

NOTICE

difethialone

[in the product: Rodilon Paste Professional Rodenticide]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd for registration of a new product containing the active constituent difethialone. The product is RODILON PASTE PROFESSIONAL RODENTICIDE containing 0.025 g/kg difethialone. The product is for use in the management of rat and mouse infestations in and immediately around industrial, commercial, agricultural and domestic buildings and public services.

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 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

Proposed product name:	RODILON PASTE PROFESSIONAL RODENTICIDE
Applicant company:	Bayer CropScience Pty Ltd
Name of active constituent:	difethialone
Signal heading:	Schedule 6
Statement of claims:	A palatable soft-block bait for use in the management of rat and mouse infestations
Pack sizes:	5kg
Withholding period:	Not applicable

Summary of the APVMA's evaluation of RODILON PASTE PROFESSIONAL RODENTICIDE 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 RODILON PASTE PROFESSIONAL RODENTICIDE would not be an undue hazard to the safety of people exposed to it during its handling and use.

The Office of Chemical Safety (Occupational Health and Safety Section (OCS OHS) has conducted a risk assessment on RODILON PASTE PROFESSIONAL RODENTICIDE and recommended that it can be used safely. The APVMA accepts the findings and recommendations of its advisers on this criterion.

The product will be formulated in Italy; repackaging will not be required in Australia. RODILON PASTE PROFESSIONAL RODENTICIDE is determined to not be a hazardous substance according to NOHSC approved criteria for classifying hazardous substances.

- (ii) The APVMA is satisfied that the proposed use of RODILON PASTE PROFESSIONAL RODENTICIDE will not be an undue hazard to the safety of people using anything containing its residues. The product is not intended for use in food producing situations and Maximum Residue Limits (MRLs) and Withholding Periods (WHPs) are therefore not required to be set for RODILON PASTE PROFESSIONAL RODENTICIDE.
- (iii) The APVMA is satisfied that the proposed use of the product RODILON PASTE PROFESSIONAL RODENTICIDE is not likely to be harmful to human beings if used according to the product label directions.

The active constituent difethialone has been evaluated and approved and the product is scheduled as Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The appropriate Signal Heading is on the label. First Aid and Safety Directions for difethialone have been recommended by the Office of Chemical Safety 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 RODILON PASTE PROFESSIONAL RODENTICIDE in and immediately around industrial, commercial, agricultural and domestic buildings and public services is not likely to have an unintended effect that is harmful to animals, plants or the environment.

The Department of the Environment and Water Resources (DEW) has assessed data in support of RODILON PASTE PROFESSIONAL RODENTICIDE and recommends that the application contains adequate environmental fate and toxicity data to demonstrate that the use of RODILON PASTE PROFESSIONAL RODENTICIDE according to the label is unlikely to result in adverse effects to non-target wildlife.

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

- (v) The APVMA is satisfied that the proposed use of RODILON PASTE PROFESSIONAL RODENTICIDE would not adversely affect trade between Australia and places outside Australia as the product is not intended for use on food commodities.

In relation to its assessment of efficacy under section 14(3)(f), the APVMA proposes to determine that:

- (i) The APVMA is satisfied that data from trials supporting the efficacy of RODILON PASTE PROFESSIONAL RODENTICIDE adequately demonstrate that under local conditions this product is effective for the proposed uses.

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

Public consultation - difethialone
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4748
Fax: (02) 6210 4776
Email: AgProductscoordinator@apvma.gov.au