



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

MELISSAE AETHEROLEUM

SUMMARY REPORT

1. *Melissae aetheroleum* is the volatile oil obtained by steam distillation from fresh or dried balm leaves (*Melissae folium*) from the plant *Melissae officinalis* L. The pharmacologically and toxicologically relevant components of the essential oil, representing at least 0.05%, are the monoterpene aldehydes citronellal and citral a and b (together 40 to 75%), monoterpenes as linalool, geraniol, geranylacetate, methylcitronellate and trans- β -ocimen and sesquiterpenes as β -caryophyllen, germecren D and caryophyllene epoxide and further approximately 60 minor components in low concentrations
2. *Melissae aetheroleum* is contained in a concentration of 0.025% (w/w) in a combination product containing in total 10 plant essential oils, administered as a spray to newborn calves as a respiratory stimulant. The administered dosis is 5 times 1 ml within 2 hours.

Melissae folium, from which *Melissae aetheroleum* is obtained, is used in traditional human medicine to treat nervous sleeping disorders, and functional disorders of the gastro-intestinal tract. The antiviral effects are used in virostatica against herpes simplex. The balm leaves are also used for preparation of teas and as spices and therefore it can be concluded that the normal human diet already contains *Melissae aetheroleum*.

3. *Melissae folium* and their preparations have a sedative and carminative effect. In addition, antiviral, spasmolytic, antioxidative and choleretic effects have been reported.
4. No specific information of residues resulting from the use of *Melissae aetheroleum* in veterinary medicine has been provided. However, considering a worst-case scenario on the basis of the dose used for treatment of calves as respiratory stimulant, assuming that the total amount ($5 \times 25 \text{ mg}/100 \text{ ml} = 1.25 \text{ mg}$) is being absorbed the resulting accumulated concentration in the calve (20 kg edible tissues) would amount to 0.0625 mg/kg. According to this worst case calculation 300 g meat would contain 0.0187 mg *Melissae aetheroleum*.

The amount ingested by drinking a cup of tea made from balm leaves, for which the content of the essential oil can be estimated to be 1.5 mg (3 g leaves for 1 cup, content of essential oil in leaves 0.05%). It is therefore considered that the estimated worst case intake of 0.0187 mg *Melissae aetheroleum* will not pose any risk to the consumer.

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:

- *Melissae aetheroleum* is used only for occasional treatment of individual animals,
- The components of *Melissae aetheroleum* are also part of *Melissae folium*, which is considered as a normal component of human food;

the Committee for Veterinary Medicinal Products considers that there is no need to establish an MRL for *Melissae aetheroleum* 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>Melissae aetheroleum</i>	All food producing species	