



Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-1847
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Reptile 80% WDG WSP Herbicide
Registration Number: 34554
Active ingredient (a.i.): Flumetsulam
PMRA Document Number : 3357307

Purpose of Application

The purpose of this application was to register Reptile 80% WDG WSP Herbicide, a new herbicide end-use product to control weeds in hybrid field corn and soybeans, based on a registered precedent product.

Chemistry Assessment

Reptile 80% WDG WSP Herbicide is formulated as water dispersible granules containing flumetsulam at a concentration of 80.0 %. This end-use product has a density of 0.85 g/mL and pH of 6.9 (1% solution). The required chemistry data for Reptile 80% WDG WSP Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

Reptile 80% WDG WSP Herbicide is considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Reptile 80% WDG WSP Herbicide is considered to be of low acute toxicity by the oral, and dermal routes and slightly acutely toxic via the inhalation route. It is minimally irritating to the eyes and skin. Reptile 80% WDG WSP Herbicide is not considered to be a dermal sensitizer.

The requested use pattern of Reptile 80% WDG WSP Herbicide containing flumetsulam 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 this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for flumetsulam were submitted or are required to support the registration of Reptile 80% WDG WSP Herbicide. Previously reviewed residue data were re-assessed in the framework of this petition.

The use directions on the Reptile 80% WDG WSP Herbicide label, including

the target crops, method (ground), rates and timing of application, geographic restrictions, 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). Consequently, dietary exposure to residues of flumetsulam is not expected to increase with the registration of Reptile 80% WDG WSP Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern and application rate on the label of Reptile 80% WDG WSP Herbicide is within the currently registered use pattern for the active flumetsulam. Therefore, no additional risk is expected when Reptile 80% WDG WSP Herbicide is used in accordance with the label, which includes statements to mitigate risks to the environment.

Value Assessment

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

The formulation of Reptile 80% WDG WSP Herbicide was compared to the formulation of the cited precedent product. The differences between the two formulations were considered minor, which are unlikely to result in any significant impact on product performance, in terms of efficacy and/or crop tolerance. The agronomic equivalence between Reptile 80% WDG WSP Herbicide and the cited precedent product was established. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the Reptile 80% WDG WSP Herbicide label subject to the required label amendments/updates.

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 Reptile 80% WDG WSP Herbicide.

References

PMRA Document Number	Reference
3140989	2019, Flumetsulam 80 % Physical-Chemical Properties and Accelerated Storage Study, DACO: 3.4.1, 3.5, 3.5.1, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7 CBI
3140991	2019, Flumetsulam 80 % WG Reducing / Oxidizing Test, DACO: 3.5 CBI
3225681	2020, DACO 3 for Sharda Flumetsulam 80 WDG, DACO: 3.0, 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.2.3, 3.3.1, 3.5.13, 3.5.15 CBI

3225684	2021, Determination of Flammability of flutmesulam WDG 80%, DACO: 3.5.12 CBI
3225685	2021, Determination of explodability of flutmesulam WDG 80%, DACO: 3.5.11 CBI
3329806	2022, Manufacturing Process Flumetsulam 80% WG, DACO: 3.2 CBI

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