



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ANGELICAE RADIX AETHEROLEUM

SUMMARY REPORT

1. *Angelicae radix aetheroleum* is the volatile oil obtained by steam distillation from roots of *Angelica archangelica* L. (synonym: garden angelica) the pharmacological and toxicological relevant components are: α - and β -phellandrene, α -pinene, α -thujene, limonene, β -caryophyllene, linalool, borneol, acetaldehyde, 15-oxypentadecene lactone (main component). The oil is claimed to be devoid of furanocoumarins, which are present in the root.
2. *Angelicae radix aetheroleum* is contained in one veterinary medicinal product in combination with 9 other active principles. The percentage of *Angelicae radix aetheroleum* in the product is 0.003%. The product is used as a nose-spray to facilitate breathing in new-born animals of all food producing species. The dose ranges from 0.1 to 0.3 g of the product, depending on bodyweight. This corresponds to a maximal single dose of 0.009 mg of *Angelicae radix aetheroleum*. The treatment may be repeated after 10 to 15 seconds.

No particular information on the use of the oil in human medicine has been provided, but a daily human dose of the oil is reported to be 10 to 20 drops, which corresponds to a maximum dose of 400 mg.

Angelicae radix aetheroleum is also used as a fragrance in cosmetic products and the root itself, which contains 0.35 to 1% of the volatile oil, is widely used in food.
3. No information on the pharmacological activity and the pharmacokinetics of the oil was provided.
4. The provided summary data report an oral LD₅₀ of 2.2 g/kg bw in mice and of 11.6 g/kg bw in rats. The dermal LD₅₀ in rabbits is reported to be greater than 5 g/kg bw. Reports on phototoxicity are contradictory, but have mainly been attributed to the furanocoumarines, which are claimed to be absent from the oil.
5. Rats are reported to tolerate an oral daily dose of 1.5 g *Angelicae radix aetheroleum*/kg bw for eight weeks. No further information on repeated dose toxicity was provided.
6. No reports on effects on reproduction and teratogenicity have been provided.
7. No reports on the effects of *Angelicae radix aetheroleum* on mutagenicity, carcinogenicity or immunotoxicity have been provided.
8. The related species *Angelica silvestris* is listed by the Council of Europe as a source of natural food flavouring, which may be used in a traditionally accepted manner, although there is insufficient information available for an adequate assessment of its potential toxicity. *Angelica* is listed as 'Generally recognised as safe' in the USA.
9. In view of the limited use of *Angelicae radix aetheroleum* in veterinary medicine, information on possible residues or residue depletion was not considered necessary.

Conclusions and recommendation

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

- the root of *Angelica archangelica* and related *Angelica* species are a normal component of the human diet,
- *Angelicae radix aetheroleum* is used only in a small number of animals for infrequent and non-regular treatment,
- the animals are unlikely to be sent for slaughter during or immediately after treatment;

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