potential for non-occupational, non-dietary exposure to the general population is not expected to be significant.

D. Cumulative Effects

There is no reliable information to indicate that cloransulam-methyl has a common mechanism of toxicity with any other chemical compound or that potential toxic effects of cloransulam-methyl would be cumulative with those of any other pesticide chemical. Thus DowElanco believes it is appropriate to consider only the potential risks of cloransulam-methyl in its exposure assessment.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above, and based on the completeness and reliability of the toxicity data, DowElanco has concluded that aggregate exposure to cloransulam-methyl will utilize only about 0.01 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, DowElanco concludes that there is a reasonable certainty that no harm will result from aggregate exposure to cloransulam-methyl residues (<0.02 ppm) on soybeans. The complete toxicology profile for cloransulam-methyl shows no evidence of physiological effects characteristic of the disruption of the hormone estrogen. Based upon this observation, cloransulam-methyl does not meet the criteria for an estrogenic compound.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of cloransulam-methyl, data from developmental toxicity studies in rats and rabbits and a multigeneration reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of offspring.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base. Base on the current toxicological data requirements, the data base for cloransulam-methyl relative to pre- and post-natal effects for children is complete. Further, for cloransulam-methyl, the NOEL in the chronic feeding study which was used to calculate the RfD (0.05 mg/kg/day) is already lower than the NOELs from the developmental studies in rats and rabbits by a factor of more than 60 to 200–fold.

Concerning the reproduction study in rats, there were no effects on reproduction or fetal development, even at a dose 100× the NOEL used to establish the RfD. Therefore, DowElanco concludes that an additional uncertainty factor is not needed and that the RfD at 0.05 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described, the percent RfD utilized by the aggregate exposure to residues of cloransulam-methyl on soybeans is 0.07 percent for non-nursing infant, the most sensitive population subgroup. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, DowElanco concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cloransulam-methyl on soybeans.

F. International Tolerances

There are no Codex maximum residue levels established for residues of cloransulam-methyl on soybeans or any other food or feed crop.

II. Public Record

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number, [PF–722]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket control number [PF–722] 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.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

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

The official record for this notice, 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.

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

List of Subjects

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

Dated: March 13, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–7496 Filed 3–25–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–718; FRL–5590–3]

Novartis; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition (PP) 6F4621 proposing the establishment of a regulation for residues of the herbicide norflurazon and its desmethyl metabolite in or on bermudagrass forage and bermudagrass hay. This summary was prepared by the petitioner, Novartis. The original petitioner, Sandoz Agro, Inc., merged with Ciba-Geigy Corp., to form a new corporation, Novartis Crop Protection, Inc., on January 1, 1997, thus the name of the Petitioner has been changed.

DATES: Comments, identified by the docket control number [PF–718], must be received on or before, April 25, 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 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comment 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: Joanne Miller, Product Manager (PM) 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 has received a pesticide petition (PP) 6F4621 from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419, proposing to amend 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 bermudagrass forage at 3.0 ppm and bermudagrass hay at 2.0 ppm. The proposed analytical method of determining residues was gas chromatography. The initial notice of filing was published previously in the **Federal Register** of February 1, 1995 (61 FR 3698)(FRL–4994–3). The current notice of filing is required by EPA to fulfill FQPA requirements. Tolerances requested are the same as those proposed in the initial filing.

Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as amended, Novartis Crop Protection Inc., has submitted the following summary information, data and arguments in support of their pesticide petition. This summary was prepared by Novartis and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify the summary and to remove certain extraneous material and that the conclusions and arguments are the petitioners and not necessarily the EPA's.

I. Petition Summary

A. Chemical Uses

Norflurazon, (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2*H*)-pyridazinone), is a selective, pre-emergent herbicide used to control germinating annual grasses and broadleaf weeds.

Norflurazon is noncorrosive and is stable under alkaline and acid conditions, but is sensitive to light. Norflurazon is only slightly soluble in water (<40 parts per million (ppm)).

B. Norflurazon Safety

Novartis has submitted over 70 separate toxicology studies in support of tolerances for Norflurazon. EPA has classified norflurazon as a non-quantifiable Group C, possible human carcinogen. According to Novartis, norflurazon is not a mutagen and has low oral and dermal toxicity to mammals. (Updated studies have recently been submitted to the EPA.) Risk assessment calculations indicate margins of safety for agricultural workers and the population in general far exceed the EPA required level of 100.

The following mammalian toxicity studies have been conducted to support the tolerances of Norflurazon:

Acute Oral, Rat (Male) LD_{50}: 9.3 g/kg (Tox Category IV)

Acute Dermal, Rabbit: LC_{50} ≥20,000 mg/kg (Tox Category IV)

Acute Inhalation, Rat: LC_{50} > 2.4 mg/l (Tox Category III)

Primary Eye Irritation, Rabbit: non-irritating (Tox Category IV)

Primary Dermal Irritation, Rabbit: no irritation (Tox Category IV)

Dermal Sensitization, in male Guinea Pig: technical norflurazon at 0.1 percent did not cause sensitization (Tox Category IV)

90–day rat feeding study: 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.

A 6–month dog feeding study: 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.

A 3–week rabbit dermal study: The systemic NOEL was 375 mg/kg/day for males and females. The dermal NOEL was also 375 mg/kg/day for both sexes.

A 28–day rat feeding study: NOEL of 50.0 mg/kg/day.

A 28–day mouse feeding study: NOEL of 63.0 mg/kg/day.

A rat dermal absorption study: No more than 0.1 percent of applied dose was absorbed at doses up to 10 mg/rat.

Gene mutation assays: Negative. There was no evidence of cytotoxicity in any of the strains at any of the dose concentrations used. In an *in vitro* unscheduled DNA synthesis assay, norflurazon failed to induce unscheduled DNA synthesis in primary rat hepatocytes. In an *in vitro* chromosomal aberration assay, norflurazon did not cause a clastogenic response in the presence of liver S–9 or in the absence of S–9.

A developmental study in rats: 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.

A developmental study in rabbits: The NOEL for maternal toxicity was 30 mg/kg/day based on maternal body weight decreases at 60 mg/kg/day. The NOEL for developmental toxicity was 30 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.

A three generation reproduction study in rats showed no apparent effects on reproductive performance at any dose level tested.

A chronic toxicity and carcinogenicity study in Sprague-Dawley rats: 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. The systemic NOEL was determined to be 18.75 mg/kg/day for both sexes.

A carcinogenicity study in mice: No significant effects were observed on body weight, body weight gain, and

food consumption at any dose. The systemic NOEL was determined to be 12.8 mg/kg/day for male mice, and 58.7 mg/kg/day for female mice.

A rat metabolism study: 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 administrated 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, glutatione 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.

C. Threshold Effects

Chronic effects: Based on the available chronic toxicity data, EPA has set the Reference Dose (RfD) for norflurazon at 0.02 mg/kg/bwt/day. The RfD for norflurazon is based on the 6-month dog feeding study with a threshold NOEL of 1.53 mg/kg/day and an uncertainty factor of 100.

Acute toxicity: 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.

D. Non-threshold Effects

Carcinogenicity: The EPA'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 published in the **Federal Register** of September 24, 1986, (51 FR 33992–34003), 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 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.

E. Aggregate Exposure:

For the purposes of assessing the potential dietary exposure, Novartis has estimated the aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from the tolerances for all crops on which norflurazon-based products are labeled. The 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.

No norflurazon-based products are labeled for residential use. Non-occupational exposure for norflurazon has not been estimated since the current registrations for norflurazon-based products are limited to commercial crop production. The potential for non-occupational exposure to the general population is, therefore, insignificant.

EPA consideration of a common mechanism of toxicity is not appropriate at this time because Sandoz and EPA do not have information to indicate that toxic effects produced by norflurazon would be cumulative with those of any other chemical compounds.

F. Determination of Safety for US population

Reference Dose (RfD): 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 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. Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Sandoz concludes that there is a reasonable certainty that no harm will result from the aggregate exposure of residues of norflurazon including all anticipated dietary exposure.

G. Determination of Safety for Infants and Children

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. Based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Sandoz concludes that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of norflurazon including all anticipated dietary exposure.

H. Estrogenic Effects

No specific tests have been conducted with norflurazon to determine whether the pesticide may have an effect in humans that is similar or an effect produced by a naturally occurring estrogen or other endocrine effects.

I. Chemical Residue

The nature of the residue is adequately understood, and an adequate analytical method, gas chromatography using electron capture detection, is available for enforcement purposes.

Tolerances have been established for norflurazon in almonds, hulls and nutmeat; apples; apricots; asparagus; avocados; blackberries; blueberries; cattle, fat, meat, and meat-by-products (mbyp); 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 ppm.

J. Environmental Fate

The environmental fate of norflurazon is adequately understood. Norflurazon is persistent and may be mobile. Norflurazons primary route of dissipation appears to be photodegradation in water and on soil to desmethyl norflurazon with a half-life of 2–3 days and 12–15 days respectively. Norflurazon is stable to hydrolysis and degrades slowly under aerobic soil conditions with a half-life of 130 days. In an anaerobic aquatic study, norflurazon degrades to desmethyl norflurazon with a half-life of about 8 months.

Fish accumulation data show that norflurazon has low potential to bioaccumulate in bluegill sunfish.

Norflurazon is not currently regulated under the Safe Drinking Water Act (SWDA). Therefore, no MCL has been established and water systems are not required to sample and analyze for it. Novartis is currently performing groundwater monitoring studies to better evaluate the leaching potential of norflurazon.

Norflurazon is practically non-toxic to avian species on an acute oral and subacute dietary basis. Norflurazon is also practically nontoxic to mammals and insects (honeybees).

K. International Tolerances

No international tolerances have been established under CODEX. Therefore, there is no need to ensure consistency.

II. Public Record

A record has been established for this notice under docket control number [PF–718] (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.

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, 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.

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

List of Subjects

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

Dated: March 11, 1997.

Stephen L. Johnson,

Director, Registration Division Office of Pesticide Programs.

[FR Doc. 97–7065 Filed 3–25–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–727; FRL–5595–6]

Novartis Crop Protection, Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition proposing the establishment of a regulation for the residues of CGA–248757, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene) amino]phenyl]thio]-methyl ester in or on soybeans. This summary was prepared by the petitioner.

DATES: Comments, identified by the docket control number [PF-727], must be received on or before April 25, 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 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 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 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF–727]. 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). No 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: Joanne Miller, Product Manager (PM) 23, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: A notice of filing of pesticide petition 6F4614 was published in the **Federal Register** of June 12, l996 (61 FR 29752) (FRL–5354–7). The Notice stated that Ciba Crop Protection, Ciba-Geigy Corporation had proposed to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene) amino]phenyl]thio]-methyl ester in or on the raw agricultural commodity soybeans at 0.02 part per million (ppm). The proposed analytic method for determining residues was gas chromatographic. On January 1, l997, Ciba Crop Protection merged with Sandoz, Inc. to form a new corporation, Novartis Crop Protection, Inc.

EPA has received a second notice of filing of (PP) 6F4614, from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide CGA–248757, acetic acid [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1*H*,3*H*-[1,3,4]thiadiazolo[3,4-α]pyridazin-1-ylidene) amino]phenyl]thio]-methyl ester in or on the raw agricultural commodity soybeans at 0.01 ppm. The proposed analytical method is gas chromatography using a nitrogen phosphorus detector and a large-bore fused silica column.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Novartis Crop Protection, Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Novartis and EPA has not fully evaluated the merits of the