Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6, 3.12 Application

Application Number: 2017-5545
Application: New end use product; new combination of technical grade active ingredients and new site.
Product: Infinity FX
Registration Number: 33248
Active ingredients (a.i.): Bromoxynil;
Fluroxypyr (present as 1-methylheptyl ester);
Pyrasulfotole
PMRA Document Number: 2874592

Purpose of Application

The purpose of this application was to register Infinity FX which is a new combination of the active ingredients pyrasulfotole, bromoxylnil, and fluroxypyr, for control of broadleaf weeds in in wheat (spring, durum and winter), spring barley, triticale (spring and winter) and grasses grown for forage or seed production (perennial ryegrass, red fescues, bromegrass and timothy).

Chemistry Assessment

Infinity FX is formulated as an emulsifiable concentrate containing bromoxynil (present as mixed octanoate and heptanoate esters), fluroxypyr (present as 1-methyheptyl ester) and pyrasulfotole at concentrations of 174.3 g/L, 72 g/L and 31.1 g/L, respectively. This end-use product has a density of 1.130-1.170 g/mL and pH of 3.7. The required chemistry data for Infinity FX have been provided, reviewed and found to be acceptable.

Health Assessments

Infinity FX is of moderate acute toxicity in rats by the oral and dermal routes. It is of low acute toxicity in rats via the inhalation route. It is mildly irritating to the eyes and moderately irritating to the skin of rabbits. It is a potential skin sensitizer in mice.

The use pattern of Infinity FX on cereal crops and grasses is not expected to result in potential increase in occupational or bystander exposure over the registered uses of pyrasulfotole and bromoxynil. The occupational exposure risk assessment for fluroxypyr was updated for the addition of triticale using current unit exposure data. No occupational health risks of concern for all active ingredients in Infinity FX are expected when workers follow label directions and wear personal protective equipment as stated on the label.

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No new residue data for pyrasulfotole, bromoxynil, and fluroxypyr were submitted to support the registration of Infinity FX for use on wheat (spring, durum and winter), spring barley, triticale (spring and winter), perennial grass, bromegrasses, red fescues and timothy. Previously reviewed residue data from field trials conducted with pyrasulfotole, bromoxynil, and fluroxypyr in/on cereal grains and grasses were re-assessed in the framework of this petition. In addition, processing studies in treated cereals were also re-assessed to determine the potential for concentration of residues of these active ingredients into processed commodities.

For pyrasulfotole and bromoxynil the use of Infinity FX does not constitute an expansion of use and residues of these active ingredients in/on the food crops will be covered by the established MRLs.

Maximum Residue Limit (MRL)

The recommendation for an MRL for fluroxypyr was based upon previously reviewed field trial data on the small grain cereals wheat, barley and oats. For triticale, an MRL of 0.5 ppm is considered adequate to cover residues of fluroxypyr in/on the raw agricultural commodity (RAC) and residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodity (RAC).

Table 1 Summary of Field Trial Data Used to Support Maximum Residue Limits (MRLs) for Fluroxypyr

Commodity	Application Method/Total Application Rate (g a.i./ha)	PHI[1] (days)	Residues (ppm)		Mean Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAF T[2]	HAF T[3]			
Wheat grain	Foliar broadcast/ 250 – 500 (CDN data)[4]	64 – 85	<0.01	0.03	2x (wheat bran); 0.6x (wheat flour)	0.5 for wheat, barley and oats	0.5 for triticale
	Foliar broadcast/ 273 – 322 (US data)[4]	40 - 107	<0.01	0.12			
Barley grain	Foliar broadcast/ 250 – 500 (CDN data)[4]	66 – 96	<0.01	0.05			
	Foliar broadcast/ 273 – 322 (US data)[4]	40 – 81	<0.01	0.39			

Commodity	Application	PHI[1]	Residues (ppm)		Mean	Currently	Recommended
Oat grain	Foliar broadcast/ 273 – 322 (US data)[4]	70 – 71	<0.01	0.36			

[1] PHI = preharvest interval
[2] LAFT = Lowest Average Field Trial
[3] HAFT = Highest Average Field Trial
[4] CDN: Canadian; US: United States

Following the review of all available data, an MRL of 0.5 ppm is recommended to cover residues of fluroxypyr in/on triticale. For fluroxypyr on other food commodities, as well as pyrasulfotole and bromoxynil on all food commodities, the currently established MRLs are adequate. Based on the use pattern of Infinity FX, residues of these three active ingredients in/on these crop commodities at the proposed MRLs will not pose an unacceptable health risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

For Infinity FX, the maximum application rates for pyrasulfotole, bromoxynil, and fluroxypyr, do not exceed those of previously registered products; therefore, no additional environmental risk is expected from the use of this product. Environmental concerns have been mitigated through adequate statements on the Infinity FX label.

Value Assessment

The registration of three active ingredients from three herbicide modes of action groups in a single formulation will provide farmers an efficient tool for control of a broader spectrum of weeds as well as for herbicide resistance management.

Value information submitted for review included data from small plot replicated field trials conducted in 2015 and 2016 across the Prairie Provinces. Product performance, in terms of both efficacy and crop tolerance, of Infinity FX applied alone or in tank mixes with graminicides was evaluated and compared to those of the cited precedent applied alone or in further tank mixes with the same graminicides at comparable a.i. rates per hectare as per label instructions.

Trial information demonstrated that the performance of Infinity FX was acceptable and comparable to that of the cited precedent.

Scientifically sound rationales based on other citied precedent products containing fluroxypyr were reviewed and considered supportive of the remaining label expansions.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of Infinity FX.

References

PMRA Document Number	Reference
2805745	2007, Generic manufacturing description of formulation type EC (Emulsifiable concentrate), DACO: 3.2,3.2.2 CBI
2805746	2017, Determination of [CBI removed], DACO: 3.4.1 CBI
2805747	2017, Storage stability at elevated temperature and corrosion characteristics of [CBI removed] - Packaging material: HDPE (fluorinated) - Final report (14 days), DACO: 3.5.1,3.5.10,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.9 CBI
2805748	2017, Safety-Relevant Data of [CBI removed], DACO: 3.5.11,3.5.12,3.5.8 CBI
2811419	2017, Validation of Analytical Method AM030517MF1 - Determination of [CBI removed] - Final Report -, DACO: 3.4.1
2811420	2017, Safety-relevant data of [CBI removed] DACO: 3.5.11,3.5.12,3.5.8
2852610	2018, Infinity FX Description of Formulation Process, DACO: 3.2.1,3.2.2 CBI
2805749	2017, Bromoxynil-octanoate/heptanoate + fluroxypyr-meptyl + pyrasulfotole + CBI removed EC 391.9 (249+104+31.1+7.8 g/l): Acute oral toxicity - Up-and-down procedure in rats, DACO: 4.6.1
2805750	PMRA, 2017, PMRA Science Policy Note SPN2017-03 Acute Dermal Toxicity Study Waiver, DACO: 4.6.2
2805751	2017, Bromoxynil-octanoate/heptanoate + fluroxypyr-meptyl + pyrasulfotole + CBI removed EC 391.9 (249+104+31.1+7.8 g/l): Acute inhalation toxicity in rats, DACO: 4.6.3
2805752	2017, Bromoxynil-octanoate/heptanoate + fluroxypyr-meptyl + pyrasulfotole + CBI removed EC 391.9 (249+104+31.1+7.8 g/l): Primary eye irritation in rabbits, DACO: 4.6.4
2805753	2017, Bromoxynil-octanoate/heptanoate + fluroxypyr-meptyl + pyrasulfotole + CBI removed EC 391.9 (249+104+31.1+7.8 g/l): Primary skin irritation in rabbits, DACO: 4.6.5
2805754	2017, Bromoxynil-octanoate/heptanoate + fluroxypyr-meptyl + pyrasulfotole + CBI removed EC 391.9 (249+104+31.1+7.8 g/l): Local lymph node assay (LLNA) in mice, DACO: 4.6.6
2805740	2017, Value assessment of Infinity FX Herbicide (pyrasulfotole + bromoxynil + fluroxypyr), DACO: 10, 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(B), 10.3, 10.3.1, 10.3.2, 10.3.2(A), 10.3.3, 10.5, 10.5.1, 10.5.2, and 10.5.3.
2805741	2017, Value assessment of Infinity FX Herbicide (pyrasulfotole + bromoxynil + fluroxypyr) - Compilation of trial reports, DACO: 10, 10.2, 10.2.3, 10.2.3.3(B), 10.3, and 10.3.2(A).
1913109	2009, Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays, DACO: 5.3,5.4
2572745	2015, Agricultural Handler Exposure Scenario Monograph: Open Pour Mixing and Loading of Liquid Formulations, DACO: 5.3,5.4
	Additional Information Considered
2115788	2008, List of Data Submitted by the Agricultural Rentry Task Force (ARTF) to Support Revision of Agricultural Transfer Coefficients., DACO: 5.6

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