



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

THYMOL

SUMMARY REPORT

Name of the substance :

Thymol, Isopropylmetacresol, 2-isopropyl-5-methylphenol, Acido Timico

Indication for use :

For treatment of bronchitis, laryngitis, infections of the upper respiratory tract, bronchopneumonia, pleuritis and pneumonia. Daily oral doses recommended for horses, swine, cattle, sheep and dogs are 10 mg/animal for up to 5 days (accumulated dose 50 mg/individual).

Pharmacological activity :

Thymol has spasmolytic, antihelmintic and antimicrobial activity. It is effective against a broad spectrum of Gram negative and Gram positive bacteria, as well as against yeasts and moulds.

Pharmacokinetics :

Thymol is readily absorbed in the gastrointestinal tract. A small amount is oxidised to thymohydroquinone. About 50% of the absorbed substance is excreted via the kidney, either unconjugated or as a glucuronide or sulfate conjugate in 24 hours. The metabolite thymohydroquinone is also excreted via the kidney.

Toxicological profile :

Oral LD₅₀ is 980 mg/kg bodyweight in rats, 1800 mg/kg in mice, and 880 mg/kg in guinea pigs. No effects were seen in a 19 week oral study when rats were given 10000 (450 to 530 mg/kg bw) or 1000 ppm (45 to 53 mg/kg bw) thymol in the diet (5 male and 5 female rats per group). Thyme oil tested negative in the *Bacillus subtilis* Rec assay, as well as in the Ames test. No data on reproductive toxicity or carcinogenicity have been found.

Thymol has been used in human medicine for topical treatment of skin disorders, for inhalation in respiratory disorders and in dental care. Thymol is used for flavouring purposes in food and beverages at levels of 5-78 mg/kg. It is a natural constituent in thyme (up to 50% in essential oil) and in several other natural sources, such as in mandarin and tangerine oils (0.1-0.03%), which are widely used in soft drinks and confectionery. One meal spiced with basilica and thyme is estimated to yield more than 10 mg thymol.

Risk assessment :

Thymol has been evaluated 1992 by the Committee of Experts on Flavouring Substances of the Council of Europe. Thymol is listed among the substances that are permitted as flavouring agents. An upper limit for inclusion of thymol in food is established at 50 mg/kg and in beverages at 10 mg/kg.

Conclusions and recommendation :

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

- Σ is a natural component of the diet;
- Σ is widely used as food additive;
- Σ is rapidly metabolised and eliminated;
- Σ is intended for infrequent use in a small number of individual animals;
- Σ the residues of thymol in animal products are not likely to be of toxicological concern to humans.

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

Pharmacologically active substance(s)	Animal species	Other provisions
Thymol	All food producing species	