



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SORBITAN TRIOLEATE

SUMMARY REPORT

1. Sorbitan trioleate (CAS No 26266-58-0) is a mixture of the partial tri-esters of sorbitol and its mono- and di-anhydrides with oleic acid. Sorbitan esters being nonionic surface agents are 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 2377/90 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 have already been included in Annex II of Council Regulation (EEC) No 2377/90 for all food-producing species;
- sorbitan trioleate is not to be regarded as a new active substance;

the Committee concludes that there is no need to establish an MRL for sorbitan trioleate 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 trioleate	All food producing species	