

## Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

**Application Number:** 2010-2458  
**Application:** Changes to product chemistry: guarantee, identity of formulants, proportion of formulants  
**Product:** Banvel K Dicamba K Manufacturing Concentrate  
**Registration Number:** 20354  
**Active ingredient (a.i.):** Dicamba  
**PMRA Document Number English PDF:**2063496

### Purpose of Application

The purpose of this application was to amend the specifications and container sizes of Banvel K Dicamba K Manufacturing Concentrate.

### Chemistry Assessment

Banvel K Dicamba K Manufacturing Concentrate is a solution containing the active ingredient dicamba at a nominal concentration of 31.0%. This product has a density of 1.250 g/mL and a pH of 9.5 (neat). A storage stability study in stainless steel containers is required as a condition of full registration; otherwise, the chemistry requirements for Banvel K Dicamba K Manufacturing Concentrate are complete.

### Health Assessment

Revisions to the formulation of the manufacturing concentrate are not expected to appreciably alter its acute toxicology profile. New acute inhalation toxicity and skin sensitization data for the new version of the formulation were evaluated. The acute toxicity of the manufacturing concentrate is low via the oral and dermal routes of exposure in the rabbit and via the inhalation route of exposure in the rat. It is moderately irritating to the eye and skin of the rabbit, and is not a skin sensitizer the guinea pig.

### Environmental Assessment

An environmental assessment was not required for this application.

### Value Assessment

A value assessment was not required for this application.

## Conclusion

The PMRA conducted an evaluation of the subject application and determined that the use of the revised product in accordance with the label has value and will not pose unacceptable health or environmental risk.

## References

- 1841574 1995, Storage stability of Banvel Herbicide, DACO: 3.5.10, 3.5.14
- 1841578 1995, Storage stability of Banvel SGF, DACO: 3.5.10, 3.5.14
- 1841581 2002, BAS 662 01 H: Storage stability and corrosion characteristics in commercial type packaging, DACO: 3.5.10, 3.5.14
- 1841582 2005, BAS 653 00 H: Storage stability and corrosion characteristics in commercial type containers, DACO: 3.5.10, 3.5.14
- 1841583 1996, Storage stability of isopropylamine salt of dicamba formulation, DACO: 3.5.10, 3.5.14
- 1910410 2010, Chemistry requirements for the registration of a manufacturing concentrate formulated from a registered active ingredient, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4 CBI
- 1910411 2010, Description of starting materials, DACO: 3.2.1 CBI
- 1910412 2010, Process procedure for Banvel K / Dicamba K Manufacturing Concentrate Herbicide, DACO: 3.2.2 CBI
- 1910413 2010, Formation of impurities of toxicological concern, DACO: 3.2.3 CBI
- 1910414 2010, Establishing certified limits, DACO: 3.3.1 CBI
- 1910417 2002, BAS 653 00H: Method F-103-1 validation: "Determination of percent active ingredients in MARKSMAN formulations by HPLC", DACO: 3.4.1
- 1910418 1994, Color of Dicamba K salt formulation, DACO: 3.5.1
- 1910419 1995, SAN 859H 390SL 406DP (Dicamba K) chemical storage stability, DACO: 3.5.10
- 1910420 2010, Flammability of Banvel K / Dicamba K Manufacturing Concentrate, DACO: 3.5.11
- 1910421 2010, Explodability of Banvel K / Dicamba K Manufacturing Concentrate, DACO: 3.5.12
- 1910423 2010, Miscibility of Banvel K / Dicamba K Manufacturing Concentrate (BAS 183 14H), DACO: 3.5.13

- 1910424 1995, Determination of corrosion characteristics of potassium salt formulation of dicamba, DACO: 3.5.14
- 1910425 1994, Physical state of Dicamba K salt formulation, DACO: 3.5.2
- 1910426 1995, Determination of odor of SAN 859H 31SL 406DP (Dicamba K), DACO: 3.5.3
- 1910427 2010, Container material and description, DACO: 3.5.5
- 1910428 1994, Density of Dicamba K salt formulation, DACO: 3.5.6
- 1910429 1994, pH of Dicamba K salt formulation, DACO: 3.5.7
- 1910430 1994, Oxidizing or reducing action of Dicamba K salt formulation, DACO: 3.5.8
- 1910431 1994, Brookfield viscosity of Dicamba K salt formulation, DACO: 3.5.9
- 1946373 2010, Waiver request for the exemption from storage stability for Banvel K / Dicamba K Manufacturing Concentrate, DACO: 3.5.10
- 1960255 2010, BAS 183 14 H - Skin sensitisation study (Buehler test), DACO: 4.2.6
- 1960256 2009, BAS 183 14 H - Acute inhalation toxicity study in Wistar rats, 4-hour liquid aerosol exposure (head-nose only), DACO: 4.2.3
- 1960257 2009, Amendment no. 1 to the report: BAS 183 14 H - Acute inhalation toxicity study in Wistar rats, DACO: 4.2.3

ISSN: 1911-8082

© Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2011

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 the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.