

NOTICE

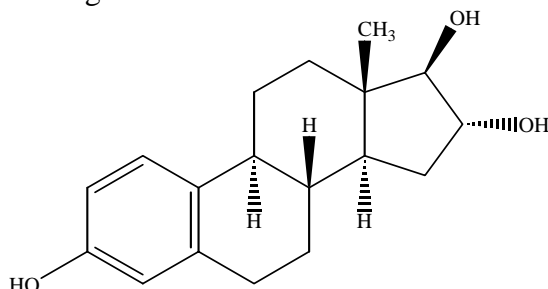
Oestriol (Estriol)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of oestriol, a new active constituent for use in veterinary chemical products. Oestriol is a short-acting oestrogen, with application in the treatment of oestrogen-related urinary incontinence in ovariohysterectomised dogs.

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of oestriol should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the APVMA is required to take into account in deciding whether to grant the approval. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of Active Constituent

Common Name:	Oestriol*
IUPAC Name:	Estra-1,3,5,(10)-triene-3,16 α ,17 β -triol
CA Name:	Estra-1,3,5,(10)-triene-3,16,17-triol, (16 α ,17 β)
CAS Number:	50-27-1
Minimum Purity:	Must comply with the British Pharmacopoeia monograph specifications for oestriol
Molecular Formula:	C ₁₈ H ₂₄ O ₃
Molecular Weight:	288.4 gmol ⁻¹
Structure:	



Chemical Family:	Oestrogen compound
Mode of Action:	Binding to oestrogen receptors in the urinary sphincter

Summary of the APVMA's Evaluation of Oestriol Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of oestriol active constituent (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Oestriol is a new active constituent for veterinary use in Australia, although it is currently registered as a prescription medicine for humans. Oestriol is the subject of monographs in the British Pharmacopoeia, the European Pharmacopoeia and United States Pharmacopoeia.

On the basis of the data provided, the toxicological assessment, and the compendial specifications, it is proposed that the following APVMA Active Constituent Standard be established for oestriol:

Constituent Requirement

Oestriol Must comply with the British Pharmacopoeia monograph specifications for oestriol

Other compounds of toxicological significance are not expected to occur in oestriol as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety of the Department of Health and Ageing has considered the toxicological aspects of oestriol, and advised that there are no toxicological objections to the approval of this chemical.

As oestriol is to be used only for treatment of dogs, neither an Acceptable Daily Intake (ADI) nor an Acute Reference Dose (ARfD) is required.

Oestriol is currently included in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), as it is currently used in human pharmaceuticals. The Office of Chemical Safety has concluded that rescheduling of oestriol to take account of the proposed veterinary chemical use is not required.

The APVMA accepts the findings and recommendations of its advisers on these criteria.

The APMVA is satisfied that the proposed importation and use of oestriol would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

Written submissions on the APVMA's proposal to grant approval for oestriol should be addressed in writing to:

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*Oestriol is the Australian Approved Name in the TGA Approved Terminology for Drugs, and is the spelling used in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). In the British, European and United States Pharmacopoeia monographs the spelling is 'estriol'.