The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TANNINUM

SUMMARY REPORT

1. Tanninum is an ester of glucose with gallic acid or 3-galloyl-gallic acid. It occurs in the bark and fruits of many plants, notably in the bark of the oak species and in immature fruits and also in coffee, tea, cocoa and wine.

2. Tanninum is an astringent. It binds complexes and precipitates proteins. It is used in all animal species orally for the treatment of diarrhoea and of poisoning with heavy metals. The recommended dose levels are 1000 mg/animal to 25000 mg for horses and cattle, 1000 mg to 2000 mg for swine and 10 to 50 mg for poultry daily for 3 to 5 days. In humans it is used at a dose of 200 mg/person.

3. Tanninum is fully degraded in the upper intestine. In urine only the degradation products can be detected.

4. The LD_{50} of tanninum in mice and rats is 2250 to 6000 mg/kg bw after oral administration and 80 mg/kg bw in mice after intravenous administration.

5. After daily oral administration of dose levels greater than 1000 mg/kg bw, or of 1 to 5% tanninum in feed to rats, bodyweight depression due to an antinutritive effect (inhibition of the resorption of nutrients) can be expected. The oral administration of 1000 mg/kg bw/day for 231 days and the administration by feed in rats (8, 80 or 800 mg/kg bw/day for 12 weeks and 1170, 1250, 2340 or 2500 mg/kg feed for 2 years) and dogs (1170, 1250, 2340 or 2500 mg/kg feed for 2 years) had no effect on bodyweight, food intake, food utilisation nor on the histopathological findings of the internal organs.

6. Three-generation studies, 2 litters per generation, were carried out in groups of 20 males and 20 females rats using Peruvian tara tannin at feeding levels of 580, 1170 and 2340 mg/kg feed. Pups of the group fed at the 2340 mg/kg feed level had significantly lower weights at weaning as compared to the controls. This effect was not seen at the lower feeding levels, nor were effects upon fertility, gestation, viability or lactation indices seen at any feeding level.

7. In a study reported by the International Agency for Recherche on Cancer (IARC) tumours have been observed in mice and rats following parenteral administration. However, in the long-term oral toxicity studies in rats and dogs, there was no evidence for carcinogenicity.

8. Tannic acid was last evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1989. An ADI "not specified" was allocated to tannic acid for use as filtering aid where the application of good manufacturing practice ensures that it is removed from food after use.

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Conclusions and recommendation

Having 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:

- tanninum is a normal constituent of food,
- the oral toxicity of tanninum is very low;

the Committee considers that there is no need to establish an MRL for tanninum and recommended 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
Tanninum	All food producing species	