Public Response and 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 address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

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

Dated: March 18, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–7494 Filed 3–25–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–722; FRL–5592–8]

DowElanco; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice is a summary announces the filing of a pesticide petition proposing the establishment of a regulation for residues of cloransulam-methyl in or on soybeans. This notice contains a summary was prepared by the petitioner, DowElanco.

DATES: Comments, identified by the docket number [PF–722], 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 be 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 in ASCII file format. All comments and data in electronic form must be identified by docket control number [PF–722]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below this document.

Information submitted as a comments 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: Philip Errico, Product Manager (PM) 25, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M. St., SW., Washington, D.C. Office location, telephone number and e-mail address: Rm. 237, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 703–305–6027. e-mail: errico.phillip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 5F4560 from DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268-1054 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide *N*-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro[1,2,4] triazolo[1,5c]pyrimidine-2-sulfonamide, (cloransulam-methyl) in or on the raw agricultural commodity soybeans at 0.02 ppm, soybean forage at 0.1 part per million (ppm) and soybean hay at 0.2 ppm. The proposed analytical method is gas chromatography coupled with a mass selective detector (GC-MSD).

EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficieny of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

Availability of the analytical method: The proposal analytical method of enforcement which measures residues of cloransulam-methyl in soybeans, and soybean forage and hay discussed below has not been validated by the Agency. Public versions of the analytical method can be obtained from the Pesticide Docket, U.S. Environmental Protection Agency, Office of Pesticide Programs, 401 M. St., SW., Washington, D.C. 20460, (703) 305–5805.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, DowElanco included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of DowElanco; EPA, as mentioned above, is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

1. *Plant metabolism*. Nature of residue studies demonstrated that residues of cloransulam-methyl and its metabolites would not be expected to accumulate to significant levels in soybeans treated either pre-plant or post-emergence, and that it was appropriate to base the magnitude of total terminal residues and proposed tolerances only on residues of the parent compound, cloransulam-methyl. A rotational crop study showed no significant level of cloransulam-methyl or any structurally-related metabolite in any crop, or crop fractions, grown in rotation 120 days after soil treatment.

2. *Analytical method*. Residue analytical methods were validated based upon gas chromatography coupled with a mass selective detector (GC- MSD). The limit of detection of the methods is 0.005 ppm and a level of quantitation is 0.01 ppm.

3. *Magnitude of residues.* No detectable residues of cloransulam-methyl resulted in soybeans from either preplant incorporated or post emergence applications, in soybean forage or hay

following preplant applications, and in the majority of cases, in soybean forage or hay following postemergence applications. No residues of cloransulam-methyl were detected in the soybeans or processed fractions above the analytical method limit of detection of 0.005 ppm following 5× the proposed maximum postemergence application rate.

B. Toxicological Profile

1. *Acute toxicity.* Cloransulam-methyl acute toxicity is low. Acute oral LD_{50} in the rat is >5,000 mg/kg in both males and females and the acute dermal LD_{50} in the rabbit is >2,000 mg/kg. The inhalation LC_{50} in the rat is >3.77 mg/l of air, which is the highest obtainable respirable aerosol concentration. Cloransulam-methyl produced no indications of dermal irritation in rabbits or sensitization in the guinea pig, and only slight transient eye irritation in the rabbit following acute exposure.

2. *Genotoxicity.* In a battery of short-term genotoxicity tests, cloransulam-methyl showed no evidence of a mutagenic potential. These tests included a bacterial reverse mutation assay (Ames test), an *in vitro* cytogenic assay in Chinese hamster ovary cells (CHO/HGPRT assay), an *in vitro* chromosomal aberration assay in rat lymphocytes, and an *in vivo* cytogenetic assay in mouse bone marrow cells.

3. *Reproductive and developmental toxicity.* Cloransulam-methyl exhibited no effects on reproduction or fetal development. In a multigeneration reproduction study in rats, no effects on reproductive performance or neonatal survival were seen at the highest dose tested.

In a developmental toxicity study in rats, no maternal or developmental toxicity was seen at the highest dose tested (limit test at 1,000 mg/kg).

In a developmental toxicity study in rabbits, the maternal NOEL was 100 mg/kg/day and the developmental NOEL was at least 300 mg/kg/day.

4. *Subchronic toxicity.* In a 21-day repeated dermal application study in rabbits, cloransulam-methyl when given at a dose of 1,000 mg/kg/day produced only slight anemia in female rabbits while male rabbits were unaffected at the highest dose tested. The NOEL was 500 mg/kg/day for females and 1,000 mg/kg/day in males. Cloransulam-methyl was evaluated in 13-week dietary studies in rats, mice and dogs. The primary target organs identified in these studies were the kidneys (rat), the liver (mouse and dog), and thyroid (rat). An NOEL was not determined in the rat base upon minor histopathological changes in the kidney (males) and the liver (females). In the mouse, the NOEL was 50 mg/kg/day in male mice and 100 mg/kg/day in female mice based upon hepatocellular hypertrophy. An NOEL was not established in the dog based upon slightly lower body weights at the lowest dose tested, 40 mg/kg/day.

5. *Chronic toxicity.* In a 2-year combined chronic toxicity/oncogenicity study in the rat, the NOEL for chronic toxicity was 10 mg/kg/day based upon kidney and thyroid effects: hypertrophy of collecting duct epithelial cells and vacuolation consistent with fatty change in the proximal tubules of males and females, and an increase in the incidence of mineralization of the renal pelvis in males. Thyroid changes were confined to the high dose males and consisted of hyperplasia and hypertrophy of follicular epithelium. In a 2- year dietary feeding study in B6C3F1 mice, the NOEL for chronic toxicity was also 10 mg/kg/day base upon the liver as he primary target organ. There were increased liver weights and histologic changes consisting of centrilobular hypertrophy in males. Kidney weights were decreased in males and females, and depletion of the normal ctyoplasmic vacuoles and decreases in the incidence of renal mineralization and renal tubular degeneration were noted in males. All of these histologic changes were interpreted to be non-adverse. There was no evidence of an oncogenic response in either male or female mice or rats. In a 1-year chronic toxicity study in dogs, the NOEL was 5 mg/kg/day based upon an increase in accumulation of pigment in Kuppfer cells and hepatocytes with changes in hepatic-related serum chemistry parameters.

6. *Animal metabolism.* Metabolism studies conducted on cloransulam-methyl indicated over 90 percent of a single or repeated dose was absorbed at 5 mg/kg and at 1,000 mg/kg/day, there was incomplete absorption of cloransulam-methyl, with only 28-30 percent of the dose absorbed. Urinary elimination was rapid with half-lives of approximately 6-9 hours. Sex dependent differences in disposition of the 5 mg/kg dose were traced to more efficient elimination of unchanged cloransulam-methyl in the female versus male kidney but are of no known toxicologic significance. Due to its rapid elimination, cloransulam-methyl has little potential to accumulate upon repeated administration.

7. *Metabolite toxicology.* The residue of concern for tolerance setting purposes is the parent material (cloransulam-methyl). Thus there is no need to address metabolite toxicity.

C. Aggregate Exposure

1. Dietary Exposure

a. Food. For Purpose of assessing the potential dietary exposure from use of cloransulam-methyl on soybeans, a conservative estimate of aggregate exposure is determined by TMRC assuming that 100 percent of the soybean crop has a residue of cloransulam-methyl at the tolerance level of 0.02 ppm. This results in an extremely conservative estimate of exposure for cloransulam-methyl, because no residues were detected in soybeans at a level 4× lower than the proposed tolerance level based upon applications made either at the proposed maximum label rate, or at a rate 5× higher than the proposed maximum application rate in an exaggerated rate residue study. The potential dietary exposure is obtained by multiplying the tolerance residue level on soybeans (0.02 ppm) by the consumption data which estimates the amount of soybean products consumed by various population subgroups. The maximum potential average daily dose (ADD) of cloransulam-methyl values determined for various populations are clearly significant overestimates compared with actual exposure. When ADDs are compared to the Reference Dose (RfD), which used the lowest NOEL of 5 mg/kgBW/day from the 1-year dog chronic toxicity study and an uncertainty factor of 100, the ADD for the average U.S. consumer utilizes only about 0.01 percent of the RfD, and even the highest risk group, non-nursing infants, would theoretically be exposed to less than 0.07 percent of the RfD. If the margin of safety (MOS) or safety factor approach is used, the calculated MOSs are 7,600 for the average U.S. population and 1,500 for non-nursing infants. DowElanco believes it is evident from these very conservative estimates that cloransulam-methyl poses no significant dietary risk to any human population.

b. *Drinking water.* Another potential source of dietary exposure are residues in drinking water. Base upon the available environmental studies conducted with cloransulam-methyl wherein it's properties show little potential for mobility in soil and extremely rapid photolysis in water, DowElanco concludes, there is no anticipated exposure to residues of cloransulam-methyl in drinking water.

2. *Non-dietary exposure.* There are no other uses currently registered for cloransulam-methyl. The proposed use in on soybeans involves application of cloransulam-methyl to crop grown in an agricultural environment. Thus, the

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