

COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

SORBITAN SESQUIOLEATE

SUMMARY REPORT

1. Sorbitan sesquioleate (CAS No 8007-43-0) is a mixture of the partial esters of sorbitol and its mono- and di-anhydrides with oleic acid. Sorbitan esters being nonionic surface agents are used as excipients in veterinary medicinal products.
2. Other sorbitan esters are authorised as food additives under European Parliament and Council Directive No 95/2/EC, namely sorbitan monostearate (E491), sorbitan tristearate (E492), sorbitan monolaurate (E493), sorbitan monooleate (E494) and sorbitan monopalmitate (E495) and therefore considered included in Annex II of Council Regulation (EEC) No 2377/990 for all food producing animal species. The closely-related substance sorbitan trioleate is also included in Annex II of Council Regulation (EEC) No 2377/90 for all food producing animal species.

Conclusions and recommendation

Considering that:

- the closely-related substances sorbitan monooleate, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate and sorbitan monopalmitate being authorised food additives and sorbitan trioleate have already been included in Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species,
- sorbitan sesquioleate is not to be regarded as a new active substance;

the Committee concluded that there is no need to establish an MRL for sorbitan sesquioleate 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
Sorbitan sesquioleate	All food producing species	