

Summary of the application: *Sclerocarya birrea* aqueous bark extract

Applicant: HERBAFOR S.L., C/ Purísima, Nº 52, Bajo Fortuna (Murcia), Spain

The product presented herein consists of a brown fine powder obtained by dehydration from an aqueous extract of the bark of *Sclerocarya birrea* tree, under the trade name SCLEROBIGENOL.

The applicant, HERBAFOR SL, placed in Fortuna (Murcia, Spain), harvests the bark of this tree and exports it under agreement with the Senegal authorities, the country of origin. From this bark, the final product is obtained following the principles of Good Manufacturing Practice by a well-established protocol, consisting of a series of physical steps aimed at conditioning the raw bark of the tree to obtain an adequate amount of bioactive compounds during the extraction in aqueous medium and subsequent drying to its final powder form.

The only raw materials involved in the whole production process are the bark tree and potable water. Therefore, no external pollutants or chemical contaminants are expected. The mild conditions used in the physical stages also guarantees that no degradation of the bioactive principles takes place during the process.

The product is intended to be used into four food matrices, namely, fruit and vegetable juices, infusions, food supplements and candies at level uses of 25/50 mg per serving up to a total of 100 mg/person/day.

The species from which the raw material is collected, *Sclerocarya birrea*, is a deciduous tree of the family Anacardiaceae, widely distributed in sub-Saharan Africa. Its fruits and seeds are edible and are often used in the production of juices, jams, oils, preserves and alcoholic beverages.

The product, as proposed by HERBAFOR S.L., would correspond to Novel Food category IV, food consisting of, isolated from or produced from plants or their parts, not used for human consumption to a significant degree within the Union before 15 May 1997.

The European Commission and the scientific panels of EFSA recommendations concerning the scientific aspects and the presentation of initial assessment report under the Regulation (EU) 2015/2283 concerning novel foods have been followed to provide enough information and studies to support the absence of toxicological concern in the conditions proposed.