

Evaluation Report for Category B, Subcategory 3.1, 3.4, 3.12 Application

Application Number: 2018-4777
Application: Changes to product label; application rate, site and method
Product: A19649 Fungicide
Registration Number: 33018
Active ingredients (a.i.): Pydiflumetofen
PMRA Document Number: 3094489

Purpose of Application

The purpose of this application was to add use of A19649 Fungicide on sunflowers (Crop Subgroup 20B), oats, rye and triticale as well as to amend the directions for registered uses, including an increase application rate for wheat.

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

A toxicological assessment was not required for this application.

The occupational exposure and risk from the addition of the use on oats, rye, triticale, sunflowers, the increase in application rate for wheat and a rate range for corn to the A19649 Fungicide label was assessed. No risks of concern are expected, provided that workers follow the label directions and wear the personal protective equipment identified on the label.

Residue data from field trials conducted in Canada and the United States were submitted to support the domestic use of A19649 Fungicide on sunflower seeds (CSG 20B). Previously reviewed residue data from field trials conducted in/on oats and wheat (extended to rye and triticale) were re-assessed in the framework of this petition. Pydiflumetofen was applied to sunflowers at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated sunflower seeds was reviewed to determine the potential for concentration of residues of pydiflumetofen into processed commodities.

Maximum Residue Limits

The recommendation for a maximum residue limit (MRL) for pydiflumetofen was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). The MRL to cover residues of pydiflumetofen in/on sunflower seeds and processed commodities is proposed as shown in Table 1.

Residues in processed commodities not listed in Table 1 are covered under the proposed MRL for the raw agricultural commodity (RAC). The existing MRLs of 3.0 ppm for oats and 0.3 ppm for wheat, rye and triticale will cover the anticipated residues of pydiflumetofen following the approved maximum rates on the A19649 Fungicide label.

TABLE 1. Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g ai/ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Sunflower seeds	Foliar broadcast/ 399-412	28-40	0.016	0.370	Refined oil: 0.06x	None	0.5 (CSG 20B)

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

Following the review of all available data, the MRL as proposed in Table 1 is recommended to cover residues of pydiflumetofen. Residues in this crop commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The addition of Crop Sub Group 20B (sunflowers), oats, rye and triticale to the product label for A19649 Fungicide is not expected to result in increased environmental risk. Therefore, the risk from the environmental viewpoint are acceptable when label directions are followed.

Value Assessment

The applicant provided the results of twenty four efficacy trials, results of mycotoxin laboratory tests and scientific rationales to support the addition of claims or revision of use directions for some uses on the A19649 Fungicide label. Field efficacy trial results supported the suppression of several diseases by ground or aerial application on wheat, barley, triticale, oats, and rye; suppression of *Sclerotinia* head rot on sunflowers (Crop Subgroup 20B) and suppression of *Fusarium* and *Gibberella* ear rots on corn. Revised application rates for suppression of *Fusarium* and *Gibberella* ear rots on corn, suppression of white mould on some field legumes and suppression of *Septoria* leaf blotch and tan spot on the aforementioned cereals were also supported by efficacy trials or other value information.

The fungal diseases controlled or suppressed by A19649 Fungicide reduce crop yields and may result in contamination of harvests with fungal toxins. Registration of claims against these diseases on the A19649 Fungicide label will provide growers of these crops with an additional tool to manage these diseases.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to amend the label of A19649 Fungicide to include use on sunflowers, oats, rye and triticale as well as to amend the directions for registered uses.

Reference

PMRA

Document

Number	Reference
1606808	2008, Description of Pest Problem: Sclerotinia Stem Rot (<i>Sclerotinia sclerotiorum</i>), DACO: 10.2.2
2569827	2015, A19649 - Adepidyn (SYN545974), 200 g/L - Document M-III, Section 7 - Efficacy and Information - Canada, DACO: 10.1,10.2.1,10.2.2,10.2.3.1,10.2.3.3,10.3.1,10.3.2,12.7
2569896	2015, Supplemental Data to Support A19649 - Adepidyn (SYN545974), 200 g/L - Document M-III, Section 7 - Efficacy and Information - Canada, DACO: 10.2.3.1,10.2.3.3,10.3.2
2706066	2015, Evaluate SYN545974 control of <i>Fusarium</i> ear rot in corn, DACO: 10.2.3.3
2772863	2015, Evaluate SYN545974 control of <i>Fusarium</i> ear rot in corn, DACO: 10.2.3.3
2772864	2015, Evaluate SYN545974 control of <i>Fusarium</i> ear rot in corn, DACO: 10.2.3.3
2772866	2015, Evaluate SYN545974 control of <i>Fusarium</i> ear rot in corn, DACO: 10.2.3.3
2919076	"2018, 10.2.3.1-1 - A19649 - Data Summary Cereal, Corn, Sunflowers, DACO: 10.2.3.1,10.3.2"
2919079	2018, Value Summary A19649 Fungicide, DACO: 10.1
2919057	2018, Pydiflumetofen SC (A19649B) - Magnitude of the Residues in or on Sunflower Canada 2016, DACO: 7.4.1,7.4.5
2919058	2018, Pydiflumetofen SC (A19649B) - Magnitude of the Residues in or on the Representative Raw Agricultural and Processed Commodities of the Sunflower Crop Subgroup (20B) USA 2016, DACO: 7.4.1

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