



## **COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS**

### **COCO ALKYL DIMETHYL BETAINES**

#### **SUMMARY REPORT**

1. Coco alkyl dimethyl betaines (synonyms: dehyton AB 30, lauryl amino dimethylaceto betain coco-betain) are betaines, i.e. internal quaternary ammonium salts of glycine. The molecules are ampholytes. Coco alkyl dimethyl betaines are incorporated as a wetting agent in pharmaceutical preparations due to their surface-active properties. In veterinary medicine the compound is used as excipient in an insect repellent preparation, at a non-specified concentration. It is also used in cosmetics, e.g. in shampoos.
2. Betaine has already been scientifically assessed by the CVMP and an entry into Annex II of Council Regulation (EEC) 2377/90 has been recommended.
3. No information on the pharmacokinetics and on the metabolism of coco alkyl dimethyl betaines was provided. However, coco alkyl dimethyl betaines belong to the family of the quaternary ammonium compounds known to be poorly absorbed from the gastrointestinal tract after oral administration.
4. The acute toxicity of the compound appears to be low, the oral LD<sub>50</sub> in rats being 5.6 ml/kg bw. The local tolerance (skin; mucous membranes) of a 0.5% solution in water is good, while concentrated solutions will cause irritation of the skin. Oral administration of concentrated solutions may cause acute gastro-enteritis with vomiting and diarrhoea.
5. While no data have been presented concerning the toxic effects following repeated exposure and the mutagenic/carcinogenic potential of the substance, such data was not considered necessary as coco alkyl dimethyl betaines belong to a family of known compounds of low toxicity after oral administration.

## 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 2277/90 and in particular that:

- coco alkyl dimethyl betaines belong to the group of quaternary ammonium compounds which are known to be of low toxicity and are poorly absorbed from the gastrointestinal tract,
- the use of coco alkyl dimethyl betaines should not result in residues in food of animal origin at concentrations which are toxicologically relevant for the safety of the consumer;
- betaine has already been scientifically assessed by the CVMP and an entry into Annex II of Council Regulation (EEC) 2377/90 has been recommended;

the Committee considers that there is no need to establish MRLs for coco alkyl dimethyl betaines 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
Coco alkyl dimethyl betaines	All food producing species	For use as excipient