Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Maldison in the product Fyfanon 440 EW Insecticide

APVMA Product Number 51150/101326

DECEMBER 2015

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, and State Departments of Primary Industry.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in the APVMA's Regulatory Guidelines.

About this document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission regarding the proposed registration of Fyfanon 440 EW Insecticide. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. In relation to this document, these grounds relate to the trade implications of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 5 February 2016 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and *confidential commercial information (CCI)*[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Scientific Assessment and Chemical Review
Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701
Email: enquiries@apvma.gov.au

Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from FMC Australasia Pty Ltd to vary the registration of Fyfanon 440 EW Insecticide, a product containing maldison, to add new use patterns for control of fruit fly in pome fruit, stone fruit, citrus fruit, grapes, persimmons, berries, fruiting vegetables (cucurbits), and fruiting vegetables other than cucurbits. The new uses on citrus fruit and grapes involve the same application rates and withholding period as currently registered, and there is no change to the residue risk. Berry fruit, persimmons, and cucurbit and non-cucurbit fruiting vegetables are not considered to be major export commodities. These commodities will not be considered further.

The potential for maldison residues arising from the proposed use to unduly prejudice trade in pome fruit and stone fruit and animal commodities is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pome and stone fruit, are considered to be major export commodities[2], as are meat and dairy products of livestock that may be fed treated fruit pomaces.

2.2 Destination and value of exports

Values of recent exports of Australian pome fruit are not readily available. In 2012–13, 1711.6 tonnes of apples were exported, out of a total production of 296282.3 tonnes, while 4391.1 tonnes of pears were exported out of a total of 101103.3 tonnes[3]. Major markets for Australian apples by volume in 2013 were Papua New Guinea, the United Kingdom, Malaysia and Thailand. Leading markets for Australian pears in 2013 were New Zealand, Indonesia and Canada[4].

Australia exported $1.4 million worth of apricots, $31.5 million worth of cherries, $18.2 million worth of nectarines and peaches and $7.1 million worth of plums in the 2012–2013 financial year. The major markets are summarised below:

[2] apvma.gov.au/node/vol_3/1017

[3] apal.org.au/statistics/

[4] apal.org.au/supply-chain/trade/export-markets/

TABLE 1: LARGEST EXPORT MARKETS BY VALUE FOR STONE FRUIT IN THE 2012-13 FINANCIAL YEAR[5]

FRUIT TYPE	DESTINATIONS
Apricots	United Arab Emirates, Hong Kong, Singapore, Saudi Arabia, the Netherlands, France, Russia, Kuwait, Bahrain
Cherries	Hong Kong, Taiwan, Singapore, Malaysia, United Arab Emirates, Vietnam, Indonesia, China, United Kingdom, the Netherlands
Nectarines and peaches	Hong Kong, United Arab Emirates, Singapore, New Caledonia, Taiwan, Saudi Arabia, Kuwait, Qatar, Malaysia, Indonesia
Plums	Hong Kong, Singapore, Malaysia, United Arab Emirates, Vietnam, Russia, Kuwait, Indonesia, New Caledonia, Papua New Guinea

Australian dairy product exports in 2013–14 totalled 1025 kt at a value of $2.7 billion[9]. Major export markets for Australian dairy products in 2013–14 included Japan, China, Indonesia, Russia, Singapore, Malaysia and Thailand.

The significant export markets for meat are defined in Part 5B of the Data Guidelines.

2.3 Proposed Australian use-pattern

TABLE 1: PROPOSED NEW USE PATTERNS FOR FYFANON 440 EW INSECTICIDE (440 g/l MALDISON)

CROP	PEST	RATE	CRITICAL COMMENTS
			To effectively manage fruit fly, a multi-faceted approach should be used. Fyfanon 440 EW assists in the management of fruit flies as part of an integrated program that includes other registered insecticides, baiting, trapping, pest monitoring, and orchard hygiene. The efficacy of the multi-faceted approach will be dependent upon the level of pest pressure during the season.
Apples, pears	Fruit fly	140–230 mL/100 L (62–101 g ai/100 L)	Apply treatment when fruit fly activity is initially observed, as determined by regular monitoring and fruit fly trapping. Apply as a thorough cover spray to the point of run-off. DO NOT spray on any plants in flower while bees are foraging. Strawberries, blueberries, rubus and ribes
Citrus			
Grapevines			
Persimmons			

[5] Source: Australian Bureau of Statistics

CROP	PEST	RATE	CRITICAL COMMENTS
Stone fruit			Apply a maximum of 6 applications per season, with a minimum of 7 days between consecutive (repeat) sprays. Other crops Apply a maximum of 4 applications per season, with a minimum of 7 days between consecutive (repeat) sprays.
Strawberries, blueberries, rubus and ribes			
Cucumbers, fruiting vegetables other than cucurbits (except sweet corn and mushroom)		140–295 mL/100 L (62–130 g ai/100 L)	
Fruit trees		Bait 700 mL–100 L (308 g ai/100 L) plus a protein bait at recommended rates.	Apply as a lower pressure coarse foliar, spot or strip spray throughout the orchard or in fruit fly hot spots. For foliar and strip spraying apply in a volume of 5–20 L/ha of bait solution. For spot spraying, apply 100–150 spots/ha at 50–100 mL/spot of bait solution. Only apply to leaves, trunk and lower limbs of trees. Apply weekly from 6 weeks before harvest to 2 weeks after harvest. If rain occurs after application, reapply as soon as possible after the rain event. Do not apply directly to fruit. Do not spray trees when bees are foraging. Do not use the bait treatment as a broadcast or cover spray.
Blueberries, rubus, ribes and strawberries			Apply only to perimeter non-crop vegetation and fruit fly resting sites. Apply as a low pressure coarse foliar, spot or strip spray. For foliar and strip spraying, apply in a volume of 5–20 L/ha of bait solution. For spot spraying, apply 100–150 spots/ha at 50–100 mL/spot of bait solution. Only apply to leaves, trunk and lower limbs of trees. Apply weekly from 6 weeks before harvest. If rain occurs after application, reapply as soon as possible after the rain event. Do not apply directly to fruit. Do not spray trees when bees are foraging. Do not use the bait treatment as a broadcast or cover spray.

Harvest withholding periods

Cucumbers:

Do not harvest for 1 day after application.

Fruit and vegetables except cucumbers.

Harvest: Do not harvest for 3 days after application.

2.4 Results from residues trials considered by the APVMA

Pome fruit

The proposed GAP for maldison in pome fruit is 4 × 100 g ai/100 L dilute foliar applications with a minimum re-treatment interval of 7 days and a harvest withholding period of 3 days.

Data from a series of trials in apples and pears conducted in South Africa, Chile and Argentina was provided. In these trials, three applications were made at 7-day intervals at a target rate of 2200 g ai/ha.

Residues of maldison (parent only, as per the Australian residue definition) at 3 days after 3 × 2200 g ai/ha applications were 0.14, 0.29, 0.32, 0.38, 0.55, and 0.91 mg/kg (STMR = 0.35 mg/kg).

The current MRL of 2 mg/kg for maldison in fruits (except citrus fruit, blackcurrant, dried fruit, grapes, pears and strawberry) is adequate to cover residues expected in pome fruit arising from the proposed use against fruit flies. It is proposed that the current MRL of 0.5 mg/kg for pears be deleted, with the fruits MRL being amended to include pears.

Stone fruit

The proposed GAP for maldison in stone fruit is 4 × 100 g ai/100 L dilute foliar applications with a minimum re-treatment interval of 7 days and a harvest withholding period of 3 days.

The combined data set for maldison in peaches and cherries at 3 days after the last of 3–6 concentrate foliar applications which match the proposed GAP after adjustment to the expected dilute spray volumes is 0.12, 0.26, 0.28, 0.44, 0.51, 0.59, 1.1, 1.6, and 2.6 mg/kg (STMR = 0.51 mg/kg).

An MRL of 5 mg/kg is proposed for maldison in stone fruit, in conjunction with a 3–day harvest withholding period.

Animal feeds

Apple pomace

Residues of maldison were observed to concentrate in dry apple pomace. Multiplying the highest processing factor for dry pomace, 12.9, by the HR for apples (0.91 mg/kg), yields an HR-P value of 11.7 mg/kg. A maximum residue level of 20 mg/kg is therefore proposed for maldison in apple pomace, dry. Using the mean processing factor (11.2) and the STMR of 0.35 mg/kg for the above pome fruit data set gives an STMR-P value of 3.9 mg/kg.

Tomato pomace

Based on a value of 5% for the dry matter content of a tomato[6], the STMR of 0.08 mg/kg for tomatoes, and the HR of 0.26 mg/kg, estimates of 1.6 and 5.2 mg/kg for the STMR-P and HR-P for tomato pomace, dry can be calculated. An MRL of 10 mg/kg is proposed for maldison in tomato pomace, dry.

Animal commodities

The STMR-P for apple pomace (dry) is 3.9 mg/kg, while the STMR-P for tomato pomace, dry is estimated at 1.6 mg/kg.

It is noted that maldison is registered for use in stored cereal grain, with an MRL of 8 mg/kg and a withholding period of 90 days, or instructions to ensure the residue has declined to 8 mg/kg. Cereal grains can be fed to livestock at up to 80% of the diet. Further, maldison is registered for use in cereal crops and pastures at up to 1.1 kg ai/ha, and a grazing withholding period of 1 day. In the Pesticide Risk Profile for pasture[7], it was noted that the anticipated residues of maldison in forage at day 0 after application at 1.1 kg ai/ha were 179 mg/kg, well in excess of the residues expected in apple or tomato pomace. There are no feeding restrictions (e.g. export slaughter intervals) on product labels for maldison in order to protect exports.

It is therefore considered unlikely that feeding of treated fruit or tomato pomaces to livestock will increase the dietary burden of maldison, and existing animal commodity MRLs for maldison remain adequate.

[6] Ep Heuvelink (ed.), *Tomatoes*, Crop Production Science in Horticulture, 13, CABI Publishing, 2005 (page 125)

[7] Dugald MacLachlan, Australian Quarantine and Inspection Service, *Pesticide Risk Profile for the Grazing of Pasture and/or Cutting of Hay and Feeding to Cattle and Sheep*, July 2003, updated February 2010 (available on the Safemeat website at safemeat.com.au/key-issues/chemical-residues.htm).

2.5 Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. The following relevant Codex and overseas country MRLs have been established for maldison.

TABLE 3: RELEVANT CODEX AND OVERSEAS COUNTRY MRLS FOR MALDISON

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF MALDISON (mg/kg)						
	AUSTRALIA	EU[8]	JAPAN[9]	CODEX[10]	TAIWAN[11]	CANADA[12]	USA[13]
Residue Definition	Maldison	Sum of maldison and malaoxon, expressed as maldison	Maldison	Maldison	-	Maldison	Maldison
Apple	2 (current and proposed)	*0.02	0.5	0.5	0.5	2	8
Pear	0.5 (current); 2 (proposed)	*0.05	0.5	-	*0.01	2	8
Cherries	5 (proposed)	*0.02	6	3	0.5	6	8
Peaches	5 (proposed)	*0.02	0.5	-	*0.01	6	8
Apricots	5 (proposed)	*0.02	8	-	*0.01	6	8
Plums	5 (proposed)	*0.02	Japanese plum (including prune): 6 Mume plum: 0.2	-	*0.01	8	8
Nectarine	5 (proposed)	*0.02	8	-	*0.01	6	8

[8] ec.europa.eu

[9] www.m5.ws001.squarestart.ne.jp

[10] www.codexalimentarius.net

[11] www.fda.gov.tw

[12] www.hc-sc.gc.ca

[13] www.ecfr.gov

2.6 Current and proposed Australian MRLs for maldison

The MRL standard contains the following relevant entries:

A full listing of MRLs can be found at apvma.gov.au/node/10806.

TABLE 4: CURRENT ENTRIES IN THE MRL STANDARD
MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Maldison		
MO 0105	Edible offal (Mammalian)	1
	Fruits [except citrus fruits; currant, black; dried fruits; grapes; pear; strawberry]	2
MM 0095	Meat [mammalian] [in the fat]	1
ML0106	Milks [in the fat]	1
FP 0230	Pear	0.5

MRL STANDARD: TABLE 2

COMPOUND	RESIDUE
Maldison	Maldison

The following changes are proposed to Australian MRL standard:

TABLE 5: PROPOSED CHANGES TO THE MRL STANDARD—TABLE 1
MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
Maldison		
DELETE:		
	Fruits [except citrus fruits; currant, black; dried fruits; grapes; pear; strawberry]	2
FP 0230	Pear	0.5
ADD:		
	Fruits [except berries and other small fruits; citrus fruits; dried fruits; stone fruits]	2
FS 0012	Stone fruits	5

TABLE 6: PROPOSED CHANGES TO THE MRL STANDARD—TABLE 4
MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
ADD:		
Maldison		
AB0226	Apple pomace, dry	20
	Tomato pomace, dry	10

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of maldison may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Residues of maldison in pome fruit may exceed the tolerances in some overseas jurisdictions, but not the USA and Canada. There is a potential risk to trade in pome fruit, however it is noted that no change to the apple MRL for maldison is proposed.

Residues of maldison in stone fruit may exceed the tolerances in most jurisdictions other than the USA, Canada, and Japan for stone fruit other than peaches. There is a potential risk to trade in stone fruit.

Residues of maldison in meat and milk are not expected to exceed the current MRLs, and there is not expected to be any increased risk to trade in meat or dairy products.

3 CONCLUSIONS

FMC Australasia Pty Ltd has made an application to vary the registration of *Fyfanon 440 EW Insecticide* containing 440 g/L maldison as the active constituent to add new use patterns for control of fruit fly in pome fruit and stone fruit.

Comment is sought on the potential risk to trade for the proposed new use of maldison in pome fruit and stone fruit, and the ability of industry systems to manage any identified risk.