[Project No. 11540–001, South Carolina]

Joyner Enterprises Association; Notice of Surrender of Preliminary Permit

January 10, 1997.

Take notice that the Joyner Enterprises Association, permittee for the Berry Shoals Project No. 11540, located on the South Tyger River in Spartanburg County, South Carolina, has requested that its preliminary permit be terminated. The preliminary permit was issued on February 7, 1996, and would have expired on January 31, 1999. The permittee states that the project would be economically infeasible.

The permittee filed the request on December 17, 1996, and the preliminary permit for Project No. 11540 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR Part 4, may be filed on the next business day.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 97–933 Filed 1–14–97; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5676–5]

Transfer of Confidential Business Information to Contractors

AGENCY: Environmental Protection Agency.

ACTION: Notice of transfer of data and request for comments.

SUMMARY: EPA will transfer Confidential Business Information (CBI) to its contractor, Industrial Economics, Inc. and its subcontractors: DPRA, Inc.; ICF, Inc.; Northbridge Environmental Management Consultants; Research Triangle Institute; Tetra Tech, Inc.; Booz, Allen & Hamilton, Inc.; Eastern Research Group; Energy and Environmental Research Corporation; Kerr & Associates, Inc.; Ross & Associates Environmental Consulting, Ltd.; SocioTechnical Research Application, Inc.; Tellus Institute and Versar, Inc. that has been or will be submitted to EPA under Section 3007 of the Resource Conservation and Recovery Act (RCRA). Under RCRA, EPA is involved in activities to support, expand and implement solid and hazardous waste regulations.

DATES: Transfer of confidential data submitted to EPA will occur no sooner than January 27, 1997.

ADDRESSES: Comments should be sent to Regina Magbie, Document Control Officer, Office of Solid Waste (5305W), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Comments should be identified as ''Transfer of Confidential Data.''

FOR FURTHER INFORMATION CONTACT: Regina Magbie, Document Control Officer, Office of Solid Waste (5305W), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, 703–308–7909.

SUPPLEMENTARY INFORMATION:

1. Transfer of Confidential Business Information

Under EPA Contract 68–W6–0061, Industrial Economics, Inc., and its subcontractors, will assist the Office of Solid Waste, Economics, Methods, and Risk Assessment Division, by providing technical support for: Methodology Development/Cross-Cutting Scoping Studies; Innovative Benefits Assessment; Economic Impacts; Industry Profiles; Screening and Prioritization; Environmental Indicators and Goals. EPA has determined that Industrial Economics, Inc., and its subcontractors, will need access to RCRA CBI submitted to the Office of Solid Waste to complete this work. Specifically, Industrial Economics, Inc. and its subcontractors, need access to the CBI that EPA collects, under the authority of Section 3007 of RCRA, in Industry Studies Surveys and other studies of industries involved with waste management.

In accordance with 40 CFR 2.305(h), EPA has determined that Industrial Economics, Inc., and its subcontractors, require access to CBI submitted to EPA under the authority of RCRA to perform work satisfactorily under the above-noted contract. EPA is submitting this notice to inform all submitters of CBI of EPA's intent to transfer CBI to these firms on a need-to-know basis. Upon completing their review of materials submitted, Industrial Economics, Inc., and its subcontractors, will return all CBI to EPA.

EPA will authorize Industrial Economics, Inc., and its subcontractors, for access to CBI under the conditions and terms in EPA's ''Contractor Requirements for the Control and Security of RCRA Confidential Business Information Security Manual.'' Prior to transferring CBI to Industrial Economics, Inc., and its subcontractors, EPA will review and approve their security plans and Industrial Economics, Inc., and its subcontractors, will sign non-disclosure agreements.

Dated: December 17, 1996.

Elizabeth A. Cotsworth,

Acting Director, Office of Solid Waste.

[FR Doc. 97–979 Filed 1–14–97; 8:45 am]

BILLING CODE 6560–50–P

[PF–686; FRL–5580–3]

Rhone-Poulenc Ag Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of pesticide petitions proposing to increase and decrease tolerances for ethephon in or on cottonseed, meat and milk, and proposes establishing new tolerances for cotton gin trash and poultry. The summary was prepared by the petitioner, Rhone-Poulenc Ag Company.

DATES: Comments, identified by the docket number [PF–686], must be received on or before, February 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 in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by docket number [PF–686]. 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 V. Errico, Acting Product Manager (PM 22), Rm., 229, CM #2, 1921 Jefferson Davis Highway, Arlington, VA., 703–305–5540, e-mail: errico.philip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions (PP) 1H5603 (originally published in the Federal Register of April 3, 1991, (56 FR 13641)), and 6F4743 from Rhone-Poulenc AG Company, P.O. Box 12014, Research Triangle Park, NC 27709 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 increasing the established tolerances for residues of the plant growth regulator, ethephon, (2-chloroethyl phosphonic acid, in or on the raw agricultural commodities (RACs) cottonseed from 4.0 parts per million (ppm) to 6.0 ppm; meat by-products (except kidney) of cattle, goats, hogs, horses, and sheep from 0.1 to 0.2 ppm; by decreasing established tolerances for ethephon in or on RACs milk from 0.1 ppm to 0.01 ppm, fat of cattle, goats, hogs, horses, and sheep from 0.1 ppm to 0.02 ppm; and by establishing tolerances for ethephon in or on cotton gin byproducts to 180 ppm; kidney of cattle, goats, hogs, horses, and sheep at 1.0 ppm; eggs at 0.002 ppm; poultry meat at 0.01 ppm; poultry liver at 0.05 ppm; poultry fat at 0.02 ppm; and poultry meat byproducts (except liver at 0.01 ppm. The proposed analytical method is analysis for ethylene release.

Pursuant to the section 408(d)(2)(A)(i) of the FFDCA, as recently amended by the Food Quality Protection Act, Rhone-Poulenc AG Company has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Rhone-Poulenc AG Company 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. Petition Summary

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residue in plants is adequately understood based on tomato, cantaloupe, apple, fig, pineapple, tobacco, grape, walnut, filbert, cherry, tangerine and lemon metabolism data. Ethephon degrades to ethylene phosphate and chloride. Data indicate that proximal and distal translocation of ethephon to fruits may occur following application to leaves. The residue of concern in plants is ethephon.

2. *Analytical method*. Adequate methods for purposes of enforcement of ethephon tolerances in plant commodities, ruminant tissues, and milk are available. The Amchem-Plant Method (PAM, Vol. II, Method I) is the recommended method for enforcement purposes for plant commodities and processed products other than wheat and barley straw. The Amchem-Cereal Method (forwarded to FDA for inclusion in the PAM, Vol. II, Method I) is the recommended method for enforcement purposes for wheat and barley straw. The Union Carbide-Animal Method (forwarded to FDA for inclusion in the PAM, Vol. II, Method III) is the recommended method for enforcement purposes for milk and animal tissues. These methods employ diazomethane as a methylating agent. A new plant and animal method has been submitted for enforcement purposes that does not employ diazomethane. The method principally involves the decomposition of ethephon to ethylene to determine the residues of ethephon. An independent lab validation of this method is in review at EPA.

3. *Magnitude of residues*. Residue studies have been conducted to support ethephon registrations on: cotton, apples, cherries, tomatoes, wheat, barley, peppers, grapes, tobacco, walnuts, almonds, blackberries, cantaloupe, pineapple, sugarcane and macadamia nuts. In addition, IR–4 is conducting work to support new uses on blueberries, coffee, cranberries, figs and guavas. All residue data requirements cited in the ethephon RED have been submitted to EPA. As a result of this work, increased tolerances have been proposed for cottonseed (6 ppm, PP 6F4743) and cotton gin by-products (180 ppm, amendment to PP 1H5603). As part of the reregistration process, the following tolerances will be revoked: cucumbers, filberts, lemons, pineapple forage and fodder, pumpkins, tangerines, tangerine hybrids and sugarcane molasses. The tolerances for residues of ethephon in or on food and feed commodities are currently based in terms of ethephon *per se*. Processing studies have been conducted on apples, barley, cottonseeds, grapes, pineapples, tomatoes, and wheat and are deemed adequate to determine the extent to which residues of ethephon concentrate in food/feed items upon processing of the raw agricultural commodity. Data indicate that ethephon residues concentrate in apple juice, dried apple pomace, barley hulls, cottonseed meal, grape juice, raisins, raisin waste, dried grape pomace, pineapple bran and pulp, dried tomato pomace, wheat bran, wheat shorts and germ and red dog. Available apple processing data indicate that residues of ethephon do not concentrate in wet apple pomace. Therefore, a feed additive tolerance on apple pomace is not required. Available tomato processing data indicate that residues of ethephon do not concentrate in tomato paste and, therefore, no tolerance is needed. Pineapple processing data indicate that residues of ethephon concentrate in dried pineapple bran (5.3X; no longer a processed commodity) and wet pulp (1.2X), but do not concentrate in juice, syrup, and slices. No feed additive tolerance for residues of ethephon in processed pineapple is required. As a result of a recent cow feeding study, new animal tolerances have been proposed. The following tolerances have been proposed for cattle, goat, horses, and sheep: meat - 0.02 ppm; meat byproducts (except kidney) - 0.20 ppm; kidney - 1.0 ppm; fat 0.02 ppm, and milk (cow and goat) - 0.01 ppm. Following a hen feeding study, new tolerances were proposed for poultry: poultry meat - 0.01 ppm; poultry meat byproducts (except liver) - 0.01 ppm; poultry fat - 0.02 ppm; poultry liver - 0.05 ppm; and eggs - 0.002 ppm.

B. Toxicology Profile

1. *Acute toxicity--Ethephon technical.* A complete battery of acute toxicity studies for ethephon technical was completed. The acute oral toxicity study resulted in a LD_{50} of 1,600 mg/kg for both sexes. The acute dermal toxicity in rabbits resulted in an LD_{50} in either sex of greater than 5000 mg/kg. The acute inhalation study in rats resulted in a LC_{50} of 4.52 mg/l. Ethephon was corrosive to the skin of rabbits in the primary dermal irritation study. Therefore, the primary eye irritation study in rabbits was not required. The dermal sensitization study in guinea pigs indicated that ethephon is not a sensitizer. Based on the results of the dermal irritation study, and the anticipated results in an eye irritation study, ethephon technical is placed in toxicity Category I.

Conclusion: Based on the acute toxicity data cited above it is concluded that ethephon technical does not pose any acute dietary risks.

2. *Genotoxicity--Ethephon technical.* The potential for genetic toxicity of ethephon was evaluated in several assays. The compound was found to be mutagenic in strain TA–1535 with and without S9 activation in the Ames assay. In the *in vitro* chromosomal aberrations study with Chinese hamster ovary cells, ethephon was negative. Ethephon was tested for unscheduled DNA synthesis in the rat hepatocyte system and was found to be negative. The weight of evidence suggests that this material is non-genotoxic.

Conclusions: Based on the data cited above, the weight of evidence indicates that ethephon technical does not pose a risk of mutagenicity or genotoxicity.

3. *Reproductive and developmental toxicity.* Ethephon has been tested for reproductive toxicity in rats and developmental toxicity in both rats and rabbits (two studies in each species). The results of these studies are summarized below:

a. In a two generation reproduction study, 28 Sprague-Dawley rats per sex per dose were administered 0, 300, 3,000, or 30,000 ppm (0,15, 150, or 1,500 mg/kg/day) of ethephon in the diet. For the offspring, a NOEL of 15 mg/kg/day and a LOEL of 150 mg/kg/day was established based on decreased body weight gain in the females at 150 mg/kg/day and in both sexes at 1,500 mg/kg/day. No effects were observed on fertility, gestation, mating, organ weights, or histopathology in any generation.

b. In rats, ethephon was administered by gavage at doses of 0, 20, 600, or 1,800 mg/kg for gestation days 6 through 15. At 1,800 mg/kg/day, 14 of the 24 treated female rats died. No toxic effects were observed at lower doses. The NOEL for maternal and developmental toxicity was 600 mg/kg/day. In a second study, rats were dosed by gavage at 0, 125, 250, or 500 mg/kg/day on days 6 through 15 of gestation. No toxic effects were observed at any dose. The NOEL for maternal and developmental toxicity was 500 mg/kg/day.

c. In rabbits, ethephon was administered by gavage at doses of 0, 50, 100, and 250 mg/kg for gestation days 6 through 19. The number of does with live fetuses were 10, 12, 8, and 5, respectively. Resorptions were increased at 100 mg/kg/day and statistically significantly increased at 250 mg/kg/day. At 250 mg/kg/day, does were depressed, ataxic, showed an increase of clinical observations and gross pathology in the gut. The NOEL for maternal toxicity was 50 mg/kg/day and the NOEL for developmental toxicity was 50 mg/kg/day. In a second study, rabbits were dosed by gavage at 0, 62.5, 125, or 250 mg/kg/day on days 6 through 19 of gestation. Maternal morbidity, mortality, and clinical signs of toxicity were observed at 250 mg/kg/day. Fetal toxicity, consisting of decreased number of live fetuses per doe, increased early resorptions and post implantation loss was observed at 250 mg/kg/day. A NOEL for maternal and developmental toxicity of 125 mg/kg/day was observed.

Conclusions: Based on the two-generation reproduction study in rats, ethephon is not considered a reproductive toxicant and shows no evidence of endocrine effects. The data from the developmental toxicity studies on ethephon show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The NOEL for both maternal and developmental toxicity in rats was 500 mg/kg/day and for rabbits the NOEL for both maternal and developmental toxicity was 50 mg/kg/day, respectively.

4. *Subchronic toxicity.* The subchronic toxicity of ethephon has been studied in three human studies and a 21–day dermal study in rabbits. These studies are summarized below:

a. Male and female subjects received ethephon at doses of 0.17 and 0.33 mg/kg/day for 22 days. The daily doses were divided into 3 gelatin capsules. No adverse effects were noted in clinical observations, hematology, serum chemistry (including RBC ChE) and urinalysis. There was a significant decrease in plasma ChE for both treatment groups, although the effect at 0.17 mg/kg/day appeared to be very close to the threshold for significance.

b. Male and female subjects received ethephon at a dosage of 0.5 mg/kg/day for 16 days. The daily dose was divided into 3 gelatin capsules. No adverse effects were noted in clinical observations, hematology, serum chemistry (including RBC ChE) and urinalysis. There was a significant decrease in plasma cholinesterase.

c. Ethephon was administered to male and female subjects at a daily dose of 124 mg/day (1.8 mg/kg/day average for both sexes) divided up into 3 gelatin capsules for 28 days. Clinical signs of toxicity were observed and included diarrhea, urgency of bowel movements, urinary urgency and stomach cramps. No effects were noted with regard to hematology, urinalysis or serum chemistry including cholinesterase evaluations.

d. In a 21–day dermal study, 10 rabbits per sex per group were dosed dermally at 0, 25, 75, and 150 mg/kg/day, five days per week for three weeks. Skin effects were observed at all doses. Effects ranged from erythema and desquamation at the lowest dose to acanthosis and chronic inflammation at 150 mg/kg/day. No systemic treatment-related effects were observed on body weight, food consumption, organ weight or histopathology. The systemic NOEL was greater than 150 mg/kg/day.

Conclusions: Based on the results of the 3 studies in humans, a LOEL of 1.8 mg/kg/day was established in the 28–day study. In the 22–day study, 0.17 mg/kg/day appeared to be very close to the threshold for significance. The systemic NOEL in the 21–day dermal study in rabbits was greater than 150 mg/kg/day.

5. *Chronic effects.* A 2 year chronic toxicity/oncogenicity study in rats, an 18 month mouse oncogenicity study, a 1–year study in dogs, and a 2–year chronic study in dogs were performed on ethephon technical. These studies are summarized below:

a. A combined chronic/oncogenicity study was performed on ethephon in Sprague-Dawley rats. Doses administered in the feed were 0, 300, 3,000, 10,000 or 30,000 ppm for 95 weeks to the males and 103 weeks for the females. The doses administered relative to body weight were 0, 13, 131, 446, or 1,416 mg/kg/day for males and 0, 16, 161, 543 or 1,794 mg/kg/day for females. Plasma and erythrocyte cholinesterase was inhibited at all doses (NOEL<300 ppm). Brain cholinesterase inhibition was not observed. A decrease in male body weight was observed at 10,000 ppm. At 30,000 ppm a body weight decrease was observed in both sexes. Additional effects at 30,000 ppm were thyroglossal duct cysts, kidney glomerulo-sclerosis and nephritis and biliary hyperplasia cholangiofibrosis. No carcinogenic effects were observed.

b. Male and female CD–1 mice were administered ethephon in the diet at 0, 100, 1,000, or 10,000 ppm (0, 15.5, 156, or 1,630 mg/kg/day) for 78 weeks. An additional dose level of 50,000 ppm was terminated at 12 weeks because of excessive morbidity and mortality. No evidence of treatment related tumors was observed. A NOEL of 15.5 mg/kg/day was determined for plasma cholinesterase inhibition. At 1,630 mg/kg/day male body weights were increased and female body weights decreased compared to controls.

c. Ethephon technical was administered in the feed at 0, 30, 300, and 3,000 ppm (0, 0.75, 7.5, or 75 mg/kg/day) to male and female beagle dogs

for 2 years. Due to toxicity/morbidity, the high dose was reduced as follows: 75 mg/kg/day weeks 0–3; 50 mg/kg/day weeks 4–5; 25 mg/kg/day weeks 6–24; 37.5 mg/kg/day weeks 25–104. Plasma cholinesterase was inhibited at all doses (NOEL<0.75 mg/kg/day). A NOEL for erythrocyte cholinesterase inhibition of 0.75 mg/kg/day with a LOEL of 7.5 mg/kg/day was observed. Histopathology showed smooth muscle atrophy in the gut at 7.5 mg/kg/day with a NOEL of 0.75 mg/kg/day.

d. Ethephon was administered in the feed at doses of 0, 100, 300, 1,000 or 2,000 ppm (0, 2.7, 8.2, 28.5, or 52.1 mg/kg/day) to male and female beagle dogs for 52 weeks. A systemic NOEL of 1,000 ppm (28.5 mg/kg/day) was observed for decreased spleen weight, body weight, hemoglobin and hematocrit in males. The females showed a decreased spleen/body weight ratio for the same NOEL. Cholinesterase inhibition was not determined.

Conclusions: The NOEL in the chronic rat study was 131 mg/kg/day based on the decreased body weight gains in males. The NOEL in the most recent one-year dog study was determined to be 28.5 mg/kg/day based on body weight, organ weight effects and hematology effects. Ethephon has been tested in both rats and mice for oncogenic activity. No oncogenic effects were observed.

6. *Animal metabolism*.

Rat metabolism--Ethephon technical. The rat metabolism study consisted of a single intravenous dose group at 50 mg/kg, and single and multiple oral high dose groups at 50 and 1,000 mg/kg. The oral Cmax (maximum concentrations were reached at 1.3 and 1 hours for the 50 mg/kg dose and 1.9 and 2.5 hours for the 1,000 mg/kg dose in males and females, respectively. The t1/2 of the rapid excretion phase (A-phase) at the 50 mg/kg dose was 7 hours for both sexes and 4 and 9 hours at 1,000 mg/kg for the males and females, respectively. Oral and intravenous doses were rapidly excreted in the urine accounted for 48 to 71 percent of the administered radioactivity. Approximately 7 percent was excreted in the feces. Exhaled ethylene was 10–20 percent and CO_2 was less than 1 percent of the administered dose. The highest tissue concentrations were found in the blood, bone, liver, kidney and spleen with no significant differences between single and multiple dosing. No significant differences were observed in the excretion pattern with either sex or multiple dosing.

Goat metabolism--Ethephon technical. In a goat metabolism study, ethephon was incorporated into natural products (glutathione conjugates, protein, glycogen, and triglycerides) and expired as CO_2 and ethylene.

Hen metabolism--Ethephon technical. In a hen metabolism study, ethephon metabolism involved an initial removal of chlorine to form 2-hydroxyethanephosphonic acid followed by further metabolism which results in the release of ethylene and carbon dioxide as well as intermediates which can enter into fundamental biochemical pathways leading to the biosynthesis of proteins and lipids.

Conclusions: Ethephon technical is not metabolized to breakdown products that can be reasonably expected to present any chronic dietary risk.

7. *Metabolite toxicology*. Ethephon degrades to ethylene phosphate and chloride. Therefore, no significant toxicity is anticipated from these breakdown/metabolites.

8. *Neurotoxicity*. The acute neurotoxicity of ethephon has been studied. The study is summarized below:

Groups of 12 male and 12 female Sprague Dawley rats were treated once by gavage with ethephon at dose levels of 0, 500, 1,000, or 2,000 mg/kg in order to assess its potential acute neurotoxicity. The time for assessing peak behavioral effects was previously determined in another study to be approximately 6 hours post dosing. At 2,000 mg/kg, mortality (females only) and transitory effects including pupillary constriction, increased urination (males only), reduced food consumption and body weight, decreased body temperature (females only), and reduced motor activity. Mortality and reduced food consumption was also observed for the 1,000 mg/kg females, motor activity was decreased for the 1,000 mg/kg males and constricted pupils were noted for some animals in all the lower dosage groups. No neuropathological lesions were seen that were attributed to treatment with ethephon. The nature of the findings suggests that they were generally isolated pharmacological effects and not of neurotoxicological significance given their transitory nature and the lack of treatment related structural lesions in the nervous system.

Conclusions: The acute neurotoxicity study demonstrated transient findings that suggested isolated pharmacological effects and no NOEL was established based on the observation of transient constricts. Ethephon does not appear to pose any significant acute neurotoxicity.

C. Aggregate Exposure

1. *Dietary exposure.* a. *Food* - Ethephon is registered for use on the following food crops: cotton, apples, cherries, tomatoes, wheat, barley, peppers, grapes, tobacco, walnuts, almonds, blackberries, cantaloupe, pineapple, sugarcane and macadamia nuts. In addition, IR-4 is conducting work to support new uses on blueberries, coffee, cranberries, figs and guavas. Ethephon has several ornamental/non-food applications as well. All residue requirements cited in the ethephon RED have been submitted to EPA. As a result of this work, increased tolerances have been proposed for cottonseed (6 ppm, PP 6F4743) and cotton gin by-products (180 ppm, amendment to PP 1H5603). As part of the reregistration process, the following tolerances will be revoked: cucumbers, filberts, lemons, pineapple forage and fodder, pumpkins, tangerines, tangerine hybrids and sugarcane molasses. The tolerances for residues of ethephon in or on food and feed commodities are currently based in terms of ethephon per se. An enforcement method was submitted to EPA for determination of residues of ethephon in/on plant commodities and in milk, ruminant and poultry tissues. The ethephon RED lists the number of treated acres by crop for all major ethephon uses in the U.S.

b. *Drinking water* - Based on the available studies and the use pattern, Rhone-Poulenc does not anticipate residues of ethephon in drinking water. There is no established Maximum Concentration Level or Health Advisory Level for ethephon under the Safe Drinking Water Act.

2. *Non-dietary*. The potential for non-occupational exposure to the general public is also insignificant since only approximately 800 lbs of ethephon technical is sold in the U.S. home and garden market annually. The residential lawn or garden uses anticipated for these products where the general population may be exposed via inhalation or dermal routes are negligible. The home and garden formulation that is sold in the U.S. contains only 3.9 percent ethephon which would further limit exposure.

D. Cumulative Effects

While ethephon is an inhibitor of ChE of the plasma and RBC, it has not demonstrated any ability to inhibit brain ChE in rats, mice, or dogs under condition of a chronic dietary dosing regimen. Furthermore, unlike classic organophosphate ChE inhibitors, ethephon did not induce symptoms of ChE inhibition, such as constriction of the pupils, salivation, lacrimation, diarrhea, urination, tremors, and convulsions under chronic feeding of

doses up to 30,000, 10,000, and 2,000 ppm in the rat, mouse, and dog, respectively. In the rat study, the plasma and RBC ChE were inhibited approximately 55 percent and 85 percent, respectively. In the mouse study, both peripheral ChEs were inhibited by approximately 70 percent. Although cholinesterase determinations were not performed in the 1 year dog study, in a 2 year dog study, plasma and RBC ChE were inhibited 60 percent and 70 percent, respectively. Despite these high degrees of inhibition of peripheral ChE, no clinical signs or symptoms consistent with ChE inhibition occurred in these studies. It is generally only under very extreme conditions such as high doses administered via oral gavage or under occlusive dermal dressing in rabbits in which signs that are consistent with ChE inhibition are observed. These clinical signs generally occur at doses that produce acute lethality. However, these signs may in fact be unrelated to CNS ChE inhibition and could be a non-specific reaction to the acidic and therefore highly irritant nature of ethephon.

Ethephon should not be regarded as a classical inhibitor of ChE such as the carbamates and organophosphates since it does not produce the typical nervous system effects of those compounds. The recently updated chronic data base adequately proves that very high dietary doses of ethephon do not inhibit brain ChE, that it does not produce the classical clinical signs of ChE inhibition, and that it does not produce life-shortening effects, despite moderate to severe lifetime inhibition of both plasma and RBC ChE. The inhibition of ChE by ethephon is only an indicator of exposure and is not a measure of its potential for inducing ChE-mediated toxicity.

In summary, Rhone-Poulenc concludes that consideration of a common mechanism of toxicity is not appropriate at this time since there is no significant toxicity observed for ethephon. Even at high doses, ethephon does not act as a classical inhibitor of cholinesterase. Exposure, even at high doses, does not lead to brain cholinesterase inhibition. There is no reliable data to indicate that the effects noted would be cumulative with those of organophosphate or carbamate-type compounds. Therefore, Rhone-Poulenc has considered only the potential risks of ethephon in its exposure assessment.

E. Safety Determination

The EPA OPP/HED RfD Peer Review Committee determined that the reference dose (RfD) should be based on the 28–day study in humans. Using the LOEL of 1.8 mg/kg/day in this study and an uncertainty factor (UF) of 100 to account for intraspecies variability and the lack of a NOEL, an RfD of 0.018 mg/kg/day was established as the chronic dietary endpoint.

1. *U.S. population--General.* A chronic dietary risk assessment which included all proposed changes in ethephon tolerances was conducted on ethephon using two approaches: (1) a Tier 1 approach using tolerance-level residues for all foods included in the analysis, and (2) Monte Carlo simulations using tolerance-level residues for all foods adjusted for percent crop treated (Tier 3). Using the Tier 1 approach, MOEs at the 95th and 99th percentiles of exposure for the overall U.S. population were 25 and 9, respectively. Using Tier 3 procedures in which residues were adjusted for the percent of the crop treated, MOEs were 114 and 42, respectively. Acute exposure was also estimated for infants and children 1 to 6 years of age. In the Tier 1 analysis, the most highly exposed subgroup was infants. For this population, MOEs at the 95th and 99th percentiles of exposure were 7 and 4, respectively. Using the Tier 3 method MOEs were 56 and 12, respectively. Even under the conservative assumptions presented here, the more realistic estimates of dietary exposure (Tier 3 analyses) clearly demonstrate adequate MOEs up to the 99th percentile of exposure for all population groups analyzed.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of ethephon, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by ethephon were considered. Developmental toxicity studies in two species indicate that ethephon is not a teratogen. The 2 generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development. Maternal and developmental NOELs and LOELS were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. It is therefore concluded that ethephon poses no additional risk for infants and children and no additional uncertainty factor is warranted. FFDCA section 408 provides that an additional safety factor for infants and children may be applied in the case of threshold effects. Since, as discussed in the previous section, the toxicology studies do not indicate that young animals are any more susceptible than adult animals and the fact that the proposed RfD calculated from the LOEL from the 28 day human study already incorporates an additional uncertainty factor, Rhone-Poulenc believes that an adequate margin of safety is therefore provided by the RfD established by EPA. Additionally, this LOEL is also 8X lower than the next lowest NOEL (2 generation reproduction study, NOEL=15 mg/kg/day) in the ethephon toxicology data base. Ethephon has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies.

Conclusion: A dietary Risk assessment was submitted to EPA in September, 1996 (MRID #44100203). An RfD of 0.018 mg/kg/day has been established by EPA based on the LOEL in the 28–day human study. Adequate MOEs exist for all populations including infants and children. No additional uncertainty factor for infants and children is warranted based on the completeness and reliability of the database, the demonstrated lack of increased risk to developing organisms, and the lack of endocrine-modulating effects.

F. International Tolerances

The Codex MRL for grapes is 10 mg/kg verses 2 ppm for U.S. tolerance. The tomato Codex MRL is 3 mg/kg verses 2 ppm for the U.S. tolerance. All other U.S. tolerances are identical to corresponding Codex MRLs.

II. Administrative Matters

Interested persons are invited to submit comments on the this notice of filing. Comments must bear a notation indicating the document control number, [PF–686]. 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 number [PF–686] 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 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 requirements.

Dated: January 7, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–983 Filed 1–14–97; 8:45 am]
BILLING CODE 6560–50–F

[PF–687; FRL–5580–4]

W. Neudorff GmbH KG; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of a regulation for an exemption from the requirement for a tolerance for residues of copper octanoate when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops. This notice includes a summary of the petition that was prepared by the petitioner, W. Neudorff GmbH KG (''Neudorff'').

DATES: Comments, identified by the docket number [PF–687], must be received on or before February 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 in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by docket number [PF–687]. 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 V. Errico, Acting Product Manager (22), Rm. 229, CM#2, 1921 Jefferson Davis Highway, Arlington, VA. 22202, 703–305–5540, e-mail: errico.philip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 6F4734) from W. Neudorff GmbH KG (''Neudorff''), c/o Walter G. Talarek, 1008 Riva Ridge Drive, Great Falls, VA 22066, 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 an exemption from the requirement for a tolerance for residues of the fungicide copper octanoate when used in accordance with good agricultural as an active ingredient in pesticide formulations applied to growing crops.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, Neudorff 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 Neudorff. 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 has made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

1. *Magnitude of the residue anticipated at the time of harvest and method used to determine the residue.* No residues are expected at the time of harvest on crops treated with copper octanoate, because rainwater readily washes copper octanoate off plants, and this chemical is biodegraded by water hydrolysis into its copper ion and fatty acid components, and then the fatty acids are further degraded by two carbon units at a time until they eventually degrade to water and CO2. In addition, the physio-chemical properties of soils naturally modify copper ion availability, and when soils are adjusted/limed to the pH required for normal crop production, the effect is to reduce copper availability to the crop. Furthermore, toxic copper levels in plants induce an imbalance with iron which causes plant dwarfing, stunted roots and decreased growth and yields, which effects appear before significant copper buildup occurs, and consequently acts as a warning which prevents excess application of copper compounds to food/feed crops. Last, even if residues were to remain on plants, the copper ion is a trace element, or micronutrient, essential for the growth and well being of higher plants and animals, including man. Therefore, the amount of this chemical proposed for application to plants is highly unlikely to cause harm to plants or animals or to leave excess residues on the plants.

2. *Statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Neudorff has not proposed a new analytical method, because copper levels harmful to plants and animals are highly unlikely to occur when its copper octanoate product is applied according to label instructions. However, should EPA require such a method, because copper octanoate is a copper salt of a fatty acid, Neudorff would propose the use of the same analytical method submitted by registrants of products containing other copper salts of fatty acids.