



INFORMAZIONI TOSSICOLOGICHE
TOXICOLOGICAL INFORMATION

Revisione n°
Revision n° 01

1. Informazioni generali <i>General information</i>	
1.1 Nome commerciale <i>Trade name</i>	ESTERTEC 2IS
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)	Ester, lubricant, used in wood processing, paper, paper products, textile products, paints, tissues. No uses advised against are identified
1.4 Nome chimico <i>Chemical name</i>	Isooctadecyl Isooctadecanoate
1.5 Nome INCI (CTFA) Composizione <i>INCI (CTFA) name</i> <i>Composition</i>	Isostearyl Isostearate ~ 100%
1.6 N° EC (EINECS-/ELINCS) <i>EC (EINECS/ELINCS) no.</i>	255-485-3
1.7 N° CAS <i>CAS no.</i>	41669-30-1

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1.8 Registrazioni (es. UE, USA, Giappone) - REACH - Certificazione <i>Registration status</i> (e.g. EU, USA, Japan) - <i>REACH - Certification</i>	TSCA (USA), DSL (Canada), AICS (Australia), ECL (Korea), ASIA-PAC (Asia-Pacific) and Reach (Europe). Product is not a biocidal according to Regulation 528/2012. The product is not a phytosanitary according to Regulation 1107/2009. REACH registration: pre-registered. No REACH Annex XVII restriction list. No REACH Annex XIV restriction list. 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. Heavy metals are listed on PO 65 (California law).
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2. Informazioni sulla produzione Information on production	
2.1 Origine della materia prima (vegetale, animale, sintetica) <i>Origin of starting material</i> (plant, animal, synthetic)	Vegetable origin (rapeseed oil)
2.2 La materia prima deriva da organismi geneticamente modificati (OGM)? <i>Is the starting material derived from genetically modified organisms (GMO)?</i>	No
2.3 Informazioni sul processo di produzione (descrizione generale) <i>Information on production process</i> (general description)	Esterification reaction between isostearic acid and isostearyl alcohol.

3. Additivi <i>Additives</i>	
3.1 Conservanti/Biocidi <i>Preservatives/Biocides</i>	Not added and not expected

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3.2	Antiossidanti <i>Antioxidants</i>	Not added and not expected
3.3	Solventi <i>Solvents</i>	None
3.4	Sbiancanti <i>Bleaching agents</i>	Not added and not expected
3.5	Altri <i>Others</i>	Catalysts are fully removed after esterification process through washing and earth filtration

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

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.

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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 (0.5% maximum).
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>	<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>

<p>5.11 Altri (e.g. CMR)</p> <p><i>Others (e.g. CMR)</i></p>	<p>Water content: 0,20% maximum Isostearyl alcohol < 10% (average values <5%) 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><i>(Data below can be also based on Read Across approach)</i></p>	
<p>6.1 Informazioni sulla tossicità acuta</p> <p><i>Information on acute toxicity</i></p>	<p>- LD50 (oral, mouse) > 2000 mg/kg bw (OECD 401, literature data) - LC50 (inhalation, rat) > 5.7 mg/l air (OECD 436, literature data)</p>
<p>6.2 Informazioni sull'irritazione cutanea</p> <p><i>Information on skin irritation</i></p>	<p>Product as it is = Not irritant (OECD 404, literature data)</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 = Not irritant (OECD 405, literature data)</p>
<p>6.4 Informazioni sulla sensibilizzazione</p> <p><i>Information on sensitisation potential</i></p>	<p>Not sensitizing (Guinea Pig maximisation test, Read Across literature data) Not sensitizing (Patch test human, Read Across literature data)</p>
<p>6.5 Informazioni sulla genotossicità</p> <p><i>Information on gene toxicity</i></p>	<p>Ames test = Negative (literature data)</p>
<p>6.6 Informazioni sull'assorbimento percutaneo</p> <p><i>Information on percutaneous permeation</i></p>	<p>Not determined</p>
<p>6.7 Altri (e.g. NOAEL)</p> <p><i>Others (e.g. NOAEL)</i></p>	<p>NOAEL = ≥1000 mg/kg bw/day (OECD 408, literature data, Read Across) Phototoxicity: No phototoxic (literature data, in vivo, guinea pigs)</p>

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7. Ecotossicità <i>Ecology</i>	
7.1 Degradabilità/Eliminazione <i>Degradability/Elimination</i>	Readily biodegradable (literature data, Read Across, OECD 301B)
7.2 Tossicità acquatica acuta <i>Acute aquatic toxicity</i>	<ul style="list-style-type: none"> - LC50 on Fish > 100 mg/l/96h (OECD 203, Read Across, literature data) - EC50 on Daphnia > 86 mg/l/48h (EU C.2, Read Across, literature data) - NOELR on Daphnia > 100 mg/l - EC 50 > 100 mg/l/72h (OECD 201 Read Across, 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.) <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 <i>BSE statement</i> Dichiarazione test animali <i>Non-animal testing declaration</i> Glicol eteri <i>Glycol ethers</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> <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>

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Ftalati, DINP (diisononyl phtalate)
Phthalates, 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

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.

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<p>Coloranti azoici <i>Azo dyes</i></p> <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>Based on information concerning the raw materials, production process and equipment used azo dyes are not likely to be present.</p> <p>Not added and not expected</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>	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)
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<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.</p>																				
<p>8.2 Stoccaggio <i>Storage recommendation</i></p>	<p>Store the product in the well sealed original containers, in a dry place and far from any heat source at room temperature (15°C-25°C).</p>																				

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8.3 Dati caratteristici (da non intendersi come specifiche)

Typical data (not to be intended as specifications)

Flash point: 255°C – 265°C
Pour point: < 15°C
Viscosity at 25 °C: 50 – 57 cst
Viscosity at 40 °C: 23-30 cst
Viscosity at 100 °C: 5.5 – 6.5 cst
Refractive Index at 20 °C: 1,454 – 1,462
Hydroxyle number: 15 mg KOH/g max
Iodine number: 2 g I₂/100 g max
Density at 20 °C: 0.860-0.880 g/cm³

Data / *Date* 15/01/18

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.