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

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SULFOGAIACOL

SUMMARY REPORT

1. Sulfogaiacol (also called potassium guaiacolsulfonate or potassium hydroxy-methoxy-benzenesulphonate hemihydrate or soluble gaiacol) is used as an expectorant in cattle, horses, pigs and poultry. In cattle and horses, the recommended dose rate is 10 to 20 mg/kg bw/day intravenously or 24 mg/kg bw/day orally. In pigs and poultry it is administered in the drinking water, at doses equivalent to 30 mg/kg bw/day and 20 mg/kg bw/day, respectively.

   Sulfogaiacol is also used in human medicine at a recommended dose rate of up to 160 mg/person every 4 to 6 hours.

2. Potassium is a normal component of diet and is particularly abundant in fruit and vegetables. The recommended daily intake varies from 350 to 1275 mg in children to 1875 and 5625 mg in adults. In the United Kingdom, the reference nutrient intake (RNI) is 3.5 g/day for adults.

2. The potassium ion itself possesses almost no toxicity following oral administration; any toxicity of the salts is associated with the anion. No information has been provided on the safety of gaiacolsulfonate ion. However, the Committee considered that such information was not necessary. Sulfogaiacol was merely the water-soluble form of gaiacol and the gaiacol moiety was responsible for the expectorant activity.

   Gaiacol and its salts had been used extensively in human medicine for many years. Gaiacol has previously been assessed by the Committee for Veterinary Medicinal Products and included in Annex II of Council Regulation (EEC) No. 2377/90.

4. No information was provided concerning the pharmacokinetics or residue depletion following administration of sulfogaiacol to the target species.

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:

- sulfogaiacol is used for infrequent or non-regular treatments,
- the animals are unlikely to be sent for slaughter during or immediately after treatment,
- gaiacol is already included in Annex II of Council Regulation (EEC) No 2377/90;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for potassium sulfogaiacol 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
Sulfogaiacol	All food producing species	

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