G. Mode of Action

Tebuconazole, the active ingredient of Folicur 3.6 F is a sterol demethylation inhibitor (DMI) fungicide. It is systemic and shows activity against powdery mildew and black rot infecting grapes. Tebuconazole provides protective activity by preventing completion of the infection process by direct inhibition of sterol synthesis. It is rapidly absorbed by plants and translocated systemically in the young growing tissues.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket control number PF–705.

A record has been established for this notice docket under docket control number PF–705 (including any 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:

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

Dated: February 19, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–5200 Filed 3–4–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–579A; FRL–5587–1]

Novartis; Pesticide Petition Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of withdrawal of pesticide petition.

SUMMARY: EPA is withdrawing a pesticide petition from Novartis (formerly known as Ciba-Geigy Corporation) for the combined residues of the insecticide cyromazine, (*N* cyclopropyl-1,3,5-triazine-2,4,6-triamine plus its major metabolite, melamine, 1,3,5-triazine-2,4-6-triamine) for use in or on certain commodites.

FOR FURTHER INFORMATION CONTACT: George T. LaRocca, Product Manager (PM) 13, 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: Rm. 200, CM#2, 1921 Jefferson Davis Highway, Arlington, VA; 703–305–6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA in a notice issued in the Federal Register of August 18, 1993 (58 FR 43892), announced that Novartis, P.O. Box 18300, Greensboro, NC 27419, had filed a pesticide petition (PP) 6F3422 proposing to amend 40 CFR part 180.414 to establish tolerances for the combined residues of the insecticide cyromazine, (*N* cyclopropyl-1,3,5-triazine-2,4,6-triamine plus its major metabolite, melamine, 1,3,5-triazine-2,4-6-triamine) for use in or on cabbage, sweet potatoes, sugar beets (roots and tops), and sorghum (grain, forage and fodder). The tolerances were to cover residues resulting from the planting of these crops as rotational crops following the harvest of cyromazine treated crops. On August 26, 1996 Novartis notified EPA that it requests that the petition be withdrawn without prejudice to future filing. The Agency has withdrawn the subject pesticide petition.

List of Subjects

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

Dated: February 17, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–4884 Filed 3–4–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–700; FRL–5586–1]

Rhone-Poulenc Ag Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing to establish tolerances for residues of thiodicarb and its metabolite in or on leafy vegetables, broccoli, cabbage and cauliflower. The notice includes a summary of the petition prepared by the petitioner, Rhone-Poulenc Ag Company.

DATES: Comments, identified by the docket control number [PF–700], must be received on or before, April 4, 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, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

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 either as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be acceped 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–700]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. No CBI should be submitted through e-mail. 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.

FOR FURTHER INFORMATION CONTACT: Dennis H. Edwards, Jr. Product Manager (PM 19), Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC. Office location, telephone number and e-mail address: Rm., 207, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.; Telephone: 703–305–6386, e-mail: edwards.dennis@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions (PP) 6F3417 and 7F3516 from Rhone-Poulenc Ag Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. These petitions propose, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. section 346a, to amend 40 CFR part 180 by establishing tolerances for the combined residues of the insecticide thiodicarb (Dimethyl *N,N*-[thiobis[[(methylimino) carbonyl]oxy]] bis [ethanimidothioate]) and its metabolite methomyl (*S*-methyl *N* [(methylcarbamoyl)oxy]-thioacetimadate) in or on the following raw agricultural commodities: leafy vegetables at 35 parts per million (ppm), broccoli at 7 ppm, cabbage at 7 ppm, and cauliflower at 7 ppm. The proposed analytical method is HPLC.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (FQPA), Rhone-Poulenc Ag Company included in the petition a summary of the petitions 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 Rhone-Poulenc Ag Company; EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

The metabolism of thiodicarb in plants and animals is adequately understood. Adequate analytical methods are available for enforcement purposes. There are no livestock feed items associated with this petition; there are no problems of secondary residues in meat, milk, poultry or eggs.

B. Toxicological Profile

1. *Acute toxicity*. EPA evaluation of the three acute oral toxicity studies in rats indicated the LD_{50} in males and females to be >50 miligrams/kilograms (mg/kg). Based on the results of these studies, thiodicarb is placed in Toxicity Category II. The acute dermal toxicity study in rabbits resulted in a LD_{50} of >2,000 mg/kg for both males and females. The acute inhalation LC_{50} was found to be >0.56 mg/l in male and female rats. The primary eye irritation study showed iridal involvement and moderate to severe conjunctival irritation. All positive reactions cleared within 4 days and eyes had returned to a normal appearance by day 7 following treatment. There was no irritation in the primary dermal irritation study. Thiodicarb was a weak dermal sensitizer in guinea pigs.

Conclusion. Based on the acute toxicity data cited above, Rhone-Poulenc Ag Company concludes that thiodicarb does not pose any acute dietary risks.

2. *Mutagenicity*. Mutagenicity studies completed include *Salmonella typhimurium* mammalian microsome reverse mutation assay (negative), *Saccharomyces cerevisiae* reverse mutation (negative), mitotic crossing over (negative) and gene conversion (positive in strain D7 and negative in strain D4), primary DNA damage in *Escherichia coli* (negative), mouse lymphoma gene mutation assay (equivocal positive), chromosomal aberration assay in CHO cells (negative), UDS assay with primary rat hepatocytes (negative), *in vivo* micronucleus test in mouse bone marrow (negative) and dominant lethal test in rats (negative).

Conclusion. Thiodicarb was tested in a variety of mutagenicity assays and was negative in all but the mouse lymphoma assay, in which there was only a weak to equivocal response and for mitotic gene conversion in *Saccharomyces cerevisiae*. EPA has previously concluded that overall there is low concern for the mutagenicity of thiodicarb.

3. *Metabolism*. The metabolism of thiodicarb has been studied in several animal and plant species and studies submitted and accepted by EPA. The metabolism in plants and animals is adequately understood for the purposes of this tolerance.

4. *Chronic effect*. Based on the available chronic toxicity data, the Health Effects Division-RfD/Peer Review Committee of the EPA recommended in their RfD/Peer Review Report (Ghali, June 18, 1996) that the Reference Dose (RfD) for thiodicarb remain unchanged from the previously established value of 0.03 mg/kg/day. The recently completed rat studies support the no observed effect level (NOEL) of 3 mg/kg/day established in previous studies. An Uncertainty Factor (UF) of 100 was applied to account for both the interspecies extrapolation and intraspecies variability.

5. *Carcinogenicity*. The potential oncogenicity of thiodicarb has been fully evaluated by the EPA's Health Effects Division Carcinogenicity Peer Review Committee (CPRC) (Taylor and Rinde, June 10, 1996). The committee determined that the available database was adequate for the determination of the carcinogenicity of thiodicarb in animals and concluded that thiodicarb should be classified in Group B2. While Rhone-Poulenc disagrees with the classification of thiodicarb and the interpretation of the study results (as described below) Rhone-Poulenc agrees with the risk characterization procedure recommended by the CPRC and concurs that the recommended procedures are fully adequate to protect humans from dietary exposure to thiodicarb.

The CPRC recommended that a margin of exposure methodology be applied for the estimation of human risk because the findings observed in the oncogenicity studies occurred only at the highest doses tested in the studies and in the case of mice the highest dose tested may even have been excessive. In addition, there was no evidence of genotoxicity.

a. Rhone-Poulenc feels that the results in the most recent oncogenicity study in rats should not be considered indicative of a carcinogenic response in the Leydig cells of the rats for the following reasons:

i. Compared to the control groups, both sexes at the high dose level displayed fewer tumors and there were fewer with multiple benign and malignant tumors.

ii. There was a statistically significant decrease in pituitary adenomas in the high dose animals relative to controls (10 percent vs 56 percent) indicating more high dose than control animals had normal pituitaries at the end of the study. The incidence of pituitary adenomas is well below the historical control range (10 percent vs a range of 43 to 80 percent). Pituitary activity is known to be critical in the regulation of benign Leydig cell tumor formation through the secretion of luteinizing hormone. Increased pituitary activity in aged male rats would be expected to secondarily result in increased benign Leydig cell tumor formation.

iii. There was no statistical increase in benign interstitial cell tumors relative to the concurrent controls when all

animals were included in the statistical analysis.

iv. There is clear evidence that exposure to 900 ppm thiodicarb resulted in increased survival for male rats relative to controls. The 2 year survival rate for high dose males was 1.3 times that of controls (58 percent vs 45 percent, respectively). Benign interstitial cell tumors are very common age related tumors. Because survival was 1.3 times higher in the high dose group than in controls, the high dose animals should be expected to have a higher raw incidence of common age related tumors.

v. Benign interstitial cell tumors do not transform into a more aggressive form with time.

vi. Benign interstitial cell tumors are very common in rats and highly uncommon in humans. There is an absence of epidemiological evidence that Leydig cell tumors in rats are relevant for human health risk assessment. The Food and Drug Administration (FDA), and European regulatory authorities in general do not consider these findings to be relevant for human health risk assessment. Numerous scientific symposia/discussions have been held regarding the lack of relevance of rat Leydig cell changes for human risk assessment.

b. Rhone-Poulenc feels that the results in the most recent mouse oncogenicity study should not be considered indicative of a carcinogenic response in the liver cells of the mice for the following reasons:

i. The evidence shows that thiodicarb is not oncogenic in mice at doses which do not exceed the maximum tolerated dose (MTD).

ii. There was no evidence to suggest liver oncogenicity in the first mouse study at doses up to 10 mg/kg/day or in the second study at doses up to 70 mg/kg/day.

iii. In the second study where there was evidence suggestive of an oncogenic response in the liver, the MTD was significantly exceeded based on increased mortality in females and a dramatic body weight gain depression in the males. The body weight gains for males at 1,000 mg/kg/day were 54 percent of the control male gains during the first year of the study. The body weight gains for the 1,000 mg/kg/day group females were 85 percent of controls for the same time period. Survivability at 97 weeks was also significantly decreased in males (41 percent versus 58 percent in control males) and females (24 percent versus 51 percent in control females).

iv. Other evidence that the MTD was exceeded included severe and sustained liver toxicity demonstrated by increased liver weights, hepatocyte hypertrophy, single cell necrosis and hemosiderin deposition by 52 weeks and increased bilirubin and ALT, increased liver weight, hepatocyte hypertrophy, bile duct hyperplasia, hepatocyte pleomorphism and hemosiderin deposition at 97 weeks of treatment.

Conclusion. The oncogenicity studies with thiodicarb fully conform to the currently accepted guidelines for this study type. Rhone-Poulenc Ag Company believes that the results of the studies provide only minimal evidence that the compound is oncogenic in rodents. After analysis of the data, EPA scientists recently determined that a margin of exposure of 100 applied to the lowest NOEL from the chronic studies with thiodicarb would provide adequate safety for any risks to humans. Rhone-Poulenc agrees with this risk assessment approach and is confident that it will provide adequate safety for all human population subgroups including infants and children.

6. *Teratology.* Several teratology studies exist on thiodicarb in rats, rabbits, and mice. These are reviewed below:

a. A teratology study in rats was conducted at doses of 0, 0.5, 1.0, 3, and 100 mg/kg/day. No signs of teratogenicity were observed.

b. A teratology study was conducted in rats at doses of 0, 1, 10 and 30 mg/kg/day. No signs of teratogenicity were observed.

Data from both studies can be (and were by EPA) used to derive maternal and developmental NOELs and lowest observed effect levels (LOELs). Based on data from both studies, the maternal NOEL and LOEL were determined to be 10 and 20 mg/kg/day, respectively. The developmental NOEL and LOEL were determined to be 3 and 10 mg/kg/day, respectively, based on delayed ossification of sternebrae.

c. A teratology study in rabbits was conducted at doses of 0, 5, 20 and 40 mg/kg/day. No signs of teratogenicity were observed. The NOEL and LOEL for maternal toxicity were determined to be 20 and 40 mg/kg/day, respectively. The developmental NOEL was determined to be 40 mg/kg/day. As this was the highest level tested, no LOEL for developmental toxicity was determined.

d. A teratology study in mice was conducted at doses of 0, 50, 100 and 200 mg/kg/day. No signs of teratogenicity were observed. The maternal NOEL and LOEL were determined to be 100 and 200 mg/kg/day, respectively. As no fetal effects were observed at all, the developmental NOEL can be considered to be 200 mg/kg/day.

Conclusion. Based on all the studies above, Rhone-Poulenc Ag Company does not believe that thiodicarb is a teratogen, or that it presents any unreasonable risk to children.

7. *Reproductive effects.* Two reproduction studies were recently conducted with thiodicarb; one dose-rangefinding study and one definitive study.

a. In the dose-rangefinding study, rats were administered thiodicarb in their diets at concentrations of 0, 200, 600, 1,800, and 3,000 ppm. Maternal toxicity, as evidenced by decreased pup viability at birth and day 4, was seen at the three highest doses. Also at the three highest doses, decreased pup growth occurred. Therefore, the NOEL for both maternal and fetal effects was determined to be 200 ppm.

b. In the definitive study, thiodicarb was administered in the diets of rats at concentrations of 0, 100, 300, and 900 ppm. Fetal body weight gain at 100 ppm was significantly decreased when compared with concurrent controls resulting in the conclusion that, strictly speaking, no NOEL was reached for fetal effects in this study. An independent expert consulting firm was contracted with to statistically derive from these data a conservative NOEL for all effects. These experts concluded that a conservative NOEL for all effects would be 80 ppm, equivalent to an average daily dose of 5.20 mg/kg/day. EPA subsequently utilized a Benchmark Dose approach to estimate the NOEL for this study, and ultimately concluded that, based on all the data and all the different analyses of the data, 100 ppm is at or near the NOEL for reproductive/developmental toxicity. It is significant, too, that this NOEL is higher than the NOEL from the chronic toxicity/oncogenicity study in rats, where the NOEL is used to determine the Reference Dose for thiodicarb.

Conclusion. Based on the studies cited above, Rhone-Poulenc Ag Company believes that thiodicarb does not pose an unreasonable risk of reproductive effects to parents or their offspring. Further, as none of the effects observed in the cited studies are classically related to any specific endocrine mechanism, Rhone-Poulenc Ag Company believes that thiodicarb is not an endocrine disrupter.

C. Aggregate Exposure/Cumulative Effects

The Dietary Analysis for the Proposed Use of thiodicarb on leafy vegetables has been run by EPA and summarized in a document dated June 17, 1991 (Schaible, S.A.). Using the Theoretical

Maximum Residue Contributions (TMRC) calculated from the tolerances and estimated consumption data for various populations (very conservative estimates) a value of 0.019213 is obtained for the TMRC which represents 64.0 percent of the established reference dose was reached for the overall U.S. population. The Dietary Analysis for the Proposed Use of thiodicarb on broccoli, cabbage and cauliflower has been run by EPA and summarized in a document dated July 9, 1990 (Briggs, R.). Using the TMRC calculated from the tolerances and estimated consumption data for various populations (very conservative estimates). A value of 0.015225 is obtained for the TMRC which represents 50.8 percent of the established reference dose utilized for the overall U.S. population. None of the population subgroups exceeded the 100 percent level of the reference dose. This value includes all pending and published tolerances, including apples, tomatoes and peppers for which Rhone-Poulenc Ag Company does not currently have a registration. This is a large overestimation of the actual dietary exposure to thiodicarb because it assumes 100 percent of crops treated and maximum residue levels present.

The FQPA of 1996 lists three other potential sources of exposure to the general population that must be addressed, these are pesticides in drinking water, exposure from non-occupational sources, and the potential cumulative effect of pesticides with similar toxicological modes of action. Based on the available studies of thiodicarb in the environment which show a short half-life in soil (1.5 days), Rhone-Poulenc Ag Company does not anticipate residues of thiodicarb in drinking water. There is no established Maximum Concentration Level or Health Advisory Level for thiodicarb under the Safe Drinking Water Act.

The potential for non-occupational exposure to the general public is also insignificant. There are no residential lawn or garden uses for thiodicarb products where the general population may be exposed via inhalation or dermal routes.

Rhone-Poulenc concludes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no reliable data to indicate that the toxic effects caused by thiodicarb would be cumulative with those of any other compound. Based on this point, Rhone-Poulenc has considered only the potential risks of thiodicarb in it's exposure assessment.

D. Safety Determinations

1. *U.S. population in general.* Using the very conservative exposure estimates described above, the conclusion reached is that aggregate exposure to thiodicarb will utilize no more than 64 percent of the established reference dose. Rhone-Poulenc Ag Company has conducted a preliminary Dietary Risk Exposure Study (DRES) with TAS, Inc. which utilizes actual data (where available) for percent crops treated and residue data from FDA and Cal-EPA monitoring programs (no detectable residues of thiodicarb were observed in these databases, so as a conservative estimate, all methomyl residues were assumed to result from thiodicarb use). Only registered and conditionally registered uses (including leafy vegetables, broccoli, cabbage and cauliflower) were included in the analysis. The study concluded that chronic exposure estimates are well below the endpoints of concern. Chronic exposure estimates are 0.1 percent of the RfD or less for all population groups. Based on this study and the above points, Rhone-Poulenc Ag Company believes there is a reasonable certainty that no harm will result from aggregate exposure to thiodicarb.

2. *Infants and children*. Referring to the conclusions and summary in the Developmental and Reproductive Toxicity section stated above, Rhone-Poulenc Ag Company believes there is no additional sensitivity for infants and children and that an additional safety factor for infants and children is not warranted. The RfD of 0.03 mg/kg/day is appropriate for assessing aggregate risk to this subpopulation. For the infant and children (1 to 6 years of age) populations only 0.1 percent of the reference dose was used in the DRES study discussed above.

Based on the completeness and reliability of the toxicology data and the dietary analysis Rhone-Poulenc Ag Company concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to thiodicarb residues.

E. International Tolerances

There are no Codex maximum residue levels established for thiodicarb on leafy vegetables, broccoli, cabbage or cauliflower.

II. Public Record

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the docket control number [PF–700].

A record has been established for this notice under docket control number [PF–700] (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 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.

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Authority: 21 U.S.C. 346a.

List of Subjects

Environmental Protection, Administrative practice and procedure, Agricultural commodities, Pesticide and pest, Reporting and recordkeeping requirements.

Dated: February 10, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–4879 Filed 3–4–97; 8:45 am]

BILLING CODE 6560–50–F

[OPP–181034; FRL 5591–2]

Bifenthrin; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Washington