



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 11

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| 1. Informazioni generali <i>General information</i> | |
| 1.1 Nome commerciale <i>Trade name</i> | SULFETAL LA - 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(even numbered)-alkyl esters, ammonium salts |
| 1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name Composition</i> | Ammonium Lauryl Sulfate: 26.5% - 27.5% Aqua: to 100% Preservative are listed at point 3.1. Benzyl alcohol is one of the 26 allergens and must be listed on label if higher than 0,01% rinse off products and 0,001% for leave on products |
| 1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i> | List number: 931-558-1 Previous EC: 292-209-0 Alternative: 218-793-9 |

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| 1.7 N° CAS CAS no. | Previous CAS: 90583-11-2 Alternative: 2235-54-3 |
| 1.8 Registrazioni (es. UE, USA, Giappone) - REACh - Certificazione Registration status (e.g. EU, USA, Japan) - REACh - Certification | For CAS 90583-11-2: KECI (Korea), NZIoC (New Zealand) and IECSC (China). For CAS 2235-54-3: IECSC (China), TSCA (USA), NZIoC (New Zealand), TCSI (Taiwan), KECI (Korea), DSL (Canada), AICS (Australia) and PICCS (Philippines). 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 registration n° 01-2119519217-42-0006. 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 point 5.7. Product is ECOCERT/COSMOS certified. |
| 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. Fatty alcohol is from vegetable origin. It comes mainly from palm kernel oil from Elaeis Guineensis (Malaysia and Indonesia). Oil is then hydrolyzed and acid so obtained hydrogenated in order to obtain fatty alcohol. NH ₃ and Sulfur are synthetic. |
| 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) | S burns in presence of air giving SO ₂ $S + O_2 \text{ (from air)} \longrightarrow SO_2$ SO ₂ is converted in SO ₃ $SO_2 + \frac{1}{2} O_2 \text{ (from air)} \longrightarrow SO_3$ |

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| | <p>SO₃ reacts with fatty alcohol giving an acidic intermediate that is then neutralized with NH₃</p> $\text{SO}_3 + \text{ROH} \longrightarrow \text{ROSO}_3\text{H}$ <p>Control: acidity number</p> $\text{ROSO}_3\text{H} + \text{NH}_3 \longrightarrow (\text{ROSO}_3)^- \text{NH}_4^+$ <p>Control: according to specifications</p> |
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| 3. Additivi <i>Additives</i> | |
| 3.1 Conservanti/Biocidi <i>Preservatives/Biocides</i> | 0.5% - 0.8% of a blend made of Benzyl Alcohol (≥ 75%), Dehydroacetic Acid (0,05%-1%) and Water (1%-5%) |
| 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> | Citric acid can be used to regulate pH |

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

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| <p>5. Residui del processo di lavorazione</p> <p>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.</p> <p><i>By-products</i></p> <p><i>The presence of traces of the substances listed in Annex II of Regulation No. 1223/2009 (replaced Directive</i></p> | |
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| <i>76/768/EEC) (incl. cmr cat. 1A, 1B and 2 substances marked with *) shall be allowed provided that such presence is technically unavoidable</i> | | |
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| 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 or, if used, is removed in a final step of the manufacturing process |
| 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> | Based on information concerning the raw materials, production process and equipment used they are not likely to be present. |
| 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. |

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| | 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) <i>Others (e.g. CMR)</i> | Unsulfated fatty alcohol: 1% maximum Ammonium sulfate: 1% maximum Ammonium chloride: 0.5% 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 <i>Toxicology</i> | |
| 6.1 Informazioni sulla tossicità acuta <i>Information on acute toxicity</i> | <ul style="list-style-type: none"> - LD50 oral on rats > 500 < 2000 mg/kg/bw (from literature, Read Across, EU Method B.1 bis, 1994) - LD50 dermic on rats > 2000 mg/kg/bw (from literature, Read Across, OECD 202, 2012) |
| 6.2 Informazioni sull'irritazione cutanea <i>Information on skin irritation</i> | <ul style="list-style-type: none"> - From light irritant to strong irritant according to concentration and application way (CIR data) - Skin Irritation on rabbits: irritant (from literature, Read Across, OECD 404, 1976) |
| 6.3 Informazioni sull'irritazione oculare <i>Information on irritation of the mucous membrane</i> | <ul style="list-style-type: none"> - Draize test, sol. 2% = 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, sol. 10% = Medium irritant after 24 hours and light irritant after 7 days (J. of the American College of Toxicology, Vol. 2, n° 7, 1983) - Draize test, sol. 20% = Strong irritant after 1 day and light irritant after 7 days (J. of the American College of Toxicology, Vol. 2, n° 7, 1983) - Eye Irritation on rabbits: irritant (from literature, Read Across, OECD 405, 1988) |

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| 6.4 Informazioni sulla sensibilizzazione <i>Information on sensitisation potential</i> | Kligman & Magnusson Test = Not sensitizing (J. of the American College of Toxicology, Vol. 2, n° 7, 1983) - In vivo (non-LLNa) = Not sensitizing (from literature, Read Across, OECD 406, 1988) |
| 6.5 Informazioni sulla genotossicità <i>Information on gene toxicity</i> | Ames test = None mutagenic effect (from literature, Read Across, OECD 471, 1987) |
| 6.6 Informazioni sull'assorbimento percutaneo <i>Information on percutaneous permeation</i> | Data from Sodium Lauryl Sulfate. Both products have in fact similar chemical structure. - The presence of a strongly anionic terminal group in the surfactant reduces its skin penetration capacity (CIR: Prottey, J. Soc. Cosmet. Chem. 26, 29-46, 1975) - In vitro, rat, 0.5 ml, sol. 25 mM: none measurable penetration till 24h after contact, 30% of marked in rinsing-off and 70% on skin after 24h (CIR: Howes J. Soc. Cosmet. Chem 26(1)47-63, 1975) - In vitro, human skin, 0.1 ml, sol. 25 mM: none measurable penetration till 24h and then 3.9 + 3.6 mg/cm ² penetration, after 48 h 87.2 + 24.1 mg/cm ² permeation (CIR: Howes J. Soc. Cosmet. Chem 26(1)47-63, 1975) |
| 6.7 Altri (e.g. NOAEL) <i>Others (e.g. NOAEL)</i> | NOAEL = 488 mg/kg x bw/d (from literature, Read Across on rats, OECD 408, 1976) |

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| 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° 5 for detergent products and n° 2005 for cosmetics) |

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| 7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i> | <ul style="list-style-type: none"> - LC50 on Fish = 3.2 mg/l/96h (from literature, Read Across, OECD 203, 1991) - EC50 on Daphnia = 4.7 mg/l/48h (from literature, Read Across, EG/92/69/EWG, 1993) - EC50 on Algae = 11 mg/l/72h (from literature, Read Across, EU Method C.3, 1995) |
| 7.3 Altri <i>Others</i> | / |

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| 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 classification see enclosed safety data sheet.) | |
| Dichiarazione BSE/TSE <i>BSE/TSE statement</i> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</i> Ftalati, DINP (diisononyl phtalate) <i>Phtalates, DINP (diisononil ftalato)</i> Etanolo <i>Ethanol</i> Glutine <i>Gluten</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/TSE free.</p> <p>ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic reason.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</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>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used it is not likely to be present.</p> |

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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 composés 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

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

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 not likely to be present.

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.

Based on information concerning the raw

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| <p>Ormoni, antibiotici e steroidi <i>Hormones, antibiotics and steroids</i></p> <p>PBT/vPvB <i>PBT/vPvB</i></p> <p>Materiale radioattivo <i>Radioactive material</i></p> <p>Nanomateriali <i>Nanomaterials</i></p> <p>Idrocarburi Policiclici Aromatici <i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p>Grado cosmetico <i>Cosmetic grade</i></p> <p>Certificato Kosher <i>Kosher certificate</i></p> <p>Convenzione CITES <i>CITES Convention</i></p> | <p>materials, production process and equipment used they are not likely to be present.</p> <p>Based on information concerning the raw materials, production process and equipment used they are not likely to be present.</p> <p>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.</p> <p>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</p> <p>Based on information concerning the raw materials, production process and equipment used polycyclic aromatic hydrocarbons are not likely to be present.</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.</p> <p>Yes</p> <p>Not applicable, cultivated vegetable raw materials</p> |
| <p>8.1 Data di retest <i>Retest date</i></p> | <p>The product, if well preserved and in its original containers, maintains its appearance and characteristics for at least six months from delivery date. After this time, product can be used but it must be rechecked (pH and microbial contamination). According to temperature, pH can decrease. This doesn't affect the quality of the product till pH is higher than 4.0. With time a yellowing/reddish process due to preservative can develop. The colour is guaranteed only at the delivery and for the following 6 months if correctly stored. Product MUST NOT be exposed to sun light.</p> |

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| 8.2 Stoccaggio <i>Storage recommendation</i> | Store at room temperature (15°C-25°C). At temperatures lower than 10°C the product can become turbid. The material can be restored to its original appearance by indirect heating at 30°C-40°C and stirring. This doesn't affect the quality of the product. Don't store (NEVER) under direct sun light and at temperature higher than 40°C for more than five days. |
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Data / *Date* 09/04/2021

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.