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

petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Novartis Petition Summary

1. *CGA–248757 uses.* 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, is a new herbicide active ingredient in the imide chemistry class. It will be formulated as a 4.75% wettable powder, packaged in water-soluble bags, and sold under the trade name Action® Herbicide. Action is a highly selective herbicide for use in soybeans postemergence, and is particularly effective in controlling velvetleaf. Control of other broadleaf weeds in soybeans is enhanced and the spectrum of control is broadened when Action is tank mixed with other postemergence herbicides registered for use in soybeans.

Action offers effective weed control at extremely low use rates. The maximum use rate per season is 0.0089 lb. active ingredient (3 ounces (oz). of formulated product) per acre consisting of a maximum of two applications. There is a wide application window extending from the first trifoliate stage of soybean development through the full flowering stage, and the amount of Action to apply depends on the weed species and weed height. Tank mixing Action with other postemergence herbicides further reduces the amount required to control target weeds.

The purpose of this petition is to establish a tolerance for CGA–248757 in soybeans. The tolerance proposed is: Soybeans—0.01 ppm.

2. *CGA–248757 safety*. In support of the petition for tolerance in soybeans, Novartis submitted a full battery of toxicology studies including, acute effects, chronic feeding, oncogenicity, teratogenicity, mutagenicity, and reproductive toxicity tests. The studies indicate that CGA–248757 has a low order of acute toxicity with acute effects in catgegory III and IV, is not neurotoxic, does not pose a genotoxicity hazard, and is not a reproductive toxicant or a teratogen.

Potential exposure to CGA–248757 *via* the diet or drinking water and through handling is very limited. Because of rapid environmental degradation, extremely low residues in food crops, and water-soluble packaging, considerable margins of safety exist for dietary exposure for all subgroups of the population and for worker exposure as well.

The following mammalian toxicity studies have been conducted to support the proposed tolerance for CGA–248757:

- A rat acute oral study with an LD_{50} > 5,000 milligram/kilogram (mg/kg).
- A rabbit acute dermal study with an LD_{50} 2,000 mg/kg.
- A rat inhalation study with an LC_{50} 5.05 mg/liter.
- A primary eye irritation study in the rabbit showing moderate eye irritation.
- A primary dermal irritation study in the rabbit showing no skin irritation.
- A primary dermal sensitization study in the Guinea pig showing no sensitization.
- Twenty-eight day dermal toxicity study in rats with a no-observed effect level (NOEL) equal to or higher than the limit dose of 1,000 mg/kg.
- Six-week dietary toxicity study in dogs with a NOEL of 6,500 ppm in males and 2,000 ppm in females based on decreased body weight gain and modest hematological changes.
- Ninety-day subchronic dietary toxicity study in rats with a NOEL of 100 ppm based on liver changes and hematological effects.
- Twenty-four-month combined chronic toxicity/carcinogenicity study in rats with a NOEL of 50 ppm. Based on reduced body weight development and changes in bone marrow, liver, pancreas and uterus the MTD was exceeded at 3,000 ppm.
- A positive trend of adenomas of the pancreas in male rats treated at 3,000 ppm and above may be attributable to the increased survival of the rats treated at high doses.
- Eighteen-month oncogenicity study in mice with a NOEL of 1 ppm. Based on liver changes, the MTD was reached at 10 ppm. The incidence of hepatocellular tumors was increased in males treated at 100 ppm and 300 ppm.
- Teratology study in rats with a maternal and developmental NOEL equal to or greater than 1,000 mg/kg/day.
- Teratology study in rabbits with a maternal NOEL greater than or equal to 1,000 mg/kg/day and a fetal NOEL of 300 mg/kg based on a slight delay in fetal maturation.
- Two-generation reproduction study in rats with a NOEL of 500 ppm, based on liver lesions in parental animals and slightly reduced body weight development in parental animals and pups. The treatment had no effect on reproduction or fertility.
- Acute neurotoxicity study in rats.
- Neurotoxic effects were not observed. The NOEL was 2,000 mg/kg.
- Ninety-day subchronic neurotoxicity study in rats. The NOEL was 10 ppm based on reduced body weight gain. No clinical or morphological signs of neurotoxicity were detected at any dose level.
- *In vitro* gene mutation tests: Ames test--negative; Chinese hamster V79 test--negative; rat hepatocyte DNA repair test--negative; *E. Coli* letal DNA damage test--negative.
- *In vitro* chromosomal aberration tests: Chinese hamster ovary--positive at cytotoxic doses; Chinese hamster lung--positive at cytotoxic doses; human lymphocyes--positive at cytotoxic doses.
- *In vivo* chromosome aberration tests: Micronucleus assays in rat liver--negative; mouse bone marrow test--negative.

3. *Threshold effects*. Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), Novartis believes the Agency will classify CGA–248757 as a Group ''C'' carcinogen (possible human carcinogen) based on findings of benign and malignant liver tumors in male mice. These tumors most likely resulted from a chronic regenerative and proliferative response of the affected epithelial cells. This response is a non-genotoxic, threshold effect which is due to the accumulation of cytotoxic porphyrins. A positive trend of proliferative pancreatic changes in male rats is likely attributable to the increased survival of the rats in the high dose groups. The lesions observed are not uncommon in the rat strain used.

Because the effects observed are threshold effects, Novartis believes that exposure to CGA–248757 should be regulated using a margin of exposure approach. The reference dose (RfD) for CGA–248757 can be defined at 0.0014 milligram/kilogram/day (mg/kg) based on an 18–month feeding study in mice with a NOEL of 0.14 mg/kg/day and an uncertainty factor of 100.

4. *Non-threshold effects*. Based on the results of an extensive program of genotoxicity studies, CGA–248757 is not mutagenic *in vivo*. As outlined above, effects observed in toxicology studies are attributable to an epigenetic, cytotoxic mechanism, resulting in degenerative and inflammatory changes in the target organs. It is therefore justified that exposure to CGA–248757 should be regulated using a margin of exposure approach.

5. *Aggregate exposure*. In this assessment, Novartis has conservatively assumed that 100% of all soybeans used for human consumption would contain residues of CGA–248757 and all residues would be at the level of the tolerance. The potential dietary exposure to CGA–248757 was calculated on the basis of the proposed

tolerance of the LOQ, 0.01 ppm, in soybeans. The proposed tolerances is set at the limit of detection in the respective commodity because, with the available methodology, there are no detectable residues of CGA–248757 in soybeans. Residues in milk, meat, and eggs due to the feeding of soybean commodities are not expected and tolerances for milk, meat, and eggs are not required. Calculated on the basis of the proposed tolerance, the dietary exposure of the U.S. population to CGA–248757 would correspond to 0.24% of its RfD.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water. Although CGA–248757 has a slight to medium leaching potential; the risk of the parent compound to leach to deeper soil layers is negligible under practical conditions in view of the fast degradation of the product. For example, the soil metabolism half-life was extremely short, ranging from 1.1 days under aerobic conditions to 1.6 days under anaerobic conditions. Even in the event of very heavy rainfalls immediately after application, which could lead to a certain downward movement of the parent compound, parent CGA–248757 continues to be degraded during the transport into deeper soil zones. Considering the low application rate of CGA–248757, the strong soil binding characteristics of CGA–248757 and its degradates, and the rapid degradation of CGA–248757 in the soil, there is no risk of ground water contamination with CGA–248757 or its metabolites. Thus, aggregate risk of exposure to CGA–248757 does not include drinking water. CGA–248757 is not registered for any other use and is proposed for use only on agricultural crops. Thus, there is no potential for non-occupational exposure other than consumption of treated commodities containing CGA–248757 residue.

Novartis also considered the potential for cumulative effects of CGA–248757 and other substances. However, a cumulative exposure assessment is not appropriate at this time because there is no information available to indicate that effects of CGA–248757 in mammals would be cumulative with those of another chemical compound. Thus Novartis is considering only the potential risk of CGA–248757 in its aggregate exposure assessment.

6. *Safety to the U.S. population*. Using the very conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data for CGA–248757, Novartis has calculated that aggregate exposure to CGA–248757 will utilize 0.24% of the RfD for the U.S. population. Thus, even a worst case exposure estimate results in human exposure to CGA–248757 which is 40,000-fold below the NOEL in the most sensitive species. As anticipated residues are below tolerance levels and the market share of CGA–248757 will not approach 25% of planted soybeans, the safety margin is likely to be at least 20 times greater. Exposures below 100 percent of the RfD are generally not of concern 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.

Also the acute dietary risk to consumers will be far below any significant level: The lowest NOEL from a short-term exposure scenario comes from the teratology study in rabbits with a NOEL of 300 mg/kg. This NOEL is 2,000-fold higher than the chronic NOEL which provides the basis for the RfD (see above). Because chronic exposure estimates did not result in any significant exposure, it is anticipated that the acute dietary risk will also be negligible with margins of acute exposure in the hundred thousands (margins of exposure of 100 or more are generally considered satisfactory). Therefore, Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to CGA–248757 residues.

7. *Safety to infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of CGA–248757, Novartis considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. A slight delay in fetal maturation was observed in a teratology study in rabbits at a daily dose of 1,000 mg/kg. In a 2-generation reproduction study, CGA–248757 did not affect the reproductive performance of the parental animals or the physiological development of the pups. The NOEL was 500 ppm for maternal animals and their offspring, which is 50,000 fold higher than the RfD.

Using the same conservative exposure assumptions as for the determination in the general population, the percent of the RfD that will be utilized by aggregate exposure to residues of CGA–248757 is 0.28% for nursing infants less than 1 year old, 1.16% for non-nursing infants, 0.45% for children 1 to 6 years old and 0.35% for children 7 to 12 years old. Novartis concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues of CGA–248757.

8. *Estrogenic effects*. Based on the results of short-term, chronic, and reproductive toxicity studies there is no indication that CGA–248757 might interfere with the endocrine system. Considering further the low environmental concentrations and the lack of bioaccumulation, there is no risk of endocrine disruption in humans or wildlife.

9. *Chemical residue*. The nature of the residues in soybeans and animals (goat and hen) is adequately understood following application of CGA–248757. Residues do not concentrate in processed commodities. There are no Codex maximum residue levels established for residues of CGA–248757 on soybeans. Ciba has submitted a practical analytical method for detecting and measuring the level of CGA–248757 in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set for the proposed tolerance. The limit of quantification of the method is 0.01 ppm. The analytical method involves extraction, filtration, and solid phase clean up. Residue levels of CGA–248757 are determined by gas chromatographic analysis utilizing a nitrogen phosphorus detector and a fused-silica column. EPA can provide information on this method to FDA. The method will be available to anyone who is interested in pesticide residue enforcement from the Field Operations Division, EPA's Office of Pesticide Programs.

The residue of concern in soybeans is CGA–248757 *per se*. Twenty field residue studies were conducted with soybeans grown in 18 states. Residues of CGA–248757 in treated soybeans were less than the method LOQ (0.01 ppm) which is the proposed tolerance. The proposed tolerance level is adequate to cover residues likely to occur when Action herbicide is applied as directed.

Livestock feeding studies have not been submitted and tolerances for residues of CGA–248757 in livestock commodities have not been requested. Results of hen and goat metabolism studies wherein CGA–248757 was fed at exaggerated rates indicated that CGA–248757 is poorly absorbed. Based upon the exaggerated feeding levels in the goat and hen metabolism studies, the results of soybean metabolism studies, the requested tolerance level of 0.01 ppm for soybeans, and the maximum dietary exposure of beef and dairy cattle and poultry to CGA–248757, detectable residues of CGA–248757 or its metabolite, CGA–300403 (> 0.01 ppm) are unlikely to occur in meat, milk, poultry, or eggs.

In studies with processed soybean fractions, concentration of CGA–248757 was not found and tolerances in processed commodities will not be

required. In addition, confined rotational crop studies indicated that CGA–248757 will not be taken up by rotational crops.

Novartis analytical Method AG–603A has been independently validated for collection of residues of CGA–248757 in soybeans and processed fractions and this method has been provided to the FDA. Residue levels of CGA–248757 are determined by gas chromatography and the limit of detection for the method is 0.01 ppm.

10. *Environmental fate*. Action degraded rapidly under laboratory and field conditions. Laboratory hydrolysis under basic conditions was T1/2 ~ 5 hours at pH 9 and stable under acidic conditions (T1/2 ~ 485 days at pH 5).The soil metabolism half-life was extremely short, ranging from 1.1 days under aerobic conditions to 1.6 days under anaerobic conditions. Photodegradation was rapid in soil (T1/2 ~ 0.5 days) and moderate in solution at pH 5 (5 days). Because of the extremely low use rate and very short half-life in the field, field dissipation experiments were conducted with radiolabeled chemical. After bare-ground application, the half-life of Action was 1 day in sandy loam and 1.8 days in clay loam. All degradates identified in the field were also identified in the laboratory studies. Parent and aged leaching laboratory experiments showed that the mobility of Action ranged from slight to medium by soil type. Based on estimates of relative mobility (K_{oc}), Action was classified as having medium mobility in sand and low mobility in loam, silt loam and clay. The major degradation products of Action were found to have high to low mobility classifications based on K_{oc} estimations. Although the data suggest that some of the degradates are highly mobile, a high degree of soil binding is expected based on results of the laboratory and the field experiments. Because weeds and crop will intercept the majority of this product when it is applied, and given the extremely low use rate and high degree of soil binding, Action herbicide is not expected to leach into groundwater.

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–727]. A record has been established for this document under docket control number [PF–727] (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 may 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 notice 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.

List of Subjects

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

Dated: March 12, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–7222 Filed 3–25–97; 8:45 am]

BILLING CODE 6560–50–F

[OPP–181039; FRL–5594–5]

Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted specific exemptions for the control of various pests to nine States listed below. Six crisis exemptions were initiated by various States and one by the United States Department of Agriculture. These exemptions, issued during the months of July, August, September, October, November, and December 1996 and January and February 1997, are subject to application and timing restrictions and reporting requirements designed to protect the environment to the maximum extent possible. Information on these restrictions is available from the contact persons in EPA listed below.

DATES: See each specific and crisis exemption for its effective date.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption for the name of the contact person. The following information applies to all contact persons: By mail: Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, CS 1B1, 2800 Jefferson Davis Highway, Arlington, VA (703–308–8417); e-mail: group.ermus@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has granted specific exemptions to the:

1. Arkansas State Plant Board for the use of metolachlor on spinach to control weeds; December 2, 1996, to February 2, 1997. (Margarita Collantes)

2. California Department of Pesticide Regulations for the use of bifenthrin on broccoli and cauliflower to control the silverleaf whitefly; January 30, 1997, to February 30, 1997. (Margarita Collantes)

3. California Department of Pesticide Regulations for the use of imidacloprid on beets and turnips to control aphids; January 29, 1997, to Auqust 4, 1997. California had initiated a crisis exemption for this use. (Margarita Collantes)

4. Minnesota Department of Agriculture for the use of triclopyr on infested water bodies to control purple loosestrife; July 31, 1996, to September 15, 1996. (Margarita Collantes)

5. New Jersey Department of Environmental Protection for the use of tebufenozide on apples to control tufted apple bud moth; August 1, 1996, to September 30, 1996. (Pat Cimino)

6. New Mexico Department of Agriculture for the use of tebufenozide on chile peppers to control beet armyworms; December 17, 1996, to December 30, 1997. (Margarita Collantes)

7. Oklahoma Department of Agriculture for the use of metolachlor on spinach to control weeds; December 2, 1996, to March 31, 1997. (Margarita Collantes)

8. Texas Department of Agriculture for the use of metolachlor on spinach to control weeds; December 2, 1996, to August 15, 1997. (Margarita Collantes)

9. Texas Department of Agriculture for the use of propiconazole on grain sorghum to control northern leaf blight; November 6, 1996, to October 31, 1997. Texas had initiated a crisis exemption for this use. (Pat Cimino)

10. Virginia Department of Agriculture for the use of metolachlor