

NOTICE

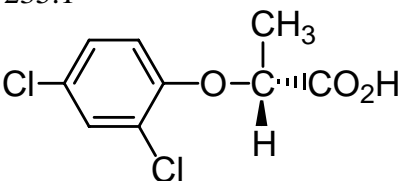
Dichlorprop-P Dichlorprop-P 2-Ethylhexyl Ester

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of two new active constituents, Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester. Dichlorprop-P is an aryloxyalkanoic acid (phenoxy propionic acid) herbicide. It is a selective hormone type herbicide absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator. Dichlorprop-P 2-Ethylhexyl Ester is the (R,S)-2-Ethylhexyl Ester of Dichlorprop-P.

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 Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester approval 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 Constituents

Dichlorprop-P

IUPAC Name:	(R)-2-(2,4-dichlorophenoxy)propionic acid
Chemical Abstracts Name:	(+)-2-(2,4-dichlorophenoxy)propanoic acid
CAS Number:	15165-67-0
Molecular Formula:	C ₉ H ₈ Cl ₂ O ₃
Minimum Purity:	900 g/kg
Molecular Weight:	235.1
Structure:	

Chemical Family:

Aryloxyalkanoic acid (phenoxy propionic acid)

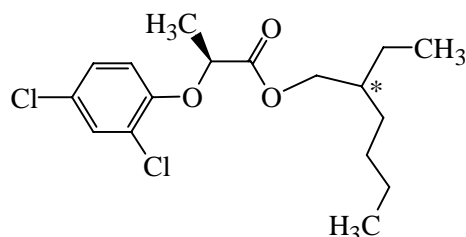
Mode of Action:

Absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator.

Dichlorpro-P 2-Ethylhexyl ester

IUPAC Name:	R-2-(2,4-dichlorophenoxy)propionic acid, 2-ethylhexyl ester
Chemical Abstracts Name:	(+)-2-(2,4-dichlorophenoxy)propanoic acid, 2-ethylhexyl ester
CAS Number:	865363-39-9
Minimum Purity:	850 g/kg
Molecular Formula:	C ₁₇ H ₂₄ Cl ₂ O ₃
Molecular Weight:	347.28

Structure:



Chemical Family:

Aryloxyalkanoic acid (phenoxy propionic acid)

Mode of Action:

Absorbed through leaves with translocation to the roots. It acts as an auxin growth regulator.

Summary of the APVMA's Evaluation of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester active constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester 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 Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester active constituents:

Dichlorprop-P

Constituent	Specification	Level
Dichlorprop-P	Dichlorprop-P	Not less than 900 g/kg
Free phenols	Free phenols calculated as 2,4-dichlorophenol	Not higher than 3 g/kg

Dichlorprop-P 2-Ethylhexyl Ester

Constituent	Specification	Level
Dichlorprop-P 2-Ethylhexyl Ester	(+)-(R)-2-(2,4-dichlorophenoxy) propionic acid, 2-ethylhexyl ester	Not less than 850 g/kg
Free phenols	Free phenols calculated as 2,4-dichlorophenol	Not higher than 3 g/kg

Other compounds of toxicological significance are not expected to occur in Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester as a result of the raw materials and the synthetic route used.

The Office of Chemical Safety of the Department of Health and Ageing has considered the toxicological aspects of Dichlorprop-P and Dichlorprop-P 2-Ethylhexyl Ester, and advised that there are no toxicological objections to the approval of this chemical.

An Acceptable Daily Intake (ADI) was established at 0.03 mg/kg bw/day, based on a No Observed Effect Level (NOEL) of 6 mg/kg bw/day in a 18-month mouse study and using a 200-fold safety factor for dichlorprop-P. An Acute Reference Dose (ARfD) was established at

0.20 mg/kg bw, based on a NOEL of 20 mg/kg bw/day in a rat developmental rat study and using a 100-fold safety factor for dichlorprop-P.

The National Drugs and Poisons Schedule Committee (NDPSC) has included Dichlorprop-P in Schedule 6 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 APMVA is satisfied that the proposed importation and use of Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester 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 Dichlorprop-P and Dichlorprop-P 2-ethylhexyl ester should be addressed in writing to:

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