



**INFORMAZIONI TOSSICOLOGICHE**  
***TOXICOLOGICAL INFORMATION***

**Revisione n°**  
***Revision n° 00***

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| <b>1. Informazioni generali</b><br><br><i>General information</i>  |  |
| <b>1.1 Nome commerciale</b><br><br><i>Trade name</i>   | <b>AMPHOTENSID GM 1993</b>   |
| <b>1.2 Produttore/Fornitore</b><br>(indirizzo, telefono, fax, contatto)<br><br><i>Manufacturer/Supplier</i><br>(address, phone no., fax no., contact person) | ZSCHIMMER & SCHWARZ ITALIANA<br>Via A. Ariotto 1/C - 13038 Tricerro (VC)<br>Italy<br>Tel: +39 (0)161 808111<br>Fax: +39 (0)161 801002<br>e.merlo@zschimmer-schwarz.com                       |
| <b>1.3 Categoria della material prima</b><br>(es. tensioattivo anionico)<br><br><i>Raw material category</i><br>(e.g. anionic surfactant)                    | Blend of amines  |
| <b>1.4 Nome chimico</b><br><br><i>Chemical name</i>  | 2,2'-(octadec-9-enylimino)bisethanol: 60% - 70%<br>Ethanol, 2,2'-iminobis-, N-tallow alkyl derivs.: 25% - 30%<br>(Z)-Octadec-9-enylamine, ethoxylated 1 - 4.5 moles ethoxylated: 10% - 12.5% |
| <b>1.5 Nome INCI (CTFA)</b><br><b>Composizione</b><br><br><i>INCI (CTFA) name</i><br><b>Composition</b>  | Not applicable   |
| <b>1.6 N° EC (EINECS-/ELINCS)</b><br><br><i>EC (EINECS/ELINCS) no.</i>   | 246-807-3 (and) 263-177-5 (and) 500-048-7  |

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| <b>1.7 N° CAS</b><br><br><b>CAS no.</b>   | 25307-17-9 (and) 61791-44-4 (and) 26635-93-8   |
| <b>1.8 Registrazioni</b> (es. UE, USA, Giappone) - REACh - Certificazione<br><br><b>Registration status</b> (e.g. EU, USA, Japan) - REACh - Certification | TSCA (USA), DSL (Canada), ASIA-PAC (Asia-Pacific), EINECS (Europe) and AICS (Australia) for CAS 25307-17-9.<br>TSCA (USA), DSL (Canada), EINECS (Europe), PICCS (Philippines), ASIA-PAC (Asia-Pacific), AICS (Australia) and ECL (Korea) for CAS 61791-44-4.<br>TSCA (USA), PICCS (Philippines), ASIA-PAC (Asia-Pacific), DSL (Canada), ENCS (Japan), NLP (Europe), AICS (Australia) and ECL (Korea) for CAS 26635-93-8.<br>Product is not a biocidal according to Regulation 528/2012.<br>The product is not a phytosanitary according to Regulation 1107/2009.<br>REACh status: all the ingredients have been pre-registered.<br>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.<br>Dioxane and heavy metals are listed on PO 65 (California law). |

| <b>2. Informazioni sulla produzione</b><br><br><b>Information on production</b>   |  |
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| <b>2.1 Origine della materia prima</b><br>(vegetale, animale, sintetica)<br><br><b>Origin of starting material</b><br>(plant, animal, synthetic)                          | Synthetic  |
| <b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b><br><br><b>Is the starting material derived from genetically modified organisms (GMO)?</b> | No   |
| <b>2.3 Informazioni sul processo di produzione</b><br>(descrizione generale)<br><br><b>Information on production process</b><br>(general description)                     | All components are blended.<br>Microbial and chemical-physical specifications are checked. |

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| <b>3.</b>  | <b>Additivi</b><br><i>Additives</i>   |                            |
| <b>3.1</b> | <b>Conservanti/Biocidi</b><br><i>Preservatives/Biocides</i>   | Not added and not expected |
| <b>3.2</b> | <b>Antiossidanti</b><br><i>Antioxidants</i>   | Not added and not expected |
| <b>3.3</b> | <b>Solventi</b><br><i>Solvents</i>  | Water                      |
| <b>3.4</b> | <b>Sbiancanti</b><br><i>Bleaching agents</i>  | Not added and not expected |
| <b>3.5</b> | <b>Altri</b><br><i>Others</i>   | Not added and not expected |
| <b>4.</b>  | <b>Specifiche microbiologiche</b><br><b>Microbiological specification</b>   |                            |
| <b>4.1</b> | <b>Conta microbica totale (ufc/g)</b><br><i>Total viable count (colony-forming units/g)</i>   | less than 10 cfu/g         |
| <b>5.</b>  | <b>Residui del processo di lavorazione</b><br>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.<br><br><i>By-products</i><br><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> |                            |
| <b>5.1</b> | <b>1,4-Diossano *</b><br><i>1,4-Dioxane *</i>   | 50 ppm maximum             |

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| 5.2  | <b>Ossido di etilene *</b><br><i>Ethylene oxide *</i>         | 5 ppm maximum (average value: lower than 1 ppm)   |
| 5.3  | <b>Solventi residui</b><br><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  | <b>Monomeri residui</b><br><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  | <b>Ammine</b><br><i>Amines</i>                                | Based on information concerning the raw materials, production process and equipment used they are not likely to be present.   |
| 5.6  | <b>Nitrosammine</b><br><i>Nitrosamines</i>                    | Based on information concerning the raw materials, production process and equipment used they are not likely to be present.   |
| 5.7  | <b>Metalli pesanti</b><br><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  | <b>Acido monocloroacetico</b><br><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  | <b>Acido dicloroacetico</b><br><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 | <b>Allergeni</b><br><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.<br>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. |

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| <b>5.11 Altri (e.g. CMR)</b><br><br><i>Others (e.g. CMR)</i> | 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: dioxane (CMR2) as impurity technically unavoidable even working in GMP (50 ppm maximum) and ethylene oxide (5 ppm maximum, average value lower than 1 ppm) |
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| <b>6. Tossicologia</b><br><br><i>Toxicology</i>   |   |
| <b>6.1 Informazioni sulla tossicità acuta</b><br><br><i>Information on acute toxicity</i>                       | LD50 (oral, rat) = 300 - 2000 mg/kg (literature data)       |
| <b>6.2 Informazioni sull'irritazione cutanea</b><br><br><i>Information on skin irritation</i>                   | Product as it is (rabbit, 4h) = Corrosive (literature data) |
| <b>6.3 Informazioni sull'irritazione oculare</b><br><br><i>Information on irritation of the mucous membrane</i> | Product as it is (rabbit) = Irritant (literature data)      |
| <b>6.4 Informazioni sulla sensibilizzazione</b><br><br><i>Information on sensitisation potential</i>            | Not sensitizing (literature data)                           |
| <b>6.5 Informazioni sulla genotossicità</b><br><br><i>Information on gene toxicity</i>                          | Not available   |
| <b>6.6 Informazioni sull'assorbimento percutaneo</b><br><br><i>Information on percutaneous permeation</i>       | Not available   |
| <b>6.7 Altri (e.g. NOAEL)</b><br><br><i>Others (e.g. NOAEL)</i>   | Not available   |

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| <b>7. Ecotossicità</b><br><br><i>Ecology</i> |  |
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| <b>7.1</b> | <b>Degradabilità/Eliminazione</b><br><i>Degradability/Elimination</i> | Readily biodegradable; 60% after 28d (OECD 301)   |
| <b>7.2</b> | <b>Tossicità acquatica acuta</b><br><i>Acute aquatic toxicity</i>     | <ul style="list-style-type: none"> <li>- LC50 on Fish (Carassius Auratus) &lt; 1 mg/l/96h (CESIO data)</li> <li>- EC50 on Daphnia &lt; 1 mg/l/48h (CESIO data)</li> <li>- EC50 on Algae = 10 - 50 mg/l (from literature)</li> </ul> |
| <b>7.3</b> | <b>Altri</b><br><i>Others</i>   | /   |

|           |  |   |
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| <b>8.</b> | <b>Informazioni aggiuntive</b><br>(Per i dettagli sulle specifiche vedere il bollettino tecnico allegato; per i dettagli sull'etichettatura e la classificazione vedere la scheda di sicurezza allegata.)<br><br><i>Additional information</i><br>(For details on specification see enclosed instruction sheet; for details on labelling and classification see enclosed safety data sheet.) |   |
|           | <b>Dichiarazione BSE</b><br><i>BSE statement</i>   | 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. |
|           | <b>Dichiarazione test animali</b><br><i>Non-animal testing declaration</i>   | ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product.   |
|           | <b>Glicol eteri, glicoli, alcoli (non dichiarati nei paragrafi precedenti)</b><br><i>Glycol ethers, glycols, alcohols (not declared in previous paragraphs)</i>  | Not added and not expected  |
|           | <b>Ftalati</b><br><i>Phthalates</i>  | 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.  |
|           | <b>Parabeni</b><br><i>Parabens</i>   | Not added and not expected  |
|           | <b>Siliconi</b><br><i>Silicons</i>   | Not added and not expected  |

**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 composés 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 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**

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.

|   |   |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |
|---|---|----------------|-----------|-----------------------|-----------|----------------------|---|---------------------------|---|------------------------|---------------|--------------|---|---------------------------------|---|-------------------|---|-------------------------|----------------|--------------------|---|
| <p><b>Ormoni, antibiotici e steroidi</b><br/><i>Hormones, antibiotics and steroids</i></p> <p><b>Materiale radioattivo</b><br/><i>Radioactive material</i></p> <p><b>Nanomateriali</b><br/><i>Nanomaterials</i></p> <p><b>Idrocarburi Policiclici Aromatici</b><br/><i>Polycyclic Aromatic Hydrocarbons (HAP)</i></p> <p><b>Grado cosmetico</b><br/><i>Cosmetic grade</i></p> | <p>Not added and not expected</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 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 expected to conform to concentration limits of Regulation (EC) 1881/2006 Annex</p> <table border="0"> <tr> <td>Benzo[a]pyrene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Dibenz[a,h]anthracene</td> <td>≤ 1 µg/kg</td> </tr> <tr> <td>Cyclopenta[cd]pyrene</td> <td>)</td> </tr> <tr> <td>Benzo[fluoranthene[b+j+k]</td> <td>)</td> </tr> <tr> <td>Indeno[1,2,3-cd]pyrene</td> <td>) Σ ≤ 5 µg/kg</td> </tr> <tr> <td>Anthanthrene</td> <td>)</td> </tr> <tr> <td>Benzo[b]naphtho[2,1-d]thiophene</td> <td>)</td> </tr> <tr> <td>Benz[a]anthracene</td> <td>)</td> </tr> <tr> <td>Chrysene + Triphenylene</td> <td>) Σ ≤ 20 µg/kg</td> </tr> <tr> <td>Benzo[ghi]perylene</td> <td>)</td> </tr> </table> <p>The product is of cosmetic grade and it can be used in cosmetic products.<br/>It is according Regulation 1223/2009, its annexes and its further amendments.<br/>We are EFfCI GMP certified (certificate n° 20782).</p> | Benzo[a]pyrene | ≤ 1 µg/kg | Dibenz[a,h]anthracene | ≤ 1 µg/kg | Cyclopenta[cd]pyrene | ) | Benzo[fluoranthene[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 | ) |
| Benzo[a]pyrene  | ≤ 1 µg/kg   |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |
| Dibenz[a,h]anthracene   | ≤ 1 µg/kg   |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |
| Cyclopenta[cd]pyrene  | )   |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |
| Benzo[fluoranthene[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><b>8.1 Data di scadenza</b><br/><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.</p>   |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |
| <p><b>8.2 Stoccaggio</b><br/><i>Storage recommendation</i></p>  | <p>It is advisable to store the product at temperatures lower than 50°C.</p>  |                |           |                       |           |                      |   |                           |   |                        |               |              |   |                                 |   |                   |   |                         |                |                    |   |

Data / *Date* 28/10/16



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**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.*