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[FR Doc. 96–14455 Filed 6–11–96; 8:45 am]
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40 CFR Part 180

[PP 2F4086/R2238; FRL–5368–4]

RIN 2070–AB78

Pesticide Tolerance for 1-[[2-(2,4-Dichlorophenyl)-4-Propyl-1,3-Dioxolan-2-yl]Methyl]-1H-1,2,4-Triazole

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the raw agricultural commodities oat grain at 0.1 parts per million (ppm), oat straw at 1.0 ppm, oat forage at 10.0 ppm, and oat hay at 30.0 ppm. The regulation to establish a maximum permissible level for residues of the fungicide was requested in a petition submitted by Ciba-Geigy Corp.

EFFECTIVE DATE: This regulation becomes effective June 12, 1996.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 2F4086/R2238], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted 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 copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 2F4086/R2238] . No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703) 305–6226; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice (FRL–4971–5), published in the Federal Register of November 15, 1995 (60 FR 57420), which announced that Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419 had submitted pesticide petition (PP) 2F4086 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish tolerances for combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H* -1,2,4-triazole in or on the raw agricultural commodities oat grain at 0.1 ppm, oat straw at 1.0 ppm, oat forage at 10.0 ppm, and oat hay at 30.0 ppm.

There were no comments received in response to the notice of filing.

The scientific data submitted in the petition and other relevant material have been evaluated. The data considered in support of the tolerance include:

1. Plant and animal metabolism studies.

2. Residue data for crop and livestock commodities.

3. Two enforcement methods and multiresidue method testing data.

4. A 90–day rat feeding study with a no-observable-effect level (NOEL) of 12 mg/kg/day.

5. A 90–day dog feeding study with a NOEL of 1.25 mg/kg/day.

6. A rabbit developmental toxicity study with a maternal NOEL of 100 mg/kg/day and a developmental toxicity NOEL of Greater than 400 mg/kg/day (highest dose tested) (HDT)).

7. A rat teratology study with a maternal NOEL of 30 mg/kg/day and a developmental toxicity NOEL of 30 mg/kg/day.

8. A 2–generation rat reproduction study with a reproductive NOEL of 125 mg/kg/day (HDT) and a developmental toxicity NOEL of 25 mg/kg/day.

9. A 1–year dog feeding study with a NOEL of 1.25 mg/kg/day.

10. A 2–year rat chronic feeding/carcinogenicity study with a NOEL of 5 mg/kg/day with no carcinogenic potential under the conditions of the study up to and including approximately 125 mg/kg/day, the highest dose tested.

11. A 2–year mouse chronic feeding/carcinogenicity study with a NOEL of 15 mg/kg/day and with a statistically significant increase in combined adenomas and carcinomas of the liver in male mice at approximately 375 mg/kg/day, the highest dose tested.

12. Ames test with and without activation, negative.

13. A mouse dominant-lethal assay, negative.

14. Chinese hamster nucleus anomaly, negative.

15. Cell transformation assay, negative.

Ciba-Geigy submitted information which resolved the previously outstanding concerns about the nature of the residue in ruminants, an explanation of recovery calculations, and an explanation of the crop field trial protocol. Data gaps exist concerning dosing in the mouse carcinogenicity study. These data requirements were required under reregistration, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq.

As part of EPA's evaluation of potential human health risks, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*- 1,2,4-triazole has been the subject of five Peer Reviews and one Scientific Advisory Panel (SAP) meeting.

The fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole was originally evaluated by the Peer Review Committee on January 15, 1987, and classified as a Group C (possible human) carcinogen with a recommendation made for the quantification of estimated potential human risk using a linearized low-dose extrapolation. The method resulted in the establishment of a Q^* of 7.9×10^{-2} $(mg/kg/day)^{-1}$.

The Peer Review Committee's decision was presented to the FIFRA Scientific Advisory Panel on March 2, 1988. The Panel did not concur with the committee's overall assessment of the

weight-of-evidence on the carcinogenicity of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole. The Panel recommended placing the chemical in Group D, indicating that the Group C classification was based on minimal evidence. The Panel's determination that EPA's Group C classification was based on minimal evidence was due to the fact that the incidence of liver tumors in male mice only occurred when the mice were given an excessive chemical dose.

As part of a fifth Peer Review, EPA considered additional information provided by the registrant in support of the registrant's argument that the high dose was excessively toxic in the mouse carcinogenicity study. It further argued that the data from the high dose (2,500 ppm) should not be included in the evaluation of carcinogenic potential of -[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole. In support of these arguments, the registrant provided two subchronic oral toxicity studies in mice. Ciba-Geigy also provided a reread of the pathology slides from a mouse oncogenicity study which it felt indicated sufficient concurrent liver toxicity at 2,500 ppm to document that this dose was excessive. These findings were not present in the original pathology report. Owing to the inconsistency in Ciba-Geigy's report and the original report, the Agency requested that an independent (third) evaluation of the pathology slides be made to determine if the pathology reported could be confirmed. The results of this (third) pathology evaluation were used in the fifth Peer Review in place of data resulting from the earlier evaluations provided by Ciba-Geigy.

The Peer Review Committee considered the following facts regarding the toxicology data on 1-[[2-(2,4-dichlorophenyl)-4- propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole in a weight-of-evidence determination of carcinogenic potential:

1. Increased numbers of adenomas (increased trend and pairwise comparison) were found in the livers of male CD1 mice given 2,500 ppm of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole in their diet.

2. The treated animals had earlier fatalities than the controls.

3. The numbers of carcinomas were increased (trend only) in male mice only at the 2,500 ppm dose level. Tumors were not significantly increased at the 500 ppm dose level. Adenomas observed in the treated animals were larger and more numerous than those in controls; however, the tumor type (adenoma) was the same.

4. No excessive number of tumors was found in female mice.

5. In a rat study conducted with acceptable doses of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2, 4-triazole, no excessive numbers of tumors were found.

The Peer Review Committee determined, based on the additional information submitted by Ciba-Geigy from two 90–day subchronic studies in mice that the 2,500 ppm dose used in the 2-year chronic study exceeded the maximum tolerated dose (MTD) based on the endpoint of hepatic necrosis, and the 500 ppm dose used in the chronic study was inadequate to assess the carcinogenicity of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole. Based on the third pathology evaluation of the chronic study, the Peer Review Committee disagreed with Ciba-Geigy's argument that the study showed excessive toxicity at the 2,500 ppm dose. However, the Peer Review Committee concluded that the 90-day subchronic studies are a better measure of what would be an MTD.

Based upon these findings, the Peer Review Committee agreed that the classification for 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole should remain a Group C (possible human) carcinogen and recommended against the previously used Q^* (viz. 0.079) for risk assessment purposes. For the purpose of risk characterization the Peer Review Committee recommended that the reference dose (RfD) approach should be used for quantification of human risk. This decision was based on the disqualification of the high dose (2,500 ppm), making the data inappropriate for the calculation of Q^*. Because the middle dose (500 ppm) was not considered sufficiently high enough for assessing the carcinogenic potential of 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, EPA has requested an additional mouse study at intermediate dose levels in male mice only. EPA does not expect that these data will significantly change the above cancer assessment that 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole poses a negligible risk to humans.

The reference dose for 1-[[2-(2,4-dichlorophenyl)-4-propyl- 1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole is 0.013 mg/kg/day, and based on a NOEL of 1.25 mg/kg/day and an uncertainty factor of 100. The NOEL is taken from a 1–year dog feeding study that demonstrated irritation of the stomach in males as an endpoint effect. The Anticipated Residue Contribution (ARC) from the current action is estimated at 0.000872 mg/kg/day and utilizes 7% of the RfD of the general population of the 48 states. The ARC for the most highly exposed subgroup, non-nursing infants less than 1 year old is 0.00405 or mg/kg/day (31% of the RfD).

The nature of the residue in plants and animals is adequately understood and an adequate analytical method, gas chromatography, is available for enforcement purposes. Adequate animal tissue, milk, and egg tolerances exist to cover secondary residues incurred in those commodities from the proposed uses.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the *Pesticide Analytical Manual*, Volume II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703) 305–5232.

There are presently no actions pending against the continued registration of this chemical. The pesticide is considered useful for the purpose for which the tolerance is sought.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be

accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under the docket number [PP 2F4086/R2238] (including any comments and data submitted electronically). 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 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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rule-making 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.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

This action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 9–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: May 23, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.434, by revising the introductory text to paragraph (a) and by adding alphabetically the entries for ''oats, grain,'' ''oats, straw,'' ''oats, forage,'' and ''oats, hay'' to the table in paragraph (a), to read a follows:

§ 180.434 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole; tolerances for residues.

(a) Tolerances are established for the combined residues of the fungicide 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1*H*-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following raw agricultural commodities:

Commodity	Parts per million
* * * * *	
Oats, grain	0.1
Oats, straw	1.0
Oats, forage	10.0
Oats, hay	30.0
* * * * *	

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[FR Doc. 96–14452 Filed 6–11–96; 8:45 am]
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40 CFR Part 180

[PP 5F4522/R2237; FRL–5367–8]

RIN 2070–AB78

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine) and its metabolites in or on leafy green vegetables. Bayer Corporation (formerly Miles, Inc.) requested this regulation to establish these maximum permissible levels for residues of the insecticide.

EFFECTIVE DATE: This regulation became effective May 28, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [PP 5F4522/R2237], may be submitted to: Hearing Clerk (A-110), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental