



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

MELISSAE FOLIUM

SUMMARY REPORT

1. The crude drug *Melissae folium* (balm leaves) consists of dried leaves of the plant *Melissae officinalis* L. The pharmacologically and toxicologically relevant components of the drug are beside the essential oil, representing at least 0.05% of the dried drug, of which the main components are citronellal, citral a and b and mono- and sesquiterpenes, tannins, phenol carbonic acids, triterpene acids, bitter compounds and approximately 0.003% flavonoids.

In veterinary medicine balm leaves and preparations of them are used to treat endometritis and unspecific sterility.

2. *Melissae folium* and a preparation thereof are contained in two veterinary medicinal products:

The pulverised leaves are part of one veterinary medicinal product containing in total 14 active principles, intended to be used for inducing heat and rut in cattle, horses, pigs, sheep and goats. *Melissae folium* constitute 10% (w/w) of this product. The doses are 50 g of the product twice a day on two consecutive days for cattle and horses, and 10-20 g twice a day on 3-4 consecutive days for sheep, goats and pigs.

A tincture from *Melissae folium* is, in a concentration of 10% (w/w), part of a suspension containing in total 4 plant originated active ingredients. The product is administered in diluted form intravaginally and intrauterinary to cows, mares and pigs. Maximum amounts of the veterinary medicinal product applied are 30 ml per cow, 25 ml per mare and approximately 30 ml per pig, mainly as a single treatment but repetition treatments are possible after 8-10 days in cows and 4-6 weeks in mares.

3. *Melissae folium* and preparations thereof have a sedative and carminative effect. In addition, antiviral, spasmolytic, antioxidative and choleric effects have been reported.
4. *Melissae folium* is used in human medicine in traditional herbal remedies to treat nervous sleeping disorders and functional disorders of the gastro-intestinal tract. The antiviral effects are used in virostatics against herpes simplex.
5. *Melissae folium* is also used for the preparation of teas and as spices and therefore it can be concluded that the normal human diet already contains *Melissae folium*.

Conclusions and recommendation

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

- *Melissae folium* is considered a normal component of human food,
- *Melissae folium* is used infrequently and for treatment of individual animals;

the Committee considers that there is no need to establish maximum residue limits for *Melissae folium* and recommends its inclusion in Annex II to Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Melissae folium</i>	All food producing species	