

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-2993
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data policy-Equivalency/Data Compensation Assessment
Product: Advantage Ethalfluralin 360 Manufacturing Concentrate
Registration Number: 34685
Active ingredient (a.i.): Ethalfluralin
PMRA Document Number: 3392269

Purpose of Application

The purpose of this application was to register a new product, Advantage Ethalfluralin 360 Manufacturing Concentrate, based on a registered precedent. The product will be used to manufacture an ethalfluralin-blended fertilizer.

Chemistry Assessment

Advantage Ethalfluralin 360 Manufacturing Concentrate is formulated as an emulsifiable concentrate containing ethalfluralin at a concentration of 360 g/L. It has a density of 1.02 – 1.04 g/mL and pH of 5.49 (1% solution). The required chemistry data for Advantage Ethalfluralin 360 Manufacturing Concentrate have been provided, reviewed and found to be acceptable.

Health Assessments

Advantage Ethalfluralin 360 Manufacturing Concentrate was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required.

No new residue data for ethalfluralin were submitted or are required to support the registration of Advantage Ethalfluralin 360 Manufacturing Concentrate. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Advantage Ethalfluralin 360 Manufacturing Concentrate label, including the target crops, method, rates and timing of application, geographic restrictions, and crop rotation restrictions are comparable to the precedent product.

Based on this assessment, residues are not expected to be greater than those for the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of ethalfluralin is not expected to increase with the use of Advantage Ethalfluralin 360 Manufacturing Concentrate and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

An occupational exposure assessment was not required for this application.

Environmental Assessment

There are no additional risks to the environment associated with the use of Advantage Ethalfluralin 360 Manufacturing Concentrate compared to its precedent product. When used according to label directions, the environmental risks are acceptable for the use of Advantage Ethalfluralin 360 Manufacturing Concentrate.

Value Assessment

Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information consisted of a comparison of the formulation of Advantage Ethalfluralin 360 Manufacturing Concentrate to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between Advantage Ethalfluralin 360 Manufacturing Concentrate and the cited precedent product was established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Advantage Ethalfluralin 360 Manufacturing Concentrate label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found it sufficient to support the registration of Advantage Ethalfluralin 360 Manufacturing Concentrate.

References

PMRA

Document

Number	Reference
3243961	2021, DACO 3.0 for Ethafluralin 360g/L EC, DACO: 3.0, 3.1, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.3.1, 3.5.13, 3.5.15, 3.5.5 CBI
3243964	2021, Physico-chemical properties of Ethafluralin 360g/L Emulsifiable Concentrates, DACO: 3.4, 3.4.1, 3.5, 3.5.1, 3.5.10, 3.5.11, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.4, 3.5.6, 3.5.7, 3.5.8, 3.5.9 CBI
3243965	2021, Manufacturing process of Ethafluralin 360g/L EC, DACO: 3.2, 3.2.1, 3.2.2 CBI

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