 1223/2009 (if used as preservative).</p> <p>For other information see point 6.7.</p>
<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>Fatty chain is from vegetable origin (RSPO producer).</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>Product is obtained starting from cetylamine added with methyl chloride</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.

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>	Free amine: 1.4% maximum
5.6	Nitrosammine <i>Nitrosamines</i>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present
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.

<p>5.11 Altri (e.g. CMR)</p> <p><i>Others (e.g. CMR)</i></p>	<p>Free amine: 1.4% maximum</p> <p>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.</p>
<p>6. Tossicologia</p> <p><i>Toxicology</i></p>	
<p>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<p>- LD50 (oral, rat) > 2000 mg/kg (calculated)</p> <p>- LD50 (dermal, rat) = 1760 mg/kg (calculated)</p>
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<p>Product as it is = Irritant (rabbit, OECD 404)</p>
<p>6.3 Informazioni sull'irritazione oculare</p> <p><i>Information on irritation of the mucous membrane</i></p>	<p>Product as it is = Corrosive (rabbit, OECD 405)</p>
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<p>Not sensitizing (guinea pig, OECD 406)</p>
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<p>None mutagenic effects (International Journal of Toxicology, Vol. 16, N° 3, 1997, 195-200)</p>
<p>6.6 Informazioni sull'assorbimento percutaneo</p> <p><i>Information on percutaneous permeation</i></p>	<p>Subchronic dermal toxicity (5/sex rabbits, 28 days, dose: 2ml/kg/day solution, from 0.5% w/v solution) = no deaths occurred. Slight to moderate erythema observed. No systemic toxicity observed (International Journal of Toxicology, Vol. 16, N° 3, 1997, 195-200)</p>
<p>6.7 Altri (e.g. NOAEL)</p> <p><i>Others (e.g. NOAEL)</i></p>	<p>NOAEL = 10 mg/kg x bw/d (12 m, chronic, rats, oral) (not be used when cetrimonium chloride is a preservative)</p> <p>Chromosomal aberration assay (CHC) = Negative (International Journal of Toxicology, Vol. 16, N° 3, 1997, 195-200)</p> <p>Cell transformation assay (Syrian golden hamster embryo cells) = Negative</p>

	<p>(International Journal of Toxicology, Vol. 16, N° 3, 1997, 195-200)</p> <p>Reproductive/developmental toxicity (20 rabbits, dose: 2ml/kg of 0.5%, 1%, 2% v/v of cetrimonium chloride, 100% active matter for 2 hr on days 7-18 of gestation) = The reproductive parameters and the incident of fetal malformations and developmental variations were not significantly different from controls (International Journal of Toxicology, Vol. 16, N° 3, 1997, 195-200)</p> <p>In the opinion of SCCS (Colipa n° P72) Cetrimonium Chloride is safe in rinse-off hair care products up to 2.5%, leave-on hair care products up to 1% and leave-on facial cream products as sum of cetrimonium and steartrimonium chloride up to 0.5%</p>
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7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	<p>Aerobic: readily biodegradable (> 60%, OECD 301 D) (Ecolabel DID List n° 2301)</p> <p>Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2301)</p>
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fish = 0,71 mg/l (OECD 203) - NOEC chronic on Fish = 0,032 mg/l/28d (U.S. EPA FIFRA 72-4(a)) - EC50 on Daphnia = 0,09 mg/l/48h (OECD 202) - EC10 on Daphnia = 0,0068 mg/l/21d (OECD 211) - EC50 on Algae = 0,18 mg/l/96h (OECD 201) - EC10 on Algae = 0,104 mg/l/72h (OECD 201)
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	
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<i>classification see enclosed safety data sheet.)</i>	
Dichiarazione BSE <i>BSE statement</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>
Dichiarazione test animali <i>Non-animal testing declaration</i>	<p>ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p>
Glicol eteri <i>Glycol ethers</i>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>
Ftalati, DINP (diisononyl phtalate) <i>Phtalates, DINP (diisononil ftalato)</i>	<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>
Glutine <i>Gluten</i>	<p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p>
Formaldeide <i>Formaldehyde (Formol)</i>	<p>Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.</p>
VOC <i>VOC compounds</i>	<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>
Pesticidi <i>Pesticides</i>	<p>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</p>
APEO, cloroparaffine, composti organici alogenati <i>APEOs, chloroparaffines, AOX</i>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>
Mercaptani <i>Mercaptanes</i>	<p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p>

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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 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

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

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

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
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
Polycyclic 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 $\leq 1 \mu\text{g/kg}$

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<p>Grado cosmetico Cosmetic grade</p>	<p>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)</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 (where is listed in Annex III n° 286 and Annex V n° 44). For all other purpose than preservative, it can be used till 2.5% for hair rinse-off products, 1% in leave-on hair products and 0.5% in face leave-on products. See legislation for more details. We are EFfCI GMP certified (certificate n° 20782).</p>
<p>8.1 Data di scadenza Shelf life</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 Storage recommendation</p>	<p>Store at room temperature; avoid high temperatures (more than 45°C and continuative) for long time (1 month maximum). Avoid low temperatures. At temperatures lower than 15°C the product can become turbid. The material can be restored to its original appearance by in direct heating at room temperature. This doesn't affect the quality of the product. If the product freeze, moderately heat it under agitation before the use. Always homogenize before use.</p>

Data / *Date* 23/05/17

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.