



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 9, 2016

Dr. James Nyangulu  
U.S. Agency Regulatory Affairs Manager  
Monsanto Company  
1300 I St., NW  
Washington, DC 20005

Subject: PRIA Label Amendment – Adding new uses on dicamba-resistant cotton and soybeans  
Product Name: M1768 Herbicide  
Alternate Brand Name: Xtendimax™ with VaporGrip™ Technology  
EPA Registration Number: 524-617  
Application Dates: 10/21/2016, 4/12/2016, and 11/19/2015, respectively  
Decision Number: 522837, 516207, and 511766

Dear Dr. Nyangulu:

1. The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(B) subject to the following conditions:
2. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
3. Be aware that proposed data requirements have been identified in a Preliminary Work Plan under Docket ID EPA-HQ-OPP-2016-0223-0010 at [www.regulations.gov](http://www.regulations.gov). For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Re-Evaluation Division.
4. This registration will automatically expire on 11/09/2018.
5. You must maintain a website at <http://Xtendimaxapplicationrequirements.com>. That website will include a list of products that have been tested pursuant to Appendix A and found, based upon such testing, not to adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology. The website will identify a testing protocol, consistent with Appendix A, that is appropriate for determining whether the tested product will adversely affect the drift properties of Xtendimax™ with VaporGrip™ Technology. The website will state that any person seeking to have a product added to the list must perform a study either pursuant to the testing protocol identified on the website or another protocol that has been approved for the particular

- purpose by EPA, and must submit the test data and results, along with a certification that the studies were performed either pursuant to the testing protocols identified on the website or pursuant to another protocol(s) approved by EPA and that the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology, to EPA. EPA will notify you when the Agency determines that a product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA. Testing of Tank-Mix Products must be conducted in compliance with procedures as stated forth in Appendix A.
6. All test data relating to the impact of tank-mixing any product with Xtendimax™ with VaporGrip™ Technology on drift properties of Xtendimax™ with VaporGrip™ Technology generated by you or somebody working for you must be submitted to EPA, along with a certification indicating whether the study was performed either pursuant to the testing protocols identified on the website or pursuant to other protocols approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology, at the following address: Chief of Environmental Risk Branch 1, Environmental Fate and Effects Division, Office of Pesticide Programs. If the certification states that the study was performed either pursuant to the testing protocol identified on the website or pursuant to another protocol approved by EPA, and the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Xtendimax™ with VaporGrip™, you may add the product to the list.
  7. The prohibition of using products in a tank-mix with Xtendimax™ with VaporGrip™ Technology unless the product used is contained on the list at [Xtendimaxapplicationrequirements.com](http://Xtendimaxapplicationrequirements.com), and the identification of the website address, shall be included in educational and information materials developed for Xtendimax™ with VaporGrip™ Technology, including the materials identified in Appendix D, Section B(1).
  8. You must develop and follow an Herbicide Resistance Management Plan (HRM) as laid out in Appendix D regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Grant Rowland by phone at 703-347-0254, or via email at Rowland.grant@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Kenny', with a long horizontal flourish extending to the right.

Daniel Kenny, Chief  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

## APPENDIX A

### Testing of Tank Mix Products for Spray Drift Properties

Products proposed for tank-mixing with may be added to the list of products that will not adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology contained on the web site if a study is performed under the testing conditions set forth below; the test information is reported as set forth below; and the results are interpreted as set forth below and the interpretation supports adding the tested product to the list of products that will not adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology:

#### Testing Conditions

Spray chamber test using conditions described in ASTM E-2798-11; or Wind Tunnel test using conditions described in EPA Final Generic Verification Protocol for Testing Pesticide Application Spray Drift Reduction Technologies for Row and Field Crops (September 2013)

Testing Media: Xtendimax™ with VaporGrip™ Technology + Xtendimax™ with VaporGrip™ Technology Proposed Tank Mix Product

Test Nozzle: Tee Jet® TTI 11004 at 63 psi

Number of Replicates: 3 for each tested medium

#### Reporting

Validation information as summarized in Appendix B

Full droplet spectrum to be reported for each replicate of each tested medium

Perform AGDISP (8.26) modeling run for each replicate droplet spectrum for each tested medium (AGDISP input parameters described in Appendix C)

Establish 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) spray drift deposition estimates from AGDISP run on each replicate for each tested medium

Establish mean and standard deviation of 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) deposition for the 3 replicates of each tested medium

One-tail (upper bound) t-test ( $p=Q.1$ ) to determine if proposed tank-mix product is above Xtendimax™ with VaporGrip™ Technology 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) spray drift deposition

### Interpretation of Results

If mean 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) deposition for proposed tank-mix product is not statistically greater than mean 110 foot deposition for Xtendimax™ with VaporGrip™ Technology, proposed tank-mix product can be added to the list of products that will not adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology contained on the web site. If mean 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) deposition for proposed tank-mix product is statistically greater than mean 110 foot (0.5 lb ae/A rate) or 220 foot (1.0 lb ae/A rate) deposition for Xtendimax™ with VaporGrip™ Technology, proposed tank-mix product cannot be added to the list of products that will not adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology contained on the web site.

Results from other testing protocols will be acceptable for adding products to the list of products that will not adversely affect the spray drift properties of Xtendimax™ with VaporGrip™ Technology provided that EPA has determined in writing that such other protocol is appropriate for such purpose.

## **APPENDIX B**

### Validation Criteria

- a. Detailed information of instrument setting and measurements
  - The distance from the nozzle tips to the laser settings
  - Measurements of airspeed and flow rate of liquid
  
- b. Detailed information of test substances
  - Volume composition and density of Xtendimax™ with VaporGrip™ Technology formulation and tank mixes
  
- c. Summary of the entire spray output distribution for each nozzle/tank mixes with statistical analysis of replicates.
  
- d. Graphical outputs of Sympatec Helos laser diffraction particle size analyzer FOR individual spectrum

Report of Dv0.1 (SD), Dv0.5 (SD), and DV0.9 (SD) as well as mean % fines of (< 141pm SD)

**APPENDIX C**  
**AGDISP Input Parameters**

Parameter	Value	Comments
<b>Application Method Section</b>		
Method	Ground	
Nozzle Type	Flat fan (Default)	The direct use of the DSD overrides the use of “nozzle type”
Boom Pressure	63 psi	If nozzles/tank mixes were tested at 63 psi. It has to be consistent with tank mix as well as Xtendimax™ with VaporGrip™ Technology for both TeeJet® and AIXR nozzles
Release Height	3 ft	Default
Spray Lines	20	Default
<b>Meteorology Section</b>		
Wind Type	Single height	Default
Wind Speed	15 mph	Under bound from label
Wind Direction	-90 deg	Worst-case and default
Temperature	65 F	Default
Relative Humidity	50%	Default
<b>Surface Section</b>		
Angles	0	Default
Canopy	None	Default
Surface Roughness	0.12 ft	Mean of “crops” cover type
<b>Application Technique Section</b>		
Nozzles	54, even spacing	Standard boom setup
DSD	From wind tunnel results, imported in library	
Atmospheric stability	Strong	Default
<b>Swath Section</b>		
Swath width	90 ft	Standard boom
Swath displacement	0 ft	Worst-case
<b>Spray Material Section</b>		
Spray volume rate	10 gal/A	From label
Volatile/nonvolatile fraction	M 1768 at 1.72% v/v	To calculate volatile/nonvolatile fraction in the tank mix for the model input, provide detailed information of the tested formulations and tank mixes. See sample calculation, below <sup>1</sup>
<sup>1</sup> The tested mixture was 1.72% (v/v) M-1768. M-1768 has a density of 10.2 lb/gal and contains 42.8% (w/v) dicamba DGA salt (2.9 lb acid equivalent/gal). For example, a 10-gallon batch would contain the following: M-1768 1.71% * 10 gal = 0.172 gal ; 0.172 gal * 10.2 lb/gal = 1.753 lb Water 10 gal (1280 fl oz) – 22 fl oz = 1258 fl oz = 82.0157 lb Total weight 1.753 lb + 82.016 lb = 83.769 lb Active ingredient fraction: 1.753 lb * 42.8% a.i. = 0.75 lb; 0.75 lb/83.769 lb = 0.00896 (dimensionless) Non-volatile fraction: 0.00896/0.428 = 0.021 (dimensionless)		

## APPENDIX D

### HERBICIDE RESISTANCE MANAGEMENT PLAN

Monsanto (MON) must:

#### A. Field Detection and Remediation Components:

1. Develop and implement an education program for growers, as set forth under the “Educational / Informational Component,” below, that identifies appropriate best management practices (BMPs), as set forth under the “Best Management Practices (BMPs) Component,” below, to avoid and control weed resistance, and that conveys to growers the importance of complying with BMPs. Such BMPs shall include that fields must be scouted after application to confirm herbicide effectiveness, and that users should report any incidence of lack of efficacy of this product against a particular weed species to Monsanto or a Monsanto representative.
2. If any grower informs you of a lack of herbicide efficacy, then you or your representative must make an effort to evaluate the field for “likely resistance” to M1768 herbicide for each specific species for which lack of herbicide efficacy is reported by applying the criteria set forth in Norsworthy, *et al.*, “Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations,” *Weed Science 2012 Special Issue:31–62 (hereinafter “Norsworthy criteria”)*<sup>1</sup> in each specific state until resistance to dicamba is confirmed for a specific weed species in that state using acceptable scientific methods. However, for each grower, you must continue to provide stewardship about resistance management throughout their use of this product. If resistance to dicamba is confirmed in a specific state for a specific weed species, then MON must immediately report such confirmation to EPA and need no longer investigate reports of lack of herbicide efficacy regarding that specific species in that specific state, but MON must continue to make an effort to help address of lack of herbicide efficacy regarding any other weed species in any such state;
3. Keep records of all field evaluations for “likely resistance” for a period of 3 years, and make such copies available to EPA upon request; and
4. If one or more of the Norsworthy criteria are met, then for a weed species not already confirmed to be resistant to dicamba in that specific state, Monsanto will:
  - a. Provide the grower with specific information and recommendations to control and contain likely resistant weeds, including retreatment and/or other non-chemical controls,

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<sup>1</sup> The Norsworthy “likely herbicide resistance” criteria are: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; or (2) a spreading patch of uncontrolled plants of a particular weed species; or (3) surviving plants mixed with controlled individuals of the same species. The identification of any of these criteria in the field indicates that “likely herbicide resistance” is present.



as appropriate. If requested by the grower, MON or their agent will become actively involved in implementation of weed control measures;

- b. Request, at the time of the initial determination that one or more of the Norsworthy criteria are met and prior to any application of alternative control practices, that the grower provide you with access to the relevant field(s) to collect specimens of the likely resistant weeds (potted specimens or seeds) for further evaluation in the greenhouse or laboratory, and so collect such specimens if possible (or, alternatively, request that the grower provide such specimens to you, at your expense);
- c. Commence greenhouse or laboratory studies to confirm resistance as soon as practicable following sample collection;
- d. To the extent possible, contact or visit the grower in an appropriate timeframe after implementation of the additional weed control measures in order to evaluate success of such measures; and
- e. If the additional weed control measures were not successful in controlling the likely resistant weeds, then:
  - i. Work with the grower to determine the reason(s) why the additional control measures were not successful;
  - ii. Report annually the inability to control the likely resistant weeds to relevant stakeholders; and
  - iii. Offer to further assist the grower in controlling and containing the likely resistant weeds, including retreatment and/or other non-chemical controls, as appropriate.

## **B. Educational / Informational Component:**

1. Develop and implement an education program for growers that includes the following elements:
  - a. The education program shall identify appropriate best management practices (BMPs), set forth under the “Best Management Practices (BMPs) Component,” below, to avoid and control weed resistance, and shall convey to growers the importance of complying with BMPs;
  - b. The education program shall include at least one written communication regarding herbicide resistance management each year, directed to users of M1768 herbicide for use over-the-top on dicamba tolerant soybean or cotton; and
  - c. You must make the education program available to MON sales representatives for distribution to growers.
2. Provide to EPA the original education program within three months of the issuance of this registration.

**C. Evaluation Component:**

1. Monsanto will annually conduct a survey directed to users of M1768 herbicide for use over-the-top of dicamba tolerant soybean or cotton. This survey must be based on a statistically representative sample. The sample size and geographical resolution should be adequate to allow analysis of responses within regions, between regions, and across the United States. This survey shall evaluate, at a minimum, the following:
  - a. Growers' adherence to the terms of the M1768 Use Directions and Label Restrictions, and
  - b. Whether growers have encountered any perceived issue with non-performance or lack of efficacy of M1768 herbicide and, if so, how growers have responded.
2. Utilize the results from the survey described in paragraph 1 of this section to annually review, and modify as appropriate for the upcoming growing season, the following:
  - a. Efforts aimed at achieving adoption of BMP's;
  - b. Responses to incidents of likely resistance and confirmed resistance; and
  - c. The education program. At the initiative of either EPA or MON, EPA and MON shall consult about possible modifications of the education program.

**D. Reporting Component:**

1. Submit annual reports to EPA by January 15 of each year, beginning on January 15, 2018. Such reports shall include:
  - a. Annual sales of M1768 herbicide by state;
  - b. The first annual report shall include the current education program and associated materials, and subsequent annual reports shall include updates of any aspect of the education program and associated materials that have materially changed since submission of the previous annual report;
  - c. Summary of your efforts aimed at achieving implementation of BMP's;
  - d. Summary of your determinations as to whether any reported lack of herbicide efficacy was "likely resistance," your follow-up actions taken, and, if available, the ultimate outcome (e.g., evaluation of success of additional weed control measures) regarding each case of "likely resistance." In the annual report, MON will list the cases of likely resistance by county and state.
  - e. The results of the annual survey described in paragraph 1 under "Evaluation Component," above, including whether growers are implementing herbicide resistance

BMPs, and a summary of your annual review and possible modification – based on that survey – of the education program, , and response to reports of likely resistance, described in paragraph 2 under “Evaluation Component,” above; and

- f. Summary of the status of any laboratory and greenhouse testing performed by, or at the direction of, Monsanto following up on incidents of likely resistance, performed in the previous year. Data pertaining to such testing need not be included in the annual reports, but such data must be made available to EPA upon request.
1. Following your submission of the annual report, you shall meet with the EPA at EPA’s request in order to evaluate and consider the information contained in the report.
  - 2.

**E. Best Management Practices (BMPs) Component:**

1. Best management practices (BMPs) must be identified in your education program. Growers will be advised of BMP’s in product literature, educational materials and training. The following are examples of BMPs:
  - a. Regarding crop selection and cultural practices:
    - i. Understand the biology of the weeds present.
    - ii. Use a diversified approach toward weed management focused on preventing weed seed production and reducing the number of weed seeds in the soil seed-bank.
    - iii. Emphasize cultural practices that suppress weeds by using crop competitiveness.
    - iv. Plant into weed free fields, keep fields as weed free as possible, and note areas where weeds were a problem in prior seasons.
    - v. Incorporate additional weed control practices whenever possible, such as mechanical cultivation, biological management practices, crop rotation, and weed-free crop seeds, as part of an integrated weed control program.
    - vi. Do not allow weed escapes to produce seeds, roots or tubers.
    - vii. Manage weed seed at harvest and post-harvest to prevent a buildup of the weed seed-bank.
    - viii. Prevent field-to-field and within-field movement of weed seed or vegetative propagules.
    - ix. Thoroughly clean plant residues from equipment before leaving fields.
    - x. Prevent an influx of weeds into the field by managing field borders.
    - xi. Fields must be scouted before application to ensure that herbicides and application rates will be appropriate for the weed species and weed sizes present.

- xii. Fields must be scouted after application to confirm herbicide effectiveness and to detect weed escapes.
- xiii. If resistance is suspected, treat weed escapes with an alternate mode of action or use non-chemical methods to remove escapes.

b. Regarding herbicide selection:

- i. Use a broad spectrum soil applied herbicide with a mechanism of action that differs from this product as a foundation in a weed control program.
- ii. A broad spectrum weed control program should consider all of the weeds present in the field. Weeds should be identified through scouting and field history.
- iii. Difficult to control weeds may require sequential applications of herbicides with alternative mechanisms of action.
- iv. Fields with difficult to control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action.
- v. Apply full rates of this herbicide for the most difficult to control weed in the field. Applications should be made when weeds are at the correct size to minimize weed escapes.
- vi. Do not use more than two applications of this herbicide or any herbicide with the same mechanism of action within a single growing season unless mixed with another mechanism of action herbicide with overlapping spectrum for the difficult to control weeds.
- vii. Report any incidence of lack of efficacy of this product against a particular weed species to Monsanto or a Monsanto representative.

This list may be updated or revised as new information becomes available.