COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TEREBINTHINAE LARICINA

SUMMARY REPORT

1. *Terebinthinae laricina* (synonym: larch turpentine) is a balsam obtained from *Larix decidua* Mill., containing oleoresin (more than 70%) and volatile oil (approximately 15%). The most relevant component in the volatile oil is α-pinene (70%), other constituents being (3)-carene (10%), β-pinene (6.5%), β-pyronene (3%) and not quantified amounts of limonene, dipentene, terpinolene, borneol, bornyl acetate and guaiacol. The resin acids contained in the oleoresin are mainly larinolic acid and α- and β-larinolic acid; it also contains lariresinol (amounts not specified). The resin further contains dihydroabietinic, isopimaric, pimaric abietinic and neoabietinic acid. The balsam also contains 14 to 15% unsaponifiable resin – laricoresene – and not specified amounts of succinic acid, larixyl acetate, bitter substances, colorants and water.

2. In veterinary medicinal products, *Terebinthinae laricina* is used in combination products (containing 3 to 4 active principles) at a concentration of 10 to 20% *Terebinthinae laricina*, for topical applications to hoof and skin wounds, for disinfection of wounds and to promote wound healing. Target animals are all food-producing species.

3. *Terebinthinae laricina* possesses antiseptic, hyperaemicising and granulating properties.

4. Percutaneous absorption of the similar compound turpentine oil obtained from *Pinus* spp. is reported.

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

Turpentine oil is mostly metabolised.

Analogous to other volatile oils, turpentine oil to undergoes rapid renal, biliary and pulmonary excretion.

5. In view of the very limited use of *Terebinthinae laricina* in veterinary medicine and the long history of safe topical use of both *Terebinthinae laricina* and the related more toxic substance turpentine oil, no further data on repeated dose toxicity, reproduction toxicity and teratogenicity, mutagenicity and carcinogenicity were considered necessary.

6. No information on the effects of *Terebinthinae laricina* in humans has been provided.

For turpentine oil obtained from *Pinus* spp. the following summary information was available.

Chronic toxic episodes have been reported after poisoning with turpentine oil, toxic signs being local burning and gastro-intestinal upset, coughing and choking, pulmonary oedema, excitement, coma, fever, tachycardia, liver damage, haematuria, albuminuria and cutaneous efflorescence such as erythema, papule and urticaria. Neurotoxic effects have also been reported following treatment of large areas of skin with turpentine oil.

Sensitisation due to exposure to turpentine oil has been reported.
7. No information on microbiological properties of residues of *Terebinthinae laricina* has been provided.

For turpentine oil obtained from *Pinus* spp. the following information was available. Turpentine oil is reported to show antimicrobial activity in dilution and agar diffusion tests against *Streptococcus* spp., *Staphylococcus* spp., *Escherichia coli*, *Bacillus* spp. and *Vibrio cholerae*. However as residues are only expected at very low concentrations further information on microbiological properties of residues of *Terebinthinae laricina* are not considered relevant.

8. In view of the very limited use of *Terebinthinae laricina* 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 laricina* has a long history of safe topical and inhalational use in traditional human medicine,
- *Terebinthinae laricina* 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 laricina* is likely to be rapidly absorbed and excreted;

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

<table>
<thead>
<tr>
<th>Pharmacologically active substance(s)</th>
<th>Animal species</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Terebinthinae laricina</em></td>
<td>All food producing species</td>
<td>For topical use only</td>
</tr>
</tbody>
</table>