

Summary of the application: Cistanche tubulosa extract

Applicant: SINPHAR TIAN-LI PHARMACEUTICAL (No.599, Hongfeng Rd, Yuhang Economic Development Zone, Hangzhou City, Zhejiang, China).

The Novel food is a stem extract of Cistanche tubulosa (Trade name: Memoregain®). This extract is produced following well-described standard operating procedures from the Cistanche tubulosa planting until the manufacturing process of the extract. In-process controls are also performed during the manufacturing process to ensure the quality of the novel food. The production process is composed of several steps: water extraction, concentration, precipitation, concentration by column and spray drying.

As per Article 3, paragraph 2 of Regulation (EU) 2015/2283, the novel food falls under the following category: iv) Food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species.

The target population is the general adult population, including the elderly. This extract is intended to be used in the following two food categories: 1) Food supplements (solid, liquid and syrup/chewable forms): 2 g/day; 2) Food for special medical purposes according to Regulation 609/2013: 100,000 ppm.

The information provided on the identity, composition, specifications and contaminants of the Cistanche tubulosa extract demonstrates control of manufacturing process and does not raise safety concerns. The shelf-life was set at 36 months (accelerated and long-term stability studies).

The applicant conducted several toxicity studies on this Cistanche tubulosa extract: three Ames tests, two in vivo micronucleus tests, two mouse sperm abnormality tests, one 90-day toxicity study, one 30-day toxicity study, two 6-month toxicity studies and four clinical trials. These studies concluded on the non-genotoxicity and the safety of the novel food and allowed the determination of a No-Observed-Adverse-Effect-Level.

According to this toxicological information and the anticipated daily intakes, the proposed uses and use levels are considered as safe for the target population (adults/elderly). As a precaution, pregnant and lactating women should not consume the product.

The applicant has applied for confidentiality and data protection in accordance with Article 23 and 26 of the novel food regulation, respectively.