



## COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

### HAMAMELIS VIRGINIANA

#### SUMMARY REPORT (1)

1. *Hamamelis virginiana*, (witch hazel) is used in the form of bark and leaves and extracts of both. It is reported to have astringent and haemostatic properties.

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 contains hexen-2-ol, hexenol,  $\alpha$ - and  $\beta$ -ionones, eugenol, safrole (maximum 0.2% of the volatile oil) and sesquiterpenes.

Other constituents include gallic acid.

*Hamamelis virginiana* is also used in human medicine and cosmetics (skin lotions, nourishing creams, pre- and after-shaves).

2. *Hamamelis virginiana* is used topically in veterinary medicine as a solution or as an ointment in combination with other herbal extracts to promote wound-healing of minor injuries of skin, for treatment of skin inflammations, ulcerations and dermatoses. The medicinal products contain 2.5 to 10.8% (w/w) of an extract of the leaves and are applied 1 to 2 times daily for 2 to 3 days.
3. No information on the pharmacokinetics of *Hamamelis virginiana* nor of its constituents was provided.
4. No information on the toxicology of *Hamamelis virginiana* nor of its constituents was provided.
5. In the summary information provided, a study investigating carcinogenic effects of *Hamamelis virginiana* is reported. When a lyophilised aqueous extract of *Hamamelis virginiana* leaves was administered subcutaneously to 15 male and 15 female NIH Black rats over 78 weeks, mesenchymal tumours were observed in 3/15 male rats. However, the tumour rate was not considered to be significantly increased in comparison with the controls.
6. In human medicine, preparations of *Hamamelis virginiana* are used for treatment of 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.

## Conclusions and recommendation

Having considered that:

- the main constituents of *Hamamelis virginiana* are tannins and saponins, which are believed not to cross skin and mucous membranes,
- the only toxicologically relevant constituent, safrole, comes from the volatile oil; however its concentration is negligible,
- *Hamamelis virginiana* is widely employed in cosmetic products.

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

- *Hamamelis virginiana* is used in individual animals for topical treatment only ,
- 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 *Hamamelis virginiana* 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>Hamamelis virginiana</i>	All food producing species	For topical use only