

Evaluation Report for Category B, Subcategories 2.3, 2.4, 2.6, 3.10 Application

Application Number: 2020-1214
Application: New EP Product Chemistry-Identity of Formulants; Proportion of Formulants; New combination of Technical Grade Active Ingredients
New Product Labels-Tank Mixes
Product: Veltyma
Registration Number: 34166
Active ingredients (a.i.): Mefentrifluconazole, Pyraclostrobin
PMRA Document Number: 3236694

Purpose of Application

The purpose of this submission is to register a new end-use product, Veltyma, containing mefentrifluconazole and pyraclostrobin, for use in canola, corn (field, pop, sweet, seed), dried shelled pea and bean (Crop Subgroup 6C), flax, mustard, potato, rapeseed, soybean, sugar beet, and wheat (all types) for control of various fungal diseases.

Chemistry Assessment

Veltyma is formulated as suspension containing mefentrifluconazole at a concentration of 200 g/L and pyraclostrobin at a concentration of 200 g/L. This end-use product has a density of 1.13 to 1.15 g/mL and pH of 5.5 to 7.0. The required chemistry data for Veltyma have been provided, reviewed and found to be acceptable.

Health Assessments

Veltyma is slightly acutely toxic in rats by the oral route, and of low acute toxicity in rats by the dermal and inhalation routes. It is minimally irritating to the eyes, mildly irritating to the skin of rabbits, and is not a dermal sensitizer in the guinea pig.

The use pattern of Veltyma fits within the registered use pattern for pyraclostrobin and mefentrifluconazole. The risk assessments on file for both pyraclostrobin and mefentrifluconazole are adequate to cover the potential exposure for mixers, loaders, applicators and postapplication workers from the proposed uses. No health risks of concern are expected for mefentrifluconazole and pyraclostrobin, provided that workers wear the recommended personal protective equipment and follow all label directions.

No new residue data were submitted or are required for mefentrifluconazole or pyraclostrobin to support registration of Veltyma. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Veltyma label, including the target crops; methods, timing and number of applications; application rates; preharvest intervals; feeding and grazing restrictions; and crop rotational restrictions are identical or similar to currently registered end-use products containing either mefentrifluconazole alone or pyraclostrobin alone.

Based on this assessment, residues are not expected to be greater than that for the currently registered uses and will be covered by the established maximum residue limits. Consequently, dietary exposure to residues of mefentrifluconazole and pyraclostrobin is not expected to increase with the registration of Veltyma and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The registration of Veltyma does not pose any additional risk to the environment.

No additional data was required for the environmental assessment. Environmental concerns are addressed in the environmental label statements.

Value Assessment

Rationales and efficacy data from 56 trials conducted in Canada (except one trial from the USA) were submitted in support of Veltyma. The assessment of the submitted value information supported use of Veltyma. Registration of Veltyma will provide Canadian growers with an additional product to control several important plant diseases on various crops. The co-formulation will also reduce the risk of resistance development, based on having two different mode of actions of mefentrifluconazole and pyraclostrobin.

Conclusion

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

References

PMRA

Document

Number	Reference
3106714	2017, [CBI Removed] - Group A - Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3106716	2017, BAS 751 06 F: Formulation / End-use Product - Product Chemistry Evaluation (Based on OECD Dossier Numbering) Identity, Physical and Chemical Properties, Analytical Methods, Confidential information, DACO: 3.4.1,3.5.1, 3.5.2,3.5.3,3.5.4
3106717	2016, Physical and chemical properties of BAS 751 01 F: 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, 3.5.5,3.5.6,3.5.7,3.5.9
3106718	2017, Physical and chemical properties of BAS 751 06 F: Accelerated storage stability and corrosion characteristics in commercial type containers, DACO: 3.5.1,3.5.10,3.5.14, 3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.9
3106719	2015, Determination of Physico-Chemical Properties According to Directive 94/37/EC (Regulation (EC) No. 440/2008), DACO: 3.5.11,3.5.12
3106720	2020, DACO 3.5.13 and DACO 3.5.15, DACO: 3.5.13,3.5.15
3106721	2016, BAS 751 01 F: Determination of Oxidation/Reduction, DACO: 3.5.8
3223637	2016, Validation of Analytical Method [CBI Removed], DACO: 3.4.1 CBI
3223638	2017, Analytical Method [CBI Removed]: Determination of Mefentrifluconazole, Fluxapyroxad and/or Pyraclostrobin Content Fungicidal Suspension Concentrate (SC) Formulations and their TGAIs by [CBI Removed], DACO: 3.4.1 CBI
3223639	2019, Physical and chemical properties of BAS 751 01 F: Storage Stability and corrosion characteristics in commercial type containers, DACO: 3.5.10
3106723	2015, BAS 751 01 F - Acute oral toxicity study in rats (Including analytical report), DACO 4.6.1
3106724	2015, BAS 751 01 F - Acute dermal toxicity study in rats, DACO 4.6.2
3106725	2015, BAS 751 01 F - Acute inhalation toxicity study in Wistar rats 4-hour liquid aerosol exposure (nose only), DACO 4.6.3
3106726	2015, BAS 751 01 F - Acute eye irritation in rabbits (Including amendment no. 1), DACO 4.6.4
3106727	2015, BAS 751 01 F - Acute dermal irritation / corrosion in rabbits, DACO 4.6.5
3106728	2015, BAS 751 01 F - Assessment of Sensitising Properties on Albino Guinea Pigs by Repeated Applications BUEHLER Test with 3 Applications, DACO 4.6.6
3106699	2020, DATA REQUIREMENT - PART 10.1 VALUE ASSESSMENT, DACO: 10.1
3106700	2020, DACO 10 - Summary tables Research Trials: corn, DACO: 10.2.3.1,10.3.1
3106701	2020, DACO 10 - Summary tables Research Trials: flax, DACO: 10.2.3.1,10.3.1
3106702	2020, DACO 10 - Summary tables Research Trials: Potatoes, DACO: 10.2.3.1,10.3.1
3106703	2020, DACO 10 - Summary tables Research Trials: pulses, DACO: 10.2.3.1,10.3.1

- 3106704 2020, DACO 10 - Summary tables Research Trials: Soybeans, DACO:
10.2.3.1,10.3.1
- 3106705 2020, DACO 10 - Summary tables Research Trials: Sugarbeets, DACO:
10.2.3.1,10.3.1
- 3106706 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Corn, DACO:
10.2.3.3(D),10.3.2(B)
- 3106707 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Flax, DACO:
10.2.3.3(D),10.3.2(B)
- 3106708 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Potatoes, DACO:
10.2.3.3(D),10.3.2(B)
- 3106709 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Pulses, DACO:
10.2.3.3(D),10.3.2(B)
- 3106710 Purdue University, 2020, DACO 10 - Trial abstracts: Purdue, DACO:
10.2.3.3(D),10.3.2(B)
- 3106711 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Soybeans, DACO:
10.2.3.3(D),10.3.2(B)
- 3106712 BASF Canada Inc., 2020, DACO 10 - Trial abstracts: Sugarbeets, DACO:
10.2.3.3(D),10.3.2(B)

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