

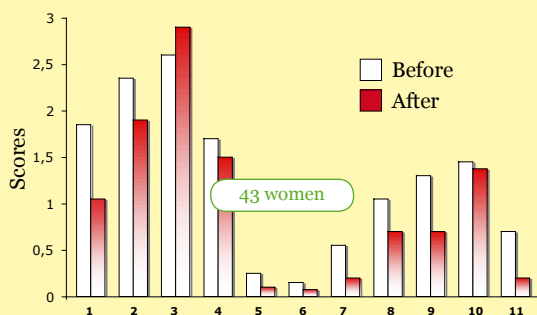


# Escin $\beta$ -sitosterol Phytosome<sup>®</sup>

Microcirculation and orange peel skin condition improver

## Anti-oedema properties

Topical treatment with 2% O/W emulsion



Improvement of the symptoms of OEFP after 30 days treatment.  
 1=Roughness; 2=Pastiness; 3=Elasticity; 4=Plicability; 5=Lipo-oedema; 6="Plaques" with oedema; 7=Spontaneous pain; 8=Provoked pain; 9=Flaccidity; 10=Striae; 11=Cold skin

43 female volunteers suffering from chronic venous stasis aged 1-5 years and oedematous-fibrosclerotic panniculopathy (OEFP, so called "cellulite") in various regions have been treated with O/W emulsion containing 2% of Escin  $\beta$ -sitosterol Phytosome<sup>®1,2</sup> or placebo.

About 1g of the "active" or "placebo" (same O/W emulsion, without 2% Escin  $\beta$ -sitosterol Phytosome<sup>®</sup>) ointments has been applied and gently massaged on the skin of the thighs, for 30 days (once a day).

The severity of each symptom was evaluated by the researchers with score-values from 0 to 4, before and after the 30-day treatment.

Statistically significant improvements were observed after treatment for the majority of the clinical symptoms, which are related to the increase in permeability of the capillaries and of the smallest postcapillary venules of the skin and hypodermis.

In another study, 20 female volunteers, aged 17-64 years with signs of oedematous-fibroplastic panniculopathy of the breast (OEFPB), have been treated with a dermocosmetological preparation containing 2% of Escin  $\beta$ -sitosterol Phytosome<sup>®</sup> and other synergistic active principles.<sup>2</sup>

To study the presence of ischemic (hypothermic) area, this group has been evaluated instrumentally using an "High Performance Contact Thermography". A constant improvement of the thermo-vascular maps, with reduction of the "cold areas" and an increased vasomotility of the smallest skin arteries have been observed; these effects are evident even 30-45 min after the application.

## Mechanism of action

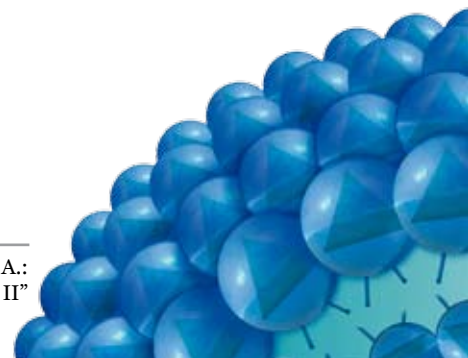
Escin  $\beta$ -sitosterol Phytosome<sup>®</sup> acts principally in capillaries. Its mechanism of action is mainly related to the modification of the vascular permeability. Escin  $\beta$ -sitosterol Phytosome<sup>®</sup> reduces the number and the diameter of the small pores of the capillary walls through which water exchange normally occurs.

The complexation of with  $\beta$ -sitosterol and phospholipids has been demonstrated<sup>2</sup> to be effective and at the same time definitely favourable in terms of tolerability, considering that escin *per se* is considered to have an irritant effect on skin (Table 1).

Tab 1 - Primary irritation of Escin and its complex on rabbit skin. Mean values									
No. of animals	24 hours				72 hours				
	erythema		edema		erythema		edema		
	intact skin	abraded skin	intact skin	abraded skin	intact skin	abraded skin	intact skin	abraded skin	
Escin (*)	6	0.17	1.5	0	1.83	0	0.33	0	0.5
Escin $\beta$ -sitosterol Phytosome <sup>®</sup>	6	0	0	0	0	0	0	0	0

(\*) Primary irritation index = 0/24 = 1.083      (\*\*) Primary irritation index = 0/24 = 0

1. European Patent: EP 0 283 713 - 2. Curri S.B., Bombardelli E., Della Loggia R., Del Negro P., Tubaro A.: "Topical antiinflammatory activity of complexes of aescin and sterols with phospholipids. Part I and II" Fitoterapia Volume LX, Suppl. al N. 1-1989



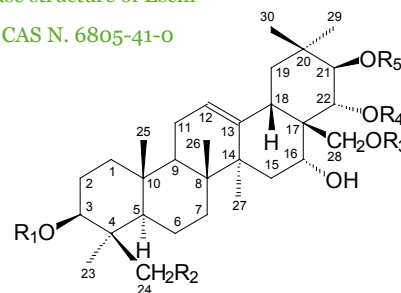
## Safety Data

A 3% gel of Escin  $\beta$ -sitosterol Phytosome® was shown not to be sensitizing on human skin (Urbino University, 1989). No intolerance reactions (irritation and/or allergy) due to the product were observed.

## Characteristics

Base structure of Escin

CAS N. 6805-41-0



### Escin $\beta$ -sitosterol Phytosome®

### Available Documentation

TLC content of escin: 32.0-40.0%  
 TLC content of beta-sitosterol: 12.5-15.5%  
 Form: light brown amorphous powder  
 Level of use: 1-2%  
 Odour: none characteristic  
 pH: not applicable (insoluble in water)  
 Water content\*:  $\leq 1.5\%$   
 Solubility\*: Ethoxydiglycol, Propylene glycol, Butylene glycol, Triticum vulgare (Wheat Germ Oil), Caprylic/Capric Triglycerides,

PEG-7 Glyceryl Cocoate, Mineral Oil (and) Lanolin Alcohol, Helianthus annuus (and) Lecithin, Phospholipids (and) Caprylic/Capric Triglyceride (and) Alcohol, Phospholipids (and) alcohol (and) Carthamus tinctorius (and) Glyceryl stearate, Phospholipids (and) Glyceryl stearate (and) Linoleic acid ethylester (and) Glycine soya.  
 Aqua (water): dispersible

Botanical Certificate  
 Methods of analysis  
 Reference Standard  
 Declaration GMO free  
 Safety Data Sheet  
 Confidential documentation

\*According to European Pharmacopoeia classification

## Formulation examples

### O/W emulsion gel

### Formulation advice

Escin $\beta$ -sitosterol Phytosome®	1.00%
Purified water	q.s.
Preservatives	q.s.
Polyacrylamide (and) C <sub>13-14</sub> Isoparaffin (and) Laureth-7	3.00%
C <sub>12-15</sub> Alkyl Benzoate	6.50%
Fragrance	0.25%

### Also suitable for

Gels, Gel-emulsions, O/W and W/O emulsions, Anhydrous gels, Ointments, Sticks, Anhydrous and aqueous pastes, Powders

The physico-chemical characteristics of Escin  $\beta$ -sitosterol Phytosome® and its ready dispersibility in water and oil virtually pose no limitations to the preparations of cosmetic formulations. Escin  $\beta$ -sitosterol Phytosome®, dispersed in aqueous phase by a homomixer or a turbomulsifier, is suitable for incorporation into monophasic and biphasic systems at a temperature lower than 40°C in order to avoid thermal stress that might damage the phospholipidic chain.

## Did you know...

Escin is obtained from the seeds of the Horse Chestnut tree, which originates from Asia and was first introduced in Europe in the XVIIIth century. The fruit is used in traditional medicine and is grinded into a flour which has always been used as a folk cosmetic to make the skin shiny or to make cleaning soaps.

TRADE NAME	INCI (CTFA)	INCI (E.U.)	EINECS N.	CAS N.	INDENA CODE
Escin beta-sitosterol Phospholipids	Phospholipids	Phospholipids	232 - 307 - 2	8002-43-5	9030000
	Escin	Escin	229-880-6	6805-41-0	
	Beta-Sitosterol	Beta-Sitosterol	201-480-6	83-46-5	