



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

OKOUBAKA AUBREVILLEI

SUMMARY REPORT

1. *Okoubaka aubrevillei* is a giant tree of the family *Octoknemaceae* (*Santalales*) of the tropical rain forests of West Africa (Ghana, Nigeria, Ivory Coast). The homeopathic mother tincture is prepared according to homeopathic pharmacopoeias by ethanolic extraction of the dried thin bark particles of *Okoubaka aubrevillei*. Characteristic constituents of *Okoubaka aubrevillei* are sterines (beta-sitosterine, stigmasterine, sterine acetate) amino acids, tannins and catechins (catechin, gallic acid, epigallocatechin, epigallocatechin-gallate, epigallocatechin-gallate). Further constituents are gallic acid, pyrogallol and di- and triglycerides.
2. In veterinary homeopathy the mother tincture of *Okoubaka aubrevillei* is intended for use in all food-producing animals. The use follows the principles of homeopathic therapy where animals are diagnosed on basis of the individual pattern of clinical signs. The recommended maximum parenteral dose for large animals is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Okoubaka aubrevillei is also used in human homeopathy as the mother tincture as well as in lower concentrations. No adverse effects or contraindications have been reported. The bark of *Okoubaka aubrevillei* is traditionally used as a herbal drug by the native Africans for treatment of alimentary poisonings and infections of the gastrointestinal tract. The dried pulverised bark is reported to be used prophylactically at oral doses of several teaspoons per day.

3. Catechin and tannin-containing drugs have bactericidal and antiphlogistic properties. Furthermore, they may have a stimulating effect on the immune system.
4. Specific data on the acute toxicity of *Okoubaka aubrevillei* or other aspects of its toxicity was not available.
5. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products, considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Okoubaka aubrevillei* and its individual constituents was considered as not giving rise to specific health concerns. Further information made available and systematic search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Okoubaka aubrevillei* and its constituents alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for Veterinary Medicinal Products for the inclusion of substances in Annex II of Council Regulation (EEC) No 2377/90 and in particular that:

- *Okoubaka aubrevillei* is used only in a small number of individual animals for non-regular treatments,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- the substance and constituents thereof do not give rise to specific consumer health concern which may result from veterinary homeopathic uses in food producing animals;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any plant constituents of *Okoubaka aubrevillei* following homeopathic uses and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Okoubaka aubrevillei</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only