Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Pyroxsulam and Cloquintocet-Mexyl in the Product Crusader Herbicide

APVMA Product Number 61277

DECEMBER 2010

The Manager, Public Affairs
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PREFACE

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

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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

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 register **Crusader Herbicide** containing the existing active constituents pyroxsulam and cloquintocet-mexyl 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. 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 **4 January 2010** 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:

Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: (02) 6210 4748
Fax: (02) 6210 4776
Email: pesticides@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on trade advice notices can be found on the APVMA website: http://www.apvma.gov.au

[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 Dow AgroSciences Australia Limited to extend the use of the product, Crusader Herbicide, containing 30 g/L pyroxsulam and 90 g/L cloquintocet-mexyl, to triticale and rye for the control and suppression of various weeds. The application also includes a reduction in the current grazing withholding period for wheat from 6 weeks to 4 weeks. The proposed use requires the establishment of permanent MRLs for pyroxsulam in triticale and rye grain, triticale and rye forage, and triticale and rye straw and fodder. A change in the current MRL for wheat forage is also required. The current MRLs for cloquintocet-mexyl remain appropriate for the proposed use pattern; therefore, no further consideration of the proposed use of cloquintocet-mexyl is required.

The potential for use of pyroxsulam in triticale and rye to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cereal grains, including triticale and rye, together with animal commodities derived from livestock and poultry that have been fed feeds containing residues are exported in varying quantities. Changes to the current animal commodity MRLs for pyroxsulam are not proposed.

2.2 Destination and value of exports

The total exports of Australian wheat and flour in 2008/2009 were 13,410 kt valued at $5,028 million[2]. Triticale is mainly used as an animal feed, with most grain used for domestic purposes. Exports have been less than 1 kt for the last 10 years. The major export destinations for Australian rye in 2005 and 2006 were the Republic of Korea, USA and New Zealand, with 984 tonnes exported in 2006 valued at $561,000[3]. The 10 largest export markets for Australian wheat and flour in 2008/2009 by volume are shown in the following table (Australian Commodity Statistics 2009).

Table 1: Australian wheat and flour exports in 2008/09[2]

DESTINATION	VOLUME (kt)
Indonesia	2,728
Iran	1,577
Malaysia	793
Japan	791
Yemen	714
Korean, Republic of	712
Iraq	531
Egypt	449
Bangladesh	337

[2] ABARE, Australian Commodity Statistics 2009, http://www.abare.gov.au/publications_html/acs/acs_09/acs_09.html

[3] Food and Agriculture Organization of the United Nations, FAOSTAT, http://faostat.fao.org

Thailand	336
Note: Exports are of wheat (including spelt, groats, meal and pellets) and meslin (mixed grain, including rye mixed with wheat), plus plain white flour, wholemeal flour and self-raising white flour in wheat equivalent.	

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Crusader Herbicide (30 g/L pyroxsulam, 90 g/L cloquintocet-mexyl) in wheat, triticale and rye is summarised below.

Table 2: Proposed use pattern

Directions for use: For application to rye, triticale and wheat (excluding durum varieties) only from 3 leaf up to 1st node of the crop.

Restraints:
DO NOT apply to crops or weeds which may be stressed due to prolonged periods of extreme cold, moisture stress (water-logging or drought) or previous herbicide treatment, as crop damage or reduced levels of control may result (see crop safety warning below).
DO NOT spray if rain is likely to occur within 6 hours.
DO NOT apply later than the 1st node stage of the crops.
DO NOT apply by air.
DO NOT apply to durum varieties of wheat.
DO NOT double overlap or double spray wheat.
DO NOT apply to paddocks where there is a high risk of weeds resistant to Group B herbicides.

TABLE 1. GRASS WEED CONTROL OR SUPPRESSION			
WEED	**WEED STAGE**	**RATE (mL/ha)**	**CRITICAL COMMENTS**
Control Brome grass (*Bromus diandrus*), Phalaris spp., Wild oats (*Avena* spp.) **Suppression** Annual ryegrass (*Lolium rigidum*), Barley grass (*Hordeum leporinum*), Silver grass (*Vulpia spp.*)	1-3 leaf (pre-tillering)	**500 mL** (15 g pyroxsulam + 45 g cloquintocet-mexyl)	**Always use BS1000 or Chemwet 1000 at 250 mL/100 L.** **Weed suppression:** Weeds may only be suppressed where densities of > 150 plants/m^2 are treated and may survive treatment, but will usually show reduced growth and seed set. Always use together with other methods of control to stop weed seed set.

TABLE 2. BROADLEAF WEED CONTROL			
WEED	**WEED STAGE**	**RATE (mL/ha)**	**CRITICAL COMMENTS**
Bedstraw (*Galium tricornutum*)	Cotyledon - 6 whorl Up to 10 cm	**500 mL**	**Always use BS1000 or Chemwet 1000 at 250 mL/100 L.** **High weed density:** For high densities (> 50/m^2) use tank-mixes and highest rate of partner herbicide where a range is stated. **Crop stage for tankmixes:** treat crop at the labelled growth stage for the partner herbicide. **MCPA tankmixes:** MCPA LVE at 500 mL/ha must be applied from 5 leaf stage wheat onwards in NSW and Qld.
Canola (*Brassica napus*)	Cotyledon - 4 leaf Up to 10 cm		
Capeweed (*Arctotheca calendula*)	Cotyledon - 6 leaf Up to 12 cm	**500 mL** + 40-60 g of Lontrel* 750 SG + 350 mL MCPA LVE (500 g/L) **or** + 500 mL Bromoxynil/MCPA (200 + 200 g/L) **or** + 500 mL Bromoxynil/MCPA + 40 g Lontrel 750 SG	
Chickpea (*Cicer arietinum*)	Cotyledon - 6 leaf Up to 15 cm	**500 mL**	
Climbing buckwheat (Black bindweed) (*Fallopia convolvulus*)	Cotyledon - 4 leaf Up to 10 cm	**500 mL** + 375-500 mL Hotshot* Herbicide	
Doublegee or spiny emex (*Emex australis*)	Cotyledon - 4 leaf Up to 10 cm	**500 mL** + 5 g Metsulfuron (600 g/kg)	
Faba bean (*Vicia faba*)	Cotyledon - 4 leaf Up to 10 cm	**500 mL**	
Field pea (*Pisum sativum*)	Cotyledon - 6 node Up to 12 cm		
Indian hedge mustard (*Sisymbrium orientale*)	Cotyledon - 6 leaf Up to 10 cm	**500 mL** + 350-500 mL MCPA LVE	
Lentil (*Lens esculentum*)	Cotyledon - 6 leaf Up to 8 cm	**500 mL**	
Lupins – suppression (*Lupinus albus*)	Cotyledon - 4 leaf Up to 6 cm		
Medic spp.	Cotyledon - 4 leaf Up to 8 cm		
Prickly lettuce (*Lactuca serriola*)	Cotyledon - 6 leaf Up to 10 cm	**500 mL** + 500 mL MCPA LVE	
Sowthistle (*Sonchus oleraceus*)	Cotyledon - 4 leaf Up to 10 cm	**500 mL** + 500 mL Hotshot* + 500 mL MCPA LVE	
Subclover (*Trifolium subterraneum*)	Cotyledon - 4 leaf Up to 5 cm	**500 mL**	
Turnip weed (*Rapistrum rugosum*)	Cotyledon - 4 leaf Up to 10 cm		
Vetch – suppression (*Vicia sativa*)	Cotyledon - 4 leaf Up to 10 cm		
Wild radish (*Raphanus raphanistrum*)	Cotyledon - 4 leaf Up to 15 cm	**500 mL** + 350-500 mL MCPA LVE	
Wireweed (*Polygonum aviculare*)	Cotyledon - 4 leaf Up to 8 cm	**500 mL**	

Adjuvants: Always use either BS1000 or Chemwet 1000 at 250 mL/100 L spray volume.

Withholding periods: When using Crusader Herbicide in a tank mix with another product, observe whichever harvest or grazing/stockfood withholding period is the longer.

Harvest: Not required when used as directed
Grazing: DO NOT graze or cut treated crops for stock feed for 4 WEEKS after application.

2.4 Results from residues trials presented to the APVMA

Residue data for the use of pyroxsulam on triticale and rye was not submitted; however, extrapolation from wheat data is acceptable for the proposed use pattern. Overseas residues studies for pyroxsulam in wheat grain, forage and straw were provided. Previously submitted Australian residue data from wheat trials was also considered.

Grain

In the Australian trials, residues of pyroxsulam in wheat grain collected at harvest (58-143 DAT) at either 15 or 30 g ai/ha (1 or 2 × proposed application rate) were below the LOD (0.003 mg/kg) in all samples (n = 24). In the European trials, residues of pyroxsulam in wheat grain collected at harvest (49-83 DAT) at between 16.7 and 20.7 g ai/ha (1.1 to 1.4 × proposed application rate) were below the LOD (0.002 mg/kg) in all samples (n=40). Samples were taken from trials conducted with and without a spray adjuvant. Therefore, it is proposed to establish MRLs for pyroxsulam use on triticale (GC 0653) and rye (GC 0650) at the LOQ of *0.01 mg/kg.

As use of the product will be restricted to use not later than the 1st node stage of crop development, a harvest withholding period of 'Not required when used as directed' is appropriate for triticale and rye, in line with the current harvest withholding period for wheat.

Straw

In the Australian trials, residues of pyroxsulam in straw collected at harvest (58-143 DAT) from trials conducted at 15 g ai/ha were <0.003 mg/kg (LOD)(n=10) and 0.02 mg/kg (n=2), fresh weight. Where samples contained residues above LOQ on a fresh weight basis, results were corrected for moisture, resulting in residues of 0.02 and 0.03 mg/kg on a dry weight basis. Residues were similar following treatment at 30 g ai/ha (2× proposed rate) with only two of the samples containing detectable residues on an as received basis (0.03 and 0.05 mg/kg).

In the European trials, residues of pyroxsulam in straw collected at harvest (49-83 DAT) from trials conducted at approximately the proposed application rate were <0.002 mg/kg (n=23), 0.002 (n=2), 0.004 (n=2), 0.005 (n=5), 0.006 (n=4), 0.007, 0.010, 0.011 and 0.022 mg/kg.

Based on the results of both the Australian and European trials, MRLs of 0.1 mg/kg are proposed for pyroxsulam use on triticale straw and fodder, dry and rye straw and fodder, dry (AS 0650). These MRLs are consistent with the current pyroxsulam MRL for wheat straw and fodder, dry.

Forage

In the Australian trials, residues of pyroxsulam in wheat forage sampled 28 DAT (proposed withholding period) from trials conducted at 15 g ai/ha were <0.003 (n=4), 0.01 and 0.10 mg/kg on a fresh weight basis. Where samples contained detectable residues on a fresh weight basis, results were corrected for moisture, resulting in residues of 0.03 and 0.29 mg/kg on a dry weight basis. The highest observed residue at the proposed application rate was 11.4 mg/kg (dry weight) in a sample taken immediately after application.

In the European trials, residues of pyroxsulam in wheat forage sampled 28 DAT were <0.002 (n=8), 0.002 and 0.004 mg/kg. The moisture content of samples was not provided; however, based on a moisture content of 75%[4], residues on a dry weight basis were 0.008 and 0.016 mg/kg. The current MRL for pyroxsulam in wheat forage, dry is 0.1 mg/kg which was established in conjunction with a 6 week withholding period. However, based on the results of both the Australian and European trials, MRLs of 0.5 mg/kg are proposed for pyroxsulam in wheat forage (green), triticale forage (green) and rye forage (green) (AF 0650) due to a reduction in the grazing withholding period from 6 to 4 weeks.

Animal Commodities

Based on data from a metabolism study, the estimated pyroxsulam residues in a lactating cow fed on 100% cereal forage, containing residues at 0.29 mg/kg (highest residue in dry wheat forage), are <0.001 mg/kg in meat, offal and milk. No changes to the current animal commodity MRLs are required and residues in animal commodities will not be considered further.

[4] OECD Guidance Document on Overview of Residue Chemistry Studies, Annex 4: Table of OECD Feedstuffs Derived from Field Crops.

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. Pyroxsulam has not been considered by Codex. The following relevant overseas residue MRLs/ tolerances have been established for pyroxsulam:

Table 3: Overseas tolerances for pyroxsulam in relevant commodities

COUNTRY	COMMODITY	TOLERANCE (mg/kg)	REFERENCE
EU	Cereals	*0.01	EU Pesticides Database, http://ec.europa.eu/sanco_pesticides/public/index.cfm (Updated on 11 October, 2010).
Japan	Cereals	None Est.	The Japan Food Chemical Research Foundation, http://www.m5.ws001. squarestart.ne.jp/foundation/search.html (Updated on 29 January, 2010).
Korea, Rep. of	Cereals	None Est.	MRLs for Pesticides in Foods, http://eng.kfda.go.kr/file/PesiticideMRLs.pdf (Updated on September, 2009).
US	Wheat, grain	0.01	Electronic Code of Federal Regulations, http://ecfr.gpoaccess.gov/ cgi/t/text/text-idx?c=ecfr&sid=5d35d354 cc838eb105a733f5dff13ab8&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl, (Updated on 13 October, 2010).
	Wheat, hay	0.01	
	Wheat, straw	0.03	
	Wheat, forage	0.06	

2.6 Current and proposed Australian MRLs for pyroxsulam

Current relevant MRLs and the residue definition for pyroxsulam are presented as follows. A full listing of MRLs can be found at http://www.apvma.gov.au/residues/standard.php.

Table 4: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
PYROXSULAM			
MO	0105	Edible offal (Mammalian)	*0.01
PE	0112	Eggs	*0.01
MM	0095	Meat [mammalian]	*0.01
ML	0106	Milks	*0.01
PO	0111	Poultry, Edible offal of	*0.01
PM	0110	Poultry meat	*0.01
GC	0654	Wheat	*0.01

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
PYROXSULAM	Pyroxsulam

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
PYROXSULAM			
AS	0654	Wheat straw and fodder, dry	0.1
		Wheat forage, dry	0.1

The following changes are proposed to Australian pyroxsulam MRLs:

Table 5: Proposed changes to the MRL Standard – Table1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
PYROXSULAM			
ADD:			
GC	0650	Rye	*0.01
GC	0653	Triticale	*0.01

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
PYROXSULAM			
DELETE:			
		Wheat forage, dry	0.1
ADD:			
AF	0650	Rye forage (green)	0.5
AS	0650	Rye straw and fodder, dry	0.1
		Triticale forage (green)	0.5
		Triticale straw and fodder, dry	0.1
		Wheat forage (green)	0.5

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of pyroxsulam 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.

At the proposed label application rates, quantifiable residues are not expected in triticale or rye grains. Therefore, the overall risk to export trade in triticale and rye grains is considered to be low.

No changes are required to animal commodity MRLs as the proposed use is unlikely to result in quantifiable residues in animal commodities.

3 CONCLUSIONS

It is proposed to establish MRLs for rye and triticale grain, rye, triticale and wheat forage (green) and rye and triticale straw and fodder, dry. Comment is sought on the potential for pyroxsulam in Crusader Herbicide to prejudice Australian trade when it is used on rye, triticale and wheat to control or suppress various weeds.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609 Office hours: 9.00 - 5.00 (EST) Monday to Friday