



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

WOOL ALCOHOLS

SUMMARY REPORT

1. Wool alcohols (lanolin alcohols, CAS 8027-33-6) are used as excipients (emulsifying agent and emulsion stabiliser). Wool alcohols are used at least in one water-in-oil emulsifying blend including also wool fat, cetearyl alcohol and vaseline/paraffin liquid. This blend contains 11 to 20% of wool alcohol and is used in ointments and emollient creams both for humans and animals. In one topical wound cream used in veterinary medicine the concentration of wool alcohols are 3 to 5%. They also are widely used in cosmetics and topical pharmaceutical formulations and are generally regarded as a nontoxic material.
2. Wool alcohols are obtained from wool fat (anhydrous lanolin) from sheep. Lanolin (hydrous wool fat containing 25 to 30% of water) contains primarily of esters of C₁₈-C₂₆ alcohols and fatty acids, sterols (cholesterol) and terpene alcohols. It is chemically a wax rather than fat. Lanolin has already been included in Annex II of Council Regulation (EEC) No 2377/90. Wool alcohols are a mixture of sterols and higher aliphatic alcohols containing not less than 30% of sterols calculated as cholesterol.
3. No information on toxicological properties of wool alcohols was provided. Due to the limited topical use in veterinary medicine, it was not considered necessary to request further information.
4. No information about pharmacokinetics or metabolism of wool alcohols was provided. It is known from the published literature that when lanolin (and/or wool alcohols) are mixed with suitable vegetable oils or with soft paraffin to produce emollient creams these creams penetrate the skin and hence facilitate the absorption of drugs. It may be assumed that the long-chain aliphatic alcohols and sterols follow normal metabolism of nutritional fats and sterols in mammalian species. Therefore, they are not considered to be able to produce residues causing a risk for consumer.

Conclusions and recommendation

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

- wool alcohols are used as excipients in the products administered topically only for individual animals.
- wool alcohols are obtained from wool fat and that lanolin (hydrous wool fat) has already been included in the Annex II,

the Committee considers that there is no need to establish an MRL for wool alcohols and recommends its inclusion in Annex II to Council Regulation (EEC) No. 2377/90 in accordance with following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Wool alcohols	All food producing species	For topical use only