

NOTICE

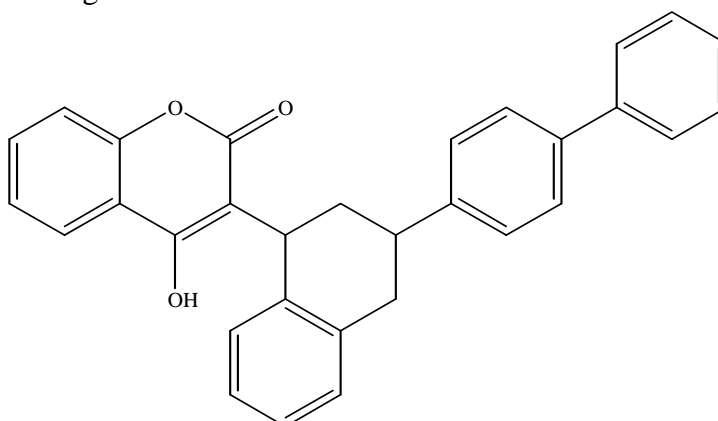
Difenacoum

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of difenacoum, a new active constituent for use in agricultural chemical products. Difenacoum is a second-generation anticoagulant rodenticide, which is to be formulated into several different forms of bait for control of rats and mice.

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 difenacoum 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:	Difenacoum
IUPAC Name:	3-[3-(Biphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
CA Name:	3-[3-([1,1'-Biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2 <i>H</i> -1-benzopyran-2-one
Isomerism:	<i>E</i> and <i>Z</i> isomers exist, typically technical grade difenacoum contains slightly more of the <i>Z</i> than the <i>E</i> isomer
Manufacturer's Codes:	WBA 8107, Tol 407
CAS Number:	56073-07-5
Minimum Purity:	960 g/kg
Molecular Formula:	C ₃₁ H ₂₄ O ₃
Molecular Weight:	444.5 gmol ⁻¹
Structure:	



Chemical Family:	Hydroxycoumarin
Mode of Action:	Inhibition of the vitamin K-dependent steps in the synthesis of the clotting factors II, VII, IX and X

Summary of the APVMA's Evaluation of Difenacoum Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of difenacoum 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, and the toxicological assessment, it is proposed that the following APVMA Active Constituent Standard be established for difenacoum active constituent:

Constituent	Specification	Level
Difenacoum	Difenacoum	Not less than 960 g/kg

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

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

As difenacoum is not currently proposed for use in food crops or animal stock feed, the OCS has not set an Acceptable Daily Intake (ADI) or an Acute Reference Dose (ARfD).

The National Drugs and Poisons Schedule Committee (NDPSC) has previously considered difenacoum, and has included it in Schedule 6 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) when present in products at levels of 0.25% or less, and in Schedule 7 in all other cases. The OCS has stated that the toxicological information provided did not indicate a need to alter the existing poison scheduling.

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

The APVMA is satisfied that the proposed importation and use of difenacoum 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 difenacoum should be addressed in writing to:

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