



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

RICINI OLEUM

SUMMARY REPORT

1. *Ricini oleum* - synonyms ricinus oil, castor oil - is the fixed oil obtained by cold expression of the seeds of the plant *Ricinus communis* L., belonging to the Euphorbiaceae family.

Fatty acid components are ricinoleic acid 87%, oleic acid 7%, linoleic acid 3%, palmitic acid 2%, stearic acid 1% and dihydroxystearic acid in trace amounts.

2. *Ricini oleum* is used in veterinary medicinal products for food producing animals as an excipient in a wound healing unguent for improved consistency, at a concentration of approximately 0.6%.

Ricini oleum is also widely employed in pharmaceutical and cosmetic industry. It is used in traditional human medicine by oral administration at a dose of 2 to 3 tablespoons per person for its cathartic properties. It is also used as an excipient in formulations for ocular, topical and parenteral administration for human use. One example of a product for intramuscular injection contains approximately 350 mg *Ricini oleum* /ml of the finished product.

3. The pharmacologically active component of *Ricini oleum* when used as a laxative is the ricinoleic acid, which stimulates the motility of the small intestine and increases the bile flow.
4. Data on absorption, distribution, metabolism and excretion of *Ricini oleum* have not been provided.
5. While no information on pharmacokinetics, oral single and repeated dose toxicity, reproductive toxicity and mutagenicity was presented, submission of such data was not considered necessary in view of the limited use of *Ricini oleum* in veterinary medicine and its long history of safe use in humans after oral, topical and parenteral administration.
6. In humans, large oral doses (amount not stated) of *Ricini oleum* may cause nausea, vomiting and colic in addition to severe purgation.

Toxicity associated to consumption of seeds of *Ricinus communis* L. has been reported in medical literature and is related to the protein ricin which remains in the seed cake after expression of the oil.

7. Data on microbiological properties of residues have not been provided but are not considered relevant for this type of substance.
8. In view of the limited use of *Ricini oleum* in veterinary medicine, no information on possible residues or residue depletion was considered necessary.

Conclusions and recommendation

Having considered the criteria laid down by the Committee for the inclusion of substances in Annex II to Council Regulation (EEC) No 2377/90 and in particular that:

- *Ricini oleum* has a long history of safe use in humans after oral, parenteral and topical administration,
- in veterinary medicine *Ricini oleum* is used only as excipient for administration to individual animals,
- treatment is infrequent and non-regular,
- the animals are unlikely to be sent for slaughter during or immediately after treatment;

the Committee concludes that there is no need to establish an MRL for *Ricini oleum* 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
<i>Ricini oleum</i>	All food producing species	For use as excipient