

# **Evaluation Report for Category B, Subcategory 2.2 Application**

**Application Number:** 2014-1075

**Application:** New end use product, chemistry-form of technical grade active

ingredient

**Product:** Banvel VM PRO

**Registration Number:** 32221

**Active ingredients (a.i.):** Dicamba (present as N,N-Bis-(3-aminopropyl)methylamine salt

(BAPMA))

PMRA Document Number: 2613225

# **Purpose of Application**

The purpose of this application was to register a new end use product containing a new salt form of dicamba for use as a herbicide on pasture, rangeland, non-crop land areas and turf.

## **Chemistry Assessment**

Banvel VM PRO is formulated as a solution containing dicamba (present as N,N-Bis-(3-aminopropyl)methylamine salt (BAPMA)) at 600 g/L. This end-use product has a pH of 5.0-8.0 and a density of 1.23-1.25 g/mL. The chemistry requirements for this product have been fulfilled.

#### **Health Assessments**

Banvel VM PRO was of low acute toxicity by the oral and dermal routes, and of moderate toxicity by the inhalation route in rats. It was mildly irritating and non-irritating to the eyes and skin of rabbits, respectively. Banvel VM PRO was a positive skin sensitizer in mice by the LLNA method.

The use of Banvel VM PRO is within the currently registered use patterns for dicamba, present as the diglycolamine salt. Since the diglycolamine salt was considered toxicologically equivalent to BAPMA salt, exposure to Banvel VM PRO is not expected to increase over the exposure from the currently registered products.

Residue data from bridging field trials conducted in the United States, including regions representative of Canada, were submitted to support the domestic use of Banvel VM PRO. Three formulations of dicamba (BAPMA; diglycolamine salt, or DGA; and diethylenetriamine salt, or DETA) were applied to corn, soybean, wheat, and pasture grass in side-by-side trials at various rates to assess the effects of formulation on residue levels.

Following review of all available data, it has been concluded that the change in formulation will not result in an increase in dicamba residues in either food or feed items.



Consequently, no revisions to the currently established MRLs are required. Therefore, there is no health risk associated with this formulation change of dicamba to any segment of the population.

#### **Maximum Residue Limits**

Based on the bridging trial data, the magnitude of residues generated for three different salt formulations show that the BAPMA salt formulation would result in similar, or lower, residues than the currently registered DGA salt formulation. Therefore, the MRLs that are currently established for dicamba are sufficient.

TABLE 1. Summary of Bridging Field Trial for Dicamba						
Commo dity	Application	Dicamba Formula	PHI (days)	Residues (ppm)		
	Method/ Total Application Rate (kg a.i./ha)			LAFT	HAFT	
Corn Grain	One pre-plant and two foliar/ 1.37-1.43	BAPMA		<0.02	<0.02	
		DGA	90-99	<0.02	<0.02	
		DETA		<0.02	0.02	
Soybean Seed	One pre-plant and	BAPMA		<0.03	1.42	
	one late foliar season/	DGA	7	<0.03	5.82	
	1.63-1.73	DETA		<0.03	6.84	
Wheat grain	One pre-plant and two foliar/	BAPMA		0.098	0.91	
		DGA	6-7	0.016	1.73	
	0.69-0.73	DETA		0.089	0.86	

BAPMA: N,N-bis-(3-aminopropyl)methylamine salt; DGA: diglycolamine salt; DETA: diethylenetriamine salt; LAFT = Lowest Average Field Trial; HAFT = Highest Average Field Trial: PHI = Pre-Harvest Interval

#### **Environmental Assessment**

The risk to the environment from the use of Banvel VM PRO, containing BAMPA salt of dicamba, is not expected to be greater than that of the currently registered products containing diglycolamine salt of dicamba, as these products are expected to have similar environmental profile and have identical use pattern and application rates.

#### Value Assessment

Efficacy of Banvel VM PRO applied alone or in tank mix with Aatrex Liquid 480 Herbicide (registration number 184750), Prowl H<sub>2</sub>O Herbicide (registration number 29542), and Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (registration number 27487) was

compared to that of Banvel VM Herbicide (registration number 29249) applied alone or in tank mix with the same herbicides at the same rates for control of a number of weed species in 40 field trials conducted on corn and non-cropland in Manitoba and Ontario in 2011, 2012, and 2013.

Mean weed control following applications of the Banvel VM PRO treatments was comparable to that of the Banvel VM treatments. Therefore, all efficacy claims and herbicide tank mix partners that are labelled for Banvel VM are supported for inclusion on the Banvel VM PRO label.

Crop safety information demonstrated that small grain cereals exhibited a comparable margin of crop safety to the Banvel VM PRO treatments over the Banvel VM Herbicide treatments. The result observed on small grain cereals can be extrapolated to support the use of Banvel VM PRO in pasture and rangeland and established turfgrass.

Banvel VM PRO contains dicamba present as the BAPMA salt, which provides strong and effective binding of dicamba spray residues, thus, suppressing potential volatilization of the herbicide application.

Based on the weight of evidence, the registration of Banvel VM PRO is supported from a value standpoint.

#### Conclusion

Following review of the application, Banvel VM PRO was granted registration for use as a herbicide on pasture, rangeland, non-crop land areas and turf.

## References

PMRA Document	
Number	Reference
2407381	2014, DACO Requirements 3.1.1- 3.1.4, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4
2407382	2014, BAS 183 22 H Group A - Product identity, composition and analysis,
	DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1
2407383	2011, BAS 183 22 H: Determination of physical/chemical properties,
	DACO: 3.5.1, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.8, 3.5.9
2407384	2013, BAS 183 WB H: Storage Stability and Corrosion Characteristics in
	Commercial Type Containers, DACO: 3.5.10, 3.5.14
2407385	2014, DACO Requirements 3.5.11, 3.5.12, 3.5.13, 3.5.15, DACO: 3.5.11,
	3.5.12, 3.5.13, 3.5.15
2407386	2014, DACO Requirements 3.5.4- 3.5.5, DACO: 3.5.4, 3.5.5
2504421	2010, GLP Validation of Analytical Method AFR0086/01 and Certification
	of BAS 183 UY H Lot 1732-9 and BAS 183 WB H Lot 1732-10, DACO:
	3.4.1
2407387	2010, BAS 183 WB H - Acute oral toxicity study in rats, DACO: 4.6.1
2407388	2011, Amendment No. 1 to the report: BAS 183 WB H - Acute oral toxicity study in rats, DACO: 4.6.1

2407389	2010, BAS 183 WB H - Acute dermal toxicity study in rats, DACO: 4.6.2
2407390	2011, Amendment No. 1 to the report: BAS 183 WB H - Acute dermal toxicity study in rats, DACO: 4.6.2
2407391	2011, BAS 183 22 H - Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure (head-nose only), DACO: 4.6.3
2407392	2010, BAS 183 WB H - Acute eye irritation/corrosion in rabbits, DACO: 4.6.4
2407393	2011, First Amendment to the report: BAS 183 WB H - Acute eye irritation/corrosion in rabbits, DACO: 4.6.4
2407394	2010, BAS 183 WB H - Acute dermal irritation/corrosion in rabbits, DACO:
2407395	4.6.5 2011, First Amendment to the report: BAS 183 WB H - Acute dermal
2407396	irritation/corrosion in rabbits, DACO: 4.6.5 2011, BAS 183 22 H - Murine local lymph node assay (LLNA), DACO:
2434045	4.6.6 2010, Dissociation rates of salts of Dicamba, DACO: 2.14.10
2434046	2014, Part 4 BASF Response to PMRA letter dated May 7 2014 Deficiency Letter, DACO: 4.1, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.3.1, 4.5.3, 4.5.4, 4.5.5, 4.5.6, 4.5.7, 4.5.9
2434047	2012, BAS 183 22 H - Salmonella typhimurium / Escherichia coli reverse mutation assay, DACO: 4.8
2434048	2012, BAS 183 22 H - In vitro chromosome aberration assay in V79 cells, DACO: 4.8
2434049	2012, BAS 183 22 H - In vitro gene mutation test in CHO cells (HPRT locus assay), DACO: 4.8
2434050	2012, BAS 183 22 H - Micronucleus test in bone marrow cells of the mouse, DACO: 4.8
2442943	2014, Dicamba BAPMA Salt Repeated dose 90-day oral toxicity study in Wistar rats Administration via the diet, DACO: 4.3.1
2442944	2014, Dicamba BAPMA Salt Prenatal Developmental Toxicity Study in Wistar Rats Oral Administration (Gavage), DACO: 4.5.2
2531515	1992, Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of technical Dicamba administered orally via capsule to New
2434055	Zealand white rabbits, DACO: 4.5.2 1995, Stability of Dicamba and 5-Hydroxy Dicamba in stored frozen field corn, DACO: 7.3
2463533	2012, Determination of the Stability of Dicamba and its Major Endogenous Metabolites in Dicamba-Tolerant Soybean MON88708 x MON89788 under
2434053	Frozen Storage Conditions, DACO: 7.3 2009, Method validation of BASF Analytical Method D0902: The determination of residues of Dicamba (BAS 183 H) and its metabolite, 5-
2434058	Hydroxy Dicamba in corn matrices using LC/MS/MS, DACO 7.2.1, 7.2.2 2013, Formulation bridging study - Magnitude of the residue of Dicamba in corn after application of BAS 183 09H, BAS UYH or BAS 183 WBH
2434059	(Clarity Herbicide and two new salt formulations), DACO 7.4.1 2013, Magnitude of the residue of Dicamba in soybean matrices, formulation bridging study, DACO 7.4.1

2434057	2013, Formulation bridging study - Magnitude of the residue of Dicamba in
	wheat after application of BAS 183 H, BAS 183 UYH, or BAS 183 WBH
	(Clarity herbicide and two new salt formulations), DACO 7.4.1
2434060	2012, Magnitude of the residue of Dicamba in pasture grasses, formulation
	bridging study, DACO 7.4.1
2407369	2014, BAS 183 22 H Herbicide Value 10 - Application to register BAS 183
	22 H Herbicide, DACO: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3,
	10.3, 10.3.1, 10.3.2, 10.4, 10.5, 10.5.2, 10.5.3.

# **Additional Information Used**

## **Published Reference**

2614800 2016, N,N-bis(3-aminopropyl)methylamine Registration Dossier - The European Chemicals Agency (ECHA). Foreign Review of Toxicology, DACO 12.5.4.

ISSN: 1911-8082

8 Her Majesty the Queen in Right of Canada, represented by the Minister of Public Works and Government Services Canada 2016

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.