Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.2 Application

Application Number: 2014-1076
Application: New end use product, chemistry-form of technical grade active ingredient
Product: Engenia Manufacturing Concentrate
Registration Number: 32222
Active ingredients (a.i.): Dicamba (present as N,N-Bis-(3-aminopropyl)methylamine salt (BAPMA))
PMRA Document Number : 2613228

Purpose of Application

The purpose of this application was to register a new manufacturing concentrate containing a BAPMA salt form of dicamba for use in manufacturing, formulating or repackaging herbicides.

Two associated end-use products were reviewed at the same time; Engenia (application number 2014-1074) and Banvel VM PRO (application number 2014-1075).

Chemistry Assessment

Engenia Manufacturing Concentrate is formulated as a solution containing dicamba (present as N,N-Bis-(3-aminopropyl)methylamine salt (BAPMA)) at 600 g/L. This manufacturing concentrate 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

Engenia Manufacturing Concentrate 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. Engenia Manufacturing Concentrate was a positive skin sensitizer in mice by the LLNA method.

Residue data from bridging field trials conducted in the United States, including regions representative of Canada, were submitted to support the domestic use of Engenia and Banvel VM PRO which includes the BAPMA salt of dicamba used on various crops. 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

Commodity	Application Method/ Total Application Rate (kg a.i./ha)	Dicamba Formulation	PHI (days)	Residues (ppm)	
				LAFT	HAFT
Corn Grain	One pre-plant and two foliar/ 1.37-1.43	BAPMA	90-99	<0.02	<0.02
		DGA		<0.02	<0.02
		DETA		<0.02	0.02
Soybean Seed	One pre-plant and one late foliar season/ 1.63-1.73	BAPMA	7	<0.03	1.42
		DGA		<0.03	5.82
		DETA		<0.03	6.84
Wheat grain	One pre-plant and two foliar/ 0.69-0.73	BAPMA	6-7	0.098	0.91
		DGA		0.016	1.73
		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 Engenia Manufacturing Concentrate, 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

A value assessment was not required for the manufacturing concentrate.

Conclusion

Following review of the application, Engenia Manufacturing Concentrate was granted registration for use in manufacturing, formulating or repackaging pesticides containing the BAMPA salt of dicamba.

References

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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
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2531515 1992, Developmental toxicity (embryo-fetal toxicity and teratogenic potential) study of technical Dicamba administered orally via capsule to New Zealand white rabbits, DACO: 4.5.2

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Additional Information Used

Published Reference

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