

Evaluation Report for Category B, Subcategory 3.11 and 3.12 Application

Application Number: 2010-1547
Application: New Product Labels – New pests and new site or host
Product: M1691 Herbicide
Registration Number: 31198
Active ingredients (a.i.): Dicamba (Present as acid, amine salt, ester, potassium salt) (DIC)
PMRA Document Number : 2359807

Purpose of Application

The purpose of this application was to register the new end-use product M1691 Herbicide, containing 480 g a.e./L dicamba, present as the diglycolamine salt. This submission was reviewed by the PMRA jointly with the US and Japan. The formulation of M1691 Herbicide is a repack of Banvel II Herbicide (Registration Number 23957). The use pattern for M1691 Herbicide is similar to that registered for Banvel II Herbicide with the exception that it is also proposed for use alone or in tank mixture with Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Reg. No. 27487) on soybeans with both the dicamba tolerance and Roundup Ready 2 Yield (i.e. glyphosate-tolerance) traits, referred to as Roundup Ready 2 Xtend Soybeans (formerly Dicamba Tolerant Soybeans).

Chemistry Assessment

A chemistry assessment was not required for this application.

Health Assessments

The weight of evidence suggests that the DCGA and DCSA dicamba metabolites were equally or less toxic than dicamba based on the results of the toxicity tests. The established dietary risk assessment endpoints for dicamba (PRVD2007-05 – *The Use of Dicamba in Agricultural and Industrial Sites*) will be protective for the DCGA and DCSA metabolites.

Plant metabolism and residue data were submitted for dicamba in dicamba-tolerant soybeans. Residue data from field trials conducted in the United States were conducted to support the domestic use of M1691 Herbicide on Roundup Ready 2 Xtend Soybeans. Dicamba was applied to dicamba-tolerant soybeans (containing the glyphosate-tolerance trait) at exaggerated rates, and harvested according to label directions. In addition, a processing study in treated dicamba-tolerant soybeans (containing the glyphosate-tolerance trait) was reviewed to determine the potential for concentration of residues of dicamba into processed commodities. The remaining crops and use directions on the M1691 Herbicide label are the same compared to the registered Banvel II Herbicide label. As such, exposure to residues of dicamba in food and drinking water should not increase for any segment of the population, including infants, children, adults and seniors.

Maximum Residue Limit(s)

Residues of dicamba in/on Roundup Ready 2 Xtend Soybeans will be covered under the maximum residue limit (MRL) of 10 ppm established for dicamba and the metabolites 5-OH dicamba (benzoic acid, 2,5-dichloro-3-hydroxy-6-methoxy-) and DCSA (benzoic acid, 3,6-dichloro-2-hydroxy-) in/on dry soybeans. Residues in processed commodities not listed in Table 1 are covered under the MRL established for the raw agricultural commodity (RAC).

TABLE 1. Summary of Field Trial and Processing Data Used to Support the Use of M1691 Herbicide on Roundup Ready 2 Xtend Soybeans.

Commodity	Application Method/ Total Application Rate (kg a.e./ha)	PHI (days)	Residues (ppm)		Experimental Processing Factor	Currently Established MRL (ppm)	Recommended MRL (ppm)
			Min	Max			
dicamba-tolerant soybeans (containing the glyphosate-tolerance trait)	Pre-emergence + Foliar/2.24	73-98	<0.044	<0.474	0.11x [refined oil]	10 [dry soybeans]	None

No increase to the dietary burden of livestock is expected from the use of M1691 Herbicide on Roundup Ready 2 Xtend Soybeans when applied according to the approved label directions.

Exposure to residues of dicamba in food and drinking water following the use of M1691 Herbicide will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

The use of M1691 Herbicide for on cereals, field corn, low-bush blueberries, summerfallow and stubble, pastures, seedling grasses, rangeland and non-crop areas to control broadleaf weeds fits within the registered use pattern for dicamba. The use of M1691 Herbicide on dicamba resistant soybeans is an expansion of use; however, the potential exposure for mixers, loaders, applicators and post-application re-entry workers is not expected to result in risks of concern. No unacceptable risk is expected when workers follow the label directions and wear the personal protective equipment identified on the label.

Environmental Assessment

Buffer zones were calculated for all use patterns including the new use pattern for the dicamba-tolerant soybeans (i.e., maximum seasonal application rate is 2.45 L/ha; one application of 1.25 L/ha and two applications of 0.6 L/ha. The use for the control of multiple annual and perennial weeds is not expected to result in an increase in exposure to non-target organisms in the environment.

The application rate for use on Dicamba Tolerant/Roundup Ready 2 Yield Soybeans is very similar to the currently registered rate on other crops, such as corn on the Banvell II herbicide, of which M1691 Herbicide is a repack. As such, the risk to non-target organisms in the environment is not expected to be a concern, if used according to the label directions.

Value Assessment

The use pattern registered for Banvel II was extended to M1691 Herbicide based on the similarity of the two products. An evaluation of efficacy and crop tolerance data was conducted for the use of M1691 Herbicide, alone or in combination with Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide, on dicamba-tolerant and glyphosate-tolerant soybean (varieties designated as “Roundup Ready[®] 2 Xtend Soybeans”).

Efficacy assessment

M1691 Herbicide alone

The efficacy claims included in the registration of M1691 Herbicide applied alone at 0.6-1.25 L/ha (288-600 g a.e./ha) are supported because:

- these claims are already included in the registration of Banvel II Herbicide for pre-emergence or post-emergence use on field corn;
- while a claim of control of smooth pigweed is not included in the registration of Banvel II, it is supported, since it is similar to redroot pigweed biologically, morphologically and in life cycle, and since these two species are known to freely hybridize.

Tank mixes of M1691 Herbicide + Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide

The requested efficacy claims for tank mixtures of 900 g a.e./ha Roundup WeatherMax plus 288 or 600 g a.e./ha M1691 Herbicide are supported for one or more of the following reasons:

- submitted data support these claims;
- these claims are already included in the registration of Roundup WeatherMax applied to glyphosate tolerant (Roundup Ready 2 Yield) soybean cultivars at the same rates;
- these claims are already included in the registration of Banvel II Herbicide for pre-emergence or post-emergence use on field corn;
- there was no evidence of antagonism between Roundup WeatherMax and M1691 Herbicide.

Efficacy data were adequate to support a maximum of three applications of M1691 Herbicide, totaling up to a yearly maximum rate of 2.45 L/ha product per year (up to 1176 g a.e./ha per year), whether applied alone or in tank mixture(s) with Roundup WeatherMax, and when applied from preplant up to early flowering (with respect to crop stage).

Residual efficacy claims

Labelled residual weed control claims are supported because:

- the registration of Banvel II includes a registered claim of extended residual control of late germinating annual weeds when applied post-emergence to field corn at 1.25 L/ha (600 g

a.e./ha);

- submitted data demonstrated that control of these weeds (suppression for velvetleaf) was achieved when evaluated at 25-44 days following a preplant or pre-emergence (to the crop) application (i.e. at the second evaluation) of a tank mixture of 900 g a.e./ha Roundup WeatherMax plus 600 g a.e./ha M1691; and

- submitted data demonstrated that suppression of these weeds was achieved when evaluated at 25-44 days after a preplant or pre-emergence (to the crop) application (i.e. at the second evaluation) of a tank mixture of 900 g a.e./ha Roundup WeatherMax plus 300 g a.e./ha M1691.

Non safety adverse effects

The tolerance of dicamba-tolerant and glyphosate-tolerant soybean (i.e. Roundup Ready 2 Xtend Soybeans) to tank mixtures of M1691 Herbicide plus Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide was evaluated in 16 replicated efficacy trials. Several herbicide treatments consisting of different sequential combinations of one or more tank mixtures of two rates (300 or 600 g a.e./ha) of M1691 Herbicide plus 900 g a.e./ha Roundup WeatherMax with or without one or more applications of 900 g a.e./ha Roundup WeatherMax were evaluated. Crop tolerance was also assessed in nine replicated dedicated crop tolerance trials. Evaluated were several herbicide treatments that consisted of different sequential combinations of two or three tank mixtures of two rates (600 or 1200 g a.e./ha) of M1691 Herbicide plus 1800 or 3600 g a.e./ha Roundup WeatherMax with or without an application of 1800 or 3600 g a.e./ha Roundup WeatherMax alone. These treatments were essentially applied at 2x the labelled rates.

The data collectively indicated that soybean, i.e. Roundup Ready 2 Xtend Soybean, can be expected to exhibit an adequate margin of crop safety to M1691 Herbicide applied at 0.6 - 1.25 L/ha alone or in tank mixture with 1.67 L/ha Roundup WeatherMax, as well as to a yearly maximum rate of 2.45 L/ha.

Application of M1691 Herbicide alone or in tank mixture with Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide to soybean varieties with the dicamba-tolerance and glyphosate-tolerance traits (i.e. Roundup Ready 2 Xtend Soybean) will provide broad spectrum weed control for up to three applications per year from preplanting to the crop early flowering stage. M1691 Herbicide, containing dicamba that is classified by the Weed Science Society of America (WSSA) as a Group 4 Herbicide (a synthetic auxin), is expected to help mitigate the development of resistance of weeds to glyphosate, a WSSA Group 9 herbicide (inhibitor of EPSP synthase) as well as herbicides of other modes of action, such as those belonging to the Group 2 mode of action (inhibitors of acetolactate synthase, e.g. herbicides of the sulfonylurea chemical family), and to control herbicide resistant weed populations already present, including later season flushes of glyphosate resistant weeds. M1691 Herbicide, therefore, offers growers the opportunity to control glyphosate resistant weeds in the soybean crop, thereby reducing their prevalence in the following year's crop.

Conclusion

The PMRA has completed an evaluation of the subject application and has found the information sufficient to register M1691 Herbicide for application alone and in several tank mixtures to labeled crops, including application alone or in tank mixture with Roundup WeatherMax with

Transorb 2 Technology Liquid Herbicide to soybean varieties with the dicamba-tolerance and glyphosate-tolerance traits (i.e. Roundup Ready 2 Xtend Soybean) traits for broad spectrum weed control.

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