The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

EUCALYPTUS GLOBULUS
(use in veterinary homeopathy)

SUMMARY REPORT

1. *Eucalyptus globulus* (synonym: blue gum tree) is a tree of the family *Myrtaceae*. The homeopathic mother tincture is prepared by ethanolic extraction of the fresh or dried leaves of *Eucalyptus globulus* according to homeopathic pharmacopoeias.

   The main relevant component of the leaves of *Eucalyptus globulus* is the essential oil (0.45 to 1.65% in fresh matter). The essential oil (*Eucalypti aetheroleum*) contains as main active constituent the terpene 1,8-cineol (80 to 90%, synonym: eucalyptol). Also present are p-cymene (2.7%), α-pinene (2.6%), limonene (0.5%), gerianol, camphene and euglobals. In leaf wax flavonoids such as quercetin, quercitrin and rutoside as well as the methylflavone eucalyptin were found (approximately 0.01%). The total contents of leaf wax is around 0.5%.

   Eucalypti aetheroleum, which is obtained by steam distillation of twigs and leaves of *Eucalyptus globulus* and other *Eucalyptus* species, as well as eucalyptol, the main component of *Eucalypti aetheroleum* and the leaves of *Eucalyptus globulus* have previously been considered by the Committee for Veterinary Medicinal Products (CVMP) and they are included in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
Eucalypti aetheroleum	All food producing species	
Eucalyptol	All food producing species	

2. This application relates to the use in veterinary homeopathy of the mother tincture of *Eucalyptus globulus* and in dilutions thereof, which are 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.

   Eucalyptus globulus is also used in human homeopathy as the mother tincture as well as in lower concentrations. In human phytotherapy, *Eucalyptus globulus* in form of *Eucalypti aetheroleum* is used against the symptoms of common cold, asthma and fever. *Eucalypti aetheroleum* has antibacterial and antifungal activity. The average oral dose is 0.3 to 0.6 g of *Eucalypti aetheroleum*; several times a day. *Eucalypti aetheroleum* is also a constituent of lozenges, which are sucked as adjuvant treatment of cold, and it is used by inhalation after mixing with with hot water.

3. Constituents of *Eucalyptus globulus* appear to be rapidly absorbed from the stomach and gut. Excretion is mainly by breathing.

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4. The oral LD_{50} for *Eucalypti aetheroleum* is about 3 g/kg bw in mice and for rats an LD_{50} of about 4 g/kg bw is given (route of administration not clear, probably oral). For cineol, the LD_{50} is 2.48 g/kg bw in rats for oral administration, higher than 5 g/kg bw in rabbits for dermal use and 100 mg/kg bw in mice for intramuscular use. In humans, poisoning is described for *Eucalypti aetheroleum* after oral doses of 10 to 20 ml in adults and 5 ml in infants (2.5 years old). Doses higher than 30 ml are generally considered to be lethal for humans, although in indicvidual cases doses as low as 5 ml were reported as fatal, while in other cases doses as high as 120 to 220 ml have not been fatal .

5. *Eucalypti aetheroleum* is used as a spice and flavouring agent for production of foods, in particular sweets. It was listed by the Council of Europe as a natural source of food flavouring. *Eucalypti aetheroleum* can be added to foodstuffs in small quantities, with a possible limitation of an active principle in the final product. The Council of Europe accepts 15 mg/kg of eucalyptol (1,8-cineol) as a permissible concentration of artificial flavouring substance in food. The oil and 1,8-cineol have status as "Generally Recognised As Safe" in the United States of America and both are approved for use in food.

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:

- the starting material used for homeopathic preparation of *Eucalyptus globulus* contains the spectrum of relevant constituents of *Eucalypti aetheroleum*, which has previously been assessed by the CVMP and is included in Annex II of Council Regulation (EEC) No 2377/90,
- eucalyptol, the main constituent of *Eucalyptus globulus* with pharmacologic and toxicologic activity also has previously been considered by the CVMP and is in cluded in Annex II of Council Regulation (EEC) No 2377/90,
- *Eucalypti aetheroleum* is used a spice and for seasoning of food, and is also contained in lozenges, and may be considered a normal component of the human diet,
- *Eucalyptus globulus* in veterinary homeopathy 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 Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Eucalyptus globulus* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
Eucalyptus globulus	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