[PF–717; FRL–5590–2]

Bayer Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing regulations establishing tolerances for residues of the pyrethroid cyfluthrin in or on the raw agricultural commodities (RACs) group citrus, fruits and to establish a maximum residue limit for cyfluthrin on citrus oil and dried pulp. This notice includes a summary of the petition that was prepared by Bayer Corporation.

DATES: Comments, identified by the docket control number [PF–717], must be received on or before April 14, 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–717]. 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: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 200, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 305–6100; larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions (PP) 4F4313 and 4H5687 from Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120. The petition proposes, pursuant to section 408(d) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. section 346a, to amend 40 CFR 180.436 to establish tolerances for residues of the insecticide cyfluthrin, [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dicloroethenyl]-2,2-dimethylcyclopropanecarboxylate] in or on the raw agricultural commodities group citrus, fruits at 0.2 part per million (ppm) and the processed commodities citrus, oil and citrus, dried pulp at 0.3 part per million (ppm). The proposed analytical method is gas chromatography equipped with electron capture detector.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Bayer Corporation 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 Bayer Corporation; EPA 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. *Use pattern*. Baythroid 2 will be used on citrus only in California and Arizona, to control citrus thrips. A dosage of 6.4 fluid ounces of Baythroid 2 (0.1 lb active ingredient per acre) will be applied by ground equipment only, in sufficient water for complete coverage of foliage in dilute or concentrate sprays, but not less than 25 gallons per acre. A single application may be made per season.

2. *Plant metabolism*. The metabolism of cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

3. *Analytical methodology*. Adequate analytical methodology (Gas liquid chromatography with an electron capture detector) is available for enforcement purposes.

The established tolerances for residues of cyfluthrin in/on eggs, milks, fat, meat and meat by-products of cattle, goats, hogs, horses, sheep and poultry are adequate to cover secondary residues resulting from the proposed use as delineated in 40 CFR 180.6(a)(2).

4. *Magnitude of the residue*. On December 20, 1993, Bayer Corp. filed a petition (PP 4F4313) for a tolerance for residues of cyfluthrin on the raw agricultural commodity, citrus and proposed food/feed additive regulation (4H5687) for citrus oil, citrus dried pulp, and citrus molasses under section 409 of FFDCA. A request was filed May 2, 1996, to withdraw the feed additive petition for citrus molasses, submitted in response to EPA's determination that citrus molasses is no longer considered a significant feed item. See EPA's final 860 Series Residue Chemistry Guidelines (860.1000) published as public drafts on August 25, 1995 (60 FR 44343) (formerly Table II of Subdivision O, Residue Chemistry, of the Pesticide Assessment Guidelines).

The food/feed additive petition for citrus oil and citrus dried pulp has been revised to propose these tolerances at 0.3 ppm under section 408 instead section 409 in accordance the Food Quality Protection Act.

The proposed section 408 tolerance for cyfluthrin on citrus is 0.2 ppm. The highest average residue found in crop field trials for cyfluthrin on citrus fruits was 0.06 ppm. A processing study showed that in producing citrus oil and dried pulp residues concentrated 530 (a concentration factor of 5.3×). Thus with this information it is likely that cyfluthrin residues of 0.32 ppm (0.06×5.3) could occur in citrus oil and dried pulp.

B. Toxicological Profile

The data base for cyfluthrin is essentially complete. Data lacking but desirable are an acute neurotoxicity study in rats and a 90-day neurotoxicity study in rats. Although these data are lacking, Bayer Corp. believes there is sufficient toxicity data to support the proposed tolerance and these missing data will not significantly change the risk assessment. In a letter dated November 2, 1995, Bayer Corp. has committed to submit the acute neurotoxicity study by December 1996

and the 90-day neurotoxicity study by May 1997.

The toxicology data cited in support of the tolerance include:

1. *Chronic effects.* A 12-month chronic feeding study in dogs with a no-observed effect level (NOEL) of 4 mg/kg/day. The lowest effect level (LEL) for this study is established at 16 mg/kg/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

A 24-month chronic feeding/carcinogenicity study in rats with a NOEL of 2.5 mg/kg/day and LEL of 6.2 mg/kg/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

2. *Acute toxicity.* For the purposes of assessing acute dietary risk, the Agency has used an oral developmental toxicity study in rabbits with a maternal NOEL of 20 mg/kg/day and a maternal LEL of 60 mg/kg/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOEL of 20 mg/kg/day and a fetal LEL of 60 mg/kg/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

3. *Carcinogenicity.* A 24-month carcinogenicity study in mice was conducted. There were no carcinogenic effects observed under the conditions of the study.

A 24-month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary(CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

4. *Other.* A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

C. Aggregate Exposure

A chronic dietary exposure/risk assessment was performed for cyfluthrin using a Reference Dose (RfD) of 0.025 mg/kg bwt/day, based on a NOEL of 50 ppm (2.5 mg/kg bwt/day) and an uncertainty factor of 100. The NOEL was determined in a 2-year rat feeding study. The endpoint effects of concern were decreased body weights in males and inflammation of the kidneys in females at the LEL of 6.2 mg/kg/day. For purposes of this dietary exposure/risk assessment tolerance level residues were used and percent crop treated assumption made for some of the commodities. The current estimated dietary exposure for the overall U.S. population resulting from established tolerances 0.009420 mg/kg/bwt/day or 37.6 percent of the RfD. The current estimated dietary exposure for the subgroup population exposed to the highest risk, non-nursing infants less than 1 year old, 0.025266 mg/kg bwt/day or 101 percent of the RfD. Although the estimate of dietary exposure for the subgroup, non-nursing infants less than 1 year old, is slightly higher than the Agency's level of concern, i.e., greater than 100 percent of the RfD, Bayer Corp. believes that actual exposure and risk would be lower. The basis for this is that the risk reflects a higher than actual dietary exposure because it assumes that 100 percent of most commodities for which cyfluthrin tolerances exist have cyfluthrin residues and that all will bear residue levels as high as the tolerances. In reality, all these commodities will not have residues of this pesticide and actual levels will be lower than tolerance levels. To assess the dietary exposure from the establishment of the proposed citrus tolerances, the incremental increase in dietary exposure was taken from the dietary exposure analysis conducted by the Agency. These estimates are based on the assumption that 100 percent of the citrus crop in the U.S. would be treated with cyfluthrin. In reality, this use of cyfluthrin will be limited to California and Arizona only for the control of citrus thrips. For the prior six years, cyfluthrin has been utilized in the California's Central Valley under the provisions of a FIFRA section 18 Emergency Exemption. In 1995, approximately 77,000 out of 170,000 acres (46 percent) of the citrus grown in Central Valley was treated with cyfluthrin. Assuming that a similar proportion of acreage, that is 46 percent, would be treated throughout California and Arizona, the total estimated acreage treated with cyfluthrin would be 94,000 acres. This represents only 9.4 percent of the 1,026,000 fruit bearing acres of citrus grown in the U.S. Therefore, a 10 percent treated crop adjustment to the dietary exposure can be considered appropriate.

Adding this incremental exposure to the current estimated dietary exposure results in a total dietary exposure for the U.S. population of 0.0094934 mg/kg bwt/day representing 38 percent of RfD. The highest exposure group, non-nursing infants will increase only very slightly, to 0.253653 mg/kg bwt/day representing 101.4 percent of the RfD. As described above, although this still slightly exceeds the RfD, actual exposure is expected to be much less.

Generally speaking, EPA has no cause for concern if the total dietary exposure from residues for uses for which there are published and proposed tolerances is less than the RfD. Therefore Bayer concludes that the chronic dietary risk of cyfluthrin, as estimated by the dietary risk assessment, does not appear to be of concern.

Other potential sources of exposure to residues of pesticides are residues in drinking water and exposure from non-occupational sources. Based on available studies used in previous EPA assessments, Bayer Corp. does not anticipate exposures to cyfluthrin in drinking water. Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. The Agency does not currently have reliable data to determine aggregate exposures from these sources. However, determinations of worst case exposure from inhalation in indoor settings (continuous exposure at saturation vapor concentration) should indicate that adequate margins of safety exist even under these conditions. Since this evaluation greatly overestimates exposure, the contribution to aggregate exposure from inhalation in normal uses would be expected to be negligible. Estimations of outdoor residential exposure have been required for cyfluthrin in a data call-in issued in 1995. These data are being generated by the Outdoor Residential Exposure Task Force (ORETF). However, available data show that the acute dermal toxicity of cyfluthrin is very low, with the LD_{50} being greater than 5,000 mg/kg, the highest dose tested. Sub-acute (21–day) dermal toxicity data showed only localized (skin) effects at higher level exposures (1,000 mg/kg/day and 340 mg/kg/day). Other than skin effects at these high exposure levels, no effects were observed at any exposure levels, the highest level tested being 1,000 mg/kg/day. The use rate for cyfluthrin on residential turf is 1 g (1,000 mg) active ingredient per 1000 square feet which would indicate that potential exposures would be well below levels tested. In addition, the localized skin effects seen at the prolonged higher exposures in animal tests have not been reported for non-occupational exposures to cyfluthrin in currently accepted uses,

indicating that exposures are below the threshold of any observable effects. Indoor uses are limited to areas with little or no contact, so exposures would be expected to be even less. Thus, the dermal route of exposure does not appear to be significant and the contribution to aggregate exposure from dermal contact would be expected to be negligible.

In consideration of potential cumulative effects of cyfluthrin and other substances that have a common mechanism of toxicity, there are currently no available data or other reliable information indicating that any toxic effects produced by cyfluthrin would be cumulative with those of other chemical compounds; thus only the potential risks of cyfluthrin have been considered in this assessment of its aggregate exposure.

D. Safety Determinations

1. *U.S. population in general.* Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data it can be concluded that total aggregate exposure to cyfluthrin from all current uses as well as the proposed tolerance and maximum residue levels for the use of cyfluthrin on citrus will utilize little more than 38 percent of the RfD for the U.S. population. EPA generally has no concerns for exposures below 100 percent of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development . The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity.

The toxicology data cited in support of the tolerance include: An oral developmental toxicity study in rats with a maternal and fetal NOEL of 10 mg/kg/day (highest dose tested). An oral developmental toxicity study in rabbits with a maternal NOEL of 20 mg/kg/day and a maternal LEL of 60 mg/kg/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOEL of 20 mg/kg/day and a fetal LEL of 60 mg/kg/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

A developmental toxicity study in rats by the inhalation route of administration with a maternal NOEL of 0.0011 mg/l and a LEL of 0.0047 mg/l, based on reduced mobility, dyspnea, piloerection, ungroomed coats and eye irritation. The fetal NOEL is 0.00059 mg/l and the fetal LEL is 0.0011 mg/l, based on sternal anomalies and increased incidence of runts. A second developmental toxicity study in rats by the inhalation route of administration has been submitted to the Agency and is currently under review.

A three-generation reproduction study in rats with a systemic NOEL of 2.5 mg/kg/day and a systemic LEL of 7.5 mg/kg/day due to decreased parent and pup body weights. The reproductive NOEL and LEL are 7.5 mg/kg/day and 22.5 mg/kg/day respectively.

The Agency used the rabbit developmental toxicity study with a maternal NOEL of 20 mg/kg/day to assess acute dietary exposure and determine a margin of exposure (MOE) for the overall U.S. population and certain subgroups. Since this toxicological endpoint pertains to developmental toxicity the population group of concern for this analysis was women aged 13 and above, the subgroup which most closely approximates women of child-bearing age. The MOE is calculated as the ration of the NOEL to the exposure. For this analysis the Agency calculated the MOE to be over 600. Generally, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk.

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 effects and the completeness of the toxicity database. Based on current toxicological data requirements, the toxicology database for cyfluthrin relative to pre- and post-natal effects is complete. The no-effect-levels observed in the developmental and reproduction study are equivalent or higher than the NOEL from the 2-year rat feeding study, used with a 100 fold uncertainty factor to establish the reference dose.

Therefore, an additional uncertainty factor is not warranted and that the RfD at 0.025 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumptions described above, EPA has previously concluded that the residues from use of cyfluthrin on citrus will contribute the highest incremental increase to the aggregate exposure to the population subgroup children 1 to 6 years old, accounting for 3.9 percent of the RfD and giving a total dietary exposure from all uses of 95.9 percent of the RfD for this subgroup. However, this assessment was based on an assumption of 100 percent crop treated. When adjusted for a 10 percent crop treatment (as described in section B. above) the incremental exposure is negligible, increasing form the current 0.022985 mg/kg bwt /day (91.9 percent of the RfD) to 0.231522 mg /kg bwt/day or 92.6 percent of the RfD. For nursing infants current exposure is 0.005692 mg/kg bwt/day or 22.8 percent of the RfD. The use on citrus would increase exposure to 0.0057377 mg/kg bwt/day representing 22.9 percent of the RfD. For children 7 to 12, current exposure is 0.015237 mg/kg bwt/ day, 60.9 percent of the RfD. The use on citrus would increase this to 0.153416 mg/kg bwt /day, or 61.4 percent of the RfD. For non-nursing infants, the current is exposure is calculated to be 0.025267 mg/kg bwt /day, 101 percent of the RfD. The use on citrus would increase this slightly to 0.0253653 or 101.4 percent. Both the current and the resulting calculated exposure from adding the estimated exposure from citrus exposure are slightly higher than the Agency's level of concern. However, the Agency has previously assessed this risk in the evaluation of PP 2F4137 and believed the actual exposure and risk would be much lower. The basis for this was the fact that this calculated exposure assumes, with the exception of citrus, that 100 percent of the commodities for which cyfluthrin tolerance exists have residues and that the residues all bear residues as high as the tolerance levels. In reality, it is known that not all commodities will have cyfluthrin residues and actual levels will be lower than the tolerance values. In addition, the food commodity that contributes most to this slight exceedence is milk, at 88.2 percent of the RfD; 71.2 percent from milk fat and 17 percent from whole milk and milk sugars. However, metabolism data indicate that essentially all of the cyfluthrin will concentrate in milk fat and there would be negligible amounts in other components. Thus the 17 percent contribution from non-milk fat portions of milk is an overestimation of actual

exposure, which would be below the RfD.

Generally, EPA has no cause for concern if the total aggregate exposure is less than the RfD, therefore it may be concluded that there is a reasonable certainty of no harm will result to infants and children.

E. Conclusions

The available data indicate that there is reasonable certainty of no harm from the incremental exposure resulting from the potential residues of cyfluthrin from the use of Baythroid 2, EPA Reg. No. 3125–351, on citrus. Thus in accordance with the provisions of the FFDCA as amended August 3, 1996, regulations to establish the tolerance and maximum residue levels to support this use can be effected.

F. International Tolerances

There are no Codex maximum residue levels (MRLs) established for residues ofcyfluthrin on citrus fruits or any resulting processed products.

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–717]. 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–717] 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 requirements.

Dated: March 7, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–6516 Filed 3–13–97; 8:45 am]

BILLING CODE 6560–50–F

[OPP–50826; FRL–5592–3]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit to the following applicant. The permit is in accordance with, and subject to, the provisions of 40 CFR part l72, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Office of Pesticide Programs, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by telephone: Rm. 3142, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, Telephone: 703–308–8715, e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has issued the following experimental use permit: *70218–EUP–1.* Issuance. This experimental use permit allows the use of 0.825 pounds of the *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein in seeds shipped on 3,305 acres of corn to evaluate the control of the European corn borer and other lepidopteran corn pests. The program is authorized in the States of Alabama, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin. The experimental use permit is effective from February 5, 1997 to November 30, 1997. This permit is issued with the limitation that all treated crops are destroyed or used for research purposes only.

Persons wishing to review this experimental use permit are referred to the designated contact person. Inquires concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.

Dated: March 5, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 97–6518 Filed 3–13–97; 8:45 am]

BILLING CODE 6560–50–F

[FRL–5710–4]

Special Report on Environmental Endocrine Disruption: An Effects Assessment and Analysis

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of risk assessment forum report.

SUMMARY: EPA is announcing the availability of the ''Special Report on Environmental Endocrine Disruption: An Effects Assessment and Analysis.'' The report provides an overview of the current state of the science for endocrine disruption. The report's major components are an introduction to the endocrine system and the endocrine disruption hypothesis; a review of potential human health and ecological risks; and an analysis section, including an overview of research needs. The report represents an interim assessment pending a more extensive review expected to be issued by the National Academy of Sciences later in 1997.

ADDRESSES: An electronic version of the report is accessible on EPA's Office of