



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CRATAEGUS

SUMMARY REPORT

1. *Crataegus* (synonyms: *Crataegus laevigata*, *Crataegus monogyna*, hawthorn) is a plant of the family *Rosaceae* widely distributed in Middle and Western Europe. In veterinary homeopathy *Crataegus* is used as the mother tincture prepared by ethanolic extraction of the fresh fruits of *Crataegus*, or by ethanolic extraction of the fresh or dried leaves, fruits or flowers (*Folia, fructi, herba cum floribus Crataegi*) and respective dilutions thereof. *Crataegus* fruits, leaves and blossoms have similar constituents but the amount of the constituents varies in the different parts of the plant. Flavonoids (2.5% in blossoms, 1.8% in leaves, 0.5% in fruits) including apigenin, luteolin, rutin, kaempferol and quercetin have been found. The amount of vitexin-2-rhamnoside in the leaves is greater than in the blossoms, vitexin-2-rhamnoside has not been identified in the fruits, whereas hyperoside is the major flavonoid of the fruits. The plant contains 2 to 3% procyanidins (oligomeric and polymeric procyanidins), chlorogenic acid and caffeic acid. Further constituents are triterpenic acids (up to 0.8%) e.g. oleanolic acid, crataegolic acid and ursolic acid.
2. The mother tinctures prepared according to homeopathic pharmacopoeias 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 is 10 ml. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Crataegus is also used in human homeopathy as the mother tincture as well in lower concentrations. The plant has been used in European phytotherapy and long experience has been gained. In human phytotherapy a powder obtained from the dried fruits of *Crataegus* is orally used for treatment of infections of the throat (gargle preparation). A drug obtained from the dried leaves and blossoms is used as a remedy to strengthen the cardiovascular system at doses of 1 g several times per day.

The fruits are also used for preparations of jam or tea.

3. The acute toxicity of an hydro-ethanolic extract of the blossoms and leaves of *Crataegus* was investigated. Intraperitoneal or oral application of 3 g/kg bw induced no lethal effects on mice and rats.
4. In a preliminary risk evaluation procedure by the CVMP considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Crataegus* 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 *Crataegus* 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:

- *Crataegus* is used in a small number of individual animals and for non-regular treatments only,
- 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 *Crataegus* 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>Crataegus</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.