

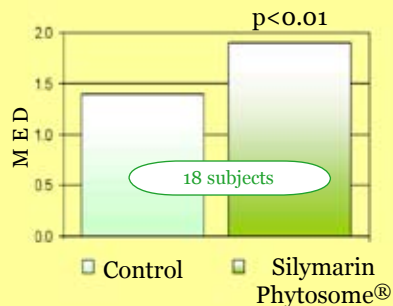


Silymarin Phytosome®

For aging and environmental skin protection

Proven efficacy on humans

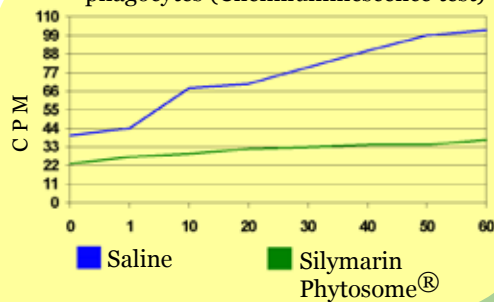
Evaluation of anti-irritant efficacy by protection from UV-B induced erythema



Eighteen volunteers have been tested for UV-induced erythema. Subjects treated with Silymarin Phytosome® 5% gel applied daily showed a 24% reduction of the UV-induced erythema as compared to blank preparation. MED, (Minimum Erythematous Dose) is the minimum required UV amount necessary to induce erythema. Blank and compound were applied for seven days on different areas. At the end of the treatment on both areas the MED has been determined. The results reported in chart 1 highlight the preventive activity on the onset of erythema and indirectly the soothing activity of the compound^{3,4}. Results are statistically significant (p < 0,01).

Free radical scavenging activity

Effect on light emission by stimulate-phagocytes (Chemiluminescence test)



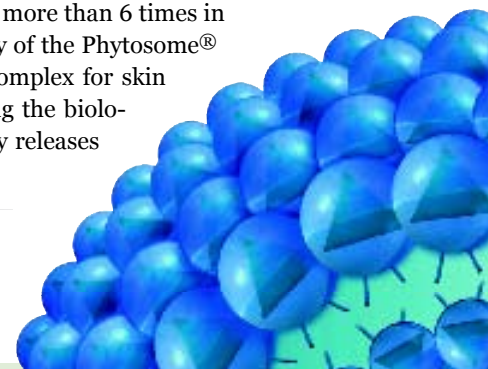
Chemiluminescence (CL) or emission of light serves as a measure of macrophage activation and is taken as an indication of the production and release of toxic oxygen species (including superoxide anion, hydroxyl radical, hydrogen peroxide) by stimulated leukocytes.

Incubation of macrophages (1 million/vial) with 1 mg of Silymarin Phytosome® was shown to produce total abrogation of macrophage CL with emission of light equivalent to background control levels^{4,5}.

Mechanism of action

The well known soothing activity of Silymarin has been shown to be increased by more than 6 times in Silymarin Phytosome® in experimental models⁴. The improvement in the activity of the Phytosome® form, compared to the free active principles, is due to a higher affinity of the complex for skin phospholipids. This not only improves the absorption of the compounds exerting the biological activity, but also increases the duration of the activity as the complex slowly releases the active principle⁶.

1. European Patent: EP 0 209 038 - 2. European Patent: EP 0 300 382 - 3. Internal Report Biolab 93/08271 - 4. Bombardelli E., Spelta M. and della Loggia R., Sosa S., Tubaro A.: "Aging skin: protective effect of Silymarin Phytosome®" - Fitoterapia Volume LXII, No. 2, 1991, pag 115-122 - 5. Internal Report: "Chemiluminescence study on Silymarin Phytosome®" prof. Martin Wilder, University of Massachusetts at Amherst - 6. Bombardelli E., Cristoni A., Morazzoni P.: "Phytosome® in functional cosmetic" - Fitoterapia Volume LXV, No 5, 1995, pp. 387-401 - 7. Internal Report: Urbino's University, 1990 - 8. Internal Report: Urbino's University, 1990.



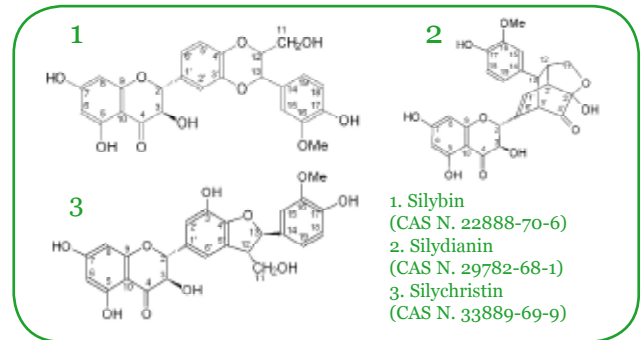
Silymarin Phytosome®

Safety Data

No irritation on human skin⁷.

No sensitizing power detected on human skin⁸.

Characteristics



| Silymarin Phytosome® | Available documentation |
|---|--|
| HPLC Content: 15-20% of Silybin-like substances (Silybin + Silychristin + Silydianin + Isosilybin) Form: yellow to light yellowish-brown amorphous powder, odorless Water content: ≤3% pH: not applicable (insoluble in water) Stability: retesting date at 24 months Levels of use: up to 3% Solubility*: ethoxydiglycol, propylene glycol - easily dispersible in water and oil | Botanical Certificate Method of analysis References Standard Declaration GMO free Safety Data Sheet Stability data in formulation and bulk material Published literature Confidential documentation |

* 50 mg Silymarin Phytosome® in 10 g of solvent at 40°C

Formulation examples

| Protecting gel ² | Formulation Advise | | | | | | | | | | | | | | | | | | |
|---|----------------------|------|--------------------|------|-------------|------|----------------------------------|-------|-------------------------------|------|---------------------|------|-----------------|------|----------------------|------|-----------------|-------|---|
| <table border="0"> <tr> <td>SILYMARIN PHYTOSOME®</td> <td>1.0%</td> </tr> <tr> <td>Imidazolidinylurea</td> <td>0.3%</td> </tr> <tr> <td>Octilnolone</td> <td>0.1%</td> </tr> <tr> <td>C8-C12 ethoxylated triglycerides</td> <td>25.0%</td> </tr> <tr> <td>Polyoxyethylene 20 oleylether</td> <td>5.0%</td> </tr> <tr> <td>Carboxyvinylpolymer</td> <td>1.5%</td> </tr> <tr> <td>Triethanolamine</td> <td>2.0%</td> </tr> <tr> <td>Perfumed composition</td> <td>0.1%</td> </tr> <tr> <td>Depurated water</td> <td>65.0%</td> </tr> </table> | SILYMARIN PHYTOSOME® | 1.0% | Imidazolidinylurea | 0.3% | Octilnolone | 0.1% | C8-C12 ethoxylated triglycerides | 25.0% | Polyoxyethylene 20 oleylether | 5.0% | Carboxyvinylpolymer | 1.5% | Triethanolamine | 2.0% | Perfumed composition | 0.1% | Depurated water | 65.0% | <p>The physico-chemical characteristics of Silymarin Phytosome® and its ready dispersibility in water and oil virtually pose no limitations to the preparations of cosmetic formulations.</p> <p>Silymarin Phytosome®, dispersed in aqueous phase by a homomixer or a turboemulsifier, 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.</p> <p>Also suitable for</p> <p>Sun care products (gels and creams) After sun products (gels, creams, lotions) Soothing and lenitive products (emulsions, masks)</p> |
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Did you know...

The Silymarin Phytosome® is an original complex between the flavanolignans (mainly silybin, silydianin, silychristin) extracted from *Silybum marianum* fruits (silymarin extract) and Soybean Phospholipids in a 1:2 ratio¹. This complex exhibits enhanced functionality of the flavanolignans resulting in a longer lasting activity and increased effectiveness on the skin⁶.

| TRADE NAME | INCI (CTFA) | INCI (E.U.) | EINECS N. | CAS N. | INDENA CODE |
|----------------------|---|-------------------------------------|---------------|----------------------------------|-------------|
| Silymarin Phytosome® | Lecithin (syn. Phosphatidylcholine) (and) <i>Silybum marianum</i> extract | Lecithin (syn. Phosphatidylcholine) | 232 - 307 - 2 | 8002 - 43 - 5 | 9065097 |
| | | <i>Silybum marianum</i> Extract | 283 - 298 - 7 | 84604 - 20 - 6 65666 - 07 - 1 | |