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

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SODIUM HYPOPHOSPHITE

SUMMARY REPORT

1. Sodium hypophosphite (NaH_2PO_2) is used in veterinary medicine as a source of phosphorous. It is an ingredient (1% w/v) of a formulation in combination with ascorbic acid and calcium glucoheptonate. It is administered to cattle and horses at doses of 10 ml/100 kg bw (1 mg/kg sodium hypophosphite) and to sheep, goats and swine at doses of 5 to 10 ml (50 to 100 mg sodium hypophosphite) per animal by the intramuscular or intravenous route.

2. Magnesium hypophosphite ($Mg_2(H_2PO)_2$), also used in veterinary medicine as a source of phosphorous, has been previously considered by the CVMP and an entry into Annex II of Council Regulation (EEC) 2377/90 has been recommended.

3. No information was provided on the absorption, distribution, metabolism and excretion of sodium hypophosphite. However, the properties of the phosphates, which are also used as a source of phosphorous, have been studied in humans and animals. Approximately 66% of the orally administered dose of phosphate is absorbed from the gastro-intestinal tract, the exact amount depending on the vitamin D status of the individual. Most of the absorbed phosphate is then filtered by the glomeruli and undergoes partial reabsorption. Almost all of the absorbed phosphate is eventually excreted in the urine. Excess phosphate is eliminated in the faeces.

4. The limited data available suggested that sodium hypophosphite is of low toxicity. The acute intraperitoneal LD_{50} for sodium hypophosphite in the mouse was 1584 mg/kg bw. Subcutaneous administration of 50 mg/kg bw of sodium hypophosphite caused no adverse effects in rabbits.

5. In human medicine, hypophosphites were formerly used as tonics. No information was available concerning the doses employed. The most common adverse effect after oral administration was reported to be diarrhoea.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for the inclusion of substances into Annex II to Council Regulation (EEC) No. 2377/90, and in particular that:

- sodium hypophosphite is used only in the treatment of individual animals,
- the animals are unlikely to be sent for slaughter during or immediately after treatment;

the Committee concluded that there was no need to establish an MRL for sodium hypophosphite and recommends its inclusion in Annex II to Council Regulation (EEC) No. 2377/90 in accordance with the following table:

Pharmacologically active substance (s)	Target species	Other provisions
Sodium hypophosphite	All food producing species	

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