

NOTICE

Quinalbarbiton Sodium and Cinchocaine hydrochloride

[in the product: Virbac Euthalose Euthanasia Solution for Horses, Dogs and Cats]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Virbac (Australia) Pty. Limited for the registration of a new product containing the active constituents QUINALBARBITONE SODIUM and CINCHOCAINE HYDROCHLORIDE. The product is VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS. The product is for use by intravenous injection in horses, dogs and cats by a registered veterinarian for rapid euthanasia only.

In accordance with section 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration 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 Application

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| Proposed product name: | VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS |
| Applicant company: | Virbac (Australia) Pty. Limited |
| Name of active constituents: | QUINALBARBITONE SODIUM CINCHOCAINE HYDROCHLORIDE |
| Signal heading: | CONTROLLED DRUG POSESSION WITHOUT AUTHORITY ILLEGAL KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY |
| Statement of claim: | For rapid euthanasia of horses dogs and cats. |
| Pack sizes: | 25mL, 50mL and 100mL |
| Withholding period: | Not applicable |

Summary of the APVMA's evaluation of VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS, 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 applications 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 VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS 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 Ageing assessed the human toxicological aspects of this application. The product is a controlled drug which will be used intravenously on individual horses, dogs and cats by a registered veterinarian. The use of the product is adequately addressed on the label.

The product will be formulated in Australia in 25mL, 50mL and 100mL amber glass poison bottles with elastomer stoppers and sealed with an aluminium flip-off cap suitable for each container size.

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

- (ii) The APVMA is satisfied that the proposed use of VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS would not be an undue hazard to the safety of people using anything containing its residues.

There are no residues concerns because the product is used in individual horses, dogs and cats only. The active constituents QUINALBARBITONE SODIUM and CINCHOCAINE HYDROCHLORIDE are unlikely to enter the human food chain because the target animals are all companion animals and not food-producing animals in Australia.

- (iii) The APVMA is satisfied that the proposed use of VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS would not be harmful to human beings if used according to the product label directions.

A Notice inviting submissions on the APVMA's proposal to grant approval for the active constituent QUINALBARBITONE SODIUM was published in Commonwealth of Australia Gazette No. APVMA 10, 4 October 2005. The active constituent QUINALBARBITONE SODIUM, APVMA Number 59175 was approved on 11 November 2005.

The product is a Schedule 8 Controlled Drug in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and the appropriate signal headings "CONTROLLED DRUG, POSSESSION WITHOUT AUTHORITY ILLEGAL, KEEP OUT OF REACH OF CHILDREN, FOR ANIMAL TREATMENT ONLY" are on the label. The OCS (formerly National Occupational Health and Safety Commission – NOHSC) assessed this application and advised that the product will be used by registered veterinary surgeons for the euthanasia of companion animals and therefore there is no need for the establishment of safety directions. The establishment of an Acceptable Daily Intake (ADI) or Acute Reference Dose (ArfD) was considered unnecessary because the active constituents, QUINALBARBITONE SODIUM and CINCHOCAINE HYDROCHLORIDE will not enter the human food chain when used in companion animals in the product VIRBAC EUTHALOSE EUTHANASIA SOLUTION FOR HORSES DOGS AND CATS.

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

