

## I. Background

In the Federal Register of December 8, 1985, notice was published announcing the final approval of a revised DOD pesticide applicator certification plan. The DOD has again revised its certification plan to reflect updated administrative procedures and the addition of three new subcategories. This newly revised plan has been submitted to EPA for approval. The revised plan will continue to cover workers from the three branches of the Armed Forces. The revised plan will retain the aerial applicator category contained in the current plan. The revised plan will add the following new subcategories: (1) Subcategory 3a., soil fumigation under the existing ornamental and turf category, (2) subcategory 6a., grassland and non-crop agricultural land under the existing right-of-way category, and (3) subcategory 7a., stored product fumigation under the existing industrial, institutional, structural, and health-related category. The remaining categories in the revised certification plan are similar to the established EPA categories. The DOD estimates that the number of applicators to be certified in the newly established subcategories will not exceed 50 applicators.

The certification program will continue to be administered by the Armed Forces Pest Management Board within the Office of the Secretary of Defense. Certification and recertification will be required by taking and passing of a written examination. Recertification will be required every 3 years.

EPA finds that the revised DOD certification plan fully meets the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act and the regulations at 40 CFR part 171. Therefore, EPA announces its intention to approve the revised DOD certification plan.

Interested persons are invited to submit written comments on EPA's intention to approve the revised DOD certification plan.

## II. Public Docket

A record has been established for this action under docket number "OPP-00465" (including comments submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field

Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this action, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

### List of Subjects

Environmental protection.

Dated: February 5, 1997.

Susan H. Wayland,

*Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

[FR Doc. 97-3381 Filed 2-11-97; 8:45 am]

BILLING CODE 6560-50-F

### [PF-707; FRL-5587-2]

#### **American Cyanamid Company; Pesticide Tolerance Petition Filing**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of filing.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of tolerances for residues of dithianon (5,10-dihydro-5,10-dioxonaphtho[2,3-b]-1,4-dithiin-2,3-dicarbonitrile) in or on pome fruits and dried hops. This notice includes a summary of the petition that was prepared by the petitioner, American Cyanamid Company.

**DATES:** Comments, identified by the docket number [PF-707], must be received on or before, March 14, 1997.

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by docket number [PF-707]. Electronic comments on this notice of filing may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Product Manager (PM 22), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, Room 229, 1921 Jefferson Davis Highway, Arlington, VA, 703-305-7740, e-mail: giles-parker.cynthia@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition (PP 6E4781) from American Cyanamid Company, P.O. Box 400, Princeton, NJ 08543, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide dithianon in or on the raw agricultural commodity (RAC) pome fruits at 5 parts per million (ppm) and dried hops at 100 ppm. The proposed analytical methods are HPLC methods with UV detection for pome fruits (apples and pears) and with electrochemical detection for quantitation for hops.

EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of the FFDCA; however, EPA has

not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

As required by section 408(d) of the FFDCFA, as recently amended by the Food Quality Protection Act (FQPA) Pub. L. 104-170, American Cyanamid included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of American Cyanamid. EPA is in the process of evaluating the petition. As required by section 408(d)(3) of the FFDCFA, EPA is including the summary as a part of this notice of filing. EPA has made minor edits to the summary for the purpose of clarity.

#### I. Petition Summary

On August 20, 1996, American Cyanamid Company petitioned the EPA for an import tolerance for dithianon residues on pome fruits (with representative crops of apples and pears) and dried hops. This is the first tolerance petition for dithianon fungicide in the United States.

Section 408(b)(2)(A) of the amended FFDCFA allows the EPA to establish a tolerance only if the Administrator determines that there is a "reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." All of the studies required for the proposed import tolerance have been completed and submitted to EPA for review. The available information indicates there is a reasonable certainty that no harm will result from various types of exposure to dithianon. The following is a summary of the information submitted to the EPA to support the establishment, under section 408(b)(2)(D) of the amended FFDCFA, of an import tolerance for dithianon on pome fruits and dried hops.

#### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of dithianon in plants is adequately understood. Metabolism studies in three diverse crops demonstrate a similar pattern of dithianon metabolism with a significant amount of unchanged parent compound remaining on the plant surfaces. The metabolism of dithianon in plants results in a large number of fragments in only trace amounts. Hence, parent dithianon is the only residue of concern.

2. *Analytical method.* Two practical analytical methods for detecting and measuring levels of dithianon in pome fruits (apples and pears) and in hops have been submitted to EPA. The analytical method for apples and pears is an HPLC method with UV detection. For hops, an HPLC method with electrochemical detection for quantitation was submitted. Both methods are appropriate for enforcement purposes.

3. *Magnitude of residues.* Residue field trials were conducted in representative countries exporting the majority of the RAC of this petition to the United States. For the pome fruit crop group, field residue trials on apples were conducted in France, New Zealand, Germany, and Brazil and on pears in France, Australia, and New Zealand. These studies cover a wide range of geography with diverse climates and growing conditions, as well as various cultural practices. The residue values reported in the tolerance petition were all less than the proposed tolerance of 5 ppm for pome fruits. Hop residue trials conducted in Germany support the dried hop tolerance. Except for one outlier, the field residue levels of dithianon in dried hops were less than the proposed tolerance of 100 ppm.

Of the crops for which this tolerance is requested, only apples have processed commodities. Apple processing studies submitted in this petition indicate that dithianon does not concentrate in apple juice, but does concentrate in the wet apple pomace. It is unlikely that apple pomace will be imported into the United States. Therefore, an import tolerance is not necessary for that processed commodity.

#### B. Toxicological Profile

A complete, valid and reliable database of mammalian toxicology studies supports the tolerance for dithianon on pome fruits and dried hops.

1. *Acute toxicity.* Dithianon has a low order of acute toxicity to rats by the oral route of exposure with an LD<sub>50</sub> (females) greater than 678 milligram/kilogram (mg/kg) and LD<sub>50</sub> (males) greater than 720 mg/kg. Since this petition is for an import tolerance, oral toxicity data sufficiently assesses the risk of acute exposure for this use.

2. *Genotoxicity.* The collective data from an extensive battery of *in vitro* and *in vivo* tests covering all major genetic end-points, including an *in vivo* chromosomal aberration assay, show that dithianon does not pose a genotoxic risk and is not likely to be a genotoxic carcinogen.

3. *Reproductive and developmental toxicity.* Results from a 2-generation reproductive toxicity study in rats show that dithianon is not a reproductive toxicant. Developmental toxicity studies in rats and rabbits revealed no evidence of teratogenic effects for fetuses of either species and no evidence of development effects in the absence of maternal toxicity. The no observed effect levels (NOELs) for fetal/developmental toxicity are established at 20 mg/kg/day in rats and 25 mg/kg/day in rabbits. The maternal NOELs are 20 mg/kg/day in rats and 10 mg/kg/day in rabbits. A 2-generation reproduction study in rats supports a NOEL for fertility/reproductive toxicity of 600 ppm (highest concentration tested) or 42 mg/kg/day. In the reproduction study, the parental NOEL was 200 ppm or 15 mg/kg/day.

4. *Subchronic toxicity.* Short-term exposure of mice and rats to dithianon technical resulted in slight anemia. Mice also exhibited hemosiderin deposition in the liver, and rats showed increased kidney and liver weights and histopathological findings in the kidney (females only). Short-term exposure of dogs to dithianon resulted in decreased body weight or weight gain, decreased food consumption, and increased kidney weight. The NOEL in a 28-day oral study in mice was 100 ppm or 15 mg/kg/day and for rats the NOEL was 315 ppm or 31.5 mg/kg/day. In 90-day oral studies in rats and dogs the NOELs were 180 ppm or 15.5 mg/kg/day and 200 ppm or 3.0 mg/kg/day, respectively.

5. *Chronic toxicity.* Findings similar to those observed in short-term toxicity studies were also apparent in the long-term dietary toxicity studies conducted in dogs, rats and mice. Pre-neoplastic and neoplastic lesions were observed in the life-time rat dietary study in females. However, the collective evidence from this study and special mechanistic studies showed that these lesions occur due to a regenerative response of the kidney basophilic tubules, which follow persistent cellular damage to kidney proximal tubular epithelial cells. Thus, a threshold for these lesions exists. Moreover, these lesions were only noted following a 24-month dietary exposure to 600 ppm of dithianon, a concentration that exceeded the Maximum Tolerated Dose (MTD), as evidenced by markedly depressed body weight gains in females as compared to controls. Pre-neoplastic or neoplastic lesions were not observed in the life-time dietary study in mice, even at a concentration of dithianon that exceeded the MTD.

In a 1-year chronic toxicity study in dogs, the NOEL was 40 ppm or 1.6 mg/

kg/day. The NOEL for chronic effects in mice from the 18-month combined chronic toxicity and oncogenicity study was 20 ppm or 3.0 mg/kg/day, while the NOEL for potential oncogenic effects was 500 ppm or 75 mg/kg/day, which is the highest concentration tested. In the 24-month combined chronic toxicity and oncogenicity study in rats, the NOEL for chronic effects was 20 ppm or 1.0 mg/kg/day. The carcinogenicity NOEL was 120 ppm for females or 6.0 mg/kg/day.

6. *Animal metabolism.* The rat and goat metabolism studies indicate that the qualitative nature of the residues of dithianon in animals is adequately understood. Elimination of dithianon via excreta is rapid. The metabolism data suggests that unabsorbed dithianon is broken down in the gastrointestinal tract, since only very low concentrations of the unaltered parent were identified in the fecal excreta. A hen metabolism study is not required, because pome fruits (represented by apples and pears) and hops are not used as significant feedstuff for poultry.

In the metabolism studies using radio labeled dithianon, examination of organs, tissues, and milk indicated that accumulation is not of concern. Additionally, repeated dosing did not result in the accumulation of total radioactive residues.

7. *Metabolite toxicology.* No toxicologically significant metabolites were detected in plant or animal metabolism studies. Therefore, toxicology studies with metabolites are not required.

8. *Endocrine effects.* Collective organ weights and histopathological findings from the 2-generation rat reproductive study, as well as from the subchronic and chronic toxicity studies in three different animal species, demonstrate no apparent estrogenic effects or treatment-related effects on the endocrine system.

### C. Aggregate Exposure

1. *Dietary Exposure—i. Food.* The Theoretical Maximum Residue Concentrations (TMRC) of dithianon on or in pome fruits, dried hops, and processed commodities (apple juice/cider, dried apples and pears, apple juice concentrate) are:

- 0.003419 mg/kg body weight (b.w.)/day for the general U.S. population.
- 0.006417 mg/kg b.w./day for non-nursing infants.
- 0.007479 mg/kg b.w./day for children 1 to 6 years of age.
- 0.005147 mg/kg b.w./day for children 7 to 12 years of age.

The TMRC for the non-nursing infants group is based on the assumption that

apple sauce, rather than unprocessed apples, would be eaten by this subpopulation. For the 7 to 12 year old age group, no consumption data was available for dried pears, so the values for dried pears from the 1 to 6 year old age group were used for the calculation. These TMRC values are calculated from the proposed tolerances of 5 ppm on pome fruits (with a 0.12 ppm residue level calculated for apple juice), 100 ppm on dried hops, and from food consumption data obtained from the Agriculture Department's (USDA) Continuing Survey of Food Intake by Individuals (CSFII) conducted from 1989 to 1992. These chronic dietary exposure estimates are very conservative, because they assume that 100% of all apples, pears, and hops for human consumption are imported. The estimates also assume that all apples, pears, and hops that are imported are treated with dithianon and that the levels of residues on the RAC are at the tolerance level.

Dietary exposure to residues of dithianon will be limited to residues on imported pome fruits, in apple and pear processed commodities, and in beer. Wet apple pomace is considered as a significant ruminant feed item, but it is unlikely that apple pomace would be imported for this use. Apple pomace is not a poultry feed item. Thus, no residues are expected in poultry or eggs. There are no other established tolerances for dithianon in the United States, and there are no registered uses for dithianon on food or feed crops in the United States.

ii. *Drinking water.* This proposed tolerance is for imported pome fruits and dried hops. Since there are no approved uses for dithianon in the United States, the potential exposure from drinking water is not relevant to this petition.

2. *Non-dietary exposure.* This petition is for a tolerance on imported pome fruits and dried hops. There is no approved use for dithianon in the United States and none is being sought. Therefore, the potential for non-dietary exposure is not pertinent to this petition.

### D. Cumulative Effects

We are aware of no information to indicate or suggest that any toxic effects produced by dithianon would be cumulative with those of any other chemical.

### E. Safety Determination

1. *U.S. population.* The RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks

to human health. For dithianon, the RfD of 0.01 mg/kg b.w./day is based on a NOEL of 20 ppm or 1 mg/kg b.w./day from the 24-month chronic toxicity study in rats and a safety (uncertainty) factor of 100. A 100-fold safety factor is supported by a threshold level for the proliferative effects in the kidney, which were only observed in females following long-term administration of an excessively toxic dietary concentration of dithianon. Thus, a quantitative cancer risk assessment is not required.

The chronic dietary exposure of 0.003419 mg/kg b.w./day for the general U.S. population will utilize 34.2% of the RfD. EPA generally has no concern for exposures below 100% of the RfD. American Cyanamid concludes that there is a "reasonable certainty of no harm" from aggregate exposure to dithianon residues. The complete and reliable toxicity data and the conservative chronic exposure assumptions support this conclusion.

2. *Infants and children.* The chronic dietary exposure estimates presented in Unit C of this document will utilize approximately 64.2% of the RfD for non-nursing infants less than 1 year old, approximately 74.8% of the RfD for children 1 to 6 years of age, and approximately 51.5% of the RfD for children 7 to 12 years of age. Thus, the conservative exposure estimates for the subpopulations of infants and children are all well below the RfD for dithianon.

A 2-generation reproductive toxicity study in rats showed that dithianon is not a reproductive toxicant. Moreover, no treatment-related effects on pup development were noted in this study, supporting a NOEL for developmental effects of 600 ppm (the highest concentration tested) or approximately 42 mg/kg b.w./day. Results of developmental toxicity studies in rats and rabbits revealed no evidence of teratogenic effects for fetuses of either species and no evidence of development effects in the absence of maternal toxicity, indicating that dithianon is not selectively toxic to the fetus. These studies support maternal NOELs of 20 and 10 mg/kg b.w./day for the rat and rabbit studies, respectively, and developmental NOELs of 20 and 25 mg/kg b.w./day for the rat and rabbit studies, respectively.

The NOEL used to calculate the RfD for the general U.S. population is 1 mg/kg b.w./day derived from the 24-month chronic toxicity study in rats. A NOEL of 1 mg/kg b.w./day is 20 to 42 times lower than the NOELs for developmental effects from the developmental toxicity and reproductive toxicity studies.

Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete, valid and reliable. Collective results from the 2-generation and teratology studies show no increased sensitivity to developing offspring. Thus, no increased sensitivity of infants and children to dithianon residues is anticipated. Therefore, American Cyanamid concludes that an additional safety (uncertainty) factor is not warranted and the RfD of 0.01 mg/kg b.w./day, which utilizes a 100-fold safety factor, is appropriate to ensure a reasonable certainty of no harm to infants and children.

#### F. International Tolerances

A Maximum Residue Limit (MRL) for dithianon at the level of 5 mg/kg was established for pome fruits by the 1992 WHO/FAO Joint Meeting on Pesticide Residues (JMPR). The MRL for pome fruits was raised to step 8 at the Codex Committee on Pesticide Residues (CCPR) meeting in 1996 and will be approved by the Codex Alimentarius Commission in 1997 for Codex Maximum Residue Limit (CXL) (final). The 1992 JMPR established an MRL for dithianon in dried hops of 100 mg/kg. This MRL for dried hops is a CXL (final).

#### II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notation indicating the docket number [PF-707].

A record has been established for this notice of filing under docket number [PF-707] including comments and data submitted electronically as described below. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

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The official record for this notice of filing, as well as the public version, as described above will be kept in paper

form. Accordingly, EPA will transfer all comments received electronically into printed paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

#### List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 3, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-3226 Filed 2-11-97; 8:45 am]

BILLING CODE 6560-50-F

[PF-698; FRL-5585-4]

#### Engelhard Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing a temporary exemption from the requirement of a tolerance for residues of kaolin in or on apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cucurbits, grapes, nuts, ornamentals, peaches, peanuts, pears, peppers, potatoes, seed crops, soybean, small grains, strawberries, sugar beets, and tomatoes. The summary was prepared by the petitioner, Engelhard Corporation.

**DATES:** Comments, identified by the docket control number [PF-698], must be received on or before March 14, 1997.

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Crystal Mall #2, Room 1132, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF-698]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as comments concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Room 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail, Sheryl Reilly, Regulatory Action Leader, (PM 90), Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Station #1, 5th Floor, 2800 Crystal Drive, Arlington, VA, 703-308-8265, e-mail: reilly.sheryl@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition [PP-7G4793] from Engelhard Corporation, 101 Wood Ave., Iselin, NJ 08830. The petition proposes, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR part 180 to establish a temporary exemption from the requirement of a tolerance for residues of the biochemical pesticide kaolin in or on the raw agricultural commodities apples, apricots, bananas, beans, cane berries, citrus fruits, corn, cotton, cucurbits, grapes, nuts, ornamentals, peaches, peanuts, pears, peppers, potatoes, seed crops, soybean, small grains, strawberries, sugar beets, and tomatoes. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports