



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

**Revisione n°**  
***Revision n° 08***

<b>1. Informazioni generali</b>  <b><i>General information</i></b>	
<b>1.1 Nome commerciale</b>  <b><i>Trade name</i></b>	<b>FLEROGUM K 38</b>
<b>1.2 Produttore/Fornitore</b> (indirizzo, telefono, fax, contatto)  <b><i>Manufacturer/Supplier</i></b> (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
<b>1.3 Categoria della material prima</b> (es. tensioattivo anionico)  <b><i>Raw material category</i></b> (e.g. anionic surfactant)	Soap
<b>1.4 Nome chimico</b>  <b><i>Chemical name</i></b>	Fatty acids, coco, potassium salts
<b>1.5 Nome INCI (CTFA)</b> <b>Composizione</b>  <b><i>INCI (CTFA) name</i></b> <b><i>Composition</i></b>	Potassium Cocoate: 34.5% min as dry matter Aqua: to 100%
<b>1.6 N° EC (EINECS-/ELINCS)</b>  <b><i>EC (EINECS/ELINCS) no.</i></b>	263-049-9
<b>1.7 N° CAS</b>  <b><i>CAS no.</i></b>	61789-30-8

<p><b>1.8 Registrazioni</b> (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), EINECS (Europe), ECL (Korea), PICCS (Philippines), ASIA-PAC (Asia-Pacific) and AICS (Australia). 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° 07535.</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: absent according to Annex V.</p> <p>None of substances listed in the “candidate” list (07 July 2017) 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 according to the Chapter of Chemical products and substances (Rev. 08, July 2015).</p>
<p><b>2. Informazioni sulla produzione</b></p> <p><b>Information on production</b></p>	
<p><b>2.1 Origine della materia prima</b> (vegetale, animale, sintetica)</p> <p><i>Origin of starting material</i> (plant, animal, synthetic)</p>	<p>Vegetable (84.8%) and mineral origin.</p> <p>Fatty acids are from vegetable origin. Origin: coconut oil from Cocos Nucifera (South East Asia and Philippines) or palm kernel oil from Elaeis Guineenis (Malaysia and Indonesia) (RSPO suppliers).</p> <p>We are RSPO member.</p> <p>Potassium Hydroxide (KOH) is mineral.</p>
<p><b>2.2 La materia prima deriva da organismi geneticamente modificati (OGM)?</b></p> <p><i>Is the starting material derived from genetically modified organisms (GMO)?</i></p>	<p>No</p>

<p><b>2.3 Informazioni sul processo di produzione</b> (descrizione generale)</p> <p><b>Information on production process</b> (general description)</p>	$\text{R}-\overset{\text{O}}{\underset{\parallel}{\text{C}}}-\text{OH} + \text{KOH} \xrightarrow{\Delta} \text{R}-\overset{\text{O}}{\underset{\parallel}{\text{C}}}-\text{O}^-\text{K}^+ + \text{H}_2\text{O}$
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<p><b>3. Additivi</b></p> <p><b>Additives</b></p>	
<p><b>3.1 Conservanti/Biocidi</b></p> <p><b>Preservatives/Biocides</b></p>	Not added and not expected
<p><b>3.2 Antiossidanti</b></p> <p><b>Antioxidants</b></p>	Not added and not expected
<p><b>3.3 Solventi</b></p> <p><b>Solvents</b></p>	Water
<p><b>3.4 Sbiancanti</b></p> <p><b>Bleaching agents</b></p>	Not added and not expected
<p><b>3.5 Altri</b></p> <p><b>Others</b></p>	0.03% of Alanine, N, N-bis(carboxymethyl)-, trisodium salt (Trilon M) (100%)

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

<p><b>5. Residui del processo di lavorazione</b></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><b>By-products</b></p> <p><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.</i></p>	
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1223/2009.		
5.1	<b>1,4-Diossano *</b>  <b>1,4-Dioxane *</b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.2	<b>Ossido di etilene *</b>  <b>Ethylene oxide *</b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.3	<b>Solventi residui</b>  <b>Residual solvents</b>	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>  <b>Residual monomers</b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.5	<b>Ammine</b>  <b>Amines</b>	Based on information concerning the raw materials, production process and equipment used they are not likely to be present.
5.6	<b>Nitrosammine</b>  <b>Nitrosamines</b>	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>  <b>Heavy metals</b>	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>  <b>Monochloroacetic acid</b>	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>  <b>Dichloroacetic acid</b>	Based on information concerning the raw materials, production process and equipment used it is not likely to be present.
5.10	<b>Allergeni</b>  <b>Allergens</b>	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.
<b>5.11 Altri (e.g. CMR)</b>  <i><b>Others (e.g. CMR)</b></i>	Free potassium hydroxide: 0.3% 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 are not likely to be present.

<b>6. Tossicologia</b>  <i><b>Toxicology</b></i>	
<b>6.1 Informazioni sulla tossicità acuta</b>  <i><b>Information on acute toxicity</b></i>	- LD50 on rats > 2000 mg/kg (from literature and information on product) - LD50 on rats > 10000 mg/kg (Gloxhuber and Künstler 1992)
<b>6.2 Informazioni sull'irritazione cutanea</b>  <i><b>Information on skin irritation</b></i>	- Product as it is = Irritant (from literature and information on product) - Soap concentrations of 10% or more may be irritating to skin and concentrations above 30% cause severe local irritation (Gloxhuber and Künstler 1992)
<b>6.3 Informazioni sull'irritazione oculare</b>  <i><b>Information on irritation of the mucous membrane</b></i>	- The only soaps that lead to permanent corneal damage are those containing large amounts free alkali and having a pH value of more than 12 (Grant and Schuman 1993) - Accidental contact of the human eye with soap or soap powder followed by rapid rinsing of the eyes is not expected to cause severe reactions and reactions observed usually disappear quickly (Gloxhuber and Künstler 1992)
<b>6.4 Informazioni sulla sensibilizzazione</b>  <i><b>Information on sensitisation potential</b></i>	Not sensitizing (from literature and information on product)
<b>6.5 Informazioni sulla genotossicità</b>  <i><b>Information on gene toxicity</b></i>	Ames test = None mutagenic effects (from literature and information on product)

6.6	<b>Informazioni sull'assorbimento percutaneo</b> <i>Information on percutaneous permeation</i>	Not determined
6.7	<b>Altri (e.g. NOAEL)</b> <i>Others (e.g. NOAEL)</i>	NOAEL = 750 mg/kg x bw/d (reproductive toxicity, rats, oral) (data from Sodium Laurate, similar molecule)  Carcinogenicity: Both oral administration and dermal exposures to soap (potassium soap) gave negative results in carcinogenicity tests with laboratory animals (Gloxhuber and Künstler 1992)
7.	<b>Ecotossicità</b> <i>Ecology</i>	
7.1	<b>Degradabilità/Eliminazione</b> <i>Degradability/Elimination</i>	Aerobic: readily biodegradable (our test SAM2467i dated 04.10.05) Anaerobic: anaerobic biodegradable (Ecolabel DID List n° 2025)
7.2	<b>Tossicità acquatica acuta</b> <i>Acute aquatic toxicity</i>	- LC50 on Fish > 1 mg/l (from literature) - EC50 on Daphnia > 1 mg/l (from literature) - EC50 on Algae > 1 mg/l (from literature)
7.3	<b>Altri</b> <i>Others</i>	/
8.	<b>Informazioni aggiuntive</b> (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.)	
	<b>Dichiarazione BSE</b> <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.

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## **Dichiarazione test animali**

### ***Non-animal testing declaration***

ZSCHIMMER & SCHWARZ ITALIANA has never made or commissioned animal tests on this product for cosmetic purpose.

## **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.

## **Parabeni**

### ***Parabens***

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

## **Siliconi**

### ***Silicons***

Based on information concerning the raw materials, production process and equipment used they 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 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***

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 they are not likely to be present.

**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**

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.

**Ormoni, antibiotici e steroidi**  
**Hormones, antibiotics and steroids**

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

**PBT/vPvB**  
**PBT/vPvB**

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

**Materiale radioattivo**  
**Radioactive material**

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.

**Nanomateriali**  
**Nanomaterials**

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

**Idrocarburi Policiclici Aromatici**  
**Polycyclic Aromatic Hydrocarbons (HAP)**

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	≤ 1 µg/kg
Dibenz[a,h]anthracene	≤ 1 µg/kg
Cyclopenta[cd]pyrene	)
Benzofluoranthene[b+j+k]	)
Indeno[1,2,3-cd]pyrene	) Σ ≤ 5 µg/kg



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<p><b>Grado cosmetico</b> <i>Cosmetic grade</i></p> <p><b>Convenzione CITES</b> <i>CITES Convention</i></p>	<p>Anthanthrene ) Benzo[b]naphtho[2,1-d]thiophene ) Benz[a]anthracene ) Chrysene + Triphenylene ) <math>\Sigma \leq 20 \mu\text{g/kg}</math> 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>Not applicable, cultivated vegetable raw materials</p>
<p><b>8.1 Data di scadenza</b> <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> <i>Storage recommendation</i></p>	<p>Store in cool and adequately ventilated premises; protect from cold.</p>

Data / *Date* 30/08/17

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.

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