



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

POLYETHYLENE GLYCOL 7 GLYCERYL COCOATE

SUMMARY REPORT

1. Polyethylene glycol 7 glyceryl cocoate (macrogol 7 glycerol cocoate, PEG-7-glyceryl cocoate; Cetiol HE) is a polyol fatty acid ester used as an excipient (solubiliser) in pharmaceutical products. In veterinary medicine the product is used in an insect repellent, where it is present at a concentration of approximately 4.5%. The product is diluted with water 1:200 before use (final concentration of polyethylene glycol 7 glyceryl cocoate 0.0225%). The product is intended for external use only. Target animal species and dosage for the product have not been specified in the documentation. The compound is also incorporated as an excipient in cosmetics, e.g. in "foam bath" fluids and shampoos.
2. The acute toxicity of the compound is low, the oral LD₅₀ in rats being in excess of 20 g/kg bw.
3. Few data have been presented concerning the pharmacodynamics, pharmacokinetics, and the toxicology of the substance. No residue depletion studies were carried out with the compound. However, taking into account the low oral toxicity, it appears unlikely that concentrations of residues of polyethylene glycol 7 glyceryl cocoate likely to occur in edible tissues of food animals following recommended use of veterinary medicinal products will pose any significant risk to the health of the consumer.

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:

- the low toxicity of polyethylene glycol 7 glyceryl cocoate,
- the low concentrations at which the substance are incorporated in veterinary medicinal products,
- that products containing the substance are administered topically only;

the Committee concludes that there is no need to establish an MRL for polyethylene glycol 7 glyceryl cocoate and recommends 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
Polyethylene glycol 7 glyceryl cocoate	All food producing species	For topical use only