

NOTICE

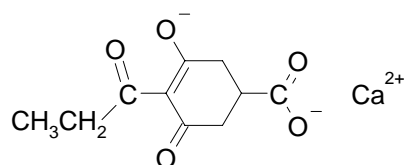
Prohexadione-calcium

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, prohexadione-calcium. Prohexadione-calcium is foliarly applied plant regulator which reduces vegetative growth by inhibiting the synthesis of gibberellin, a naturally occurring plant hormone. Specifically it decreases the length of shoot internodes.

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 prohexadione-calcium 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 the Active Constituent

Common Name:	Prohexadione-calcium
IUPAC Name:	Calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate
CA Name:	Calcium 3,5-dioxo-4-(1-oxopropyl)cyclohexanecarboxylate
CAS Number:	127277-53-6
Manufacturer's Codes:	BX-112, KUH-883, KUM-883, LAB 285 342, BAS 9054 W, BAS 122 W, BAS 125 W
Minimum Purity:	890 g/kg
Molecular Formula:	C ₁₀ H ₁₀ CaO ₅
Molecular Weight:	250.26
Structure:	



Pesticide Type:	Plant growth regulator
Mode of Action:	Gibberellin inhibition

Summary of the APVMA's Evaluation of Prohexadione-calcium Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of prohexadione-calcium 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 prohexadione-calcium active constituent:

Constituent	Specification	Level
Prohexadione-calcium	Prohexadione-calcium	Not less than 890 g/kg

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

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of prohexadione-calcium, and advised that there are no toxicological objections to the approval of this chemical.

An acceptable daily intake (ADI) of 0.2 mg/kg bw/d is recommended based on no observed effect levels (NOEL) of 20 mg/kg bw/d in a 52 week study in dogs supported by a 2-year chronic study in rats, using a safety factor of 100, and an Acute Reference Dose (ARfD) of 1.5 mg/kg bw, based on a NOEL of 150 mg/kg bw/d in a rabbit developmental study, using a safety factor of 100, have been established.

The National Drugs and Poisons Schedule Committee (NDPSC) has included prohexadione-calcium into Schedule 5 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 prohexadione-calcium 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 prohexadione-calcium should be addressed in writing to:

Dr Paul Sethi
Chemistry Manager
Chemistry and Residues Program
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6272 3987
Fax: (02) 6272 3551