



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TEREBINTHINAE AETHEROLEUM RECTIFICATUM

SUMMARY REPORT

1. *Terebinthinae aetheroleum rectificatum* (synonym: turpentine oil) is the oil distilled from the oleoresin obtained from pine species, mainly *Pinus nigra* Arn., *Pinus silvestris* L., *Pinus palustris* Mill., *Pinus pinaster* Sol., *Pinus halepensis* Mill., and freed from unpleasant odour and taste by rectification.

The pharmacologically and toxicologically relevant components of *Terebinthinae aetheroleum rectificatum* are besides α - and β -pinene (approximately 95%, ratio 2:1), limonene, 3-carene, terpinolene, bornyl acetate.

2. *Terebinthinae aetheroleum rectificatum* is used in both human and veterinary medicine.

Terebinthinae aetheroleum rectificatum is present at a concentration of 5% in an ointment for topical use in cows, which is indicated for treatment of mastitis, phlegmon, tendinitis, rheumatic disorders. The daily dose of *Terebinthinae aetheroleum rectificatum* is 500 to 1500 mg, which is administered three times a day for a number of days (until recovery).

In other veterinary medicinal products for food-producing animals, *Terebinthinae aetheroleum rectificatum* is used in both liquid and semisolid combination products, at a concentration varying from 20% to 50%, for dermal administration. Therapeutic veterinary applications as rubefacient also occur.

In human medicine internal or external administration of *Terebinthinae aetheroleum rectificatum* is used for treatment of bronchial diseases, whereas only external administration is applied to rheumatic and neuralgic pain. *Terebinthinae aetheroleum rectificatum* is also administered by inhalation, at a dosage of 300 mg/day; some drops of oil are added to boiling water and vapours are inhaled.

3. *Terebinthinae aetheroleum rectificatum* is reported to have rubefacient and antiseptic properties.

4. Percutaneous absorption of *Terebinthinae aetheroleum rectificatum* is reported.

Meat and milk of animals, which are topically treated with *Terebinthinae aetheroleum rectificatum* present a strong odour. It is also known that the highly liposoluble terpenes - components of *Terebinthinae aetheroleum rectificatum* (amount not specified) - can cross the blood-brain barrier.

Terebinthinae aetheroleum rectificatum is mostly metabolised.

Analogous to other volatile oils *Terebinthinae aetheroleum rectificatum* undergoes rapid renal, biliary and pulmonary excretion.

5. An intravenous LD₅₀ for *Terebinthinae aetheroleum rectificatum* in mice is reported to be 1.18 (1.11-1.25) mg/kg bw and the LC₅₀ (inhalation 2 hours) for mice is reported to be 29.0 (25.6-32.8) mg/l.

6. In view of the limited use of *Terebinthinae aetheroleum rectificatum* in veterinary medicine and its long history of safe topical and inhalatory use in traditional human medicine, no further data on repeated dose toxicity, reproduction toxicity and teratogenicity, mutagenicity and carcinogenicity were considered necessary.
7. In humans acute toxic episodes have been reported following oral poisoning with *Terebinthinae aetheroleum rectificatum*, toxic signs being local burning and gastrointestinal upset, coughing and choking, pulmonary oedema, excitement, coma, fever, tachycardia, liver damage, haematuria, albuminuria and cutaneous efflorescence such as erythema, papule and urticaria. The reported data are, however, contradictory. Neurotoxic effects have also been reported following treatment of large areas of skin with *Terebinthinae aetheroleum rectificatum*.

Sensitisation due to exposure to *Terebinthinae aetheroleum rectificatum* has been reported.

8. *Terebinthinae aetheroleum rectificatum* is reported to show antimicrobial activity in dilution and agar diffusion tests against *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Bacillus* spp. and *Vibrio cholerae*. Supporting data were not provided. However as residues are only expected at very low concentrations further information on microbiological properties of residues of *Terebinthinae aetheroleum rectificatum* are not considered relevant.
9. In view of the limited use of *Terebinthinae aetheroleum rectificatum* in veterinary medicine residues are only expected at very low concentrations and no further information was considered necessary.

Conclusions and recommendation

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

- *Terebinthinae aetheroleum rectificatum* has a long history of safe topical and inhalational use in traditional human medicine,
- *Terebinthinae aetheroleum rectificatum* is used only for infrequent and non-regular treatment of individual animals
- the animals are unlikely to be sent for slaughter during or immediately after treatment,
- *Terebinthinae aetheroleum rectificatum* is likely to be rapidly absorbed and excreted;

the Committee concludes that there is no need to establish an MRL for *Terebinthinae aetheroleum rectificatum* and recommends its inclusion in Annex II to Council Regulation (EEC) No 2377/90 in accordance with the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Terebinthinae aetheroleum rectificatum</i>	All food producing species	For topical use only