GENERAL INFORMATION

Select Botanical, SL manufactures highest quality extracts following strictest Quality Management System in compliance with the “Good Manufacturing Practices” requirements, carrying on the last manufacturing steps in classified areas (Clean Rooms).
Select Botanical, SL assures the traceability with rigorous analysis form raw material to finished product.

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Raw material</th>
<th>Leaves of <em>Hedera helix</em> L.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>- Macroscopic</td>
<td>Complies Ph. Eur. current Ed.</td>
</tr>
<tr>
<td>- Microscopic</td>
<td>Complies Ph. Eur. current Ed.</td>
</tr>
<tr>
<td>Loss on drying:</td>
<td>≤ 10 % w/w</td>
</tr>
<tr>
<td>Pesticides</td>
<td>According to Ph. Eur. current ed.</td>
</tr>
<tr>
<td>Assay (HPLC):</td>
<td>Hederacoside C</td>
</tr>
</tbody>
</table>

Composition of Extract Preparation

- Native dry extract
- Maltodextrin (if it is necessary)
- Colloidal silicon dioxide

Extract Specifications

- Loss on drying: ≤ 6 % w/w
- Total ash: ≤ 15 % w/w
- Heavy metals: Analysis of Pb,Hg,Cd and As
- Microbiological assay: According to Ph. Eur. current Ed “5.1.8. Point B”
- Residual solvents: According to guidelines CPMP/ICH/283/95
- Assay (HPLC): Hederacoside C

REGISTRY NUMBERS

<table>
<thead>
<tr>
<th>CAS:</th>
<th>84082-54-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS:</td>
<td>282-000-2</td>
</tr>
<tr>
<td>INCI/UE:</td>
<td>HEDERA HELIX LEAF EXTRACT</td>
</tr>
</tbody>
</table>

INFORMATION ABOUT PLANT ORIGIN

Botanical Description

The plant can grow as a woody vine (juvenile form) or a shrub (adult form). Vining stems can grow up to 99 feet. In its juvenile form, the plant produces adventitious roots that allow climbing stems to anchor to vertical surfaces. Adult branches extend away from the juvenile form’s support and do not produce adventitious roots. Ivy leaves are alternate and leathery, with long petioles. On juvenile plants, leaves are deeply 3 to 5 lobed and 1.6 to 4 inches long and wide.

Analytical marker / Active principle

**Hederacoside C**

![Hederacoside C structure](image)
PHARMACOLOGICAL STUDIES

- **Spasmolytic / bronchodilatating effect**: it has been documented in vitro experiments and in vivo studies in the compressed air model in conscious guinea pig. Saponins and phenolic compounds isolated from a 30 % ethanolic extract of ivy leaf exhibited spasmolytic activity against acetylcholine-induced contractions of isolated guinea pig ileum. (2,4)

- **Anti-inflammatory activity**: The anti-inflammatory effects have been shown in different in-vivo models, for example, with orally administered ethanol ivy leaf extract. (2,4)

- **Secretolytic activity**: (2,4)

PHYTOTHERAPY

Activities

- **Spasmolytic** (1,2,3)
- **Bronchodilatating** (1,2,3)
- **Secretolytic** (1,2,3)
- **Anti-inflammatory** (1,2,3)

Indications:

**Oral use** (3):

- Herbal medicinal product used as an expectorant in case of productive cough. (2,3)
- As adjuvant treatment of inflammatory bronchial diseases. (2)
- Traditional herbal medicinal product used as an expectorant in cough associated with cold. (3)

Undesirable effects:

There are no reported toxic effects or intolerance phenomenon to normal use doses. Allergic reactions and gastrointestinal reactions have been reported. (4)

Dosage and administration:

**Oral use** (3):

Ivy leaf Dry Extract may be found formulated in liquid and solid preparations.

For well-established use and traditional use, posology is indicated in the EMEA/HMPC/289430/2009 monograph.

For instance,

- **Well-established use**: Dry extract (DER 4-8:1), extraction solvent ethanol 24-30% m/m.
  - **Adolescents, adults and elderly**: 15-65 mg, one to three times daily up to a daily dose of 45-105 mg.
  - **Children between 6-12 years of age**: 11-33 mg, two to three times daily up to a daily dose of 33-70 mg.
  - **Children between 2-5 years of age**: 8-18 mg, two to three times daily up to a daily dose of 24-36 mg.

BIBLIOGRAPHY AND OTHER REFERENCES SOURCES