



**US Environmental Protection Agency
Office of Pesticide Programs**

**Extension of the Exclusive Use
Period for Rynaxypyr Technical**

January 29, 2007

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**PESTICIDE PETITION
FOR EXEMPTION FROM THE REQUIREMENT FOR TOLERANCES FOR
RESIDUES OF DPX-E2Y45 (CHLORANTRANILIPROLE) ON
BRASSICA VEGETABLES, COTTON, CUCURBITS, GRAPES, FRUITING
VEGETABLES, LEAFY VEGETABLES, POME FRUITS, POTATOES & STONE
FRUITS**

NOTICE

The Information Herein Contains Material of a Proprietary Nature
And is Provided for use only in Considering the Proposed Labeling and the Proposed
Experimental Use Permit

Submitted by
E.I. du Pont de Nemours and Company

E.I. du Pont de Nemours and Company
DuPont Crop Protection
Newark, Delaware 19711-0030
January 2007

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DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

ACTION: Food use - Submitted after an Experimental Use Permit

FEE CATEGORY: R-5

REGISTRATION FEE: \$183,750

January 29, 2007

DELIVERED BY COURIER SERVICE

Document Processing Desk – (REGFEE)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Application for Registrations of Products Containing A New Active Ingredient, DPX-E2Y45 (Chlorantraniliprole):

- o DuPont™ Rynaxypyr™ Technical Insecticide,
- o DuPont™ Coragen™ SC Insecticide,
- o DuPont™ Altacor™ WG Insecticide and
- o DuPont™ E2Y45 SC Insecticide;

A Petition for Establishment of Tolerance Exemptions; and
A Request for Extension of Exclusive Use under FIFRA (C)(1)(F)(ii)

To Whom It May Concern:

DuPont herein submits an application for registration of products containing the active ingredient DPX-E2Y45 (Common name: chlorantraniliprole):

- DuPont™ Rynaxypyr™ Technical Insecticide,
- DuPont™ Coragen™ SC Insecticide,
- DuPont™ Altacor™ WG Insecticide and
- DuPont™ E2Y45 SC Insecticide

This application covers both food uses (PRIA Fee Category R-5) and non-food uses (PRIA Fee Category R-7). DuPont has previously submitted an application for an Experimental Use Permit for this active ingredient (352-EUP-RTN) and has paid the \$367,500.00 fee for this application. According to EPA's PRIA fee policy, "[a]ll uses (food and nonfood) included in any original application or petition for a new active

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ingredient or a first food use are covered by the base fee for that application" (Footnote 1, Table 1, 69 FR 12772 - 12780, March 17, 2004). Therefore, DuPont proposes that the PRIA fee for this submission should be no greater than \$183,750.00.

DuPont understands that this submission will be used in a workshare project between several international regulatory agencies. DuPont supports this workshare effort with the understanding that the Agency will maintain all of DuPont's data protection and other rights outlined in the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

DuPont is simultaneously submitting an identical applications to the California Department of Pesticide Regulation (CDPR). We hereby request that the Agency support and cooperate with CDPR to enable a rapid review and approval at the state level.

DuPont wishes to acknowledge its cooperation with and the support of the US IR-4 Program and the Canadian Pest Management Centre in this submission. These programs conducted two of the magnitude of residue studies which resulted in the following included reports: "E2Y45: Magnitude of the Residue on Grape" (Report No. IR-4 09388, MRID 46979944) and "E2Y45: Magnitude of the Residue on Peach" (Report No. IR-4 09389, MRID 46979945).

Accompanying this letter are:

- Three copies of CDs containing the data supporting the proposed labeling
- Two copies of data supporting the proposed labeling printed from the CDs
- A Data Transmittal Document which has MRID numbers previously provided by the Agency assigned to the studies being submitted
- A letter petitioning the Agency for tolerance exemptions
- EPA forms 8570-1 (application) and 8570-4 (CSF) for each proposed product
- EPA data matrix forms 8570-35 (public) and 8570-35 (confidential)
- Five copies of proposed labeling for each product

Also enclosed with this letter is a list of documents (Attachment 1) included in the EUP submission which are not relevant for this submission.

A Request for Extension of Exclusive Use under FIFRA (C)(1)(F)(ii)

FIFRA (C)(1)(F)(ii) requires the Agency to extend the period of exclusive use for data supporting pesticide products 1 additional year for each 3 minor uses registered within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator. The extension is required if the Administrator "determines that, based on information provided by an applicant for registration... that... (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health; (III) the minor use pesticide plays or

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will play a significant part in managing pest resistance; or (IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.”

In this application, DuPont has submitted information which clearly establishes that DPX-E2Y45 is considerably less toxic to humans than many alternative insecticides. In fact, DPX-E2Y45 is remarkable in its low toxicity to humans and other mammals, birds, fish and many other non-target species. A summary of the toxicology results for DPX-E2Y45 can be found in the ANNEX IIA: SECTION 3: MAMMALIAN TOXICOLOGY (TIER II - DOCUMENT M-II), DuPont Report No. DuPont-18271 (MRID 46979810). A comparison of the toxicology of DPX-E2Y45 with other competitive compounds can be found in the document entitled “Reduced Risk Rationale for Use of DPX-E2Y45 on Apples, Lettuce, Peaches, Pears, Tomatoes and Turf” (DuPont Report Number DuPont-20218, MRID 46980001).

Additionally, due to its unique mode of action, which is unlike any currently registered insecticide, DPX-E2Y45 will play an important role in managing pest resistance. The availability of many different products with differing modes of action is of vital importance to extending the usefulness of insect resistance management programs. Lack of cross resistance makes E2Y45 an ideal tool for controlling pyrethroid-resistant, organophosphate-resistant and carbamate-resistant lepidopteran pests. The E2Y45 label will specify that no more than two consecutive (successive) applications can be made to a given pest species. Then, E2Y45 should be rotated with an effective product having a different mode of action. The label will also recommend limiting the number of applications to two for a particular pest insect within any 30 day period.

Also, E2Y45 may be used as part of an IPM program, which can include biological, cultural, and genetic practices, aimed at preventing economic pest damage. IPM principles and practices include field scouting or other detection methods, correct target pest identification, population monitoring, rotation of insecticides with different modes-of-action, and treating when target pest populations reach locally determined action thresholds.

E2Y45 will help broaden and strengthen the use of integrated pest management (IPM) strategies. It is fully compatible with use in IPM programs. E2Y45 is complementary to other lower-risk products, such as Bt, spinosad, indoxacarb, and certain insect growth regulators such as methoxyfenozide and tebufenozide, all of which fit well with IPM programs. E2Y45 can be used in programs that include both foliar-applied Bt and Bt-modified crops. It complements the spectrum of Bt by controlling difficult insect pests like beet armyworm and fall armyworm. When integrated into field programs, it will help preserve most beneficial species, including parasites and predators, which play an important role in IPM.

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DuPont is submitting data for the following minor crops in this submission:

1. Pear
2. Peach
3. Plum
4. Sweet Cherry
5. Sour Cherry
6. Broccoli
7. Cauliflower
8. Mustard Greens
9. Cabbage
10. Cucumber
11. Summer Squash
12. Cantaloupe/Muskmelon
13. Bell Pepper
14. Non-Bell Pepper
15. Head Lettuce
16. Leaf Lettuce
17. Celery
18. Spinach

The proposed labeling submitted for approval contains these crops, along with several major crops. As such, DuPont is hereby requesting that the Administrator approve an extension of the exclusive use period for an additional 3 years.

Please call me at 302/451-4517 if you have any questions.

Sincerely,



Richard A. Carver, Ph.D.
Sr. Product Registration Manager