

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2020-0102  
**Application:** Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation Assessment  
**Product:** VenIM B Herbicide  
**Registration Number:** #####  
**Active ingredient (a.i.):** Bentazon (present as sodium salt)  
**PMRA Document Number :** 3202597

### Purpose of Application

The purpose of this application was to register VenIM B Herbicide based on a precedent, for selective postemergence broadleaf weed control in a variety of crops.

### Chemistry Assessment

VenIM B Herbicide is formulated as a solution containing bentazon at 480 g/L (present as the sodium salt). This end-use product has a density of 1.205 g/mL and pH of 8 - 10. The required chemistry data for VenIM B Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

VenIM B Herbicide was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. VenIM B Herbicide is considered to be of low toxicity to rats via the oral, dermal, and inhalation routes. It is considered to be mildly irritating to the eye and minimally irritating to the skin of rabbits. VenIM B Herbicide is not considered to be a potential skin sensitizer.

The use pattern of VenIM B Herbicide is identical 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 bentazon were submitted or are required to support the registration of VenIM B Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions on the VenIM B Herbicide label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are identical to those on 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 MRLs. Consequently, dietary exposure to residues of bentazon is not expected to increase with the registration of VenIM B Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

As the use patterns, application methods, and application rates are the same as those for the precedent product, the registration of VenIM B Herbicide will not pose any additional risks to the environment. The required environmental risk mitigation measures are present on the label. When used according to label directions, the environmental risks are acceptable for VenIM B Herbicide.

### **Value Assessment**

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

The formulation of VenIM B 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 both efficacy and crop tolerance. The agronomic equivalence between VenIM B Herbicide and the cited precedent product can be established. Therefore, all uses and claims found on the precedent product label are supported for inclusion on the VenIM B Herbicide 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 VenIM B Herbicide.

### **References**

PMRA Document Number	References
3076068	2013, VenIM B_NUL 2621 Technical Package, DACO: 3.2.1, 3.2.2, 3.5.4, 3.5.5 CBI
3076069	2019, VenIM B_EAM_50934, DACO: 3.4.1
3076070	2019, VenIM B_Phys Chem_50935, DACO: 3.5.1, 3.5.11, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
3076071	2019, VenIM B_SS & CC_50934, DACO: 3.5.10

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written

permission of Health Canada, Ottawa, Ontario K1A 0K9.