Advisory Commission for Plant Preparations

Advice of 4th April 2022 emitted by the Advisory Commission for Plant Preparations concerning the use of *Sideritis scardica* and its preparations as food supplements.

The Advisory Commission for Plant Preparations was asked by the Directorate-General Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment to issue an advice about the safe use of food supplements containing *Sideritis scardica* Griseb. or its preparations.

Regarding the Royal Decree of 31 August 2021 concerning the manufacture of and trade in foodstuffs composed of or containing plants or plant preparations, and in particular Article 5, §6.

Considering that *Sideritis scardica* Griseb. is not mentioned in the annexes of the Royal Decree of 31 August 2021; considering that *Sideritis syriaca* L. is mentioned on List 3 of the Royal Decree of 31 August 2021 (Plants to be notified if in a pre-dosed form) with the following restriction: "Only the use of the following plant parts is permitted: aerial parts"

Considering

- In the study of Feistel et al (2018)[1] a range of basic toxicity tests was conducted to explore the nonclinical safety of a dry hydroethanolic (20% EtOH) extract (DER 5-9:1, 70% native extract adjusted with 30% maltodextrin) from the herb of *S. scardica* with the following results:
    - The LD50 was higher than 2000 mg/kg bw;
    - In a 28-day repeated-dose toxicity study, the NOAEL was determined at 1000 mg dry extract/kg bw/day, the highest dose tested;
    - Mutagenicity tests (3 dry extracts, resp. water, 50% ethanol, n-heptane) did not reveal concerns for mutagenicity;
- The publication of Feistel and Appel (2013)[2] shows the similarity of an aqueous extract and a 20% hydroalcoholic extract. Extracts prepared with 40% and 60% alcohol cannot be considered as similar due to the differences in composition and a reduction in IC_{50} values for extracts prepared with 40 and 60% EtOH (IC_{50} Serotonin, IC_{50} Dopamin and IC_{50} Noradrenalin)
- The results of the toxicity tests can therefore not be extrapolated to extracts prepared with a percentage of alcohol higher than 20%
- The HPLC-DAD phytochemical profile of *S. scardica* compared to that of *S. syriaca* shows a similarity which can be considered as strong enough to draw the same conclusions for both species (unpublished results, October 2021)
- Both species are known as a traditional herbal medicinal product (infusions of the aerial parts of the plant) for the relief of cough associated with cold and for the relief of mild gastrointestinal disorders[3];

The Advisory Commission on Plant Preparations concludes that

- *Sideritis scardica* Griseb. can be included in List 3 of the RD of 31.08.2021, with the following restrictions:
    - only the use of the following plant parts is permitted: aerial parts
    - only the use of aqueous and slightly alcoholic (max. 20%) extracts is authorized.
- *Sideritis syriaca* L. remains on List 3 of the RD of 31.08.2021, but the following restriction is added:
    - only the use of aqueous and slightly alcoholic (max. 20%) extracts is authorized.

The Advisory Commission on Plant Preparations reserves the right to re-examine this advice in the light of new considerations.

References

1. Feistel, B. et al, "Assessment of the Acute and Subchronic Toxicity and Mutagenicity of Sideritis scardica Griseb. Extracts", Toxins 2018, 10, 258; doi:10.3390/toxins10070258
2. Feistel, B. and Appel, K. "Extrakte aus Griechischem Bergtee hemmen die Wiederaufnahme von Neurotransmittern", Phytokongress 2013, 08 – 10 März 2013, Leipzig
3. EMA Assessment report on Sideritis scardica Griseb.; Sideritis clandestina (Bory & Chaub.) Hayek; Sideritis raeseri Boiss. & Heldr.; Sideritis syriaca L., herba, February 2016