



COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

POLYOXYETHYLENE SORBITAN MONOOLEATE AND TRIOLEATE

SUMMARY REPORT

1. Polyoxyethylene sorbitan monooleate (CAS number: 9005-65-6) and polyoxyethylene sorbitan trioleate (CAS number: 9005-70-3) are oleate esters of sorbitol. The chemical name polyoxyethylene sorbitan monooleate covers the substances known by the commercial names Polysorbate 80, and Polysorbate 81. Polyoxyethylene sorbitan trioleate covers the substance known by the commercial name Polysorbate 85. The substances are used as excipients (emulsifiers and dispersing agents) in medicinal products. They are also widely used as emulsifiers in foods products and cosmetics.

Polysorbate 80 was included in Annex II of Council Regulation (EC) No 2377/90 for all food producing animals under the group “Substances Generally Recognised as Safe” for which no individual assessment was carried out.

For the inclusion of substances in the group “Substances Generally Recognised as Safe” the Committee for Medicinal Products for Veterinary Use (CVMP) took into account the following aspects:

- pharmacologically active substances used in veterinary medicinal products rapidly metabolised to simple organic metabolites such as carbon dioxide, acetic acid and ethanol;
- pharmacologically active substances used in veterinary medicinal products having a low oral bioavailability;
- conditions of use of veterinary medicinal products.

The Annex II entry for Polysorbate 80 was subsequently modified following a request from a company to include the similar substance Polysorbate 81. The CVMP agreed that Polysorbate 81 would be covered by the assessment and Annex II entry for Polysorbate 80 and recommended that the name be replaced by the chemical name polyoxyethylene sorbitan monooleate for the substances known as Polysorbate 80 and Polysorbate 81.

Polyoxyethylene sorbitan monooleate is included in Annex II of Council Regulation (EC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Polyoxyethylene sorbitan monooleate	All food producing species	

2. Polyoxyethylene sorbitan monolaurate (Polysorbate 20), polyoxyethylene sorbitan monopalmitate (Polysorbate 40), polyoxyethylene sorbitan monostearate (Polysorbate 60) and polyoxyethylene sorbitan tristearate (Polysorbate 65) as well as polyoxyethylene sorbitan monooleate (Polysorbate 80) are approved as food additives by Directive 95/2/EC on food additives other than colours and sweeteners, with the E numbers E-432, E-434, E-435, E-436 and E-433, respectively. Therefore, they are included in Annex II of Council Regulation (EC) No 2377/90 by virtue of the entry for substances approved under Directive 95/2/EC as additives in foodstuffs for human consumption with an E-number.
3. A request was submitted to the EMEA to consider whether the substance Polysorbate 85 would be covered by the existing assessment and entry in Annex II of Council Regulation (EEC) No 2377/90 for polysorbates, in particular polyoxyethylene sorbitan monooleate.
4. For the assessment of the request the CVMP took into account the fact that polyoxyethylene sorbitan trioleate is a closely related substance to polyoxyethylene sorbitan monooleate, and also to other polyoxyethylene sorbitan mono- and triesters of fatty acids already included in Annex II. Therefore, the Committee concluded that polyoxyethylene sorbitan trioleate falls under the assessment previously carried out for polyoxyethylene sorbitan monooleate and other polyoxyethylene sorbitan mono- and triesters of fatty acids.

Conclusions and recommendation

Having considered that:

- polyoxyethylene sorbitan monooleate is already included in Annex II of Council Regulation 2377/990 for all food producing species,
- other polyoxyethylene sorbitan mono- and triesters of fatty acids are included in Annex II of Council Regulation 2377/990 for all food producing species, by virtue of their status as approved food additives,
- polyoxyethylene sorbitan trioleate is a closely related substance to polyoxyethylene sorbitan monooleate and other polyoxyethylene sorbitan mono- and triesters of fatty acids;

the Committee recommends the modification of the current entry in Annex II of Council Regulation (EEC) No 2377/90 for polyoxyethylene sorbitan monooleate, in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Polyoxyethylene sorbitan monooleate and trioleate	All food producing species	