



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

AILANTHUS ALTISSIMA

SUMMARY REPORT

1. *Ailanthus altissima* (Mill.), (synonym: Tree of heaven), is a plant of the family *Simaroubaceae*. In veterinary homeopathy *Ailanthus altissima* is used as mother tincture prepared by ethanolic extraction of two parts of fresh, flowering twigs and one part of fresh stem bark of the tree *Ailanthus altissima* according to homeopathic pharmacopoeias, and dilutions thereof. Constituents of *Ailanthus altissima* stem or root bark are (bitter tasting) quassinoids of the ailanthone type as ailanthone (e.g. stem 0.01%, based on dry matter) or shinjulactones (shinjulactone E, stem 0.0001%), of the amarolide type as amarolide (stem 0.006%) and 11-acetylamarolide (stem 0.0004%), further shinjulactone B (stem 0.001%) and shinjudilactone (stem 0.0004%). Further bark (only root bark data available) and leaves contain indole alkaloids derived from the β -carboline and canthin-6-one type. The bark is said to contain quinones as 2,6-dimethoxy-benzoquinone (less than 0.001%). In the leaves flavones, glycoflavones and flavonols as apigenin, apigenin-7-O-glucoside, luteolin-7-O-glucoside, quercetin-3-O-galactoside, kaempferol and quercetin as well as flavone glycoside gallates as luteolin 7-O-beta-(6"-galloyl)glucopyranoside) are found. Leaves and bark are said to contain chemically unspecified tannins (2.5% in bark).
2. *Ailanthus altissima* is 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 is 10 ml/animal. Corresponding doses in form of tablets, globules or drops are reported to contain lower amounts of *Ailanthus altissima* than the injectable form. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Ailanthus altissima is also used in human homeopathy as the mother tincture as well as in lower concentrations. In human phytotherapy the drug prepared from *Ailanthi* cortex (root and stem) bark is used orally at doses of 6 to 9 g daily for its antimalarial properties, possibly exerted by some quassinoids. The bark consumed in large amounts (not specified) is reported to act laxative and to cause nausea, vertigo, headaches and cold sweating.
3. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products (CVMP) considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Ailanthus altissima* and its individual constituents was considered as not giving rise to specific health concern. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Ailanthus altissima* alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of any suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents.

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:

- *Ailanthus altissima* is used 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 substance and constituents thereof do not give rise to specific consumer health concern which may result from the use in veterinary homeopathy;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any plant constituents following homeopathic use of *Ailanthus altissima* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 according to the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Ailanthus altissima</i>	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