

NOTICE

Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate, Dimethyl Pimelate

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application for the approval of the following new active constituents for use in veterinary chemical products: Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate. Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate may be used in combination as synthetic analogue of feline facial pheromones.

In accordance with section 12 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the applications for approvals of Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate 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: Methyl Laurate
IUPAC Name: Methyl dodecanoate
CAS Number: 111-82-0
Molecular Formula: $C_{13}H_{26}O_2$
Molecular Weight: 214.35

Common Name: Methyl Linoleate
IUPAC Name: Methyl cis, cis-9,12-octadeca-dienoate
CAS Number: 112-63-0
Molecular Formula: $C_{19}H_{34}O_2$
Molecular Weight: 294.47

Common Name: Methyl Oleate
IUPAC Name: Methyl (Z)-9-octadecenoate
CAS Number: 112-62-9
Molecular Formula: $C_{19}H_{36}O_2$
Molecular Weight: 296.49

Common Name: Methyl Myristate
IUPAC Name: Methyl tetradecanoate
CAS Number: 124-10-7
Molecular Formula: $C_{15}H_{30}O_2$
Molecular Weight: 242.40

Common Name: Methyl Palmitate
IUPAC Name: Methyl hexadecanoate
CAS Number: 112-39-0
Molecular Formula: $C_{17}H_{34}O_2$
Molecular Weight: 270.45

Common Name: Methyl Pentadecanoate
IUPAC Name: Methyl Pentadecanoate
CAS Number: 7132-64-1
Molecular Formula: $C_{16}H_{32}O_2$
Molecular Weight: 256.42

Common Name: Methyl Stearate
IUPAC Name: Methyl octadecanoate
CAS Number: 112-61-8
Molecular Formula: $C_{19}H_{38}O_2$
Molecular Weight: 298.5

Common Name: Dimethyl Azelate
IUPAC Name: dimethyl nonanedioate
CAS Number: 1732-10-1
Molecular Formula: $C_{11}H_{20}O_4$
Molecular Weight: 216.74

Common Name: Dimethyl Pimelate
IUPAC Name: dimethyl heptanedioate
CAS Number: 1732-08-7
Molecular Formula: $C_9H_{16}O_4$

Summary of the APVMA's Evaluation of Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate

The Chemistry and Residues Program of the APVMA has evaluated the Chemistry aspects of Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate active constituents (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate are not subject to an accepted pharmacopeia monograph.

The Office of Chemical Safety (OCS) of the Department of Health and Ageing has considered the toxicological aspects of Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate, and advised that there are no toxicological objections to the approval of these chemicals.

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

The APVMA is satisfied that the proposed importation and use of Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate 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 Methyl Laurate, Methyl Linoleate, Methyl Oleate, Methyl Myristate, Methyl Palmitate, Methyl Pentadecanoate, Methyl Stearate, Dimethyl Azelate and Dimethyl Pimelate should be addressed in writing to

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