

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2021-0287
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data (PIIP) Policy – Equivalency/Data Compensation Assessment
Product: Bastante Herbicide
Registration Number: 34571
Active ingredient (a.i.): Bentazon (present as sodium salt)
PMRA Document Number: 3326649

Purpose of Application

The purpose of this application was to register Bastante Herbicide, a new herbicide end-use product to control postemergence broadleaf weeds in various crops and sites, based on a registered precedent product.

Chemistry Assessment

Bastante Herbicide is formulated as a solution containing bentazon (present as the sodium salt) at a concentration of 480 g/L. This end-use product has a density of 1.2 g/cm³ and pH of 5.45 (1% solution). The required chemistry data for Bastante Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

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

The use pattern of Bastante Herbicide containing bentazon 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 product containing 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 bentazon were submitted and none are required to support the registration of Bastante Herbicide, containing 480 g/L bentazon, for use on soybeans, dry and snap common beans, peas, lima beans, fababeans, corn (grain, silage, sweet

and seed), flax (including low linolenic acid varieties), peanuts, blueberries, turf, spring wheat (excluding durum), snow peas, seedling and established forage legumes and seedling forage grasses (seed production only for forage legumes and grasses), and newly-planted fruit trees (apple, apricot, cherry, peach, pear and nectarine), based on the precedent end-use product, given that the current application does not constitute an expansion of use.

A comparison of the submitted label and the cited registered precedent product label demonstrated that the use directions are comparable; there are no other amendments to the currently registered use patterns of bentazon on the requested crops - as such, no additional residue data or revised environmental exposure concentrations (EECs) are required to support the current application. Therefore, the registration of Bastante Herbicide for use on the indicated crops and target sites will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors provided that the label directions are followed.

Environmental Assessment

As the use patterns, application methods, and application rates are the same as those for the cited precedent product, the registration of Bastante Herbicide will not pose any additional environmental risks. When used according to label directions, the environmental risks are acceptable for Bastante Herbicide.

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 Bastante Herbicide to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between Bastante Herbicide 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 Bastante Herbicide label.

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 Bastante Herbicide.

References

PMRA Document Number	Reference
3193330	2021, Additional Product Chemistry for Aceto Bentazon 480, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.4,3.5.5
3193332	2020, AG36425 R334.1 4 SL Herbicide, Physical and Chemical Properties Product Chemistry, Group A: Product Identity and Composition, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3193333	2020, AG36425 R334.1 4 SL Herbicide, Physical and Chemical Properties Waiver Requests of Product Chemistry Data, DACO: 3.5.11,3.5.12,3.5.13,3.5.15
3193334	2020, Physical and Chemical Characteristics of AG36425 4 SL, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9
3193335	2020, Storage Stability and Corrosion Characteristics of AG36425 4 SL, DACO: 3.4.1,3.5.10,3.5.14

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