Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-5901
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Product: Downforce AG
Registration Number: 34723
Active ingredient (a.i.): Fluazinam [FLZ]
PMRA Document Number : 3303943

Purpose of Application

The purpose of this application was to register Downforce AG, a new fungicide end-use product to control fungal diseases in various crops and sites, based on a registered precedent product.

Chemistry Assessment

Downforce AG is formulated as a suspension concentrate containing fluazinam at a concentration of 40%. This end-use product has a density of 1.25 g/mL and pH of 5.77 for a 1% dilution. The required chemistry data for Downforce AG have been provided, reviewed and found to be acceptable.

Health Assessments

Downforce AG was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Downforce AG is considered to be of low acute toxicity by the oral, dermal and inhalation routes. It is considered to be minimally irritating to the eyes, moderately irritating to the skin, and a dermal sensitizer.

The registration of Downforce AG is supported from an occupational exposure perspective, as it fits within the registered use pattern of the precedent product. As such, exposure to fluazinam is not expected to exceed that of the registered uses. No health risks of concern are expected, provided that workers wear the appropriate personal protective equipment and follow all label directions for use.

No new residue data for fluazinam were submitted or are required to support the registration of Downforce AG. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Downforce AG label, including the target crops, method (ground and aerial), rates, number and timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to the precedent end-use product. 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 (MRLs). Dietary exposure to residues of fluazinam is not expected to increase with the registration of Downforce

AG 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 Downforce AG for the control and suppression of labeled diseases on various outdoor food and feed crops and for the suppression of mites on apples will not pose any additional risks to the environment. The required environmental precautions statements to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for Downforce AG.

Value Assessment

No value data was submitted to support the use claims. A comparison of product formulations determined that the formulations are similar and are expected to have similar efficacy when used according to the use pattern. Extrapolation of all uses registered on the label of the precedent product to the Downforce AG label is supported.

Fluazinam has a unique mode of action compared to alternative products registered for the same uses. It is an important component of a resistance management program for the listed crops. Access to a product similar to the precedent product provides flexibility to growers with respect to accessibility.

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 Downforce AG.

References

PMRA Document Number	Reference
3182460	2020, Additional Product Chemistry for Downforce AG, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.3.1, 3.5.11, 3.5.12, 3.5.13, 3.5.15, 3.5.4, 3.5.5
3182462	2020, Sipcam Downforce AG Formulation Process, DACO: 3.2.1, 3.2.2, 3.2.3 CBI
3182463	2020, Downforce AG: Physical and Chemical Characteristics: Color, Physical State, Odor, Oxidation/Reduction, pH, Viscosity, and Density/Relative Density, DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3182464	2019, Downforce AG: Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.4.1, 3.5.10, 3.5.14
3295834	2021, Description of Formulation Process - batch size, DACO: 3.2.2 CBI