Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2015-0433
Application: Changes to product label – new site
Product: Priaxor
Registration Number: 30567
Active ingredients (a.i.): Fluxapyroxad (FXP) and Pyraclostrobin (PYA)
PMRA Document Number : 2535600

Purpose of Application

The purpose of this application was to add the use of control of common leaf spot and the suppression of blossom blight on non-grass animal feeds (forage, fodder, straw and hay) (Crop Group 18) to the Priaxor label. Priaxor is a broad-spectrum fungicide that is currently registered for the control or suppression of various diseases in barley, wheat, rye, corn, soybean, legumes, canola, flax, sunflower, sugar beet, and grasses and alfalfa grown for seed production in Canada.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of Priaxor on Non-grass Animal Feed (Crop Group 18). Pyraclostrobin and fluxapyroxad were applied to alfalfa and clover (the representative crops for Crop Group 18) at application rates and harvest intervals which are both according to label directions.

Maximum Residue Limits

Residue data for clover and alfalfa were reviewed, and the dietary burden calculation was updated for pyraclostrobin and fluxapyroxad in order to estimate the residue transfer to livestock commodities. Residue data for pyraclostrobin (and the BF 500-3 metabolite) and fluxapyroxad (and the M700F008 metabolite) are shown in Table 1.

TABLE 1. Summary of Field Trial Data for Pyraclostrobin and Fluxapyroxad Used for Dietary Burden Calculations.

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Combined Residues of Pyraclostrobin and BF 500-3 (ppm)	
			LAFT	HAFT

Canada

TABLE 1. Summary of Field Trial Data for Pyraclostrobin and Fluxapyroxad Used for Dietary Burden Calculations.				
Commodity	**Application Method/ Total Application Rate**	**PHI (days)**	**Combined Residues of Pyraclostrobin and BF 500-3 (ppm)**	
Pyraclostrobin				
Clover forage	Foliar / 332-381	14	0.39	10.06
Clover hay	Foliar / 332-381	14	2.63	37.84
Alfalfa forage	Foliar / 336	12-16	0.58	6.41
Alfalfa hay	Foliar / 336	12-16	2.87	17.93
Fluxapyroxad				
Commodity	**Application Method/ Total Application Rate (g a.i./ha)**	**PHI (days)**	**Combined Residues of Fluxapyroxad and M700F008 (ppm)**	
			LAFT	**HAFT**
Clover forage	Foliar / 166-191	14	0.18	4.24
Clover hay	Foliar / 166-191	14	0.75	15.23
Alfalfa forage	Foliar / 165-175	13-15	0.10	2.75
Alfalfa hay	Foliar / 165-175	13-15	0.31	7.00

LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

Based on the updated dietary burden calculations, the existing MRLs for pyraclostrobin and fluxapyroxad in/on animal commodities are sufficient to cover the new use on Non-grass Animal Feed (Crop Group 18). As such, the new use will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The addition of all crops from Crop Group 18 – Non-grass animal feeds (forage, fodder, straw and hay) to the Priaxor label is not expected to result in potential occupational or bystander exposure over the registered uses of both active ingredients. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

Environmental Assessment

No additional environmental data were required for the use of Priaxor on Crop Group 18: Non-grass Animal Feeds (Forage, Fodder, Straw and Hay). The environmental exposure resulting from the use on this crop group is not expected to exceed that from the registered uses of the two active ingredients. Thus, increased environmental risk is not expected compared to currently registered uses on other crops.

Value Assessment

Results from 15 efficacy trials on alfalfa and brome grass (mostly on alfalfa) in AB, MB and ON

in 2013 and 2014 were submitted to support the claim of control of common leaf spot on non-grass animal feeds. Priaxor applied either once or twice per season significantly reduced common leaf spot infection in forage alfalfa at either first cut or second cut. The beneficial effect of Priaxor on forage yield in alfalfa was also confirmed in some trials when yield data were collected. Priaxor is registered for control of common leaf spot in alfalfa for seed production, so the value of Priaxor on this disease had been established.

A scientific rationale was provided to support the use claim of suppression of blossom blight on non-grass animal feeds. Priaxor is currently registered for suppression of certain diseases caused by *Sclerotinia sclerotiorum* on various crops, including suppression of blossom blight at the same rate on alfalfa for seed production. The value of Priaxor on suppression *Sclerotinia* diseases had been established previously; moreover, *S. sclerotiorum* is a non-host specific pathogen and may potentially infect all members of the crop group of non-grass animal feeds.

The supporting evidence confirmed the value of Priaxor on the control of common leaf spot and suppression of blossom blight in non-grass animal feeds. The registration of these two new uses provides Canadian growers with a new product to manage these important diseases in non-grass animal feeds.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided in support of the product, Priaxor, and has found the information sufficient to add the use of control of common leaf spot and the suppression of blossom blight on non-grass animal feeds (forage, fodder, straw and hay) (Crop Group 18).

References

PMRA Document Number	**Reference**
2499382	2008, Magnitude of Pyraclostrobin and Boscalid Residues in Seedling Alfalfa Following Application of Pristine Fungicide, DACO: 7.4.1
2499384	2014, Magnitude of the Residues of Fluxapyroxad in/on Alfalfa, and Fluxapyroxad and Pyraclostrobin in/on Clover Following Applications of BAS 703 02 F, DACO: 7.4.1
2499377	2015, Use Site Description: Priaxor (Fluxapyroxad and Pyraclostrobin) Containing Products on Crop Group 18: Non-grass Animal Feeds (Forage, Fodder, Straw and Hay) Group, DACO: 5.2
2499374	2015, DACO 10.1 Summary, DACO: 10.1
2499375	2015, Individual Trial Reports, DACO: 10.2.3.3(D),10.3.2(B)
2532829	2015, Rationale for inclusion of blossom blight (*Sclerotinia Sclerotiorum*) to the label, DACO: 10.2.3.2(D)

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