COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CORIANDRI AETHEROLEUM

SUMMARY REPORT

1. *Coriandri aetheroleum* is the essential oil obtained by steam distillation of the ripe fruits of *Coriandrum sativum* L. It is contained in the fruits at a concentration of approximately 1%. It contains mainly linalool (60 to 75%, mainly the (3S)-(+) enantiomer).

2. *Coriandri aetheroleum* is contained in one veterinary medicinal product containing also 9 other active ingredients. The percentage of the oil in the product is 0.005%. The product is used as a nose-spray to facilitate breathing in new-born animals of all food producing species. The dose is 0.1 to 0.3 g of the product, depending on the size of the animal. This corresponds to a maximal single dose of 0.015 mg of *Coriandri aetheroleum*. Treatment may be repeated after 10 to 15 seconds.

In humans in traditional medicine *Coriandri aetheroleum* has been used topically in diluted form against neuralgia and rheumatism.

*Coriandri aetheroleum* is also used as a fragrance in cosmetic products, such as soaps, creams and lotions and perfume in concentrations of 0.05 to 0.6%. It is also used for the production of lily of the valley-fragrance and from it the fragrance substances linalool and decanal are obtained.

Both the fruit and the leaves of *Coriandrum sativum* are used as a spice of human food (e.g. bread and confectionery), and the fruits are also used in the production of alcoholic beverages.

3. *Coriandri aetheroleum* has antimicrobial activity *in vitro*. No further information was available.

4. In the summary information provided the LD<sub>50</sub> in rats is reported to be 4.13 g/kg bw, but there is no information on the route of administration.

5. There is no information on long-term toxicity, or on effects on reproduction and teratogenicity.

6. The summary information provided reports that the mutagenic potency of *Coriandri aetheroleum* could not be evaluated in *Salmonella typhimurium* strains TA 92, TA 94, TA 98, TA 100, TA 1535 and TA 1537 due to its antimicrobial activity. In Chinese hamster fibroblasts no chromosomal aberrations could be observed up to the cytotoxic concentration of 0.125 mg/ml.

7. No information on the carcinogenicity of *Coriandri aetheroleum* was provided.

8. The summary information provided states that undiluted *Coriandri aetheroleum* did not irritate intact or broken rabbit skin. In human volunteers also no skin irritation was observed in a 48 hour-closed patch test, and no sensitisation was observed after administration of 6% *Coriandri aetheroleum* in paraffin in a maximisation test.

9. The use of *Coriandri aetheroleum* in the doses recommended is unlikely to result in residues in edible tissues posing a risk to the health of the consumer.
Conclusions and recommendation

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

- *Coriandri aetheroleum* is obtained from the fruit and the leaves of *Coriandrum sativum* which are used as a spice in human food,
- *Coriandri aetheroleum* is used only for newborn animals,
- the animals are unlikely to be sent to slaughter immediately after treatment;

the Committee considers that there is no need to establish an MRL for *Coriandri aetheroleum* 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>Coriandri aetheroleum</em></td>
<td>All food producing species</td>
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