Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 5.0 Application

Application Number: 2020-1209
Application: New Maximum Residue Limits for previous assessed Technical Grade Active Ingredient
Product: Fluensulfone Technical
Registration Number: 32820
Active ingredient (a.i.): Fluensulfone
PMRA Document Number: 3188069

Purpose of Application

The purpose of this application was to establish maximum residue limits (MRLs) for fluensulfone for various imported commodities.

Health Assessments

Residue data from field trials conducted in Canada and the United States were submitted to support the MRLs on several imported crops and crop groups/subgroups. Fluensulfone was applied to crops at rates equivalent to those on the foreign registered labels, and harvested according to label directions. In addition, processing studies in treated crops were reviewed to determine the potential for concentration of residues of fluensulfone into processed commodities.

Maximum Residue Limits

The recommendation for MRLs for fluensulfone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. MRLs to cover residues of fluensulfone and the BSA metabolite in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

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

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor[2]	Recommended MRL (ppm)
			LAFT	HAFT		
Radish	PPI /4.01-4.13	34-56	0.13	3.51	None required	4.0 (CSG 1B, except
Carrot	PPI/4.0-4.2	76-177	<0.02	2.20		

Canada

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor[2]	Recommended MRL (ppm)
			LAFT	HAFT		
Turnip	PPI or DRIP/3.97-4.02	83-115	<0.02	0.58		sugarbeet)
Potato	PPI/4.0-4.3	71-148	0.08	0.60	Potato chips: 1.6x Potato flakes: 2.4x	0.8 (CSG 1C) 2.0 (potato chips and flakes)
Head lettuce	PPI or DRIP/3.93-4.07	53-96	<0.02	0.43	None required	4.0 (CG 4)
Leaf lettuce	PPI or DRIP/3.91-4.02	43-116	<0.02	1.36		
Spinach	PPI or DRIP/3.97-4.13	64-88	<0.02	1.78		
Celery	PPI or DRIP/3.95-4.18	78-104	<0.02	1.03		
Cabbage	PPI or DRIP/3.93-4.13	66-94	0.05	1.11	None required	1.5 (CSG 5A)
Cauliflower	PPI or DRIP/3.82-3.99	63-137	<0.02	0.28		
Mustard greens	PPI or DRIP/3.97-4.19	34-71	0.12	6.49		20 (CSG 5B)
Mizuna	PPI or DRIP/3.93-4.15	36-90	0.78	7.98		
Grapefruit	Chemigation/3.98-4.01	58-60	<0.02	0.08	Juice: <0.3x Oil: <0.5x - >70x Marmalade: <0.2x	0.3 (CG 10R) 15 (Citrus oil)
Lemon	Chemigation/4.0	60-61	<0.02	0.13		
Orange	Chemigation/3.99-4.01	58-60	<0.02	0.07		
Apples	Chemigation/ 3.91-4.16	91-165	<0.02	0.16	Juice: 1.7x Sauce: 1x Dried apples: 5.5x	0.4 (CG 11-09) 0.9 (Dried apples)
Pears	Chemigation/3.91-4.06	62-151	<0.02	0.21		
Sweet and tart cherries	Chemigation/3.96-4.07	43-83	<0.02	0.05	Dried plums: 2.9x	0.15 (CG 12-09)

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	PHI (days)	Residues[1] (ppm)		Experimental Processing Factor[2]	Recommended MRL (ppm)
			LAFT	HAFT		
Peach	Chemigation/3.99-4.02	48-141	<0.02	0.08	Plum juice: 1.2x Plum puree: 0.9x	
Plum	Chemigation/3.98-4.01	65-144	<0.02	0.03		
Grapes	Chemigation/3.96-4.05	61-143	<0.02	0.49	Raisins: 2.4x Juice: 0.74x	0.8 (CSG 13-07D) 1.5 (Raisins)
Fuzzy kiwifruit	Chemigation/3.98-4.02	123-157	<0.02	0.32		
Strawberries	PPI or DRIP/3.89-4.01	62-199	<0.02	0.28	None	0.5 (CSG 13-07G)
Almonds	Chemigation/3.96-4.02	60-90	<0.02	<0.02	None	0.02 (CG 14-11)
Pecans	Chemigation/3.96-4.02	57-90	<0.02	<0.02		
Sugarcane	Chemigation/3.88-4.18	235-265	<0.02	0.04	Molasses:7.3x Refined sugar: <0.4x	0.06 0.3 (Sugarcane molasses)

PPI = Soil Pre-plant Incorporated; DRIP = Soil Pre-plant drip irrigation; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial

1. Residues include fluensulfone and the metabolite BSA, expressed as parent equivalents
2. With the exception of citrus oil, the processing factors listed apply to the BSA metabolite only, as residues of fluensulfone were non-quantifiable in both the RAC and processed commodities and a processing factor could not be calculated. For citrus oil, the range reflects the range of processing factors for each analyte, fluensulfone and BSA.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total residues of fluensulfone and the metabolite BSA. Residues in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Chemistry, Environmental and Value Assessments

Chemistry, environmental and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed the assessment of the available information and found it acceptable to recommend MRLs for fluensulfone as proposed in Table 1.

References

PMRA Document Number	Reference
3106563	2015, Magnitude of the Residue of MCW-2 in Brassica Vegetables, DACO: 7.4.1
3106565	2014, Magnitude of the Residue of MCW-2 in Japanese Leafy Vegetables, DACO: 7.4.1
3106566	2014, Magnitude of the Residue of MCW-2 in Japanese Root Vegetables, DACO: 7.4.1
3106567	2014, Magnitude of the Residue of MCW-2 in Strawberries, DACO: 7.4.1
3106568	2015, Magnitude of the Residue of MCW-2 in Leafy Vegetables, DACO: 7.4.1
3106569	2014, Magnitude of the Residue of MCW-2 in Radish, DACO: 7.4.1
3106571 3232678	2016, Magnitude of Residue of MCW-2 in Citrus (Orange, Lemon and Grapefruit) and Citrus Processed Commodities, DACO: 7.4.1,7.4.5
3106572	2016, Magnitude of the Residue of MCW-2 in Stone Fruit (Cherry, Peach and Plum), DACO: 7.4.1
3106573	2016, Magnitude of the Residue of MCW-2 in Pome Fruit Crops (Apples and Pears), DACO: 7.4.1
3106574	2016, Magnitude of the Residue of MCW-2 in Sugarcane and Sugarcane Processed Commodities, DACO: 7.4.1
3106575	2016, Magnitude of Residue of MCW-2 in Tree Nut Crops (Almonds and Pecans), DACO: 7.4.1
3106576	2015, Magnitude of the Residue of MCW-2 in Vine Crops (Grape and Kiwifruit) and Processed Commodities of Grape, DACO: 7.4.1
3106577	2015, Fluensulfone: Magnitude of the Residue on Carrot, DACO: 7.4.1
3106578	2015, Fluensulfone: Magnitude of the Residue on Potato, DACO: 7.4.1
3106579	2016, Fluensulfone: Stability of MCW-2 (Fluensulfone) and its Metabolites in Potato Processsing Matrices, DACO: 7.4.1,7.4.5
3106580	2015, Fluensulfone: Magnitude of the Residue on Radish, DACO: 7.4.1
3106581	2017, Magnitude of the Residue of Fluensulfone in Carrot, Potato, Sugar Beet, and Radish from Formulation Bridging with 15G and 480 EC, DACO: 7.4.1
3232679	2017, Freezer Storage Stability of Fluensulfone and Butene Sulfonic Acid in Citrus and Citrus Processed Commodities, DACO: 7.3
3232680	2016, Magnitude of Residue of MCW-2 in Peanut and Peanut Processed Commodities, DACO 7.4.1