

NOTICE

Hydrocortisone aceponate

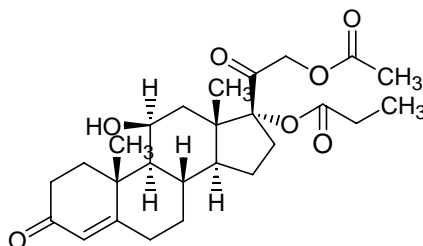
in the product: CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Virbac (Australia) Pty Limited for the approval of a new active constituent, hydrocortisone aceponate and for the registration of a new product containing hydrocortisone aceponate. The product is CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS. The product is for use on dogs.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for active constituent approval and registration of product should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the application. Comments must be received by the APVMA within 28 days of the date of this notice.

Particulars of Active Constituent

IUPAC Name:	[(8 <i>S</i> ,9 <i>S</i> ,10 <i>R</i> ,11 <i>S</i> ,13 <i>S</i> ,14 <i>S</i> ,17 <i>R</i>)-17-(2-acetyloxyacetyl)-11-hydroxy-10,13-dimethyl-3-oxo-2,6,7,8,9,11,12,14,15,16-decahydro-1 <i>H</i> -cyclopenta[α]phenanthren-17-yl]propanoate
CA Name:	21-(acetyloxy)-11 beta-hydroxy-17 alpha-(propionyloxy)-4-pregnene-3,20-dione
Manufacturer's Code:	HC63 M
CAS No:	74050-20-7
Molecular Formula:	C ₂₆ H ₃₆ O ₇
Molecular Weight:	460.56
Structure:	



Chemical Family:	Corticosteroid
Mode of Action:	Immunosuppression and inhibition of prostaglandin and leukotriene production.

Summary of the APVMA's Evaluation of Hydrocortisone Aceponate Active Constituent

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

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

Constituent	Specification	Level
Hydrocortisone aceponate	Hydrocortisone aceponate	Not less than 985 g/kg (anhydrous, solvent free basis)

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

The Office of Chemical Safety in the Commonwealth Department of Health and Aging has considered the toxicological aspects of hydrocortisone aceponate, and advised that there are no toxicological objections to the approval of this chemical.

Since hydrocortisone aceponate is not intended for use in food production, an Acceptable Daily Intake (ADI) and an Acute Reference Dose (ARfD) are not considered necessary.

The National Drugs and Poisons Schedule Committee (NDPSC) has included hydrocortisone aceponate into Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

The APVMA is satisfied that the proposed importation and use of hydrocortisone aceponate active constituent would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

Particulars of Application

Proposed product name:	CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS
Applicant company:	Virbac (Australia) Pty Limited
Signal heading:	Schedule 4 Prescription Animal Remedy
Statement of claims:	For topical use as an aid in the reduction of dermatological signs in localised lesions associated with flea allergy dermatitis and for the symptomatic relief of inflammatory and pruritic skin conditions when used under veterinary direction.
Pack sizes:	76ml
Withholding period:	Not applicable.

Summary of the APVMA's evaluation of hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS in accordance with Section 14(3)(e) and (f) of the Agricultural and Veterinary Chemicals Code (the 'Agvet Code'), scheduled to the Agricultural and Veterinary Chemicals Code Act 1994

The APVMA has evaluated the application and in its assessment in relation to human and environmental safety under section 14(3)(e) of the Agvet Code, it proposes to determine that:

- (i) The APVMA is satisfied that the proposed use of hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (OCS) in the Commonwealth Department of Health and Aging assessed the human toxicological aspects of this application.

The product will be formulated in France. Hydrocortisone aceponate has low acute oral, dermal and inhalation toxicity, low skin irritant, moderate eye irritant and unlikely to be a skin sensitizer. OCS advised the APVMA that there are no toxicological objections to the registration of the product and recommended safety directions with respect to eyes. The APVMA accepts the findings and recommendations of the OCS evaluation.

- (ii) The APVMA is satisfied that the proposed use of hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS will not be an undue hazard to the safety of people using anything containing its residues. The OCS determined that because the product is for use in companion animals only, hydrocortisone aceponate is unlikely to enter the food chain.
- (iii) The APVMA is satisfied that the proposed use of the hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS is not likely to be harmful to human beings if used according to the product label directions.

The National Drugs and Poisons Scheduling Committee (NDPSC) has examined the active constituent and placed it in Schedule 4 Prescription Animal Remedy of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The appropriate Signal Heading is on the product label. First Aid and Safety Directions for hydrocortisone aceponate have been recommended by the Office of Chemical Safety in the Commonwealth Department of Health and Aging and have been included on the label.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (iv) The APVMA is satisfied that the proposed use of hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS is not likely to have an unintended effect that is harmful to animals, plants or the environment.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) has assessed data in support of product registration. In considering the proposed use pattern and the relatively low amount proposed for use, DEWHA has advised that this will not result in a significant environmental hazard.

The APVMA accepts the findings and recommendations of its advisers on this criterion.

- (v) The APVMA is satisfied that the proposed use of hydrocortisone aceponate in CORTAVANCE CUTANEOUS SPRAY SOLUTION FOR DOGS would not adversely affect trade between Australia and places outside Australia as is for use in dogs only.
- (vi) In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that it is satisfied that the data from trials supporting the efficacy of the products demonstrate that the product is safe and effective for the proposed uses.

Written submissions on the APVMA's proposal to grant the application for approval of the active constituent and the applications for registration of the products should be addressed to:

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