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ESAFLOR PFT

1. CHEMICAL DESCRIPTION

Chemical name Guar gum, 2-hydroxypropyl 2-hydroxy-

3-(trimethylammonio)propyl ether, chloride.

CAS number 71329-50-5

INCI name Hydroxypropyl Guar Hydroxypropyltrimonium

Chloride.

2. GENERAL CHARACTERISTICS

Appearance at 20°C Powder

Dry matter, % min. 90%

(internal method Z0010)

Moisture, % max. 10%

(internal method Z0010)

pH (1% dispersion) 8.0 - 11.0

(internal method L0278)

3. ADDITIONAL DATA

(i.e. preservatives, stabilizers)

Excipients Absent.

Impurities Sodium Chloride, Sodium Acetate: < 20%

(internal method by Ionic Chromatography) 2,3-Dihydroxypropyl-N-

trimethylammonium chloride: < 4.0%

(GC method) Propylene glycols (MPG and DPG): < 2.0%

(Monopropylene/Dipropylene glycols)

(ICP method) Free Boron as Boric acid: < 0.02%

(In industrial use condition the product might release additional quantity of Boron.).

CHPTAC (3-Chloro-2-hydroxypropyl < 100 ppm

trimethylammonium chloride)

(method by LC/MS/MS)

EPTAC (2,3-Epoxypropyltrimethylammonium < 100 ppm

chloride) (method by LC/MS/MS)

Total Heavy metals - Limit test (as Pb) < 10 ppm

(method C 2.4.8.Eu.Ph.)



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(ICP method) Arsenic (As): < 2 ppm

Cobalt (Co): < 3 ppm Chromium (Cr): < 3 ppm Nickel (Ni): < 3 ppm Antimony Sb): < 5 ppm Mercury (Hg): < 1 ppm Cadmium (Cd): < 5 ppm

Total microbial count max. 500 CFU/g (bacteria, yeasts and moulds).

(Chapter 2.6.12 Eur.Ph. latest edition)

Gram negative bacteria count < 10 CFU/g (Gram-).

(internal method, Micro 02)

4. TOXICOLOGICAL DATA

We hereby declare that the toxicological data derive from literature or are not derived from animal tests carried out for cosmetic purposes as indicated in Directive 2003/15/EC and in European Cosmetic Regulations (EC) No. 1223/2009.

Acute oral toxicity LD50 > 5000 mg/kg/rats.*

Acute skin irritation Not irritant.* (Shelanski and Shelanski

Human Epicut. repeated test).

Acute eye irritation Not eye irritant.

Repeated and prolonged contacts may cause

slight irritation.*

Skin sensitization.* (Shelanski and Shelanski

Human Epicut. repeated test).

Mutagenicity Ames test: negative (method OECD 471).*

May cause allergenic reactions in susceptible people by inhalation.*

5. MANUFACTURING ASPECTS

Chemicals and chemical modified natural products

inorganic raw materials	yes 🗆	no <u>x</u>
based on mineral oil	yes □	no x
chemical origin raw materials	yes x	no 🗆
vegetable origin raw materials	ves 🗓	no 🗆



^{*:} Literature data by analogy to product with similar composition.

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from genetically modified organism	m yes □ no x unknown □
animal origin raw materials	yes □ no x
from tallow derivatives obtained the	nrough:
transesterification or hydrolysis at least 200°C at an ap (glycerol, fatty acids and fatty acid esters)*	propriate corresponding pression, for 20 minutes yes □ no □ unknown □
saponification with NaOH 12M (glycerol and soaps) with process at 140°C, 2 bars (2000 hPa) for 8 minutes or e	
*: European Commission decision 2000/418/EC ad 76/768/CEE on	opted as amendment n.419 of annex II to Directive Cosmetic Products.
6. OTHER INFORMATION	
Cosmetic grade	We confirm that the product is in compliance with the provisions of Cosmetic Regulation. (European Cosmetics Regulation (EC) No.1223/2009.)
BSE/TSE statement	The product is a chemical obtained from chemical and vegetable raw materials and does not contain any raw materials from animal origin. Therefore <i>ESAFLOR®</i> PFT can be considered "BSE/TSE" free.
GMO statement	The vegetable raw materials used in the manufacturing of <i>ESAFLOR®</i> PFT do not contain genetically modified species. Therefore <i>ESAFLOR®</i> PFT can be considered "GMO" free.
Animal testing Ban	Regulation prohibits the testing of animals in the European Union for finished products and ingredients or combinations of ingredients we confirm that this product and individual ingredients have never been tested or re-tested on animal for cosmetic purpose, according to the Cosmetics Regulation (EC) No.1223/2009.
Nanomaterials	This product does not contain nanomaterial as defined by European Commission and by European Cosmetics Regulation (EC) No.1223/2009.
Parabens	The product <u>does not contain Parabens</u> (considering the chemical group composed by



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butyl-, propyl-, isopropyl -, isobutyl -, pentyl -, phenyl - and benzyl- parabens and their salts).

MIT (Methylisothiazolinone)

The product does not contain MIT.

Phtalates The product does not contain Phtalates.

CMR substances The product does not contain, as intentional

ingredients, substances classified as CMR. (Carcinogenic, Mutagenic or Reprotoxic). European Cosmetic Regulations (EC) No.

1223/2009.

Allergens The product does not contain any of twenty-

six allergenic fragrances. (European Cosmetic

Regulations (EC) No. 1223/2009.)

Convention on Internal Trade in The product does not contain any material

Endangered Species (CITES) derived from the CITES.

Gluten The product does not contain Gluten.

Residual solvents Not intentionally added and not expected.

Pesticides Not expected from raw materials used.

Radiations The product is not irradiated.

California Proposition 65 The product does not contain, as intentional

ingredients, substances listed in California

Proposition 65.

Formaldehyde Not intentionally added and not expected.

Nitrosamines Not intentionally added and not expected.

