The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

EMEA/MRL/448/98-FINAL
June 1998

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CETOSTEARYL ALCOHOL

SUMMARY REPORT

1. Cetostearyl alcohol (synonyms: cetearyl alcohol, cetyl stearyl alcohol; CAS No. 8005-44-5 and 67762-27-0) is a mixture of saturated fatty alcohols. It contains 65 to 80% stearyl alcohol ($C_{18}H_{37}OH$, 1-octadecanol) and 20 to 35% cetyl alcohol ($C_{16}H_{33}OH$, 1-hexadecanol). The European Pharmacopoeia requires a content of stearylalcohol not less than 40% and that the sum of the contents of cetyl alcohol and of stearylalcohols is not less than 90%. Cetostearylalcohol is obtained by reduction of the appropriate fatty acids in coconut oil and palm kernel oil. Cetostearylalcohol is also a natural component in whale oil (spermaceti).

   Cetostearyl alcohol is used in combination with other excipients as emulsifying agent in cosmetics and in human medicinal products for topical use. In veterinary medicine it is used, together with other excipients, as emulsifier in at least two ointments. One ointment is used for disinfection of the udder in cows, mares, sows, ewes and goats and cetostearyl alcohol is contained at a concentration of 2 to 3% (recommended dosage of the ointment is 20 grams twice a day for 5 days). The other product contains 1 to 2 % of cetostearylalcohol. No information on the target species or the posology of this product has been provided.

   Apart from its wide use in cosmetics, synthetic cetostearyl alcohol is approved by the FDA for use as indirect food additive, as adhesive and as component of coating. Stearyl alcohol (1-octadecanol) is listed by the Council of Europe as an artificial flavouring substance which may be added to foodstuffs without hazard to public. The Council of Europe accepts 1 mg/kg as ADI for stearyl alcohol. From published literature, various studies indicate that long-chain aliphatic alcohols are oxidised to their corresponding fatty acids in mammalian tissues.

2. The acute oral toxicity of cetostearyl alcohol was tested in Wistar rats. The LD_{50} was greater than 10000 mg/kg bw.

3. In repeated dose toxicity studies in Sprague Dawley rats with cetyl alcohol and stearyl alcohol NOELs of more than or equal to 1000 mg/kg bw were deduced.

4. Stearyl alcohol was not mutagenic in the Ames test and did not induce micronuclei in bone marrow erythrocytes from mice.

5. Cetostearyl alcohol was non irritating in studies on rabbits. In addition, cetylalcohol was non irritating in several studies in humans.

6. In the Magnusson-Kligman test on guinea pigs the substance did not show any sensitising potency. In addition, sensitisation reactions were not observed in a study on 25 humans that were exposed to a cream containing 3% cetosteary alcohol.

7. From knowledge of related compounds it can be deduced that cetostearyl alcohol is metabolised to endogenous substances, such as fatty acids.

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Conclusions and recommendations

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

- cetostearyl alcohol is a component of the human diet
- cetostearyl alcohol is of low oral toxicity
- products containing the substance are administered topically only;

the Committee concludes that there is no need to establish an MRL for cetostearyl alcohol 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
Cetostearyl alcohol	All food producing species	