



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

MENTHOL

SUMMARY REPORT

1. Menthol is a cyclohexanol obtained from the leaves of various species of *Mentha* (Labiatae). This crystalline powder accounts for 40 to 80% of the essential oil of mint.
2. In veterinary medicine, menthol is occasionally used in ointments for its antiseptic and analgesic properties. It may be used in cattle as a carminative. It is also used in steam vaporizers for respiratory problems in horses.

Menthol is often added to pharmaceuticals as a flavouring agent.

3. Menthol is known to act on sensory nerves. Menthol has stimulating properties on gastric secretions and regulates gastro-intestinal motility. Menthol acts as a calcium-channel antagonist and inhibits calcium influx through smooth muscles cells.

Menthol has also stimulating properties on the production of bile.

As many essential oils, menthol has bactericidal and irritating properties.

4. After absorption, menthol was widely distributed and metabolised to form glucurono and sulfoconjugates and was rapidly excreted.
5. The LD50s were determined in several species and for the different routes. After subcutaneous administrations, the LD50s were higher than 14000 mg/kg bw for mice and higher than 1000 mg/kg bw for rats. The oral LD50s values were close to 3100 mg/kg bw for mice and 2900 mg/kg bw for rats.

The menthol acute poisoning caused inhibition of the voluntary movements and reflexes, nervousness, twitching, hyperesthesia before sedation and death.

6. Menthol may give rise to hypersensitivity reactions, including contact dermatitis in infants.
7. No data are reported regarding mutagenic effects of menthol.
8. The USEPA (United States Environment Protection Agency) and NCI (National Cancer Institute) regulations have stated that this substance is not a carcinogen.
9. An estimated ADI has been established by the FAO/WHO in 1976 up to 0.2 mg/kg bw i.e 12 mg/person.
10. Menthol is frequently used in human food as flavouring agent.

Conclusion 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:

- * Menthol is used very occasionally in veterinary medicine as local analgesic and antiseptic in a small number of individual animals;
- * Menthol accounts for 40 to 80% of the essential oil of mint;
- * Menthol is frequently added to human food and pharmaceuticals as a flavouring agent.

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

Pharmacological active substance	Animal species	Other provisions
Menthol	All food producing species	