



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

BROMIDE, POTASSIUM SALT

SUMMARY REPORT

1. Potassium bromide is used as a hypnotic and sedative in cattle, horses, sheep and pigs. It is also used as an adjunct in the treatment of colic and tetany in horses and acetonæmia in cattle. The normal oral dose is in the range of 60 to 120 mg/kg bw for cattle and horses, 40 mg/kg bw for sheep and 50 mg/kg bw for pigs. Horses may also be treated intravenously at a dose of 30 to 60 mg/kg bw. One or two doses may be administered.

In human medicine potassium bromide is used as an adjunct to phenobarbital in the treatment of epilepsy. In the past, it was used in humans as a sedative and anti-convulsant at doses of up to 6 g/person/day (expressed as bromide).

2. The potassium ion itself possesses almost no toxicity after oral administration; any toxicity of the salt is, in this case, associated with the anion. The toxicity of the bromide ion has already been considered in relation to sodium bromide (see summary report EMEA/MRL/182/97). An ADI of 0.4 mg/kg bw (i.e. 24 mg/person) was established for inorganic bromide. This ADI was estimated by applying a safety factor of 10 to the NOEL of 4 mg bromide/kg bw/day, obtained in pharmacological studies in humans. The Committee recommended the inclusion of sodium bromide in Annex II of Council Regulation (EEC) No 2377/90 for topical use only.
3. No information was provided on the pharmacokinetics or residues depletion of bromide residues in tissues and milk following the administration of potassium bromide to the target species.
4. Bromine is widely distributed in the environment and bromide occurs naturally in foodstuffs. Market basket surveys sponsored by the Netherlands government have shown that consumers are exposed to up to 13.4 mg Br⁻/person/day (with mean intakes estimated to be in the region of 8.4 to 9.4 mg Br⁻/person/day) from other dietary sources of bromide. MRLs recommended by Codex allow concentrations of 20 to 400 mg/kg of bromide ion in various foodstuffs, and EU legislation regarding pesticides set an MRL of 50 mg/kg for inorganic bromide in cereals (Council Directive 86/362).

Potassium is a normal component of the 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.

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:

- bromide is a normal component of the diet in humans,
- potassium bromide is used for infrequent or non-regular treatments,
- the animals are unlikely to be sent for slaughter during or immediately after treatment,
- the very limited use of potassium bromide in veterinary medicine is unlikely to result in significantly enhanced bromide residues in food products from treated animals;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for potassium bromide 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
Bromide, potassium salt	All food producing species	