



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TERPIN HYDRATE

SUMMARY REPORT

1. Terpens, the chemical family to which terpin hydrate belongs, are natural compounds present in a very large number of fruits (grapes), alimentary or aromatic plants (oregano, thyme, stick of liquorice, coriander, laurel) and in medicinal plants (eucalyptus, arabic gum). No precise data have been provided about the actual concentrations in the different vegetables. Terpin hydrate is usually prepared from oil of turpentine. It is also obtained from red and white camphor oils.

Terpin hydrate is used only occasionally in a small number of individual animals as an expectorant (cattle, pig, sheep and goats). In animals, the prescribed parenteral doses do not exceed 0.375 mg/kg bw

Terpin hydrate is used as an intermediate product in the perfume industry for the manufacture of terpineol and in pharmaceutical industry, due to its disinfectant qualities, as an expectorant. It has also been suggested as a means of improving the durability of paper and cardboard.

2. Terpin hydrate has been stated to increase the bronchial secretion and to assist expectoration in humans. It is used in chronic bronchitis and in the treatment of unproductive cough at oral doses of up to 200 mg every 4 hours. An alkali-treated terpin hydrate, heated with pretreated maltose and mixed with rosin is an effective non-toxic antidote to nicotism and has prophylactic properties when mixed with cigarette tobacco.

In vitro, terpin decreases surface tension at the air/water interface and shows a modest bronchodilator activity *in vivo*.

3. While no studies on single and repeated dose toxicity, reproductive toxicity, teratogenicity, mutagenicity and carcinogenicity were provided, this information is not necessary due to the fact that terpin hydrate belongs to the family of terpenes, natural compounds present in a large variety of fruits, alimentary and aromatic plants.
4. In humans, nausea, vomiting or abdominal pain may follow the ingestion of terpin hydrate on an empty stomach.

Conclusions and recommendation

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

- terpin hydrate belongs to the terpens family, natural compounds present in many ingredients of human diet,
- terpin hydrate has a long history of safe use in human medicinal products,
- terpin hydrate is used only occasionally in a small number of individual animals;

the Committee considers that there is no need to establish MRLs for terpin hydrate and recommends its inclusion in Annex II to Council Regulation (EEC) N° 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Terpin hydrate	Bovine, ovine, caprine, porcine	