



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-6448
Application: Submissions subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Tide Clethodim 240 EC Herbicide
Registration Number: 34965
Active ingredient (a.i.): Clethodim
PMRA Document Number: 3435626

Purpose of Application

The purpose of this application was to register Tide Clethodim 240 EC Herbicide, an end-use product for post-emergent weed control in labelled terrestrial food and feed crops, based on a registered precedent product.

Chemistry Assessment

Tide Clethodim 240 EC Herbicide is formulated as an emulsifiable concentrate containing clethodim at a concentration of 240 g/L. This end-use product has a density of 0.95 – 0.96 g/mL and pH of 4.0 – 6.0. The required chemistry data for Tide Clethodim 240 EC Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Tide Clethodim 240 EC Herbicide is of low toxicity by the oral, dermal and inhalation routes. It is moderately irritating to the eyes, mildly irritating to the skin, and is not a dermal sensitizer.

The registered use pattern of Tide Clethodim 240 EC Herbicide is comparable to the registered use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of clethodim. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for clethodim were submitted or were required to support the registration of Tide Clethodim 240 EC Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Tide Clethodim 240 EC Herbicide label, including the target crops, method (ground or aerial), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the precedent product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of clethodim and its metabolites is not expected to increase with the registration of Tide Clethodim 240 EC Herbicide 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 Tide Clethodim 240 EC Herbicide for selective control of grasses on labelled crops does not pose any additional risk to the environment when used according to the label.

Value Assessment

The availability of Tide Clethodim 240 EC Herbicide provides farmers with another option to control grassy weeds in an array of crops. Registration of a generic product may increase product competition, which may in turn reduce purchasing costs of similar products.

The formulation of Tide Clethodim 240 EC Herbicide was compared to the formulation of the precedent product. The differences between the formulations were considered minor, and are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the precedent product label, which are not restricted by other product labels, are supported for inclusion on the Tide Clethodim 240 EC Herbicide label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found the information acceptable to support the registration of Tide Clethodim 240 EC Herbicide.

References

PMRA Document Number	Reference
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3298294	2020, The Formulation Process of Tide Clethodim 240 EC, DACO: 3.2.1,3.2.2 CBI
3298295	2021, Method Validation and Quantitative Analysis for Clethodim 2EC, DACO: 3.4.1 CBI
3298296	2021, Physical and Chemical Characterization of Clethodim 2EC, DACO: 3.5 CBI
3298297	2021, Physical and Chemical Characterization of Clethodim 2EC, DACO: 3.5 CBI

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