

NOTICE

Neem Seed Extract Powder

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of a new active constituent, Neem Seed Extract Powder for use in agricultural chemical products. Neem Seed Extract Powder has insecticidal properties and acts slowly and more specifically as an insect antifeedant and growth regulator. It causes growth disruption due to interference with insect hormone production.

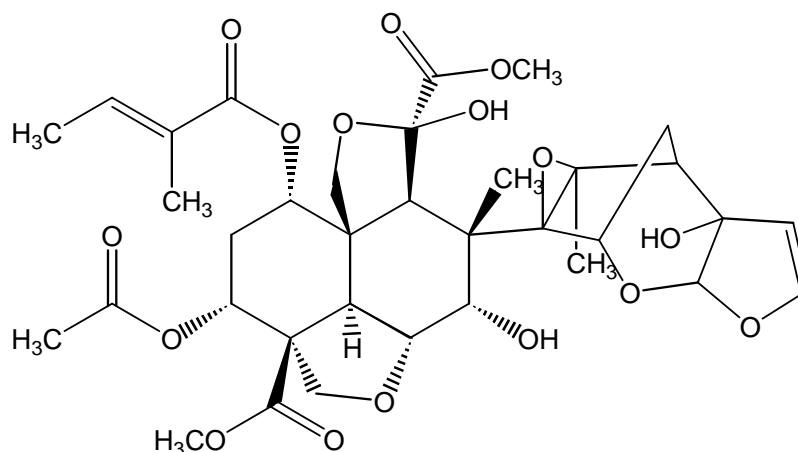
In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for approval of Neem Seed Extract Powder should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only 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

The Neem Seed Extract Powder contains a complex array of compounds. The insecticidal properties of the extract are due to the presence of a mixture of structurally related tetranortriterpenoids isomers collectively known as azadirachtins, and particularly to the major isomer azadirachtin-A in the mixture.

Common Name:	Azadirachtin A
IUPAC Name:	dimethyl (3 <i>S</i> ,3 <i>aR</i> ,4 <i>S</i> , 5 <i>S</i> ,5 <i>aR</i> , 5 <i>a</i> ¹ <i>R</i> 7 <i>aS</i> ,8 <i>R</i> ,10 <i>S</i> ,10 <i>aS</i>)-8-acetoxy-3,3 <i>a</i> ,4,5 <i>a</i> ,5 <i>a</i> ¹ ,7 <i>a</i> ,8,9,10-decahydro-3,5-dihydroxy-4- {(1 <i>S</i> ,3 <i>S</i> ,7 <i>S</i> ,8 <i>R</i> ,9 <i>S</i> ,11 <i>R</i>)-7-hydroxy-9-methyl-2,4,10-trioxatetracyclo[6.3.1.0 ^{3,7} .0 ^{9,11}]dodeca-5-en-11-yl}-4-methyl-10[(<i>E</i>)-2-methylbut-2-enoyloxy]-1 <i>H</i> ,7 <i>H</i> -naphtho[1,8 <i>a</i> ,8- <i>bc</i> :4,4 <i>a-c'</i>]difuran-3,7 <i>a</i> -dicarboxylate
CA Name:	dimethyl [2 <i>aR</i> -[2 <i>a</i> α ,3 <i>\beta</i> ,4 <i>\beta</i> (1 <i>aR</i> *,2 <i>S</i> *,3 <i>aS</i> *,6 <i>aS</i> *,7 <i>S</i> *,7 <i>aS</i> *), 4 <i>a\beta</i> ,5 <i>\alpha</i> ,7 <i>aS</i> *,8 <i>\beta</i> (<i>E</i>),10 <i>\beta</i> ,10 <i>a</i> α , 10 <i>b\beta</i>]]-10-(acetyloxy)octahydro-3,5-dihydroxy-4-methyl-8-[(2-methyl-1-oxo-2-butenyl)oxy]-4-(3 <i>a</i> ,6 <i>a</i> ,7,7 <i>a</i> -tetrahydro-6 <i>a</i> -hydroxy-7 <i>a</i> -methyl-2,7-methanofuro[2,3- <i>b</i>]oxireno[<i>e</i>]oxepin-1 <i>a</i> (2 <i>H</i>)-yl)-1 <i>H</i> ,7 <i>H</i> -naphtho[1,8- <i>bc</i> :4,4 <i>a-c'</i>]difuran-5,10 <i>a</i> (8 <i>H</i>)-dicarboxylate
CAS Number:	11141-17-6
Molecular Formula:	C ₃₅ H ₄₄ O ₁₆
Molecular Weight:	720

Structure:



Summary of the APVMA's Evaluation of Azadirachtin Manufacturing Concentrate Active Constituent

The Chemistry and Residues Program of the APVMA has evaluated the chemistry aspects of Neem Seed Extract Powder active constituent ((including the physico-chemical properties, spectral data, manufacture and quality control aspects, impurity formation, declaration of composition, batch analysis data, analytical methods and validation data, and package information) 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 Neem Seed Extract Powder active constituent:

Constituent	Specification
Azadirachtin A	Not less than 40.00 g/kg
Azadirachtin B	Not less than 31.2 g/kg
Aflatoxins	20 parts per billion (ppb) maximum

Other compounds of toxicological significance (e.g. nitrosamines, dioxins, hexachlorobenzene) are not expected to occur in azadirachtin manufacturing concentrate active constituent as a result of the raw materials and the extraction method used.

The Office of Chemical Safety of the Therapeutic Goods Administration has considered the toxicological aspects of Neem Seed Extract Powder and advised that there are no toxicological objections to the approval of this chemical produced by the company proprietary extraction procedure for non-food producing applications only.

No Acceptable daily Intake (ADI) and Acute Reference Dose (ARfD) has been established, as the toxicology data package is inadequate to set an ADI or ARfD.

Azadirachta indica extracts (neem, its extracts and derivatives) are included in schedule 6 and 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 use of Neem Seed Extract Powder active constituent as an agricultural chemical 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 Neem Seed Extract Powder should be addressed in writing to:

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