

ARIZONA—CARBON MONOXIDE—Continued

Designated area	Designation		Classification	
	Date	Type	Date	Type
28. thence, easterly along the southern line of Township 2 South to the point of beginning which is a point where the southern line of Township 2 South intersects with the eastern line Range 7 East.				
Tucson Area:				
Pima County (part)	11/15/90	Nonattainment	11/15/90	Not classified.
Township and Ranges as follows: T11–12S, R12–14E; T13–15S, R11–16E; and T16S, R12–16E Gila and Salt River Baseline and Meridian excluding portions of the Saguaro National Monument and the Coronado National Forest.				
Rest of State	11/15/90	Nonclassifiable/ Attainment	
Apache County				
Cochise County				
Coconino County				
Gila County				
Graham County				
Greenlee County				
La Paz County				
Maricopa County (part)				
Area outside Phoenix Area:				
Mohave County				
Navajo County				
Pima County (part)				
Area outside Tucson Area:				
Pinal County				
Santa Cruz County				
Yavapai County				
Yuma County				

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[FR Doc. 96–19194 Filed 7–26–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 180**[PP 9F3766/R2254; FRL–5385–3]****RIN 2070–AB78****Norflurazon; Pesticide Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final Rule.

SUMMARY: This rule establishes tolerances for residues of the herbicide norflurazon (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) and its desmethyl metabolite (4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) in or on the following raw agricultural commodities (RACs): alfalfa, forage, alfalfa, hay, alfalfa, seed; and in or on meat by products (except liver) of cattle, goats, hogs, horses, and sheep and in or on liver of cattle, goats, hogs, horses and sheep resulting from the use of norflurazon in the culture of alfalfa. This regulation to establish a maximum permissible level for the residues of norflurazon was requested in a petition submitted by Sandoz Agro, Inc. of 1300 East Touhy Avenue Des Plaines, Illinois 60018–3300.

EFFECTIVE DATE: July 29, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [PP 9F3766/R2254], 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 docket 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 36277M, Pittsburgh, PA 15251. Information not marked confidential may be disclosed publicly by EPA without prior notice. 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 as ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [PP 9F3766/R2254]. 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 in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne Miller, Product Manager (23) Registration Division (7505C), Office of Pesticide Programs, Environment Protection Agency, 401 M St. SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 305-6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice of filing, published in the Federal Register of June 29, 1989 (54 FR 27423), which announced that

Sandoz Crop Protection Corp., of 1300 East Touhy Avenue, Des Plaines, IL 60018 had submitted a request for an EPA Pesticide Petition, PP 9F3766, for the purpose of amending 40 CFR part 180, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), by establishing tolerances for combined residues of the herbicide norflurazon, (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) and its desmethyl metabolite (4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) in or on alfalfa, forage at 3.0 ppm, alfalfa, hay at 5.0 ppm, alfalfa, seed at 0.1 ppm. The proposed analytical method of determining residues was gas chromatography.

A second notice of filing was published in the Federal Register (61 FR 30238, June 14, 1996) (FRL-5370-7). The notice announced that Sandoz had revised requested tolerances for residues of norflurazon (4-chloro-5-(methylamino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) and its desmethyl (metabolite 4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone) in or on the following raw agricultural commodities: alfalfa, forage at 3.0 ppm, alfalfa, hay at 5.0 ppm and alfalfa, seed at 0.1 ppm; and in or on meat-by-products (except liver) of cattle, goats, hogs, horses, and sheep at 0.1 ppm and in or on liver of cattle, goats, hogs, horses and sheep at 0.25 ppm.

There were no comments received in response to the notices of filing. The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. The following acute studies with norflurazon:

Acute Oral, Rat (Male) LD₅₀: 9.3 g/kg, Toxicity Category IV.

Acute Dermal, Rabbit: LC₅₀ ≤ 20,000 mg/kg, Toxicity Category IV.

Acute Inhalation, Acceptable study unavailable.

Primary Eye Irritation, Rabbit: Toxicity Category IV.

Primary Dermal Irritation, Rabbit, non-irritating: Category IV.

Dermal Sensitization, Guinea Pig, technical norflurazon at 0.1 percent did not cause sensitization in males, a repeat study is required because of flaws in the study.

2. A 90-day rat feeding study at nominal dosages of 0, 12.5, 25.0 and 125.0 mg/kg/day. There were no significant effects of norflurazon on survival, body weight, body weight gain and food consumption in male and female rats at any dose level. At the

125.0 mg/kg/day dose level, the following effects were observed at 13 weeks: an increase in red cell count of 19 percent in male rats; a decrease in alkaline phosphatase activity of 38 percent and 42 percent in male and female rats, respectively; a decrease in SGOT activity of 36 percent in female rats; an increase in liver weight of 14 percent and 12 percent in male and female rats, respectively; an increase in thyroid weight of 96 percent in male rats; and an increase in the incidence of hypertrophic acinar epithelium and colloid depletion of the thyroid in male rats. At the 25.0 mg/kg/day level after 13 weeks of treatment, thyroid weight was increased by 20 percent in male rats with an increased incidence of hypertrophic acinar epithelium and colloid depletion. In addition, red cell count was increased by 14 percent in male rats, SGOT was decreased by 10 percent in female rats, and liver weight was increased by 14 percent in males. The systemic no-observable-effect-level (NOEL) was considered to be 12.50 mg/kg/day in male rats, and 25.0 mg/kg/day in female rats. The systemic lowest-effect-level (LEL) was considered to be 25.0 mg/kg/day in male rats based on increased red cell count, increased thyroid and liver weight, and increased incidence of hypertrophic acinar epithelium and colloid deposition in the thyroid. The systemic LEL was considered to be 125.0 mg/kg/day in female rats, based on an increased liver weight and liver-to-body weight ratio. The decreased alkaline phosphatase and SGOT activity observed in females at this dose were of unknown biological significance.

3. A 6-month dog feeding study at dosages of 0, 1.53, 5.02 and 14.27 mg/kg/day for males and 0, 1.58, 4.77 and 17.75 mg/kg/day for females, technical norflurazon (99.2 percent a.i.). At the mid-dose level, liver weight was increased by 38 percent in male dogs and by 23 percent in female dogs. Thyroid weight was increased by 33 percent in male dogs and 37 percent in female dogs at those dose levels. Also, as noted at the mid-dose level there were increases of cholesterol in both sexes (23 to 40 percent in males, 6 to 34 percent in females), a decrease in SGPT (36 to 38 percent in males, 13 to 20 percent in females) and SGOT (4 to 23 percent in males, 13 to 23 percent in females). At the highest level, similar changes were observed in male and female dogs, with the additional observation of a decrease in red cell count in female dogs (79 to 92 percent of control). The systemic NOEL was determined to be 1.53 mg/kg/day for

males and 1.58 mg/kg/day for females. The systemic LEL was determined to be 5.02 mg/kg/day for males and 4.77 mg/kg/day for females, based on increased absolute and relative liver weight and increased cholesterol in both sexes.

4. A 3-week rabbit dermal study with 80 percent norflurazon wettable powder. Dermal applications were made at doses of 150 mg (approximately 375 mg/kg/day) and 400 mg (approximately 1,000 mg/kg/day) 5 days per week, 6 to 8 hours per day, for the 3-week study. The systemic NOEL was 375 mg/kg/day for males and females, and the systemic LEL was 1,000 mg/kg/day for males and females, based on increases in alkaline phosphatase activity, liver weight and liver to body weight ratio in both sexes. The dermal NOEL was also 375 mg/kg/day for both sexes, and the dermal LEL was 1,000 mg/kg/day for both sexes, based on slight erythema observed immediately after bandage removal.

5. A 28-day rat feeding study at dosages of 0, 25.0, 50.0 and 250.0 mg/kg/day with a NOEL of 50.0 mg/kg/day. The effect was hyperplasia and hypertrophy of liver and higher liver, kidney, adrenal, and heart/body weight ratios.

6. A 28-day mouse feeding study at dosages of 0, 10.5, 31.5, 63.0, and 378.0 mg/kg/day with a NOEL of 63.0 and 378.0 mg/kg/day with a NOEL of 63.0 mg/kg/day and a LEL of 378.0 mg/kg/day. The effect was diffused and smooth granular livers and an increase in the liver/body weight ratios.

7. A rat dermal absorption study at dosages of 0, 0.1, 1.0 and 10.0 mg/rat showing that no more than 0.1 percent of applied dose was absorbed at doses up to 10 mg/rat.

8. Gene mutation assays in *Salmonella typhimurium* (strains TA98, TA100, TA1535, TA1537 and TA1538), and *Saccharomyces cerevisiae* (strain D4), *in vitro*, in the absence and presence of metabolic activation (Aroclor 1254 induced rat liver S-9). Norflurazon technical at concentrations of 0, 0.1, 1.0, 10, 100, or 500 µg/plate (non-activation) and concentrations of 0, 0.1, 1.0, 10.0, 100 or 500 µg/plate activation) [1,000 µg/plate for TA1537 in a second assay] showed no evidence of mutagenicity in this study. There was no evidence of cytotoxicity in any of the strains at any of the dose concentrations used. Positive controls appeared adequate for all strains except TA100, where positive controls in the absence and presence of S-9 gave less than 2 times the number of revertants observed in negative controls. In the absence of data demonstrating toxic effects, the highest concentration used in this study is inadequate and higher concentrations

should have been assayed. In an *in vitro* chromosomal aberration assay, norflurazon did not cause a clastogenic response at doses of 63 to 500 µg/ml in the absence of liver S-9 and at doses of 125 to 1,000 µg/ml in the presence of S-9. In an *in vitro* unscheduled DNA synthesis assay, norflurazon at doses ranging from 1 to 333 µg/ml failed to induce unscheduled DNA synthesis in primary rat hepatocytes.

9. A developmental study in rats at dosages of 0, 100, 200 and 400 mg/kg/day showed no maternal or developmental effects at 400 mg/kg/day. Maternal NOEL was <100 mg/kg/day; maternal LEL was 100 mg/kg/day, based on reductions in body weight for the period of dosing and for the dosing plus post-dosing period.

10. A developmental study in rabbits at dosages of 0, 10, 30 and 60 mg/kg/day showed maternal body weight decreases at 60 mg/kg/day. Developmental effects seen at 60 mg/kg/day were decreased fetal weight and incomplete ossification of the skull, fore and hind limb middle phalanx, metacarpal, and proximal epiphysis of the tibia. The NOEL for maternal toxicity was 30 mg/kg/day. The NOEL for developmental toxicity was 30 mg/kg/day.

11. A three generation reproduction study in rats at dosages of 0, 6.25, 18.75 and 51.25 mg/kg/day showed no apparent effects on reproductive performance at any dose level tested.

12. A chronic toxicity and carcinogenicity study in Sprague-Dawley rats at dosages of 0, 6.25, 18.75 and 51.25 mg/kg/day for 104 weeks. No significant effects of technical norflurazon were evident for survival, body weight, body weight gain, or food consumption in male or female rats at any dose level tested. At the 18.75 mg/kg/day dose, liver weight was increased by 17 percent and 13 percent in males and females at 52 weeks and at 51.25 mg/kg/day by 24 percent and 27 percent in both sexes. At 104 weeks, liver weight was increased by 12 to 14 percent in both males and females, and kidney weight by 16 to 39 percent vs. controls. The weight of the thyroid was also increased at the 51.25 mg/kg/day dose in male rats at 104 weeks. An increased incidence of hydronephrosis was observed in high dose male rats at 52 weeks vs. control, while the incidence of nephritis was increased in male rats (terminal sacrifice plus dying on test) at the 51.25 mg/kg/day dose. The incidence of tubular casts was increased in female rats at the high dose in those rats surviving to study termination. Other microscopic alterations observed at the high dose included an increased incidence of

parathyroid hyperplasia (both sexes), hemosiderin pigment deposition in the spleen (males only) and liver (both sexes), and endometritis and squamous metaplasia of the uterus (females).

The systemic NOEL was determined to be 18.75 mg/kg/day for both sexes. The systemic LEL was determined to be 51.25 mg/kg/day in both sexes, based on the increased kidney weight and accompanying microscopic pathologic changes, as well as the increase in liver weight in male and female rats and the increase in thyroid weight in males. There was no evidence of carcinogenicity for norflurazon.

13. A carcinogenicity study in CD-1 HaM/ICR Swiss mice at dosages of 0, 12.8, 58.7 and 218.8 mg/kg/day technical norflurazon in the diet for 100 to 104 weeks. No significant effects were observed on body weight, body weight gain, clinical toxicity, and food consumption at any dose. Liver weight was increased by 9 percent and 15 percent in male and female mice at the 58.7 mg/kg/day dose, and by 27 percent and 21 percent at the 218.8 mg/kg/day dose, respectively. The liver to body weight ratio was increased by 19 percent and 4 percent in male and female mice at the 58.7 mg/kg/day dose, and by 43 percent and 19 percent at the 218.8 mg/kg/day dose, respectively. Increased incidence of enlarged spleen, nephritis, swollen/enlarged liver, and nodular enlargement of the liver were observed in high dose male mice, while increased incidences of pyelonephritis, enlarged liver, and cystic ovaries were observed in high dose female mice. Carcinogenic potential was evidenced by an increased incidence of hepatic adenoma and combined adenoma/carcinoma in high dose male mice.

The systemic NOEL was determined to be 12.8 mg/kg/day for male mice, and 58.7 mg/kg/day for female mice. The systemic LEL was determined to be 58.8 mg/kg/day for male mice, based on the increased incidence of enlarged spleen, increased absolute and relative liver weight, and increased incidence of nephritis. The systemic LEL was determined to be 218.8 mg/kg/day for female mice, based on the increased incidence of enlarged liver and cystic ovaries, the increased absolute and relative liver weight, and the increased incidence of pyelonephritis.

14. A rat metabolism study at single oral doses of 2 or 110 mg/kg, a single i.v. dose of 2.0 mg/kg, or a single oral dose at 2 mg/kg after animals had ingested 0.1 mg/kg for 14 days showed that less than 1.0 percent of the administered dose remained 96 hours after dosing. Thirteen metabolites were isolated. Norflurazon appears to be metabolized

by *N*-demethylation, displacement of the chlorine atom by glutathione, glutathione attack on the aromatic ring, and replacement of the chlorine atom with hydrogen. Norflurazon appears to be rapidly absorbed from the gastrointestinal tract and extensively metabolized.

The Agency's Health Effects Division Peer Review Committee classified norflurazon as a Group C, possible human carcinogen, based on the criteria in the Agency's Guideline for the Classification of Carcinogens (51 FR 33992-34003, September 24, 1986) and the statistically significant increase in comparison to controls in hepatocellular adenomas and combined hepatocellular adenomas and carcinomas in male CD-1 mice as well as the statistically significant positive trend for hepatocellular adenomas and combined adenomas and carcinomas.

That committee also recommended that for the purposes of risk characterization the Reference Dose (RfD) approach should be used for the quantification of human risk. This recommendation was supported by the presence of only benign tumors in only one sex of one species at one dose level, and adequate but negative mutagenicity data and no positive analogues. EPA believes norflurazon poses a negligible cancer risk to humans.

Since the committee's review, the Agency has reevaluated the gene mutation assay in *Salmonella typhimurium*, strain TA100 and determined that it was inadequate. Sandoz Agro, Inc. has agreed to submit a repeat study by August 15, 1996. The Agency does not believe that the study would significantly change the risk analysis for the use of norflurazon in the culture of alfalfa, as proposed in the subject petition.

Using a 100-fold safety factor and the NOEL of 1.53 mg/kg/day determined by the most sensitive species (the 6-month dog feeding study), the RfD is 0.02 mg/kg/bwt/day. The theoretical maximum residue contribution (TMRC) from the established and the proposed tolerances is 0.002041 and utilizes 10.2 percent of the RfD for the overall U.S. population. The exposure of the most highly exposed subgroup in the population, non-nursing infants, is 0.009356 mg/kg/bwt/day and utilizes 46.8 percent of the RfD.

In a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with norflurazon is minimal for alfalfa commodities and does not exceed the RfD for any of the subgroups.

Because developmental effects were seen in the rabbit developmental study, the Agency assessed acute dietary risk from developmental effects for the subgroup females (13+ years) the only appropriate group of acute dietary concern. The Margin of Exposure (MOE), a measure of how closely the high-end exposure comes to the NOEL, was calculated as the ratio of the NOEL to the exposure and determined to be 3,000. The Agency is not generally concerned unless the MOE is below 100 when based upon data generated in animal studies.

Previous tolerances have been established for norflurazon in almonds, hulls and nutmeat; apples; apricots; asparagus; avocados; blackberries; blueberries; cattle, fat, meat, and meat-by-products (mbp); cherries; citrus fruit; cottonseed; cranberries; filberts; goats, fat, meat and mbp; grapes; hogs, fat, meat, and mbp; hops, green; horses, fat, meat, and mbp; milk; nectarines; peaches; peanuts; peanut hay, hulls and vines; pecans; pears; plums (fresh prunes); poultry, fat, meat and mbp; raspberries; sheep, fat, meat and mbp; soybeans, forage and hay; and walnuts. The metabolism of norflurazon in plants is adequately understood. Metabolism of norflurazon in livestock has been studied and tolerances for livestock commodities have been established. A ruminant study adequately identified the metabolites in milk, liver and kidney. Norflurazon was not detected in ruminant milk or tissue, and total radioactive residues in fat and muscle were <0.01 part per million (ppm).

The nature of the residue is adequately understood, and an adequate analytical method, gas chromatography using electron capture detection, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information 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. 242, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-4432.

The pesticide is considered useful for the purposes for which the tolerances are sought. Based on the information and data considered, the Agency concludes that the establishment of the tolerances will protect the public health.

Registration for use in the culture of alfalfa will be conditioned on the basis that Sandoz Agro, Inc., the registrant will submit an acute inhalation study, a mutagenicity study and a dermal sensitization study. These studies are replacement studies for studies that were determined to be inadequate during the Agency's review of norflurazon for a Reregistration Eligibility Decision (presently not issued). There are presently no actions pending against the continued registration of this chemical. Therefore, the tolerances are 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 docket number [PP 9F3766/R2254] (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 a.m. to 4:30 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 rulemaking, 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 Virginia address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 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).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. 804(2) of the APA as amended.

Pursuant to the requirements of the Regulatory Flexibility Act (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 explaining the factual basis for this determination 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: July 18, 1996.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 be 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 § 180.356, the table is amended by adding alphabetically the entries for Alfalfa, forage; Alfalfa, hay; Alfalfa, seed; Cattle, liver; Goats, liver; Hogs, liver; Horse liver; and Sheep, liver, and by revising the entries for Cattle, mby; Goats, mby; Hogs, mby; Horse, mby; and Sheep, mby; to read as set forth below:

§ 180.356 Norflurazon; tolerances for residues.

*	*	*	*	*
Commodity				Parts per million
*	*	*	*	*
Alfalfa, forage				3.0
Alfalfa, hay				5.0

Commodity				Parts per million
Alfalfa, seed				0.1
* * * *				*
Cattle, liver				0.25
Cattle, mby (except liver)				0.1
* * * *				*
Goats, liver				0.25
Goats, mby (except liver)				0.1
* * * *				*
Hogs, liver				0.25
Hogs, mby (except liver)				0.1
* * * *				*
Horses, liver				0.25
Horses, mby (except liver)				0.1
* * * *				*
Sheep, liver				0.25
Sheep, mby (except liver)				0.1
* * * *				*

[FR Doc. 96-19082 Filed 7-26-96; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Part 180

[PP 5E04443/R2258; FRL-5386-8]

RIN 2070-AB78

1,1-Difluoroethane; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) when used as an inert ingredient (*aerosol propellant*) in aerosol pesticide formulations used for insect control in food- and feed-handling establishments and animals. The Dupont Company requested this regulation pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA).

EFFECTIVE DATE: This regulation becomes effective July 29, 1996.

ADDRESSES Written objections, identified by the document control number, [PP 5E04443/R2258] 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 request 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.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 5E04443/R2258]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed 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: Amelia M. Acierio, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North, 6th Fl., 2800 Crystal Drive, Arlington, VA 22202, (703) 308-8375; e-mail: acierio.amelia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1996 (61 FR 28118), EPA issued a proposed rule (FRL-5371-5) that gave notice that The Dupont Company, 1007 Market Street, Wilmington, DE 19898 had submitted pesticide petition (PP) 5E04443 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), propose to amend 40 CFR 180.1001(c) and (e) by establishing an exemption from the requirement of a tolerance for residues of 1,1-difluoroethane (CAS Reg. No. 75-37-6) when used as an inert ingredient (*aerosol propellant*) in pesticide formulations used for insect control in food- and feed-handling establishments and animals.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are