



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CITRONELLAE AETHEROLEUM

SUMMARY REPORT

1. *Citronellae aetheroleum* is the volatile oil of the aerial parts of several species of the genus *Cymbopogon* (synonym: lemongrass). *Citronellae aetheroleum* is used in one veterinary medicinal product, according to the German Pharmacopoeia (6th edition). This monograph states the source of the oil as *Cymbopogon. winterianus* Jowitt. The following discussion refers to this species. *Citronellae aetheroleum* contains: citronellal (32 to 45%), geraniol (12 to 18%), citronellol (11 to 15%), geranylacetate (3 to 8%) and citronellylacetate (2 to 4%). More than 50 other components are present in low concentrations.
2. *Citronellae aetheroleum* is contained in a veterinary medicinal product in combination with 9 other active principles. The percentage of the oil in the product is 0.002%. The product is intended to be used as a nose-spray to facilitate breathing in new-born animals of all food producing species. The dose is 0.1 to 0.3 g of the product, depending on the size of the animal. This corresponds to a maximal single dose of 0.006 of *Citronellae aetheroleum*. Treatment may be repeated after 10 to 15 seconds.
Citronellae aetheroleum is used in human medicine against inner restlessness. It is administered in baths containing at least 0.04 g oil/l at a temperature of 26 to 38°C for 10 to 20 minutes.
3. Oral doses of 1 g/kg bw of *Citronellae aetheroleum* reduced the spontaneous motility in mice.
4. No information on pharmacokinetics was provided.
5. There are no animal data on toxic effects directly related to oil from *C. winterianus*. An oral LD₅₀ of more than 5 g/kg bw is reported for rats for a "citronella" oil. The dermal LD₅₀ in rabbits of 4.7 ml/kg bw was reported for the same oil.
6. No information on reproduction and teratogenicity has been provided.
7. In the summary information provided *Citronellae aetheroleum* is reported to be mutagenic. No further information was provided.
8. No information on carcinogenicity has been provided.
9. *Citronellae aetheroleum* can cause allergic reactions. No animal studies were provided. No irritation was observed in a 48 hours closed patch test in 25 human subjects at a concentration of 8%. No sensitisation reactions were reported from the same test.
10. A child, 21 months old, died after ingesting 10 ml of a liquid containing *Citronellae aetheroleum* as the main component. In a placebo-controlled clinical experiment bathing in water containing 0.04 to 0.08 g/l of *Citronellae aetheroleum* improved sleep quality.

11. Citronella oil has "Generally Recognised As Safe" status in the USA and is approved for food use by FDA in USA and by the Council of Europe. In the summary information provided, it is stated that an ADI of 500 µg/kg bw has been established for citral, citronellal and geranylacetate all calculated as citral.
12. The use of *Citronellae aetheroleum* in the doses recommended is unlikely to result in residues in edible tissues posing a risk to the health of the consumer.

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:

- *Citronellae aetheroleum* is used only for newborn animals,
- the animals are unlikely to be sent to slaughter immediately after treatment;

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