

NOTICE

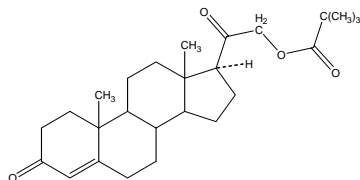
Deoxycortone pivalate (Desoxycorticosterone pivalate)

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of deoxycortone pivalate, a new active constituent for use in veterinary chemical products. Deoxycortone pivalate is a mineralocorticoid hormone. It is to be used in a product to treat Addison's disease in 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 deoxycortone pivalate 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:	Deoxycortone pivalate
IUPAC Name:	21-(2,2-Dimethyl-1-oxopropoxy)-pregn-4-ene-3, 20-dione
CAS Number:	808-48-0
Manufacturer's Codes:	7767MO
Minimum Purity:	97 % (USP)
Molecular Formula:	C ₂₆ H ₃₈ O ₄
Molecular Weight:	414.58 gmol ⁻¹
Chemical Family:	Corticosteroid
Structure:	



Summary of the APVMA's Evaluation of Deoxycortone pivalate Active Constituent

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

Compounds of toxicological significance are not expected to occur in deoxycortone pivalate 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 deoxycortone pivalate, and advised that there are no toxicological objections to the approval of this chemical.

The establishment of an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) is not considered necessary given the non-food use of the active constituent.

The existing Poisons Schedule classification for deoxycortone (Schedule 4) remains appropriate.

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

On the basis of the data provided, it is proposed that the following APVMA Active Constituent Standard be established for deoxycortone pivalate active constituent:

Constituent	Specification	Standard
Deoxycortone pivalate	Deoxycortone pivalate	Complies with the USP monograph for “Desoxycorticosterone pivalate”

The APMVA is satisfied that the proposed importation and use of deoxycortone pivalate 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 deoxycortone pivalate should be addressed in writing to:

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