



COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

POLYOXYETHYLENE SORBITAN MONOOLEATE

SUMMARY REPORT

1. Polyoxyethylene sorbitan monooleate (CAS number: 9005-65-6) is an oleate ester of sorbitol. The chemical name covers the substances known by the commercial names Polysorbate 80 and Polysorbate 81. Both products 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 is approved as a food additive by Directive 92/2/EEC on food additives other than colours and sweeteners, with the number E 433.

Polysorbate 80 is 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.

Polysorbate 80 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
Polysorbate 80	All food producing species	

2. A request was submitted to the EMEA to consider whether the substance Polysorbate 81 would be covered by the existing assessment and entry in Annex II of Council Regulation (EEC) No 2377/90 for Polysorbate 80 and whether the chemical name polyoxyethylene sorbitan monooleate could be used to cover both substances.
3. For the assessment of the request the CVMP took into account the fact that Polysorbate 81 is a closely related substance to Polysorbate 80 already included in Annex II. Both substances have the same chemical name. Therefore, the Committee concluded that Polysorbate 81 falls under the assessment previously carried out for Polysorbate 80.

Conclusions and recommendation

Having considered that:

- Polysorbate 80 is already included in Annex II of Council Regulation 2377/990 for all food producing species,
- Polysorbate 81 is a similar substance to Polysorbate 80 falling under the same CAS number,
- Polysorbate 81 is covered by the existing assessment for Polysorbate 80,
- Polyoxyethylene sorbitan monooleate is the chemical name for the substances known as Polysorbate 80 and Polysorbate 81;

the Committee recommends the modification of the current Annex II of Council Regulation (EEC) No 2377/90 for Polysorbate 80 replacing it by the chemical name of the substance, in accordance with the following table:

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