

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 12, 2017

E. David Lewis Agent for Nissan Chemical Industries, Ltd. c/o Lewis & Harrison, LLC 122 C St., NW, Suite 505 Washington, DC 20001

Subject: PRIA Label Amendment – New Use on Quizalofop-Resistant Provisia[™] Rice Product Name: Quizalofop-P-Ethyl MUP Herbicide EPA Registration Number: 33906-10 Application Date: May 21, 2015 Decision Number: 505383

Dear Mr. Lewis:

The application referred to above, submitted under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA section 3(c)(5) with the following conditions:

- 1. You must submit and/or cite all data required for registration/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
- 2. The use on Provisia[™] Rice will automatically <u>expires on January 15, 2022</u>, unless the Agency amends this condition otherwise.
- 3. You must develop and follow an Herbicide Resistance Management Plan (HRM) as described in Appendix A regarding grower agreements, field detection and remediation, education, evaluation, reporting, and best management practices (BMPs).
- 4. You must submit annual reports to the Agency by January 15th of each year beginning in 2018 as outlined in Appendix A Section D, "Reporting Component," until the Agency amends this condition otherwise.

A stamped copy of the labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one 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.

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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 these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Mindy Ondish by phone at 703-605-0723, or via email at <u>ondish.mindy@epa.gov</u>.

Sincerely.

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

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APPENDIX A

Herbicide Resistance Management Plan for ProvisiaTM Rice

Nissan Chemical Industries, Ltd. ("Nissan") must:

A. Grower Agreements, Field Detection and Remediation Components

- Require that any person who purchases any Provisia[™] Rice seed sign an enforceable binding contract (similar to the sample agreement provided to the EPA), herein referred to as a "grower agreement." In such grower agreement, Nissan will reinforce with users of this product the critical importance of following resistance-management practices. This includes stressing the need for pre- and post-application field scouting and that a lack of herbicide efficacy should be reported promptly to Nissan or its representatives;
- 2. Provide a copy of the grower agreement to EPA;
- 3. Retain copies of all executed grower agreements for a minimum of three years from the date of execution, and make such copies available to EPA upon request;
- 4. If any grower informs Nissan or its representatives of a lack of herbicide efficacy in a weed species listed on product labeling, then Nissan or its representatives must make an effort to evaluate the field for likely-resistance to this product by applying the criteria below, as set forth in Norsworthy, *et al.*, "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations" Weed Science 2012 Special Issue: 31-62 ("Norsworthy criteria");

Norsworthy, et al. Criteria for Determining Possible (Likely) Herbicide Resistance

- 1) Failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; and/or
- 2) A spreading patch of non-controlled plants of a particular weed species; and/or
- *3)* Surviving plants mixed with controlled individuals of the same species.
- 5. Keep records of all field evaluations for likely-resistance for a minimum of three years, and make such copies available to EPA upon request; and
- 6. If one or more of the Norsworthy criteria are met, then:
 - a. Provide the grower with specific information and recommendations to control and contain likely-resistant weeds, including retreatment and/or other non-chemical controls, as appropriate. If requested by the grower, Nissan 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 access to the relevant field(s) to collect specimens of the likelyresistant weeds (potted specimens or seeds) for potential further evaluation in the greenhouse or laboratory, and to collect such specimens if possible (or, alternatively, request that the grower provide such specimens to Nissan at Nissan's expense);

- c. Conduct greenhouse or laboratory studies to confirm resistance as soon as practicable following sample collection, if technically feasible;
- 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 unsuccessful;
 - ii. Report annually the inability to control the likely-resistant weeds to relevant stakeholders; and
 - iii. Offer to further assist the grower with technical expertise on how to control and contain the likely-resistant weeds, including retreatment and/or other non-chemical controls, as appropriate.

B. <u>Educational/Informational Component</u>

- 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 "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 to purchasers of Provisia[™] Rice seed (separate and apart from the grower agreement); and
 - c. The education program shall be made available to Nissan sales representatives for distribution to growers.
- 2. Provide a copy of the education program to EPA.

C. Evaluation Component

- 1. Annually conduct a survey of users of Provisia[™] Rice seed. This survey must be based on a statistically representative sample of users of Provisia[™] Rice seed. 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 grower agreements; and
 - b. Whether growers have encountered any perceived issue with non-performance or lack of efficacy of this product, 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 compliance with the grower agreement;
 - b. Responses to incidents of likely weed resistance and confirm weed resistance; and
 - c. The education program. At the initiative of either EPA or Nissan, both parties shall consult about possible modifications to the education program.

D. <u>Reporting Component</u>

- 1. Submit annual reports to EPA by January 15th of each year beginning in 2018. The reports shall include:
 - a. Annual sales of Provisia[™] Rice seed and its associated herbicide product by state;
 - b. The current grower agreement;
 - c. 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;
 - d. Summary of efforts aimed at achieving compliance with the grower agreement;
 - e. Summary of determinations as to whether any reported lack of herbicide efficacy was due to likely-resistance, any follow-up actions taken, and if available, the final outcome (e.g., evaluation of success of additional weed control measures) regarding each case of likely-resistance. The annual report shall list the cases of likely-resistance by county and state;

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- f. The results of the annual survey described in paragraph 1 of the Evaluation Component above, including whether growers are implementing herbicide resistance BMPs, and a summary of Nissan's annual review and possible modification, based on the survey, of the education program, grower agreement compliance efforts, and response to reports of likely-resistance, described in paragraph 2 of the Evaluation Component above; and
- g. Summary of the status of any laboratory and greenhouse testing performed by or at the direction of Nissan, in response to 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.
- 2. Following submission of the annual report, Nissan shall meet with EPA at EPA's request in order to evaluate and consider the information contained in the report.

E. <u>Best Management Practices Component</u>

Identify best management practices (BMPs) in the education program. The grower agreement shall advise growers to follow BMPs. The following are examples of BMPs:

Regarding crop selection and cultural practices:

- Understand the biology of the weeds present.
- Use a diversified approach towards weed management focused on preventing weedseed production and reducing the number of weed seeds in the soil seed-bank.
- Emphasize cultural practices that suppress weeds by using crop competitiveness.
- Plant into weed-free fields, keep fields as weed-free as possible, and note areas where weeds were a problem in prior seasons.
- 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.
- Do not allow weed escapes to produce seeds, roots, or tubers.
- Manage weed seed at harvest and post-harvest to prevent a buildup of the weed seedbank.
- Prevent field-to-field and within-field movement of weed seed or vegetative propagules.
- Thoroughly clean plant residues from equipment before leaving fields.
- Prevent an influx of weeds into the field by managing field borders.
- Fields should be scouted before application to ensure herbicide and application rates will be appropriate for the weed species and weed sizes present.
- Fields should be scouted after application to confirm herbicide effectiveness and to detect weed escapes.

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• If resistance is suspected, treat weed escapes with an alternate mode-of-action herbicide or use non-chemical methods to remove escapes.

Regarding herbicide selection:

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.

- 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.
- Difficult-to-control weeds may require sequential applications of herbicides with alternative mechanisms of action.
- Fields with difficult to control weeds should be rotated to crops that allow the use of herbicides with alternative mechanisms of action.
- Apply full rates of this herbicide for the most difficult to control weeds in the field. Applications should be made when weeds are at the correct size to minimize weed escapes.
- 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.
- Report any incidence of non-performance of this product against a particular weed species to Nissan or its representative.

Quizalofop-P-Ethyl MUP	DIRECTIONS FOR USE It is a violation of Federal law to use this product in a manner inconsistent with its
Harbicida	only for formulation into an end use herbicide for the following uses:
FOR FORMULATION USE ONLY	1. Terrestrial Food and Nonfood Crops Barley, Canola and Crambe, Cotton, Dry and Succulent Peas, Dry Beans, Eucalyptus, Flax, Lentils, Mint (Spearmint and
ACTIVE INGREDIENT: Quizalofop-P-ethyl Ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	Peppermint), Non-Food/Non-Feed Crops Grown for Seed Production, Pineapple, Quizalofop-Tolerant Provisia TM Rice, Quizalofop-Tolerant Perennial Ryegrass (Non- Food/Non-Feed) Grown Only for Seed Production, Snap Beans, Soybeans, Sugarbeets, Sunflowers, Wheat 2. Terrestrial Non-crop areas.
EPA Reg. No. 33906-10 EPA Est. No. 33906-JP-002	Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
KEEP OUT OF REACH OF CHILDREN	 Uses for experimental purposes that are in compliance with USEPA requirements.
CAUTION PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS	Formulators using this product are responsible for obtaining EPA registration of their formulated product.
CAUTION! CAUSES EYE IRRITATION. Do not get in eyes, on skin or on clothing. Avoid inhaling dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.Remove and wash	STORAGE AND DISPOSAL Do not contaminate water, food or feed by storage or disposal.
contaminated clothing before reuse. FIRST AID	vater, other pesticides, fertilizer, food or feed in storage.
If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.	PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container.
If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.	Utter for recycling, it available, or for reconditioning, it appropriate. <u>Fiber Drum With Liner:</u> Completely empty liner by shaking and tapping sides or bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of <u>lister is a constant loadell or bit indication</u> and load load or theories.
If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if	drum is contaminated and cannot be reused, dispose of drum in same manner.
possible. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or	In case of large-scale spillage regarding this product, call: CHEMTREC 800-424-9300
doctor, or going for treatment. ENVIRONMENTAL HAZARDS	
This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes streams, ponds, estuaries, oceans or other	ACCEPTED
waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has	01/12/2017
been notified in writing prior to discharge. Do no discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For quidance contact your State Water Board or Regional Office of	Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the posticide realistered under
the EPA. Do not contaminate water when disposing of equipment washwaters.	EPA Reg. No. 33906-10

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Net 110 Ib (50 kg) Lot No._____ Made in Japan

NOTICE OF WARRANTY

Nissan warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Nissan. To the extent consistent with applicable law, In no case shall Nissan be liable for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. With regard to any formulator's product prepared from this manufacturing use product, Nissan disclaims any liability related to unsupported and unlisted uses not appearing on this label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NISSAN MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE

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