



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2021-1868  
**Application:** Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment  
**Product:** Dakota  
**Registration Number:** 34698  
**Active ingredient (a.i.):** Imazamox  
**PMRA Document Number:** 3393262

### Purpose of Application

The purpose of this application was to register a commercial end-use product, Albaugh Imazamox 70 WG Herbicide, to control broadleaf weeds and grasses in soybean, field pea, dry edible bean and a variety of imazamox-tolerant crops, based on precedent products.

### Chemistry Assessment

Albaugh Imazamox 70 WG Herbicide is formulated as wettable granules containing imazamox at a concentration of 70%. This end-use product has a density of 0.55-0.57 g/mL and pH of 2.91. The required chemistry data for Albaugh Imazamox 70 WG Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Albaugh Imazamox 70 WG Herbicide is of low acute oral, dermal and inhalation toxicity in rats. It was non-irritating to the eyes and skin of rabbits. It was not a dermal sensitizer in guinea pigs.

The use pattern of Albaugh Imazamox 70 WG Herbicide fits within the registered or historically-registered use pattern of the precedent products. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered uses of this active ingredient. 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 imazamox were submitted or are required to support the registration of Albaugh Imazamox 70 WG Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the Albaugh Imazamox 70 WG 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 those on the label of the precedent end-use products.

Based on this assessment, residues are not expected to be greater than those from the currently registered and historical uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of imazamox is not expected to increase with the registration of Albaugh Imazamox 70 WG 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 for Albaugh Imazamox 70 WG Herbicide is within the registered use pattern of imazamox, therefore, no additional risk is expected from the use of Albaugh Imazamox 70 WG Herbicide. The label includes all the required environmental precautions, directions for use and spray buffer zone information which adequately mitigate risks to the environment. Risk from use of Albaugh Imazamox 70 WG Herbicide is acceptable from the environmental perspective when used according to label directions.

### **Value Assessment**

The availability of Albaugh Imazamox 70 WG Herbicide provides farmers with an alternative option to manage broadleaf and grassy weeds in soybean, field pea, dry edible bean and a variety of imazamox-tolerant crops. Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

The formulation of Albaugh Imazamox 70 WG Herbicide was compared to the formulations of the precedent products. It was concluded that differences in the formulations would be unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance.

### **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 Albaugh Imazamox 70 WG Herbicide.

## References

<b>PMRA Document Number</b>	<b>Reference</b>
3226232	2021, Manufacturing Process of Imazamox 700 g/kg WG, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1 CBI
3226233	2021, Study on the Physico Chemical Properties of Imazamox 700 g/kg Water Dispersible Granules, DACO: 3.3.1, 3.5.1, 3.5.11, 3.5.12, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8
3226234	2021, Study on the Method Validation of Imazamox 700g/kg Water Dispersible Granules, DACO: 3.4.1
3226235	2021, Study on the Method Validation of Imazamox 700g/kg Water Dispersible Granules, DACO: 3.5.10, 3.5.14
3226236	2021, Additional Product Chemistry for Rotam Imazamox 70 WG Herbicide, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.5.13, 3.5.15, 3.5.4, 3.5.5
3287340	2021, Imazamox 700 g/kg WG: Skin Sensitization Study (Magnusson and Kligman Test) in Guinea Pigs., DACO: 4.6.6
3287341	2021, Imazamox 700 g/kg WG: Acute Eye Irritation Study in New Zealand White Rabbits., DACO: 4.6.4
3287342	2021, Imazamox 700 g/kg WG: Acute Oral Toxicity Study (Up-and-Down Procedure) in female wistar rats., DACO: 4.6.1
3287343	2021, Imazamox 700 g/kg WG: Acute Dermal Irritation Study in New Zealand White Rabbits., DACO: 4.6.5
3287344	2021, Imazamox 700 g/kg WG: Acute Dermal Toxicity Study in Wistar Rats., DACO: 4.6.2
3287345	2021, Imazamox 700 g/kg WG: Acute Inhalation Toxicity Study in Wistar Rats, DACO: 4.6.3

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