The European Agency for the Evaluation of Medicinal Products Veterinary Medicines Evaluation Unit

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

ALLIUM CEPA

SUMMARY REPORT

- 1. Allium cepa L. (synonyms: Allium esculentum, Cepa esculenta, Onion) is a plant of the family Alliaceae (Liliaceae) widely distributed and cultivated in Europe and North America. In veterinary homeopathy Allium cepa is used as mother tincture prepared by ethanolic extraction of the whole fresh bulbs of Allium cepa according to homeopathic pharmacopoeias, and dilutions thereof. Constituents of Allium cepa are alkylcysteine sulphoxides, gamma-glutamylpeptides, sulphur-containing gamma-glutamic acids, alliinase, flavonoids (quercetin) and the respective glycosides, phenolic derivatives, (protocatechic acid, ferulic acid, phloroglucin), vitamin B1 (700 mg/kg of fresh onion) and vitamin C (50 mg/kg of fresh onion). Thiopropanal-5-oxide is the tear fluid irritant of Allium cepa.
- 2. *Allium cepa* is intended for use in all food-producing animals. The use follows the principles of homeopathic therapy where animals are diagnosed on basis of the individual pattern of clinical signs. The recommended maximum parenteral dose 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.
 - Allium cepa is also used in human homeopathy as the mother tincture as well as in lower concentrations and in human phytotherapy. It is used for treatment of gastro intestinal disorders, asthma and bronchitis. The recommended mean oral dose is 50 g of fresh onion or 20 g of dried onion per day. The fresh bulbs or an extract thereof are also used topically for treatment of insect stings and warts.
- 3. *Allium cepa* is a normal component of human diet. There are no reports on intoxications of humans or animals published in the literature.

Conclusions and recommendation

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

- Allium cepa is a normal component of human diet,
- Allium cepa is used in a small number of individual animals and for non-regular treatments only,
- animals are unlikely to be sent for slaughter during or immediately after treatment,
- the substance and constituents thereof do not give rise to specific consumer health concern which may result from the use in veterinary homeopathy;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any constituents of *Allium cepa* and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 according to the following table:

Pharmacologically active substance(s)	Animal species	Other provisions
Allium cepa	All food producing species	For use in homeopathic veterinary medicinal products prepared according to homeopathic pharmacopoeias at concentrations corresponding to the mother tincture and dilutions thereof only