Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on chlorantraniliprole in the product DuPont Altacor Insecticide

for use on pulses

APVMA Product Number 61824

AUGUST 2017

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Comments and enquiries regarding copyright:

Director Public Affairs and Communication
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

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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 and Aging, Department of the Environment and Energy, 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 regulatory guidance published on the APVMA website.

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 as to whether the application to vary the registration of *DuPont Altacor Insecticide* should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on Friday 1 September 2017 **a**nd 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:

Residues and Trade
Scientific Assessment and Chemical Review
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 can be obtained via the contact details provided above.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

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

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from DuPont (Australia) Pty Ltd, to vary the registration of DuPont Altacor Insecticide containing chlorantraniliprole. The product is currently registered for use on chickpeas, mung beans and soybeans. The Applicant proposes to extend the same use pattern to all pulses.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Pulses including lupins, field peas, chickpeas, faba beans, navy beans and mung beans are considered to be major export commodities[2], as are commodities of animal origin such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from pulses treated with DuPont Altacor Insecticide. Residues in these commodities resulting from the use of DuPont Altacor Insecticide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Total pulse exports were 2,029 kilotonnes, valued at $1.75 billion, in 2015–16, with the most significant export commodities being chickpeas (1140 kt, $1013 m), lupins (232 kt, $94 m) and field peas (143 kt, $86 m)[2]. Major export markets for Australian pulse crops are presented below.

Table 1: Major destinations (2014-15) for Australian Pulse crops (supplied by Applicant)

CROP	MAJOR DESTINATIONS
Faba and broad beans	Egypt, Saudi Arabia, United Arab Emirates, Indonesia, Malaysia
Field peas	India, Malaysia, Sri Lanka, Bangladesh, Belgium, Fiji
Lentils (Red and green)	Sri Lanka, Bangladesh, India, Pakistan, United Arab Emirates
Lupins (ASL and Albus)	Sri Lanka, Bangladesh, India, Pakistan, United Arab Emirates
Peas, dry	Rep of Korea, Netherlands, Egypt, Japan, Spain

The destination and value of exported chickpea, mung bean and soybean crops, for which the use is currently allowed, were addressed under the Trade Advice Note arising from application 61824/60085 (consultation period 16 April 2014–14 May 2014).

[2] Australian commodity statistics 2016, Australian Bureau of Agricultural and Resource Economics and Sciences December 2016, http://data.daff.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022016_Sn9Dg/ACS_2016_v1.1.0.pdf

2.3 Proposed Australian use-pattern

DUPONT ALTACOR INSECTICIDE (350 G/KG CHLORANTRANILIPROLE)

CROP	PEST	RATE	CRITICAL COMMENTS
Winter pulse crops including: Chickpea*, Faba/ Broad bean, Field pea, Lentil, Lupin, Vetch	Cotton bollworm (*Helicoverpa armigera*) Native budworm (*Helicoverpa punctigera*)	70g/ha (≡ 24.5 g ai/ha) + non ionic surfactant @ 125g ai/100L.	A maximum of two applications are to be applied to any one crop per season. Further treatments should be made with alternative mode of action insecticides. Regularly scout crops to monitor for larvae. Target sprays against larvae. Apply as larvae reach threshold numbers. Larvae in entrenched feeding sites will not be controlled. Use enough water to ensure thorough coverage of the crop. Target a minimum of 100L/ha by ground rig and a minimum of 30 L/ha by aircraft. Use in accordance with Crop Life Insecticide Resistance Management Strategy Guidelines. Target brown eggs and hatchlings (neonates or first instar) to small larvae (second instar) when they reach the economic spray threshold and before they become entrenched in flowers or pods.
Summer pulse crops including: Azuki/ Adzuki bean, Cow pea, Mung bean*, Navy bean, Pigeon pea, Soybean*	Bean podborer (Maruca vitrata) Cotton bollworm (Helicoverpa armigera) Native budworm (Helicoverpa punctigera) Soybean looper (Thysanoplusia orichalcea) Bean looper (Mocis alterna) Irrorated tabby (Anticarsia irrorata)		

*The chickpea, mung beans and soybean uses above, are already approved

Withholding periods:

Harvest: DO NOT harvest for 14 days after application
Grazing: DO NOT graze or cut for stock food for 14 days after application

Restraints:

DO NOT apply if heavy dew is present on crops, or if rainfall is expected within 2 hours of application.

DO NOT make more than 3 applications per cotton crop per season, and no more than 2 consecutive sprays per field per season.

DO NOT make more than 2 applications per pulse crop per season. Application must be a minimum of 7 days apart.

Spray Drift Restraints:

DO NOT apply with spray droplets smaller than a MEDIUM spray droplet size category according to nozzle manufacture specifications that refer to ASAE S572 Standard or the BCPC guidelines.

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply during surface temperature inversion conditions at the application site.

EXPORT STATEMENT: Import tolerances for produce treated with DuPont Altacor Insecticide may be pending in some countries. Consult with your exporter or DuPont before applying Altacor to export crops.

2.4 Results from residues trials presented to the APVMA

The complete pulses data set of residues observed in Australian trials in faba beans (<0.01 mg/kg, n=4) and field peas [<0.01 (3) mg/kg and 0.024 mg/kg], submitted with the current application in trials carried out at GAP, and previously submitted chick peas and soybeans residues data from trials carried out according to GAP, are in rank order:

<0.005 (3), 0.009, <0.01 (7), 0.015, 0.024, 0.025 and 0.029 mg/kg (n = 15, STMR = <0.01 mg/kg).

Noting the already established MRLs for VD 0524 Chick pea (dry) and VD 0541 Soya bean (dry) established at 0.07 mg/kg to cover residues in those crops arising from the proposed use pattern, it is considered appropriate to establish a group MRL for VD 0070 Pulses [except Mung bean (dry)] at 0.07 mg/kg. The established chick pea (dry) and soya bean (dry) MRLs will be deleted. In addition, an MRL for adzuki beans, recommended at the time of the residues evaluation for Permit 14586 (expired 31/5/2014), will be deleted.

The MRL of 0.7 mg/kg established for VD 0536 Mung bean (dry) will remain unchanged.

The residues data for faba bean forage and fodder submitted with the current application and previously submitted pulse forage, trash and pods data indicate that the established MRL for AL 0157 Legume animal feeds set at 10 mg/kg, will cover residues in forage and fodder of winter and summer pulse crops arising from the proposed use pattern. The current grazing withholding period ‘DO NOT graze or cut for stock food for 14 days after application’ remains applicable.

The calculated Maximum Feeding level of 5.84 ppm for cattle was based on consumption of 100% field pea forage.

CATTLE- 500 KG BW, 20 KG DM/ DAY

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, MG/KG	% DM	LIVESTOCK DIETARY EXPOSURE		
						MG/ANIMAL	PPM	MG/KG BW
Pulses/legumes	Forage/fodder	100	20	5.84 (HR)*	100	116.8	5.84	0.234
Total							5.84	

*Residue observed in field pea forage

Based on a calculated maximum residue of 0.0104 mg/kg in kidney, from consideration of residues in tissues in a cattle feeding study, it is proposed that the MRL for MO 0105 Edible offal (Mammalian)[except liver] at *0.01 mg/kg should be amended to MO 0105 Edible offal (Mammalian) at 0.02 mg/kg. This MRL will cover residues in liver expected from the proposed use pattern and the current chlorantraniliprole MRL for liver at 0.02 mg/kg will be deleted. The current chlorantraniliprole animal MRL for Meat (mammalian) [in the fat] is adequate to cover animals consuming treated pulse forage and fodder.

Based on a calculated maximum residue of 0.0104 mg/kg it is proposed that the MRL for chlorantraniliprole in milks be increased from *0.01 to 0.02 mg/kg. The established MRL for FM 0183 Milk Fats at 0.1 mg/kg remains appropriate.

It is noted that based on the expected high residues in kidney and milk and the half-lives calculated from the lactating cow depuration study, it is expected that residues will be <0.01 mg/kg after one day on clean feed.

The established MRLs for poultry commodities remain appropriate for the proposed use.

2.5 Overseas registration and approved label instructions

The applicant indicated that chlorantraniliprole products are registered extensively throughout the globe including in the following countries: Argentina, Brazil, Canada, China, Cyprus, France, Greece, Italy, Netherlands, New Zealand, South Africa, Spain and the USA.

Chlorantraniliprole products (granules or liquid products) are registered for use on crops in the pulse or legume group in various countries including Argentina, Canada, India and Japan. The following use patterns are currently registered overseas and are similar to the use pattern proposed in Australia.

PARAMETER	AUSTRALIA	CANADA	INDIA	JAPAN
Crop	Chickpeas	Legume vegetables (includes fava bean, lentil, lupin, mung bean, soybean)	Bengal gram	Soybean
Pest	Cotton bollworm Native budworm	Various chewing pests, including Armyworm, European corn borer, Cabbage looper	Pod borers	Common cutworm
Product	350 g/kg; WG	200 g/L; SC	200 g/L; SC	50 g/L; SC
Rate	70 g/ha (24.5 g a.i./ha)	250-375 mL/ha (50-75 g a.i./ha)	125 mL/ha (25 g a.i./ha)	25 mL/100L/ha (37.5 g a.i./ha) Max. 3000 L/ha
Retreatment Interval	Minimum 7 days	Minimum 3 days	Minimum 10 days	Minimum 7 days
Number of applications	2 (maximum)	4 (maximum)	2 (maximum)	3 (maximum)
Withholding period	14 days	1 day	11 days	7 days

2.6 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. Chlorantraniliprole has been considered by Codex, however Codex CXLs have not been established for pulse crops at this time. The Applicant has noted that DuPont Pty Ltd is preparing a case for the nomination of a pulse MRL for chlorantraniliprole in 2018.

The following relevant international MRLs have been established for chlorantraniliprole:

Table 2: Relevant overseas MRLs for chlorantraniliprole in pulses

COUNTRY/ STATUS	RESIDUE DEFINITION	COMMODITY	TOLERANCE (mg/kg)
AUSTRALIA	Parent	Adzuki bean (dry)	T0.5 ***(to be deleted)***
		Chick-pea (dry)	0.07 ***(to be deleted)***
		Mung bean (dry)	0.7
		Pulses [except mung bean (dry)]	0.07 ***(proposed)***
		Soybeans, dried	0.07 ***(to be deleted)***
CANADA	Parent	Adzuki beans (dry); Beans, dry; Blackeyed peas (dry); Broadbeans (dry); Chickpea (dry); Field peas (dry); Kidney beans (dry); Lentils (dry); Mung beans (dry); Navy beans (dry); Pigeon pea (dry); Soybeans (dried)	2
EU	Parent	Pulses, dry	*0.01
		Soybeans, dried	0.05
JAPAN	Parent	Beans, dry; Broadbeans; Other legumes, pulses	1
		Soybeans, dried	0.2
KOREA	Parent	Other agricultural products	0.05
TAIWAN	Parent	Broadbeans (fresh);Chick-pea, Cowpea (fresh), Lima bean, Pea, Pigeon pea (fresh)	1
		Cowpea (dry); Mung bean, Pigeon pea (dry); Soybean	0.3
		Vegetable soybean	0.5
USA	Parent	Vegetable, legume, group 6	2.0

Table 3: Relevant overseas MRLs for chlorantraniliprole in animal commodities

COUNTRY/ STATUS	RESIDUE DEFINITION	COMMODITY	TOLERANCE (mg/kg)
AUSTRALIA	Animal commodities other than milk: Parent, Milk: Parent + IN-K9T00 + IN-HXH44	Edible offal (mammalian)	0.02 ***(proposed)***
		Edible offal (mammalian) [except liver]	*0.01 ***(to be deleted)***
		Liver	0.02 ***(to be deleted)***
		Meat (mammalian)[in the fat]	0.02
		Milks	*0.01 ***(to be deleted)*** 0.02 ***(proposed)***
		Milk fats	0.1
CODEX	Parent	Edible offal (mammalian)	0.2
		Meat (in the fat)	0.2
		Whole milk	0.05
		Milk fats	0.2
CANADA	Parent	Edible offal (mammalian); Cattle meat; Sheep meat	0.01
		Whole milk	0.02
		Cattle fat; Cattle meat byproducts; Sheep fat; Sheep meat, byproducts	0.05
EU	Parent	Whole milk	0.05
		Edible offal (mammalian); Kidney (mammalian); Liver; Cattle meat; Cattle fat; Sheep meat; Sheep fat	0.2
JAPAN	Parent	Whole milk	0.05
		Edible offal (mammalian); Kidney (mammalian); Cattle meat; Other terrestrial mammals, kidney; Other terrestrial mammals, muscle	0.2
		Cattle fat; Liver; Other terrestrial mammals, fat; Other terrestrial mammals, liver;	0.3
USA	Parent	Cattle meat; Sheep meat; Whole milk	0.1
		Cattle fat; Cattle meat byproducts; Sheep fat; Sheep meat byproducts	0.5

2.7 Current and proposed Australian MRLs for chlorantraniliprole

Table 4: Current relevant entries in the MRL Standard—Table 1

COMPOUND		FOOD	MRL (mg/kg)
CHLORANTRANILIPROLE			
VD	0560	Adzuki bean (dry)	T0.5
VD	0524	Chick-pea (dry)	0.07
MO	0105	Edible offal (Mammalian)[except liver]	*0.01
PE	0112	Eggs	0.03
MM	0099	Liver (Mammalian)	0.02
MM	0095	Meat (mammalian) [in the fat]	0.02
FM	0183	Milk fats	0.1
ML	0106	Milks	*0.01
VD	0536	Mung bean (dry)	0.7
PO	0111	Poultry, Edible offal of	*0.01
PM	0110	Poultry meat (in the fat)	*0.01
VD	0541	Soya bean (dry)	0.07

Table 5: Proposed changes to MRL Standard—Table 1

COMPOUND		FOOD	MRL (mg/kg)
CHLORANTRANILIPROLE			
DELETE:			
VD	0560	Adzuki bean (dry)	T0.5
VD	0524	Chick pea (dry)	0.07
MO	0105	Edible offal (Mammalian)[except liver]	*0.01
MM	0099	Liver (Mammalian)	0.02
ML	0106	Milks	*0.01
VD	0541	Soya bean (dry)	0.07
ADD:			
MO	0105	Edible offal (Mammalian)	0.02
ML	0106	Milks	0.02
VD	0070	Pulses [except mung bean (dry)]	0.07

2.8 Potential risk to trade

The residue definition for plant commodities in Australia and overseas is chlorantraniliprole.

The risk to trade in chickpeas, mung beans and soya beans from the proposed use pattern, was previously considered in the published Trade Advice Note for P61824 (consultation period 16 April 2014–14 May 2014). No change to the use of, or MRL for, mung beans is proposed and therefore the risk to trade in mung beans is unchanged and does not need further consideration.

The proposed Australian MRLs of 0.07 mg/kg for Pulses [except mung bean (dry)] is comparable to or lower than other pulse MRLs established for chlorantraniliprole in overseas countries. For example, Japan has MRLs at 1 mg/kg for various pulses. Korea has an MRL at 0.05 mg/kg for other agricultural products and Taiwan has MRLs at either 1 mg/kg (chick-pea, lima bean, pea) or 0.3 mg/kg (pigeon pea). Canada and the USA have established MRLs for pulses at 2 mg/kg.

In the Australian trials observed STMRs were 0.015 mg/kg for chick-peas (3 trials), 0.007 mg/kg for soybeans (4 trials) and <0.01 mg/kg for both faba beans (4 trials) and field peas (4 trials). It is noted that residues above LOQ were not observed in the new faba bean and field pea trials with the exception of one field pea trial (0.024 mg/kg), while low finite residues were observed in chickpeas and soybeans which are currently approved.

The residue definition for animal commodities in Australia and overseas is generally chlorantraniliprole except for milk in Australia, for which the definition is Parent + IN-K9T00 + IN-HXH44.

The proposed increased MRL in edible offal (*0.01 as edible offal except liver amended to 0.02 mg/kg for edible offal due to an increase in expected residues in kidney) and milks (*0.01 to 0.02 mg/kg) are lower than the limits established by Codex, USA, the European Union and Japan. The proposed milk MRL is the same as that established in Canada, while the proposed edible offal MRL is higher than in Canada (0.01 mg/kg).

The Applicant has proposed to manage the risk to trade through the following label statement:

Export Statement: Import tolerances for produce treated with DuPont Altacor Insecticide may be pending in some countries. Consult with your exporter or DuPont before applying Altacor to export crops.

3 CONCLUSIONS

DuPont (Australia) Pty Ltd, has applied for a variation of the registration of *DuPont Altacor Insecticide*, which is currently registered for use on chickpeas, mung beans and soybeans, to allow use on all pulses. Comment is sought on the potential risk to trade in pulses and animal commodities from the proposed use and the ability of the industry to manage any potential risk.