



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 05

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	SULFETAL MG - HE
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)	Anionic surfactant
1.4 Nome chimico <i>Chemical name</i>	Sulfuric acid, mono-C12-14-alkyl esters, magnesium salts
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i>	Magnesium Lauryl Sulfate: 24% - 27% Benzyl Alcohol: 0.65% - 0.95% Dehydroacetic Acid: 0.04% - 0.1% Aqua: to 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	292-222-1 (alternative 221-450-6)
1.7 N° CAS <i>CAS no.</i>	90583-23-6 (alternative 3097-08-3)

<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) and ECL (Korea).</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° 08345.</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 registration: pre-registered (registration 31.05.2018)</p> <p>None of substances listed in the "candidate" list (20 June 2016) of substances of very high concern (SVHC) are contained in the product in a relevant amount.</p> <p>Heavy metals are listed on PO 65 (California law).</p> <p>Product is ECOCERT/COSMOS certified.</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>Vegetable, mineral and synthetic origin.</p> <p>Fatty alcohol is from vegetable origin. It comes from coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia) (RSPO suppliers). Oil is then hydrolyzed and acid so obtained hydrogenated in order to obtain fatty alcohol.</p> <p>We are RSPO member (membership n° 2-0434-14-000-00).</p> <p>MgO is mineral and Sulfur and preservatives are synthetic.</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>Information on production process (general description)</p>	<p>S burns in presence of air giving SO₂</p> $\text{S} + \text{O}_2 \text{ (from air)} \longrightarrow \text{SO}_2$ <p>SO₂ is converted in SO₃</p> $\text{SO}_2 + \frac{1}{2} \text{O}_2 \text{ (from air)} \longrightarrow \text{SO}_3$ <p>SO₃ reacts with fatty alcohol giving an acidic intermediate that is then neutralized with MgO</p> $\text{SO}_3 + \text{ROH} \longrightarrow \text{ROSO}_3\text{H}$ <p>Control: acidity number</p> $2\text{ROSO}_3\text{H} + \text{MgO} \longrightarrow (\text{ROSO}_3)_2^- \text{Mg}^{2+} + \text{H}_2\text{O}$ <p>Control: according to specifications</p>
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<p>3. Additivi</p> <p><i>Additives</i></p>	
<p>3.1 Conservanti/Biocidi</p> <p><i>Preservatives/Biocides</i></p>	<p>0.8% - 1.0% of a blend made of Benzyl Alcohol (≥ 75%), Dehydroacetic Acid (5%-10%) and Water (1%-5%)</p>
<p>3.2 Antiossidanti</p> <p><i>Antioxidants</i></p>	<p>Not added</p>
<p>3.3 Solventi</p> <p><i>Solvents</i></p>	<p>Water to 100%</p>
<p>3.4 Sbiancanti</p> <p><i>Bleaching agents</i></p>	<p>Not added</p>
<p>3.5 Altri</p> <p><i>Others</i></p>	<p>Citric acid can be used to regulate pH</p>

<p>4. Specifiche microbiologiche</p> <p>Microbiological specification</p>	
<p>4.1 Conta microbica totale (ufc/g)</p> <p><i>Total viable count (colony-forming units/g)</i></p>	<p>Less than 10 cfu/g</p>

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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 <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 * 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	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 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 <i>Dichloroacetic acid</i>	<p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p>
5.10 Allergeni <i>Allergens</i>	<p>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.</p> <p>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) <i>Others (e.g. CMR)</i>	<p>Magnesium sulfate: 1% maximum Unsulfated fatty alcohol: 1% 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>
6. Tossicologia <i>Toxicology</i>	
6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i>	<p>LD50 (on rats) > 2000 mg/kg (CIR: Product safety Labs 1980)</p>
6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i>	<ul style="list-style-type: none"> - Patch test on 2% active matter = It isn't irritant (Paerfumerie und Kosmetik 1,28-32, 1995) - From light to strong irritant according to concentration and application way (CIR data)
6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i>	<ul style="list-style-type: none"> - Draize test, 2% sol. = Lightly irritant after 1 hour and not irritant after 7 days (J. of the American College of Toxicology, Vol. 2, N° 7, 1983) - Draize test, 10% sol. = Moderately irritant after 24 hours and lightly irritant after 7 days (J. of the American College of Toxicology, Vol. 2, N° 7, 1983) - Draize test, 20% sol. = Strong irritant after 1 day and lightly irritant after 7 days (J. of the

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	American College of Toxicology, Vol. 2, N° 7, 1983)
6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i>	Kligman & Magnusson test = Not sensitizer (J. of the American College of Toxicology, Vol. 2, N° 7, 1983)
6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i>	- Ames test = None mutagenic effect (our test protocol n° MUTMG) - Ames test = Non mutagenic (J. of the American College of Toxicology, Vol. 2, N° 7, 1983)
6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i>	Not determined
6.7 Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i>	NOAEL = 300 mg/kg x bw/d (28 die, subacute, rats, oral) (value based on Sodium Lauryl Sulfate. Both molecules have in fact similar chemical structure)
7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467-4i dated 04.10.05 made on Sodium Lauryl Sulfate. Both molecules have in fact similar chemical structure) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2542)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	- LC50 on Fish = 1 - 100 mg/l/96h (from literature data) - EC50 on Daphnia = 1 - 100 mg/l/48h (from literature data)
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.)	

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Additional information <i>(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.)</i>	
<p>Dichiarazione BSE <i>BSE statement</i></p> <p>Dichiarazione test animali <i>Non-animal testing declaration</i></p> <p>Glicol eteri <i>Glycol ethers</i></p> <p>Ftalati, DINP (diisononyl phthalate) <i>Phthalates, DINP (diisononil ftalato)</i></p> <p>Glutine <i>Gluten</i></p> <p>Formaldeide <i>Formaldehyde (Formol)</i></p> <p>VOC <i>VOC compounds</i></p> <p>Pesticidi <i>Pesticides</i></p> <p>APEO, cloroparaffine, composti organici alogenati <i>APEOs, chloroparaffines, AOX</i></p> <p>Mercaptani <i>Mercaptanes</i></p> <p>Melamine <i>Melamine</i></p>	<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> <p>ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.</p> <p>Not added and not expected</p> <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> <p>Not added and not expected</p> <p>Based on information concerning the raw materials, production process and equipment used formaldehyde is not likely to be present.</p> <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> <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> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>Not added and not expected</p> <p>Not added and not expected</p>

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

Polycyclic Aromatic Hydrocarbons (HAP)

Not added and not expected

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

The product doesn't contain natural latex and that natural latex is not used/produced in any step of the production process.

Not added and not expected

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.

Not added and not expected

Not added and not expected

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 any nanotechnology is used to produce it

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

Dibenz[a,h]anthracene $\leq 1 \mu\text{g/kg}$

Cyclopenta[cd]pyrene)

Benzo[fluoranthene[b+j+k])

Indeno[1,2,3-cd]pyrene) $\Sigma \leq 5 \mu\text{g/kg}$

Anthanthrene)

Benzo[b]naphtho[2,1-d]thiophene)

Benz[a]anthracene)

Chrysene + Triphenylene) $\Sigma \leq 20 \mu\text{g/kg}$

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<p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p>	<p>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. We are EFfCI GMP certified (certificate n° 20782).</p> <p>Yes</p>
<p>8.1 Data di scadenza <i>Shelf life</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 time, product can be used but it must be rechecked. According to temperature, pH can decrease. This doesn't affect the quality of the product till pH is higher than 3.0. With time a yellowing process due to preservative can develop. This doesn't affect quality of product. The colour is guaranteed only at the production moment.</p>
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>It is recommended to store the product at temperatures higher than 15°C (that is 20°C-30°C). At low temperatures and on prolonged storage the product can become turbid. The material can be restored to its original appearance by in direct heating (40°C-50°C) and stirring. This doesn't affect the quality of the product. Overheating should be avoided. Possible precipitate can be found on the bottom of container but it is typical of the product without affecting its quality. Always homogenize before using.</p>

Data / *Date* 09/08/16

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.