[PF–675; FRL–5574–4]

Pesticide Tolerance Petition; Notice of 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 residues of clopyralid in or on field corn. This summary was prepared by the petitioner.

DATES: Comments, identified by the docket number [PF–675], must be received on or before, January 10, 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 docket number [PF-675]. 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 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Joanne Miller, PM–23, (7505C) Rm. 237, Crystal Mall #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) 8F3622 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 clopyralid in or on the raw agricultural commodities (RACs) field corn, fodder at 10.0 ppm; field corn, forage at 3.0 ppm; field corn, grain at 1.0 ppm and on processed agricultural commodity (PAC) field corn, milling fractions at 1.5 ppm. The proposed analytical method is available for enforcement purposes.

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

I. DOWELANCO Petition Summary:

A. Residue Chemistry

1. *Plant Metabolism*. The metabolism in plants is adequately understood. No metabolites of significance were detected in plant metabolism studies.

2. *Analytical Method*. There is a practical analytical method for detecting and measuring levels of clopyralid in or on food with a limit of quantitation that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement.

3. *Magnitude of Residues*. Time limited tolerances were established on April 25, 1994 (59 FR 19639) for residues of the herbicide clopyralid in or on the following raw agricultural commodities which are to expire December 31, 1996: field corn, grain at 1.0 parts per million (ppm), field corn, fodder at 10.0 ppm, field corn, forage at 3.0 ppm, and for corn processed milling fractions at 1.5 ppm. Adequate residue data supporting these tolerances were submitted to the Agency in mid year 1994.

4. *Residues of Clopyralid Found in Field Corn* - Clopyralid was applied at the maximum label rate and residues were detected at the following ppm ranges; Grain 0.01 - 0.8, Fodder 0.02 - 8.8, and Silage 0.04 - 2.7. The proposed tolerances would adequately cover these anticipated residues.

5. *Residues of Clopyralid Found in Processed Field Corn* - Clopyralid was applied to corn at approximately 1X and 5X the label rate. The 5X treatment was used for the processing residue study. At the 5X rate, the corn grain RAC (raw agricultural commodity) sample was found to contain 4.3 ppm clopyralid. Starch and refined oil samples obtained from the wet milling of corn contained no residues above the LOQ (0.05 ppm) of the method, while crude oil was found to contain 0.063 ppm. The dry milling fractions contained 4.9 ppm in flour, 2.7 ppm in meal, with no residues above the LOQ found in crude and refined oil. Grain dust contained 4.8 ppm clopyralid, similar to levels found in the RAC. The proposed milling fractions tolerance would cover these residue levels when adjusted from the 5X treatment rate.

B. Toxicological Profile

1. *Acute Toxicity*. Clopyralid has low acute toxicity. The rat oral LD50 is 5000 mg/kg or greater for males and females. The rabbit dermal LD50 is ≤2000 mg/kg and the rat inhalation LC50 is ≤1.0 mg/L air (the highest attainable concentration). In addition, clopyralid is not a skin sensitizer in guinea pigs and is not a dermal irritant. Technical clopyralid is an ocular irritant but ocular exposure to the technical material would not normally be expected to occur to infants or children or the general public. End use formulations of clopyralid have similar low acute toxicity profiles and most have low ocular toxicity as well. Therefore based on the available acute toxicity data, clopyralid does not pose any acute dietary risks.

2. *Genotoxicity*. Clopyralid is not genotoxic. The following studies have been conducted and all were negative for genotoxic responses. Ames bacterial mutagenicity assay (with and without exogenous metabolic activation) Host-Mediated assay In vivo cytogenetic test, rat; In vivo cytogenetic test, mouse; In vivo dominant lethal test, rat; In vitro unscheduled DNA synthesis assay in primary rat hepatocyte cultures; In vitro mammalian cell gene mutations assay in Chinese hamster ovary cell cultures (with and without exogenous metabolic activation).

3. *Reproductive and Developmental Toxicity*. Developmental toxicity was studied using rats and rabbits. The developmental study in rats resulted in a developmental NOEL of >250 mg/kg/

day (a maternally toxic dose) and a maternal toxicity NOEL of 75 mg/kg/day. A 1974 study in rabbits revealed no evidence of developmental or maternal toxicity at 250 mg/kg/day; thus the developmental and maternal NOEL was >250 mg/kg/day. A more recent study in rabbits (1990) resulted in developmental and maternal NOELs of 110 mg/kg/day based on maternal toxicity at 250 mg/kg/day. Based on all of the data for clopyralid, there is no evidence of developmental toxicity at dose levels that do not result in maternal toxicity.

In a 2–generation reproduction study in rats, pups from the high dose group which were fed diets containing clopyralid had a slight reduction in body weight during lactation and an increase in liver weights in fla and flb weanlings. The NOEL for parental systemic toxicity was 500 mg/kg/day. There was no effect on reproductive parameters at >1500 mg/kg/day nor was there an adverse effect on the morphology, growth or viability of the offspring; thus, the reproductive NOEL is >1500 mg/kg/day.

4. *Subchronic Toxicity*. The following studies have been conducted using clopyralid. In a rat 90–day feeding study, Fischer 344 rats were fed diets containing clopyralid at doses of 5, 15, 50 or 150 mg/kg/day with no adverse effects attributed to treatment. In a second study, Fischer 344 rats were fed diets containing clopyralid at doses of 300, 1500 and 2500 mg/kg/day. Effects at the highest doses were decreased food consumption accompanied by decreased body weights and weight gains in both males and females. Slightly increased mean relative liver and kidney weights were noted in males of all 3 doses and in females at the top 2 doses. Because there were no other effects, the kidney and liver weight effects were judged as being adaptive rather than directly toxic. The no-observed-adverse effect level (NOAEL) was 1500 mg/kg/day for males and females. The no-observed-effect level (NOEL) was 300 mg/kg/day for females.

In a mouse 90–day feeding study, B6C3F1 mice were fed diets containing clopyralid at doses of 200, 750, 2000 or 5000 mg/kg/day. A slight decrease in body weight occurred at the top dose in both sexes. The liver was identified as the target organ based on slight increases in liver weights and minimal microscopic alterations at the higher dose levels. The liver changes were considered to be reversible and adaptive. The NOEL for males was 2000 mg/kg/day and for females was 750 mg/kg/day.

In a 180–day feeding study, beagle dogs were fed diets containing clopyralid at doses of 15, 50 or 150 mg/kg/day; there were no adverse effects. In a second dietary study, dogs also were fed diets containing clopyralid at doses of 15, 50 or 150 mg/kg/day; the only effect was an increase in the mean relative liver weight in females at the 150 mg/kg/day.

In a 21–day dermal study, clopyralid was applied by repeated dermal application to New Zealand White rabbits at dose levels up to 1000 mg/kg/day. Treatment produced no systemic effects.

5. *Chronic Toxicity*. In a chronic toxicity and oncogenicity study, Sprague-Dawley rats were fed diets containing clopyralid at doses of 5, 15, 50 or 150 mg/kg/day. The only effect was a trend toward a decreased body weight of female rats receiving the 150 mg/kg/day dose with a NOEL of 50 mg/kg/day. In a second study clopyralid was fed to Fischer 344 rats in the diet at doses of 15, 150 or 1500 mg/kg/day. The effects were confined almost entirely to the 1500 mg/kg/day dose groups and included slightly decreased food consumption and body weights, slightly increased liver and kidney weights and macroscopic and microscopic changes in the stomach. No tumorigenic response was present. The NOEL for this study was 15 mg/kg/day.

B6C3F1 mice were maintained for 2 years on diets formulated to provide targeted dose levels of 10, 500 or 2000 mg/kg/day. The only evidence of toxicity was body weight depression in males dosed at 2000 mg/kg/day. There was no evidence of tumorigenic response at any dose level.

Based on the chronic toxicity data, EPA has established the RfD for clopyralid at 0.5 milligrams (mg)/kilogram (kg)/day. The RfD for clopyralid is based on a 2–year chronic oncogenicity study in rats with a no-observed-effect level (NOEL) of 50 mg/kg/day and an uncertainty (or safety) factor of 100. Thus, it would not be necessary to require the application of an additional uncertainty factor above the 100–fold factor already applied to the NOEL.

6. *Carcinogenicity*. Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), clopyralid would be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of the carcinogenicity studies. There was no evidence of carcinogenicity in 2–year feeding studies in mice and rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment would not be appropriate.

7. *Animal Metabolism*. Disposition and metabolism of clopyralid were tested in male and female rats at a dose of 5 mg/kg (oral). The majority of a radioactive dose was excreted in 24 hours of all dose groups. Fecal elimination was minor. Detectable levels of residual radioactivity were observed in the carcass and stomach at 72 hours post-dose. HPLC and TLC analysis of pooled urine and fecal extracts showed no apparent metabolism of clopyralid.

8. *Metabolite Toxicity*. There are no clopyralid metabolites of toxicological significance.

9. *Endocrine Effects*. There is no evidence to suggest that clopyralid has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary Exposure - Food*. For purposes of assessing the potential dietary exposure under these tolerances, exposure is estimated based on the TMRC from the existing and pending tolerances for clopyralid on food crops. The TMRC is obtained by multiplying the tolerance level residues by the consumption data which estimates the amount of those food products eaten by various population subgroups. Exposure of humans to residues could also result if such residues are transferred to meat, milk, poultry or eggs. The following assumptions were used in conducting this exposure assessment: 100% of the crops were treated, the RAC residues would be at the level of the tolerance, certain processed food residues would be at anticipated (average) levels based on processing studies and all current and pending tolerances were included. This results in an overestimate of human exposure and a conservative assessment of risk.

Based on a NOEL of 50 mg/kg/day in a 2–year chronic feeding/oncogenicity study in the rat and a hundredfold safety factor, the reference dose (RfD) would be 0.5 mg/kg/day. Consequently, all existing and pending tolerances have a theoretical maximum residue contribution of 0.001535 mg/kgBW/day and would utilize less than 2.3 percent of the RfD.

2. *Dietary Exposure - Drinking Water*. Another potential source of dietary exposure to residues of pesticides are residues in drinking water. There is no established Maximum Concentration Level for residues of clopyralid in drinking water. Although there has been limited detections at ppb levels in some of the specially designed studies under highly vulnerable test conditions, no ongoing monitoring studies (U.S. Geological Survey, Selected Water Resources

Abstracts, and Pesticides in Ground Water Database - A Compilation of Monitoring Studies: 1971 - 1991 National Summary; U.S. Department of Agriculture, AGRICOLA database; U.S. Department of Commerce, National Technical Information Service) have reported residues of clopyralid in ground or surface waters.

Consequently, these data on potential water exposure indicate insignificant additional dietary intake of clopyralid and any exposure is more than compensated for in the conservative dietary risk evaluation.

3. *Non-Dietary Exposure*. Non-occupational exposure to clopyralid is limited to re-entry to treated turf grass sites. Estimated exposures for children is less than 0.05 mg/kg/day or 10% of the reference dose.

D. Cumulative Effects

The potential for cumulative effects of clopyralid and other substances that have a common mechanism of toxicity was considered. The mammalian toxicity of clopyralid is well defined. However, no reliable information exists to indicate that toxic effects produced by clopyralid would be cumulative with those of any other chemical compound. Therefore, consideration of a common mechanism of toxicity with other compounds is not appropriate. Thus only the potential exposures to clopyralid were considered in the aggregate exposure assessment.

E. 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 is concluded that aggregate exposure to clopyralid will utilize approximately 7 percent of the RfD for the U.S. population. Generally, exposures below 100 percent of the RfD are of no concern because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to clopyralid residues.

2. *Infants and Children*. In assessing the potential for additional sensitivity of infants and children to residues of clopyralid, data from the previously discussed developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat were considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism during prenatal development resulting from pesticide exposure to one or both parents. Reproduction studies provide (1) information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and (2) data on systemic toxicity. These studies indicate no evidence of developmental toxicity at dose levels below those that cause maternal toxicity.

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 database. Based on the current toxicological data requirements, the database relative to pre and post-natal effects for children is complete. Therefore, it is concluded that an additional uncertainty factor is not warranted and that the RfD at 0.5 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumptions, it is concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of clopyralid will be less than 12 percent of the RfD for all populations and subgroups. This estimate represents the ''worst case'' exposure for a given population (i.e. children ages 1–6), exposure is less for any other sub-population e.g. infants. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposures to clopyralid residues.

F. International Tolerances

There are no Codex maximum residue levels established for clopyralid.

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the document control number, [PF–675]. 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 be established for this notice under docket number [PF–675] 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: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, Rm. 1132, 1921 Jefferson Davis Highway, Arlington, VA 22202.

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

Dated: November 27, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–31345 Filed 12–10–96; 8:45 am]

BILLING CODE 6560–50–F

FARM CREDIT ADMINISTRATION

Sunshine Act Meeting; Farm Credit Administration Board

AGENCY: Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552(e)(3)), of the forthcoming regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on December 12, 1996, from 10:00 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Floyd Fithian, Secretary to the Farm Credit Administration Board, (703) 883–4025, TDD (703) 883–4444.