



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

HAMAMELIS VIRGINIANA (use in veterinary homeopathy)

SUMMARY REPORT (2)

1. *Hamamelis virginiana* (synonym: witchhazel) is a plant of the family *Hamamelidaceae*. The homeopathic mother tincture of *Hamamelis virginiana* is prepared according to homeopathic pharmacopoeias by ethanolic extraction of fresh bark of roots and the branches.

Both bark and leaves contain volatile oil (0.1% and 0.01 to 0.05%, respectively), tannins and saponins (up to 12% and up to 5%, respectively); the leaves also contain flavonoids (1.9%). The volatile oil (in leaves 0.01 to 0.5%) contains aliphatic alcohols (40%), aliphatic esters (15%), acetadehyde (3.2%) n-hexene-2-al (9.7%), hexene-2-ol (no quantitative data available), hexenol, α - and β -ionones (4.5%), eugenol, traces of safrole (maximum 0.2% of the essential oil) and sesquiterpenes. Other constituents include gallic acid.

Hamamelis virginiana has previously been assessed by the Committee for Veterinary Medicinal Products (CVMP) in respect to its use in veterinary phytotherapy and is included in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Hamamelis virginiana</i>	All food producing species	For topical use only

2. This application relates to the homeopathic mother tincture of *Hamamelis virginiana* and dilutions thereof, which 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 for large animals is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Hamamelis virginiana is also used in human medicine. Indications include inflammation of the skin and mucous membranes, varicose veins, and haemorrhoids. Topically administered products contain between 5 to 10% of the drug in ointment and up to 30% in poultices. Suppositories contain 0.1 to 1 g drug and are applied 1 to 3 times daily. Furthermore *Hamamelis virginiana* is frequently contained in cosmetics (skin lotions, nourishing creams, pre- and after-shaves).

3. The topical use of *Hamamelis virginiana* in medicinal products used in veterinary homeopathy in all concentrations used therein including the mother tincture is covered by the above Annex II entry.

The use of *Hamamelis virginiana* in veterinary homeopathy was further 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. The only toxicologically relevant constituent, safrol, which is a constituent of the volatile oil, is only present in trace amounts and is thus considered negligible as concerns consumer safety. Further information made available and systematic search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Hamamelis virginiana* and its constituents 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 suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents. It was concluded, that for all other routes of administration homeopathic dilutions of *Hamamelis virginiana* resulting in concentrations in the veterinary medicinal product not exceeding 1 part per 10 may be used, as they can be considered as not giving rise to any specific consumer health concerns and provide a sufficient margin of safety.

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:

- *Hamamelis virginiana* has already been included in Annex II of Council Regulation (EEC) No 2377/90 for topical use,
- *Hamamelis virginiana* 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,
- *Hamamelis virginiana* and individual constituents thereof do not give rise to specific consumer health concern which may result from veterinary homeopathic uses;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for *Hamamelis virginiana* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Hamamelis virginiana</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 ten only