



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### LACHNANTHES TINCTORIA

#### SUMMARY REPORT

1. *Lachnanthes tinctoria* (synonyms: *Dilatris carolinana*, red root), is a plant of the family *Haemodoraceae* with orange-red-pigmented roots, reaching a height of 30 to 50 inches. *Lachnanthes tinctoria* grows on sandy grounds at the coast and on sandy swamps situated in the United States of America (Florida, Carolina). The mother tincture is prepared according to homeopathic pharmacopoeias by ethanolic extraction of the entire flowering plant of *Lachnanthes tinctoria*.

*Lachnanthes tinctoria* is a rich source of red pigments. The major pigments are 9-phenylphenalenone pigments, 2,5,6-trihydroxy-9-phenylphenalenone (1, lachnanthoside aglycone) and 2,6-dihydroxy- 5-methoxy- 9-phenylphenalenone (2, haemocorin aglycone). The pericarp and the seeds contain lachnanthocarpone and the flowers lachnantonin. Further constituents are glycosides (dilatrins, lachnanthoside aglycone 1-glucoside, haemocorin aglycone) chelidonic acid and naphthalene derivatives.

2. In veterinary homeopathy the 1:1000 dilution of *Lachnanthes tinctoria* is intended for oral or parenteral use in all food-producing species. 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. Corresponding oral doses of 1:1000 as tablets, globules or drops are reported to contain lower amounts of *Lachnanthes tinctoria* than the injectable form. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

*Lachnanthes tinctoria* is also used in human homeopathic medicine as the mother tincture as well as in lower concentrations. Contraindications and unwanted side effects are not described.

3. Little information is available on the pharmacodynamic activity of *Lachnanthes tinctoria*. In published literature *Lachnanthes tinctoria* is said to colour pig bones red and to induce detachment of the hooves (no dose information available). It is known that *Lachnanthes tinctoria* has photodynamic properties. These properties are attributed to naphthalene derivatives. Naphthalene derivatives are also reported to be retinotoxic; systemic absorption of naphthalene vapour may result in cataracts. The biochemical basis for naphthalene cataract has been investigated and shown to be related to the liver metabolite 1,2-dihydro-1,2-dihydroxy-naphthalene, which in turn is autoxidised to 1,2-naphthoquinone.
4. Information on the pharmacokinetics and metabolism of *Lachnanthes tinctoria* was not provided.
5. No data on acute toxicity of *Lachnanthes tinctoria* was provided and no information on repeated dose toxicity, immunotoxicity, mutagenicity, teratogenicity or carcinogenicity of *Lachnanthes tinctoria* was provided. In literature, *Lachnanthes tinctoria* has not been connected with mutagenic, carcinogenic or teratogenic effects.

6. Possible consumer exposure to residues resulting from use of *Lachnanthes tinctoria* in veterinary homeopathy may be based on the following considerations: a 1:1000 dilution of the mother tincture, containing at maximum 0.1% of total plant material, is used. In the absence of data, it is arbitrarily assumed that the plant material of *Lachnanthes tinctoria* contains an exaggerated content of 30% of constituents of consumer concern (i.e. naphthalene derivatives and others) and, that all these constituents are completely soluble upon ethanolic extraction. The 1:1000 dilution would then contain 0.3 mg/ml of these constituents. A maximum (intravenous) dose of 10 ml for large animals (500 kg bw) would correspond to 6 µg/kg bw. Assuming no metabolism or detoxification and excretion, this dose would amount to 3 µg of residues in a standard edible meat portion. In a similar calculation for milk based on a daily milk production of 20 liters by a 500-kg cow and assuming a proportion of 2% of the dose to be excreted into milk, milk residues would amount to a maximum of 3 µg/l. These estimated worst case amounts of residues of the total, chemically complex plant constituents in the low µg range may be considered insignificant with respect to levels of possible consumer health risk.
7. The use of *Lachnanthes tinctoria* in a dilution of 1:1000 in veterinary homeopathy was considered in a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products, considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000. It was concluded, that the substance and its individual constituents in a dilution of 1:1000 can be classified as not giving rise to any specific consumer health concerns.

### 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:

- *Lachnanthes tinctoria* is used only as a diluted homeopathic extract not exceeding concentrations of one part per thousand;
- *Lachnanthes tinctoria* is used only in a small number of individual animals for non-regular treatments,
- the 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 any constituents of *Lachnanthes tinctoria* in a dilution of 1:1000 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>Lachnanthes tinctoria</i>	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations in the products not exceeding one part per thousand only