



Australian Pesticides &
Veterinary Medicines Authority

Trade Advice Note

on

Trinexapac-ethyl

in the product

Moddus Yield and Quality Enhancer
(APVMA Product Number 60214)

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Trade Advice Note on the Product

Moddus Yield and Quality Enhancer (250 g/L trinexapac-ethyl)

Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Crop Protection Pty Limited to register the use of *Moddus Yield and Quality Enhancer* in thebaine poppies, sugar cane and annual and perennial ryegrass. The product is a plant growth regulator used to increase seed yields in rye grass seed crops, improve the percentage of thebaine in poppies and the sugar content in sugarcane.

The APVMA invites any person to submit a relevant written submission with respect to whether the proposed new use is likely to unduly prejudice trade or commerce between Australia and Australia's trading partners. **Please provide your submission by 31 March 2007.** Any submissions provided after this date may be unable to be considered before the regulatory decision is made. All submissions should be addressed to the above contact.

Trade consideration

1. Commodities exported

The following commodities relevant to this application are considered by the APVMA to be major export food commodities (as listed in Appendix 1 of Part 5B: *Overseas trade aspects of residues in food commodities*): meat, dairy products and sugar.

2. Destination and Value of Exports

Thebaine poppy and sugarcane

MRLs are quality indicators that demonstrate a chemical has been applied according to the label directions and as such, MRLs apply to commodities at the farm gate. The commodities derived from both sugarcane and thebaine poppies (sugar and opiate drugs) are highly processed and no residues are expected to occur in the exported commodities of these two crops. The use of *Moddus Yield and Quality Enhancer* on sugarcane and thebaine poppies is not expected to prejudice trade between Australia and its trading partners. As such, trade in these commodities are not discussed further.

Cattle

The volume of Australian beef, cattle and veal exports (live and dress wt.) in 2003-04 was 1465.3 ktonne at an estimated value of \$4.7179 billion. The five largest export markets for Australian beef, cattle and veal exports were (in order of value) Japan, United States, Republic of Korea, Indonesia and Chinese Taipei.

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Value \$m of beef veal and live cattle exports 1997 – 2004

	1997	1998	1999	2000	2001	2002	2003	2004
Beef and veal								
Americas								
Canada	80.6	104.6	128	148.1	204.4	320.2	110.9	38.1
United States	500.4	735.2	805.1	1172.8	1699.7	1593.6	1332.3	1374.4
Asia								
Chinese Taipei	112.9	108.2	123.2	116.7	132.6	152.3	126.7	119.5
Hong Kong, China	13.5	23.6	16.6	18.2	17.8	17.1	15	27.2
Indonesia	59.4	6.1	33.3	40.8	37.2	46.1	38.4	26.6
Japan	1207.9	1312.4	1369.7	1537.3	1728.2	1237.7	1384.4	2189.8
Korea, Rep. of	144.7	87.6	201.9	221.7	228.9	320.4	250.7	434.4
Malaysia-Singapore	71.7	66.7	68.7	70.6	78.7	91.4	86.8	74.6
Philippines	51.6	40.4	38.5	34.3	55.8	36.1	23	4.4
Europe								
European Union (a)	54.7	58.6	61.3	37.4	48.4	53.5	49.2	62.7
CIS	20.9	58.2	18.1	3.8	14.4	2.9	0.7	2
Eastern Europe	19.7	43.6	6.9	6.3	1.2	9.1	4.5	1.4
Middle East								
Kuwait	1.9	3.6	1.6	0.3	4.6	1.8	9.8	3.4
Saudi Arabia	3	7.4	3.3	2.1	23	11.6	7.8	3.2
UAE	3.6	5.4	2.5	4.4	11.6	10.9	7.8	11.8
Oceania								
New Zealand	3.5	4.5	5	11.1	6.3	25.6	15.9	9.9
Pacific Isles	6	6.2	4.1	5.2	7.2	7.4	5.4	4.5
PNG	19	12.3	14.1	14.1	11.5	9.8	4.9	5.2
Total Beef and veal	2412.1	2768.3	2963.3	3464.1	4357.3	4002.6	3475.3	4390.2
Live Cattle (b)								
Asia								
Indonesia	209.4	18	68.5	143.1	171.8	254	203.4	207.3
Japan	14.9	11.6	7.8	9.8	12.7	11.2	16.6	14.6
Malaysia	26.3	15.3	29.9	25.7	38.5	45.1	38.9	25.2
Philippines	117.9	87.7	126.7	117.8	58.4	65.8	39.1	30.1
Middle East								
Egypt	19.3	61.6	131.2	129.7	153.8	94.9	5	0
Israel	0	5.7	3.8	9	15.4	23.9	22.8	11.9
Jordan	1.3	7.7	15.7	18.1	6.7	2.4	12.9	15.3
Libya	57.7	64.9	13.5	0	0	0	0	0
Saudi Arabia	0.5	0	0	0	14.9	32.5	9.4	0
Total live Cattle	453.8	280.3	409.2	471.7	514.4	580.8	376.5	327.7

a) Regarded as fifteen countries to May 2004, then twenty five countries from June 2004. b) Excludes animals for breeding. Source: Department of Agriculture, Fisheries and Forestry, Export Statistics, Livestock Exports, Canberra; ABS, International Trade, Australia, cat. no. 5465.0, Canberra.

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3. Proposed Use Pattern

The maximum proposed Australian use-pattern for *Moddus Yield and Quality Enhancer* involves the application of 400 g ai/ha to ryegrass crops. Harvest WHPs, grazing intervals, export grazing intervals and livestock protection statements are proposed for inclusion on the label to reduce residues from grazing and spray drift to <LOQ levels when the product is used as directed.

CROP	USE	RATES	CRITICAL COMMENTS
Poppies (Thebaine varieties)	Modify alkaloid ratio, improving the percent of thebaine	1 to 2.5 L/ha (equ to 250 – 625 g ai/ha)	Apply to an actively growing, healthy poppy crop. Apply from mid run-up (MRU) until early flowering. Use higher rates to provide higher thebaine yields
Ryegrass seed crops (Annual and perennial)	Increase seed yield via improved seed set	800 mL to 1600 mL (equ to 200 – 400g ai/ha)	Apply to an actively growing, healthy ryegrass seed crop. Apply at growth stage (GS) 31-32, when the 2 nd node is visible on the main tiller and the majority of the other tillers have the 1 st node detectable above ground level. The higher rate of 1600 mL is recommended on high fertility paddocks with good moisture (eg under irrigation)
Sugarcane	Increase Commercial Cane Sugar (CCS) percentage	800 mL/ha (equ to 200g ai/ha)	Apply MODDUS to healthy, actively growing sugarcane. Apply between 8 weeks (56 days) and 5 weeks (35 days) prior to harvest.

Critical Comments:

Do NOT apply to crops under stress, suffering from nutrient deficiency, disease, drought stress, insect damage or herbicide effects.

To be applied by either ground application or aerial application. Ensure complete spray coverage of all leaves and stems is obtained.

Ground application: Apply according to the table below. The use of flat fan nozzles is recommended using a fine to medium quality spray pattern.

Aerial application: Apply according to the table below, with the lower rates being used when applications are made with a cross wind of not less than 5 knots. Use the higher rates when applying to dense crops.

CROP	WATER VOLUME	
	Boom application	Aerial Application
Poppies	150 – 250	25 – 60
Ryegrass	50 – 200	10 – 20
Sugarcane	150 – 500	25 – 60

Growing Conditions:

In general, *Moddus* should be applied under good growing conditions with adequate soil moisture. *Moddus* should not be applied to crops that are under stress due to very dry, very wet, frosty conditions, nutrient deficiency, or high insect pressure, as this may give less than reliable results.

Withholding Periods:

Poppies: Not required when used as directed
 Ryegrass: Do not graze or cut for stock food for 4 weeks after application
 Sugarcane: Harvest: Do not harvest for 5 weeks after application
 Grazing: Do not graze or cut for stock food for 5 weeks after application

Export Slaughter Interval (ESI): An ESI is not required when used as directed.

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Livestock Destined for Export Markets

Grazing withholding periods apply to stock slaughtered for domestic market. Some export markets apply different standards. To meet these standards, ensure that the export grazing interval is observed before stock are sold or slaughtered.

Spray Drift: Protection of Livestock

The grazing of spray drift affected pastures by livestock destined for export markets may result in violation of export market standards. To ensure compliance with export standards livestock should be restricted from grazing spray drift affected pastures for three weeks following application.

Export Grazing Interval (EGI):

Ryegrass: Do Not Graze or Cut for Stock Food for 6 Weeks After Application.

4. Results from trials presented to the APVMA

Poppies

Residues of trinexapac acid (CGA1795000) were detected in poppy seeds harvested 62 - 68 days after at single application of Moddus at an application rate up to 750 g a.i./ha. The highest residue found was 3.9 mg/kg when Moddus was applied at 2L/ha (500 gai/ha) at late runup/bud in apex stage. The use pattern indicates *Moddus Yield and Quality Enhancer* may be applied up to early flowering as this would normally occur within days of the 'bud in apex' stage the residue trials are considered appropriate for the evaluation of residue levels in the commodities of concern (poppy seed). However, as the use pattern is restricted to Thebaine poppy varieties an MRL in this commodity is not required as this commodity is not edible.

Ryegrass

In the Australian residue trials, residues of trinexapac acid in foliage declined over the sampling period but were still measurable at the highest rate (1600 mL/ha) when the last foliage samples were taken 55-56 days after application (highest 0.35 mg/kg, dry weight). A similar residue decline in foliage was seen in the New Zealand trials where the highest rate was 3200 mL/ha (2x). At harvest residues of trinexapac acid were not detected in straw at any application rate; however, in the Australian trials, low residues were found in grain (0.03 mg/kg) at the 1600 mL/ha rate. In one trial (Carrick, TAS) residues were found at harvest on a whole plant basis with the highest residue being 0.28 mg/kg (dry weight).

The proposed withholding period for grazing is 28 days. At this sampling time the highest residue found in foliage was 2.4 mg ai/kg dry weight (0.46 mg ai/kg wet weight) at the highest label rate of 1600 mL/ha. At the 3200 mL/ha (2x) rate in the New Zealand trials the highest residue found at 28 days after application was 4.6 mg/kg (dry weight).

The data provided support the establishment of an MRL of 3 mg/kg for 'Rye straw and fodder (dry)' in Table 4 of the MRL Standard.

Sugar cane

Residues of the free acid in sugarcane stalk taken at 34 days (proposed WHP: 35 days) were a maximum of 0.08 mg/kg (wet weight). Residues in the foliage taken at 34 days (proposed grazing interval: 35 days) were a maximum of 0.80 mg/kg (dry weight).

The data provided support the establishment of a sugar cane MRL of 0.1 mg/kg in Table 1 of the MRL Standard and MRLs of 1 mg/kg for both sugar cane forage and fodder in Table 4 of the MRL Standard.

Processing studies

Several studies were submitted examining the concentration of trinexapac-ethyl residues in the processed fractions of sugarcane. Given the highly water-soluble nature of the free acid metabolite no accumulation of residues were observed in the processed commodities made available for either human or animal consumption.

Animal transfer Studies and associated MRLs

The applicant has provided one study detailing animal transfer in dairy cattle.

Lactating cows were dosed with CGA 179500 for 29-30 days at nominal dose levels of 40, 120 and 400 mg/animal/day. The actual dose levels were equivalent to 1.9, 5.2 and 19.4 ppm in the diet or 0.06, 0.19

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and 0.67 mg/kg bw. For the lowest feeding level residues in tissues and milk were <LOQ excluding kidney were residues were at 0.03 mg/kg.

5. Overseas registration and approved label instructions

The applicant has indicated that trinexapac-ethyl in various formulations is registered for use on cereals, grasses (for seed, grazing and ornamental) and sugarcane in large number of countries.

6. Codex Alimentarius 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. Trinexapac-ethyl has not been considered by Codex.

Overseas tolerances for trinexapac-ethyl in various commodities

COUNTRY	CROP	MRL (mg/kg)
Argentina	Barley, grain	0.2
	Barley, forage	0.2
	Wheat, forage	0.2
	Wheat, grain	0.2
Austria	Cereal grain	0.5
	Rape	1
	Other plant products	0.05
Belgium	Milk	0.01
	Kidney	0.05
	Milk	0.01
	Rape	1
	Triticale, grain	0.1
	wheat, grain	0.1
Brazil	Barley, group	0.02
	Sugarcane	0.05
	Wheat, group	0.02
Denmark	Barley, grain	0.2
	Rye, grain	0.2
	Triticale, grain	0.2
	Wheat, grain	0.2
Estonia	Cereal	0.2
France	Barley, grain	0.2
	Cereals ,grain	0.2
	Oats, grain	0.2
	Rye, grain	0.2
	Triticale, grain	0.2
	Wheat, grain	0.2
Germany	Cereal, grain	0.5
	Rape Seed	1
	Other plant products	0.05
Japan	Rice, grain	0.5
Korea (South)	Rice, grain	0.5
Latvia	Cereals	0.2
	Rape	2
Luxembourg	Wheat	0.1
Netherlands	Cereals	0.2
	Other plant products	0.05

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COUNTRY	CROP	MRL (mg/kg)
Slovenia	Cereals	0.2
	Rape	2
Switzerland	Cereals, grain	0.2

7. Proposed Australian MRLs

Table 1

Compound	Code	Food	MRL (mg/kg)
trinexapac-ethyl	GS 0659	Sugar cane	0.1
	ML 0812	Milks	*0.005
	MO 0105	Edible Offal (mammalian)	0.05
	MM 0095	Meat (mammalian)	*0.02

Table 4

Compound	Animal feed commodity	MRL (mg/kg)	
trinexapac-ethyl	AS 0650	Rye straw and fodder (dry)	3
	AM 0659	Sugar cane fodder	1
	AV 0659	Sugar cane forage	1

For full details of trinexapac-ethyl MRLs, please refer to the APVMA website <http://www.apvma.gov.au> and follow the Residues link.

8. Potential for risk to trade

Residues in the offal of animals exposed to feed treated with *Moddus Yield and Quality Enhancer* may be above LOQ. This has the potential to prejudice trade between Australia and its major trading partners. However, the applicant has submitted sufficient pasture degradation and animal metabolism data to support appropriate Spray Drift Protection, Export Grazing Interval and ESI statements to minimise the potential for residues above LOQ to occur. The proposed statements incorporate a sufficient time interval to ensure animal commodities remain below LOQ following the grazing of exposed pastures.

Accordingly, use of *Moddus Yield and Quality Enhancer* on ryegrass and sugarcane does not require the establishment of export slaughter intervals (ESIs). The APVMA confirm the proposed and recommended label statements support the mitigation of trade risk from the use of *Moddus Yield and Quality Enhancer*.

9. Conclusions

Residue data indicate that trinexapac-ethyl residues in the relevant crops will be below the Australian MRLs when the product is used according to label directions. Residues in ryegrass straw and fodder and sugarcane fodder and forage will be at levels that allow these commodities to be used as animal feed in Australia, without violation of the existing Australian animal commodity MRLs.

The APVMA welcomes comment to whether the proposed use of trinexapac-ethyl as a growth regulator for sugarcane, poppy and ryegrass poses an undue prejudice to Australia's trade in these commodities.