



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ANISI STELLATI FRUCTUS

SUMMARY REPORT

1. *Anisi stellati fructus* is the fruit of *Illicium verum* Hook. f. (star anise). The fruit contains essential oil (2.5 to 8%) with *trans*-anethole as the main component (80 to 90%). The oil also contains methylchavicol (an isomer of anethole), p-methoxyphenylacetone, anisaldehyde, fenchone and about 5% of monoterpene hydrocarbons (e.g. limonene, α -pinene and linalol). A polymerization product - dianethole - can occur in aged samples of the oil. The fruit also contains tannins, fatty oil and flavonoids.
2. In veterinary medicine *Anisi stellati fructus* is used in a preparation containing also *Rhei radix*, *Cinchonae cortex*, *Torula* yeast, calcium hydroxide, calcium carbonate, magnesium oxide, cobalt sulphate heptahydrate and, as excipients, sodium lauryl sulphate and sucrose. The concentration of *Anisi stellati fructus* in the preparation is 2.88%. The indications for use are various gastric complaints including forestomach atony, acute indigestion with ruminal atony and gastric catarrh. The preparation is intended to be used for cattle, sheep and goats in doses corresponding to 20 g of *Anisi stellati fructus* to cattle weighing more than 200 kg and 5 g to sheep and goats (up to 50 kg bw).

In human medicine *Anisi stellati fructus* has a limited use as a stomachic and as an expectorant. For preparation of a tea the average dose is 0.5 to 1 g, and the average daily dose is about 3 g. The average daily dose of the essential oil is 0.3 g. The fruit is also used as a spice. The essential oil is used as an expectorant and is a common ingredient in alcoholic beverages, confectionery, toothpaste etc.
3. The essential oil causes a mild irritant action on the oral mucosa which stimulates secretion of saliva. It also stimulates peristalsis and inhibits development of gas and intestinal meteorismus. The essential oil is eliminated through the pulmonary alveolar surface where it exerts balsamic action and functions as a fluidifier of the mucus thereby facilitating expectoration. The polymerization product dianethole, which can occur in aged essential oil, has oestrogenic properties.

The essential oil (*Anisi aetheroleum*) of *Anisi stellati fructus* is also used in veterinary medicine. It has been previously assessed by the Committee for Veterinary Medicinal Products and included in Annex II of Council Regulation (EEC) No 2377/90 for all food producing species.
4. No information was provided on pharmacokinetics.
5. No information was obtained on acute toxicity or on repeated dose toxicity. Neurotropic sesquiterpenoids (anisatin, vernasitins A, B and C) have been isolated from the fruit. The fruit is also reported to contain about 0.0009% of the mutagenic and cytotoxic compound safrole.
6. No information was provided on reproductive toxicity, teratogenicity, mutagenicity or cancerogenicity.

7. Sensitization to the essential oil has been reported. Active sensitization to the oil in 1 and 2% concentrations was produced in 5% of the test subjects and positive patch tests in 36 and 34%, respectively, of consecutive patients with dermatitis. The oil does not give cross-reactions or pseudo cross-reactivity.
8. No information on antimicrobial activity was provided but can be expected due to the content of essential oil.
9. No information on residues was provided.

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:

- *Anisi stellati fructus* is expected to be used in a small number of individual animals only, for infrequent or non-regular treatments,
- the animals treated with *Anisi stellati fructus* are unlikely to be sent for slaughter during or immediately after treatment,
- *Anisi stellati fructus* is used as a spice and its essential oil is a common ingredient in alcoholic beverages and confectionary,
- *Anisi aetheroleum*, the main active principle of *Anisi stellati fructus* is already included in Annex II;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Anisi stellati fructus* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Anisi stellati fructus</i> , standardised extracts and preparations thereof	All food producing species	