

Evaluation Report for Category B, Subcategories Application 6-21E and 6-21F

Application Number: 2021-5872
Application: New End Use Product Chemistry-New Combination of Technical Grade Active Ingredients
New Product Labels-New Pests
Product: RevyPro
Registration Number: 34671
Active ingredients (a.i.): Mefentrifluconazole, Prothioconazole
PMRA Document Number: 3410107

Purpose of Application

The purpose of this application was to register a new end-use product containing prothioconazole and mefentrifluconazole, a new combination of active ingredients, for control or suppression of listed fungal diseases on Crop Subgroups 6-21E (dried shelled beans, except soybean) and 6-21F (dried shelled peas).

Chemistry Assessment

RevyPro is formulated as an emulsifiable concentrate containing mefentrifluconazole at a concentration of 50 g/L and prothioconazole at a concentration of 100 g/L. This end-use product has a density of 0.990 to 1.101 g/mL and pH of 5.0-7.0. The required chemistry data for RevyPro have been provided, reviewed and found to be acceptable.

Health Assessments

RevyPro was of low acute toxicity via the oral, dermal, and inhalation routes of exposure. It was moderately irritating to the eyes and skin and it was not a dermal sensitizer.

The use of RevyPro on crop subgroups 6-21E and 6-21F (dried shelled beans and dried shelled peas (including lentil, field pea, chickpea, fava bean, and dry bean)) is not expected to result in occupational or bystander exposures greater than the registered uses of mefentrifluconazole and prothioconazole. No risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data were submitted or required to support the use of mefentrifluconazole and prothioconazole on the RevyPro label. These co-active ingredients are already registered for use in Canada on dried shelled peas and beans. Previously reviewed residue data were re-assessed in the framework of this application.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for mefentrifluconazole and prothioconazole was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover residues of mefentrifluconazole and prothioconazole, including the metabolite prothioconazole-desthio in/on crops and processed commodities are proposed as shown in Table 1A and Table 1B, respectively. Residues in processed commodities not listed in Tables 1A and 1B are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table 1A Mefentrifluconazole Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Edible-podded succulent beans	Foliar/broadcast/449-467	21	<0.01	0.02	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)
Shelled succulent beans	Foliar/broadcast/445-456	21	<0.01	0.02	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)
Edible-podded succulent peas	Foliar/broadcast/444-459	21	<0.01	0.08	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)
Shelled succulent peas	Foliar/broadcast/444-459	21	<0.01	<0.01	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)

Commodity	Application Method/	PHI (days)	Residues (ppm)		Experimental Processing	Currently Established	Recommended MRL
Dried beans	Foliar/broadcast/436-461	21	<0.01	0.05	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)
Dried peas	Foliar/broadcast/449-460	21-22	<0.01	0.09	Not applicable	0.15 (CG6, except dry lentils and dry soybeans)	0.15 (CG6-21, except dry lentils and dry soybeans)

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

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

Commodity	Application Method/ Total Application Rate (g a.i./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			LAFT	HAFT			
Dry beans	Foliar broadcast/598-650	7-8	<0.05	0.243	Not applicable	0.9 (CSG6C, except soybeans)	0.9 (CSG6-21E, except soybeans)
Dry peas	Foliar broadcast/595-615	7-8	<0.05	0.661	Not applicable	0.9 (CSG6C, except soybeans)	0.9 (CSG6-21F)

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

Following the review of all available data, MRLs as proposed in Tables 1A and 1B are recommended to cover residues of mefentrifluconazole and prothioconazole. Residues of mefentrifluconazole and prothioconazole 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.

Environmental Assessment

The use of RevyPro will not pose any additional risks to the environment. When used according to label directions, the environmental risks are acceptable for RevyPro.

Value Assessment

Rationales and reports of 35 trials conducted in Canada in 2016 – 2021 demonstrated that RevyPro applied at 1.0 L/ha can be expected to control or suppress labelled diseases on pea, lentil, chickpea and bean. Based on a review of the rationales, it was concluded that a similar level of efficacy against the same diseases can be expected for RevyPro applied to other pulse crops within Crop Subgroups 6-21E (dried shelled beans) and 6-21F (dried shelled peas). The efficacy data also confirmed that RevyPro was effective on certain causal pathogen isolates resistant to Group 11 (strobilurin, QoI) fungicides. Pulse crops exhibited a high degree of tolerance to RevyPro.

The supporting evidence confirmed the value of RevyPro for control of anthracnose, mycosphaerella blight and ascochyta blight, or for suppression of grey mould, powdery mildew and white mould on listed crops. The registration of RevyPro will provide Canadian growers with a new product to manage these important diseases on dried shelled beans and peas.

Conclusion

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

References

PMRA

Document

Number	Reference
3284295	2021, RevyPro Group A- Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3284296	2021, GLP Validation of Analytical Method AFR0172/01 and Certification of BAS 754 01 F, Lot FD-201221-1003, DACO: 3.4.1
3284297	2021, Physical and chemical properties of BAS 754 01 F: Accelerated Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.9
3284298	2021, DACO 3.5.13 and DACO 3.5.15, DACO: 3.5.13,3.5.15
3284299	2021, BAS 754 01 F: Determination of Oxidation/Reduction, Chemical Incompatibility, DACO: 3.5.8
3284300	2021, BAS 754 01 F Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12,3.5.8
3284302	2021, BAS 754 01 F - Acute oral toxicity study in rats, DACO: 4.6.1
3284303	2021, BAS 754 01 F - Acute dermal toxicity study in rats, DACO: 4.6.2
3284304	2021, BAS 754 01 F - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure (nose only), DACO: 4.6.3
3284305	2021, BAS 754 01 F - Acute eye irritation in rabbits, DACO: 4.6.4
3284306	2021, BAS 754 01 F - Acute dermal irritation / corrosion in rabbits, DACO: 4.6.5
3284307	2021, BAS 754 01 F - BUEHLER test in guinea pigs, DACO: 4.6.6
3284308	2021, DACO 5.2 Use Site Description_RevyPro, DACO: 5.1,5.2
3284290	2021, DACO 10.1 Value Assessment: RevyPro for Use in Crop SubGroup 6C (Dried Shelled Peas and Beans, except Soybean), DACO: 10.1
3284293	BASF Canada Inc., 2021, DACO 10.2.3, 10.3.2 RevyPro Trial Reports, DACO: 10.2.3.3(D), 10.3.2(B)

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