

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

INFORMAZIONI TOSSICOLOGICHE TOXICOLOGICAL INFORMATION

Revisione n° Revision n° 02

1.	Informazioni generali General information	
1.1	Nome commerciale Trade name	ZETEMULS HC PLUS
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 80811 Fax: +39 (0)161 801002 el.merlo@zschimmer-schwarz.com
1.3	Categoria della material prima (es. tensioattivo anionico) Raw material category (e.g. anionic surfactant)	Blend of non ionic and cationic surfactants, base for hair conditioners
1.4	Nome chimico Chemical name	1) Alcohols, C16-18 2) Glycerides, C16-18 mono- and di- 3) N-[3-(dimethylamino)propyl]stearamide 4) Myristyl lactate 5) Quaternary ammonium compounds, C20- 22-alkyltrimethyl, chlorides 6) Dodecan-1-ol 7) Tetradecan-1-ol
1.5	Nome INCI (CTFA) Composizione INCI (CTFA) name Composition	1) Cetearyl Alcohol: 20% - 30% 2) Glyceryl Stearate: 20% - 30% 3) Stearamidopropyl Dimethylamine: 10% - 20% 4) Myristyl Lactate: 10% - 20% 5) Behentrimonium Chloride: 5% - 10% 6) Lauryl Alcohol: 1% - 5% 7) Myristyl Alcohol: 0.5% - 3%

		·
1.6	N° EC (EINECS-/ELINCS) EC (EINECS/ELINCS) no.	1) 267-008-6 2) 286-490-9 3) 231-609-1 4) 215-350-1 5) 271-756-9 6) 203-982-0 7) 204-000-3
1.7	N° CAS CAS no.	1) 67762-27-0 2) 85251-77-0 3) 7651-02-7 4) 1323-03-1 5) 68607-24-9 6) 112-53-8 7) 112-72-1
1.8	Registrazioni (es. UE, USA, Giappone) - REACh - Certificazione Registration status (e.g. EU, USA, Japan) - REACh - Certification	IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Cetearyl Alcohol. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Glyceryl Stearate. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Stearamidopropyl Dimethylamine. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Myristyl Lactate. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), NDSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Behentrimonium Chloride. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Lauryl Alcohol. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Lauryl Alcohol. IECSC (China), NZIoC (New Zealand), TCSI (Taiwan), TSCA (USA), DSL (Canada), AICS (Australia), PICCS (Philippines) and KECI (Korea) for Myristyl Alcohol. Japanes have recently changed their system, so that publication in the Japanese list of approved ingredients is no longer necessary. Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009.

REACh registrations: n° 01-2120092297-47-xxxx for Cetearyl Alcohol, n° 01-2119495562-30-XXXX for Glyceryl Stearate, n° 01-2119979089-19-XXXX for Stearamidopropyl Dimethylamine, n° 01-2120747792-45-0003 for Myristyl Lactate, n° 01-2119484817-22-XXXX for Behentrimonium Chloride, n° 01-2119485976-15-XXXX for Lauryl Alcohol and n° 01-2119485910-33-XXXX for Myristyl Alcohol.

None of substances listed in the "candidate" list of substances of very high concern (SVHC) are contained in the product in a relevant amount.

PO 65 (California law): see points 5.6 and 5.7. Note: Behentrimonium chloride is permitted in Europe for use other than preservative till 5% in rinse off products, 3.0% in leave-on hair products and 1.0 % in leave on face products, that means 50% of the blend for rinse of products, 30% for leave on hair products and 10% for leave on face products (Regulation 286/2004)

2. Informazioni sulla produzione Information on production

2.1 Origine della materia prima

(vegetale, animale, sintetica)

Origin of starting material (plant, animal, synthetic)

Vegetable and synthetic origin.

Cetearyl Alcohol is vegetable. It is obtained through hydrolysis and further hydrogenation of oils extracted from palm oil from Elaeis Guineenis (Malaysia and Indonesia).

Glyceryl Sterate is vegetable. It is obtained through esterification of glycerin with stearic acid. Both are derived through hydrolysis of palm/palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia).

Stearamidopropyl Dimethylamine is vegetable and synthetic. Stearic acid comes from cleavage and further distillation of palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia). DMAPA is synthetic.

Myristyl Lactate is vegetable. Lactic acid is prepared by lactic acid fermentation of carbohydrates such as glucose, sucrose and lactose. Myristyl alcohol comes from palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia).

Behentrimonium Chloride is vegetable and synthetic. Reaction of Behenyl dimethylamine with methylchloride. Behenyl part is vegetable

		and derives from rapeseed oil. Lauryl Alcohol is vegetable. It comes from palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia). Myristyl Alcohol is vegetable. It comes from palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia).
2.2	La materia prima deriva da organismi geneticamente modificati (OGM)?	No
	Is the starting material derived from genetically modified organisms (GMO)?	
2.3	Informazioni sul processo di produzione (descrizione generale)	All components are blended and heated at 70°C-80°C till homogeneity. Flakes are then made.
	Information on production process (general description)	

3.	Additives	
3.1	Conservanti/Biocidi Preservatives/Biocides	Not added and not expected
3.2	Antiossidanti Antioxidants	Not added and not expected
3.3	Solvents	Not added and not expected
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)

less than 100 ufc/g

Total viable count (colony-forming units/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.

	technically unavoidable in good manufacturing practice at 1223/2009.	nd that it conforms with Article 17 of Regulation No.
5.1	1,4-Diossano * 1,4-Dioxane *	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
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	15 ppm maximum of methanol (present in cetearyl alcohol)
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	DMAPA: 10 ppm maximun Alkyldimethylamine: 0.5 % maximun
5.6	Nitrosammine Nitrosamines	Not expected but as product contains residue of dimethylamine, 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) < 20 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) Others (e.g. CMR)	Hydrocarbons (from cetearyl alcohol): 0.1% max Free glycerol (from glyceryl stearate): 1% max Methyl Chloride (from Behentrimonium Chloride): 10 ppm maximum Water: 2% 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 and (EC) 2019/831 are not likely to be present.

6.	Tossicologia Toxicology	
6.1	Informazioni sulla tossicità acuta	1) Cetearyl Alcohol
		- LD50 (oral, rat) > 5000 mg/kg (OECD 401)
	Information on acute toxicity	- LD50 (dermal, rabbit) > 5000 mg/kg (OECD
		402)
		- LC50 (inhalation, rat) > 0,375 mg/l (OECD
		403)
		2) Glyceryl Stearate
		- LD50 (oral) > 2000 mg/kg bw (from literature,
		OECD 401, 1999)
		- LD50 (inhalation) > 1,86 mg/kg bw (from
		literature, OECD 403, 1976)
		- LD50 (dermal) > 2000 mg/kg bw (from
		literature, OECD 403, 1976)

		3) Stearamidopropyl Dimethylamine - LD50 (oral) > 2000 mg/kg (OECD 423, literature data) - LC50 (inhalation) < 1 mg/l (OECD 203) 4) Myristyl lactate - LD50 (oral) > 2000 mg/kg - LD50 (dermal) > 2000 mg/kg 5) Behentrimonium Chloride - LD50 (oral) > 5000 mg/kg - LD50 (dermal) > 5000 mg/kg - LC50 (inhalation) > 0,375 mg/l 6) Lauryl Alcohol - LD50 (dermal) > 5000 mg/kg - LC50 (inhalation) > 0,375 mg/l 7) Myristyl Alcohol - LD50 (oral) > 5000 mg/kg - LD50 (oral) > 5000 mg/kg - LD50 (inhalation) > 0,375 mg/l
6.2	Informazioni sull'irritazione cutanea Information on skin irritation	1) Cetearyl Alcohol Not irritant (from literature data) 2) Glyceryl Stearate Not irritant (from literature OECD 404, 1999) 3) Stearamidopropyl Dimethylamine Not irritant (literature data, OECD 404 on rabbit), Not irritant (in vitro, literature data, OECD 439) 4) Myristyl lactate Non irritating (literature data, OECD 404, 1971) 5) Behentrimonium Chloride Product as it is: irritant (literature data) 6) Lauryl Alcohol Product as it is: Not irritant (literature data) 7) Myristyl Alcohol Product as it is = Not irritant (CESIO labelling indication)
6.3	Informazioni sull'irritazione oculare Information on irritation of the mucous membrane	1) Cetearyl Alcohol Irritant (from literature data) 2) Glyceryl Stearate Not irritant (from literature OECD 405, 1999) 3) Stearamidopropyl Dimethylamine Irritant (rabbit, OECD 405, literature data). 4) Myristyl lactate Non irritating (literature data, rabbits, 1978) 5) Behentrimonium Chloride Product as it is: irritant (literature data) 6) Lauryl Alcohol Irritant (literature data) 7) Myristyl Alcohol Product as it is = Not irritant (literature data)

6.4	Informazioni sulla sensibilizzazione	1) Cetearyl Alcohol
	Information on sensitisation potential	Not sensitizing (from literature data and our knowledge on the product) 2) Glyceryl Stearate Not Sensitising (from literature OECD 406, 1988) 3) Stearamidopropyl Dimethylamine Not sensitizing (OECD 406, literature data) 4) Myristyl lactate Non sensitizing (literature data, in-vitro test, 1976) 5) Behentrimonium Chloride Not sensitizing (from literature data) 6) Lauryl Alcohol Not sensitizing (from literature data) 7) Myristyl Alcohol Not sensitizing (from literature data)
6.5	Informazioni sulla genotossicità	Cetearyl Alcohol Amos tost on bacteria – Negative (literature)
	Information on gene toxicity	Ames test on bacteria = Negative (literature data) 2) Glyceryl Stearate Ames test = Not mutagenic (from literature OECD 474, 1985) 3) Stearamidopropyl Dimethylamine Not mutagenic (literature data) 4) Myristyl lactate None mutagenic effect (literature data, OECD 471) 5) Behentrimonium Chloride Not mutagenic effect (literature data) 6) Lauryl Alcohol Ames test = Negative (OECD 471, literature data) 7) Myristyl Alcohol Not mutagenic effect (literature data)
6.6	Informazioni sull'assorbimento percutaneo	Not determined
	Information on percutaneous permeation	
6.7	Altri (e.g. NOAEL) Others (e.g. NOAEL)	1) Cetearyl Alcohol NOAEL > 1000 mg/kg x bw/d (rat, repeated dose); NOAEL for reproduction = 2000 mg/kg (rat, OECD 422);
		NOAEL for growth = 2000 mg/kg (rat, OECD 422) 2) Glyceryl Stearate NOAEL (oral) = 5000 mg/kg x bw/d (from literature 408, 1992)

NOAEL (dermal) = 2000 mg/kg x bw/d (from
literature, 1980)
3) Stearamidopropyl Dimethylamine
· · · · · · · · · · · · · · · · · · ·
NOAEL (Reproduction) = 200 mg/kg bw/d,
literature data
4) Myristyl lactate
NOEL > = 500 mg/kg bw/day (literature data,
rabbits, 1982)
5) Behentrimonium Chloride
NOAEL (28 day ora/study) = 10 mg/kg bw,
literature data)
6) Lauryl Alcohol
NOAEL (oral, rat) = 2000 mg/kg (OECD 422)
Not cancerogenic (literature data)
7) Myristyl Alcohol
; , , , ,
NOAEL (Reproduction) (1243 mg/kg bw/d
female and 127 mg/kg bw/d male)

7.	Ecotossicità	
	Ecology	
7.1	Degradability/Elimination Degradability/Elimination	1) Cetearyl Alcohol Aerobic: readily biodegradable (Ecolabel DID List n° 34) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 34) 2) Glyceryl Stearate From information on similar products (e.g. glycol distearate from DID List of Ecolabel Legislation n° 185) the product can be regarded as aerobic/anaerobic biodegradable. 3) Stearamidopropyl Dimethylamine Readily biodegradable 4) Myristyl lactate Readily biodegradable (from literature, Read Across data) 5) Behentrimonium Chloride Biodegradable > 60% (OECD 301B, literature data) 6) Lauryl Alcohol 69% - 83% (OECD 301B); Readily biodegradable (literature data) 7) Myristyl Alcohol Readily biodegradable
7.2	Tossicità acquatica acuta	1) Cetearyl Alcohol - CL50 on Fish > 0,4 mg/l/96h (OECD 203)
	Acute aquatic toxicity	- CE50 on Daphnia > 70 mg/l/48h (OECD 202) - CE50 on Algae = 250 mg/l/72h (OECD 201) - NOEC (long term) (Daphnia) > 0,98 mg/l

(OECD 202) 2) Glyceryl Stearate - Fish (Cyprinus Carpio): Toxic Dose > 100 mg/kg (V.S. Fish. Wildl. Serv., Sp. Sci. Rep Fish. No 471 Washington, DC:124) - Bacterial acute toxicity: EC0 > 100 mg/l (from information on similar products) 3) Stearamidopropyl Dimethylamine - CL50 on Fish < 1 mg/l/96h (OECD 203) - CE50 on Daphnia 0,381 mg/l/48h (OECD 202) - CE50 on Algae 0,14 mg/l/72h (OECD 201) - NOEC (long term) (Fish) 0,316 mg/l (OECD 212) - NOEC (long term) (Daphnia) 0,2 mg/l (OECD 211) - NOEC (long term) (Algae) 0,0316 mg/l (OECD 201) 4) Myristyl lactate - CL50 on Fish 0,26 mg/l/96h - CE50 on Daphnia 0,36 mg/l/48h - CE50 on Algae 0,09 mg/l/96h - NOEC (long term) (Fish) 0,01 mg/l - NOEC (long term) (Daphnia) 0,086 mg/l - NOEC (long term) (Daphnia) 0,086 mg/l - NOEC (long term) (Algae) 0,07 mg/l
- CL50 on Fish 3,5 mg/l/96h (OECD 203) - CE50 on Daphnia 1,4 mg/l/48h (OECD 202) - CE50 on Algae 3,4 mg/l/72H (OECD 201) - CE10 on Algae 0,78 mg/l/72h (OECD 201) - NOEC (long term) (Fish) 0,24 mg/l (OECD 212) - NOEC (long term) (Daphnia) 0,13 mg/l (OECD 211) 6) Lauryl Alcohol - CL50 on Fish 1,01 mg/l/96h - CE50 on Daphnia 0,77 mg/l/48h (OECD 202) - CE50 on Algae 0,66 mg/l/72h (OECD 201) 7) Myristyl Alcohol - CL50 on Fish > 1 mg/l/96h (OECD 203) - CE50 on Daphnia 3,2 mg/l/48h (OECD 202) - CE50 on Algae > 10 mg/l/72h (OECD 201) - NOEC (long term) (Daphnia) 0,0016 mg/l (OECD 211)
/

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

allogata \	
Additional information (For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)	
Dichiarazione BSE/TSE BSE/TSE 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/TSE free.
Dichiarazione test animali Non-animal testing declaration	ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product or on its ingredients 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.
Glutine Gluten	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
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" or according to Directive 2004/42/EC.
Fitofarmaci Plant protection products	Based on information concerning the raw materials, production process and equipment used plant protection products are not likely to be present
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

Melamine Melamine

Lattosio Lactose

Aflatossine/Micotossine Aflatoxines/Mycotoxines

Lattice Latex

Nitrati e Nitriti Nitrates and Nitrites

Amine aromatiche Aromatic amines

Coloranti azoici Azo dyes

Ormoni, antibiotici e steroidi Hormones, antibiotics and steroids

PBT/vPvB PBT/vPvB

Materiale radioattivo Radioactive material

Nanomateriali Nanomaterials

Idrocarburi Policiclici Aromatici
Plycyclic Aromatic Hydrocarbons (HAP)

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 they are not likely to be present.

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 aflotoxin/mycotoxin are not likely to be present

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 azo dyes are not likely to be present.

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 they are not likely to be present.

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.

The product doesn't contain any nanomaterials according to the new European Cosmetic Regulation 1223/2009/EC and 1881/2019/EC and any nanotechnology is used to produce it

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

	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.
	Certificato Kosher Kosher certificate	Yes
	Convenzione CITES CITES Convention	Not applicable, cultivated vegetable raw materials
8.1	Data di retest Retest date	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).
8.2	Stoccaggio Storage recommendation	Store at room temperature (15°C-25°C). Do not store at temperature higher than 40°C. Protect from heat and humidity.

Data / Date 23/04/2021

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.