

# SELECT BOTANICAL

## IVY LEAF

### Technical-Scientific report

#### GENERAL INFORMATION

Select Botanical 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 assures the traceability with rigorous analysis form raw material to finished product.

#### REGISTRY NUMBERS

**CAS:** 84082-54-2  
**EINECS:** 282-000-2  
**INCI/ UE:** HEDERA HELIX LEAF EXTRACT

#### INFORMATION ABOUT PLANT ORIGIN

#### SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

##### Raw material

**Definition:** Leaves of *Hedera helix* L.  
**Description:**  
- Macroscopic: Complies Ph. Eur. current Ed.  
- Microscopic: Complies Ph. Eur. current Ed.  
**Loss on drying:** ≤ 10 % w/w  
**Pesticides:** According to Ph. Eur. current ed.  
**Assay (HPLC):** Hederacoside C

##### Composition of Extract Preparation

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

##### Extract Specifications

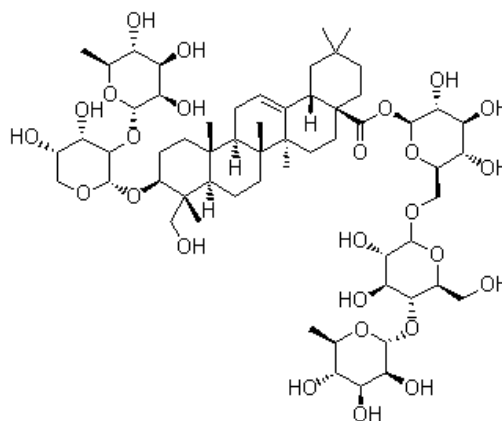
**Loss on drying:** ≤ 6 % w/w  
**Total ash:** ≤ 15 % w/w  
**Heavy metals:** Analysis of Pb,Hg,Cd and As  
According to Ph. Eur. current Ed "5.1.8. Point B"  
**Microbiological assay:**  
**Residual solvents:** According to guidelines  
CPMP/ICH/283/95  
**Assay (HPLC):** Hederacoside C

#### 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



# IVY LEAF

## Technical -Scientific report

### PHARMACOLOGICAL STUDIES

- sb** *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)
- sb** *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)
- sb** *Secretolytic activity.* (2,4)

### PHYTOTHERAPY

#### Activities

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

#### Indications:

##### Oral use:

- sb** Herbal medicinal product used as an expectorant in case of productive cough. (2,3)
- sb** As adjuvant treatment of inflammatory bronchial diseases. (2)
- sb** 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 **EMA/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

1. Blumental. The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council. Austin, Texas 1998.
2. ESCOP Monographs. Second edition. 2003
3. Community Herbal Monograph on *Hedera helix* L, leaf. EMA/HMPC/289430/2009. EMA 2011.
4. Assessment report on *Hedera helix* L, leaf. EMA/HMPC/289432/2009. March 2011.



Information contained in this Technical Scientific Report is believed to be accurate and is offered in good faith for the benefit of the user of the product. Select Botanical, SL cannot assume any liability or risk involved in the use of its products since the conditions of the use are beyond our control. The user of our product is responsible for compliance with all legal regulations applying to the use of our products, including patent laws.

Revision: 02  
July 2016