



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

OLEYLOLEATE

SUMMARY REPORT

1. Oleylolate or cetiol (9-octadecenoic acid, 9-octadecenyl ester) is the oleic ester of oleic acid. Oleylolate is a solvent for lipophilic compounds which is miscible with vegetable and mineral oils.
Oleylolate is used in veterinary medicinal products for food producing animals as an excipient in a wound healing unguent, at a concentration of 8.5%. Oleylolate is also widely used in the pharmaceutical and cosmetic industry.
2. Oleylolate is expected to be metabolised in the gut to oleic acid and oleic alcohol which are normal components of human diet. No further data on absorption, distribution, metabolism and excretion of oleylolate were available.
4. The only available toxicology study concerns an oral single dose toxicity test on rats, through which a LD₅₀ of approximately 20 g/kg has been estimated for oleylolate, showing that the compound is practically devoid of oral toxicity.
5. In spite of the absence of studies on repeated dose toxicity, reproductive toxicity, mutagenicity and immunotoxicity, they are not considered necessary to safety assessment in view of the low acute toxicity of oleylolate.
6. No residue file was provided. However, given the topical use and the wide use in cosmetic industry, it is highly unlikely that the use of oleylolate in veterinary medicine would lead to any significant residue in food-producing animals.

Conclusion and recommendation

Having considered the criteria laid down by the Committee for the inclusion of substances into Annex II to Council Regulation (EEC) 2377/90, and in particular that:

- oleylolate is expected to be metabolised in normal components of the human diet,
- oleylolate is of very low acute oral toxicity,
- oleylolate is intended as excipient for topical use only,
- oleylolate is used infrequently and for treatments of individual animals,

the Committee concluded that there was no need to establish an MRL for oleylolate 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
Oleylolate	All food producing species	For topical use only