



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

BETAINE GLUCURONATE

SUMMARY REPORT

1. Betaine glucuronate is, together with 2-aminoethanol glucuronate, used as active principle in a product for symptomatic treatment of acute or chronic disorders of the liver, such as endogenous metabolic disorders, cases of exogenous intoxication or disorders related to parasite infestations. It is administered by injection in cattle, horses, sheep, goats and pigs at doses ranging from 1.5 to 15 mg/kg bw.
2. Betaine and glucuronic acid are the immediate metabolites of betaine glucuronate.
3. Betaine, a normal component of the human diet as well as part of the human and animal metabolism, is already included in Annex II of Council Regulation (EC) 2377/90 for all food-producing species.
4. Glucuronic acid, also a part of the human and animal diet as well as part of the human and animal metabolism, is already included in Annex II of Council Regulation (EC) 2377/90 for all food-producing species in the form of potassium glucuronate.

Conclusions and recommendation

Considering that:

- the immediate metabolites betaine and glucuronic acid have already been assessed and placed in Annex II of Council Regulation (EC) 2377/90 for all food-producing species,
- betaine glucuronate is not to be regarded as a new active substance;

the Committee concludes that there is no need to establish an MRL for betaine glucuronate and recommends its inclusion in Annex II of Council Regulation (EEC) 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Betaine glucuronate	All food producing species	