

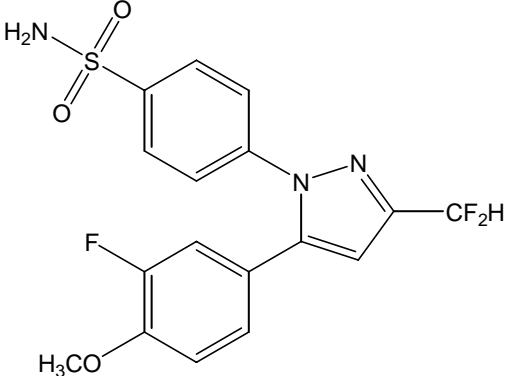
NOTICE

Deracoxib

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of deracoxib, a new active constituent for use in veterinary chemical products. Deracoxib is a non-steroidal anti-inflammatory drug (NSAID) that acts as a COX-2 inhibitor.

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 pyraflufen-ethyl 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:	Deracoxib
IUPAC Name:	4-[3-(Difluoromethyl)-5-(3-fluoro-4-methoxyphenyl)-1H-pyrazol-1-yl]benzenesulfonamide
Manufacturer's Code:	SD-6746; SC-59046
CAS Number:	169590-41-4
Minimum Purity:	980 g/kg
Molecular Formula:	$C_{17}H_{14}F_3N_3O_3S$
Molecular Weight:	397.38 gmol^{-1}
Structure:	
Chemical Family:	Diaryl substituted pyrazole
Mode of Action:	Cyclooxygenase-2 isozyme (COX-2) inhibitor

Summary of the APVMA's Evaluation of Deracoxib Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of deracoxib 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 deracoxib active constituent:

Constituent	Specification	Level
Deracoxib	Deracoxib	Not less than 980 g/kg

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

As deracoxib is not currently proposed for use in food crops or animals, 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 considered deracoxib to be appropriate for inclusion in 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 deracoxib 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 deracoxib should be addressed in writing to:

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