



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SYZYGIUM CUMINI

SUMMARY REPORT

1. *Syzygium cumini* L, (synonyms: *Eugenia cumini*, *Eugenia jambolana*, jambul, black plum) is a tree of the family *Myrtaceae* distributed in Asia (East India, Malaysia and China). The homeopathic mother tincture prepared by ethanolic extraction of the disintegrated dried seeds (cotyledons) of *Syzygium cumini* according to homeopathic pharmacopoeias.

Constituents of *Syzygium cumini* seeds are fatty oils (30 g/kg) including lauric (2.8%), myristic (31.7%), palmitic (4.7%), stearic (6.5%), oleic (32.2%), linoleic (16.1%), malvalic (1.2%), sterculic (1.8%) and vernolic acid (3%) and phyosterols such as β -sitosterol. Further constituents are tannins (6%) predominantly corilagin, ellagitannins, ellagic acid, galloyl-galactoside, and gallic acid. Additionally, phenolic components like quercetin, ferulic acid, veratrole, guajacol, and caffeic acid have been identified as constituents of *Syzygium cumini*.

2. In veterinary homeopathy the mother tincture of *Syzygium cumini* and dilutions thereof are 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 for large animals is 10 ml/animal. Treatment may be repeated but a fixed dose schedule is not common in homeopathy.

Syzygium cumini is also used in human homeopathy in dilutions beginning with the mother tincture. In human phytotherapy, the recommended daily dose of the drug (dried seeds) for oral use is 30 seeds, corresponding to 1.9 g of the powder. *Syzygium cumini* semen are traditionally used for the treatment of diabetes before insulin was available for therapy.

3. The following LD₅₀-values of a 95% ethanolic extract of *Syzygium cumini* are reported for mice: 4 g/kg bw after oral administration and 0.4 g/kg bw after parenteral administration.
4. In a preliminary risk evaluation procedure by the Committee for Veterinary Medicinal Products, considering all defended old substances used in veterinary homeopathy in concentrations greater than 1:10 000, the use of *Syzygium cumini* and its individual constituents was considered as not giving rise to specific health concerns. Further information made available and extensive search of published literature did not provide any further evidence for pharmacological or toxicological properties of *Syzygium cumini* alerting to specific health risks which may result from residues in food producing animals following the intended uses. Special emphasis was put on identification of any suspicion pointing to genotoxicity or other potential of serious health effects of plant constituents.

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:

- *Syzygium cumini* is used only in a small number of individual animals for non-regular treatments,
- 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 concerns which may result from veterinary homeopathic uses in food producing animals;

the Committee for Veterinary Medicinal Products concludes that there is no need to establish an MRL for any plant constituents of *Syzygium cumini* following homeopathic uses and recommends its inclusion in Annex II of Council Regulation (EEC) No 2377/90 as follows:

Pharmacologically active substance(s)	Animal species	Other provisions
<i>Syzygium cumini</i>	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