



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

AMITRAZ

SUMMARY REPORT (1)

1. Amitraz is an acaricide which is used in pigs, sheep and cattle for the control of ectoparasites. However, the present application concerns only use in pigs.

It is also used as a pesticide on cucumbers, some fruit crops and on olive trees.

2. Amitraz has 5HT blocking activity and α_2 -adrenoreceptor agonist activity. In laboratory animals it causes signs of CNS-depression.

Carcinogenicity studies were carried out in rats and mice. The results of a range of mutagenicity assays were largely negative.

Amitraz disrupts the normal hormone activity of rodents, prolonging oestrus and reducing blood levels of progesterone and prolactin.

3. Amitraz has no significant antimicrobial activity.

4. The WHO/FAO Joint Meeting on Pesticide Residues estimated an ADI of 0-0.003 mg/kg bw/day in 1984. It was agreed to use this figure as a provisional ADI until the CVMP had completed the evaluation of the compound.

5. Amitraz was rapidly metabolised after oral administration, producing N-(2,4-dimethylphenyl)-N'-methylformamide as the primary metabolite.

The WHO/FAO JMPR elaborated MRLs of 0.05 mg/kg for porcine muscle and 0.2 mg/kg for liver and kidney - based on the sum of the residues of amitraz and the primary metabolite.

It was agreed to adopt this figure as a provisional MRL, until the residue depletion profile arising from the veterinary use of amitraz had been reviewed by the CVMP. This provisional MRL would expire on 1.7.94.

6. Analytical methods for the determination of residues were based on GLC with electron capture detection. The methods measured the total residues of amitraz and its metabolites, following conversion to 2,4-dimethylaniline. A limit of determination of 0.05 mg/kg was established for most subnitrites.