Name	Case No.
Ben Salamoni Trucking Service Inc	RK272–01697
Clarke Oil Well Servicing Inc	RK272–01871
Excel Specialty Products	RK272–04762
Leggett & Platt, Incorporated	RF272–4705
National Beverages, Inc.	RK272–04677
Personnel Security Hearing	VSO–0206
Petrolane Gas Service Ltd. Partnership	RF340–00169
Texaco Refining and Marketing, Inc.	RR340–0001
The Brindle Excavating Co., Inc.	RK272–01477
Weinberg Chemical & Supply Company	RK272–04716
200 Varick Street Associates	RK272–04603

[FR Doc. 98–20128 Filed 7–27–98; 8:45 am]
BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–816; FRL–5799–3]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–816, must be received on or before August 27, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides 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.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment 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: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Bipin Gandhi (PM 21)	Rm. 707A, CM #2, 703–308–8380, e-mail:gandhi.bipin@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA.
Cynthia Giles-Parker (PM 22).	Rm. 247, CM #2, 703–305–7740, e-mail:giles-parker@epamail.epa.gov.	1921 Jefferson Davis Hwy.,Arlington, VA.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–816] (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 official record is located at the address in ''ADDRESSES'' at the beginning of this document.

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. Comments and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated:July 9, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and

represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Fleming Laboratories, Inc.

PP 4G4276

EPA has received a pesticide petition (PP 4G4276) from Fleming Laboratories, Inc., P.O.Box 34384, Charlotte, NC 28234 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of (4-methylphenyl)arsonic acid in or on the raw agricultural commodity fresh market grapefruit grown only in Florida at 0.5 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency 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.

A. Residue Chemistry

1. *Plant metabolism*. A plant metabolism study is being conducted at the proposed use rate of 6.22 lbs active ingredient (6.25 lbs product) per acre and has revealed approximately 0.46 ppm total radioactive residue (TRR) in whole fruit, of which 0.13 ppm or 29.2% of the TRR was parent compound. Four of the 11 metabolites isolated from whole fruit exceed 10% of the TRR. Metabolite characterization and identification is still in progress.

2. *Analytical method*. A High Performance Liquid Chromatography (HPLC) method is available to verify the certified limits of arsanilic acid in the end-use product.

Currently there is no validated method for determining any of the residues of arsanilic acid in/on grapefruit. However, method development is partially complete for an analytical method to determine residues of (4-aminophenyl)arsonic acid, *per se*, the active ingredient of Pro-Gen(r), in or on whole grapefruit. In principle, a 50 gram sample of grapefruit is extracted by homogenization with water. The extract is centrifuged, filtered, concentrated by rotary evaporation, cleaned up on a florisil column, buffered to pH 4.5, then derivatized with methyl thioglycolate. The derivative is partitioned into toluene, which is analyzed by gas chromatography (GC) and an electron capture detector (ECD). The anticipated Limit of Quantitation (LOQ) is 0.05 ppm. Method development for the metabolite residues will ensue as the metabolites are identified.

3. *Magnitude of residues*. Field residue trials are currently in progress at several sites in Florida. Mature grapefruit samples have been harvested from trees treated with 6.25 lbs Pro-Gen(r) per acre and are being stored until residue analytical method development is complete. However, based on the data from the plant metabolism study, total residues of arsanilic acid in grapefruit are expected to be less than 0.5 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Pro-Gen(r)/arsanilic acid is only moderately acutely toxic to mammals. The rat acute oral LD_{50} values were 1,411 mg/kg for males, 976 (646-2883) mg/kg for females and 1,461 mg/kg for males and females combined. A study with New Zealand white rabbits established acute dermal LD_{50} values of 922 mg/kg for males, 909 (445-1972) mg/kg for females and 921 (577-1402) mg/kg for males and females combined. Arsanilic acid has caused minimal signs of toxicity in rats following a 4 hour inhalation exposure to a measured atmospheric concentration of 5.35 mg/l. The acute inhalation LC_{50} is greater than 5.35 mg/l. Arsanilic acid is slightly irritant to rabbit eyes and is not irritant to rabbit skin.

Arsanilic acid is not considered a skin sensitizer. Arsanilic acid does not cause sensitization in guinea pigs. Additionally, arsanilic acid has been manufactured and used since the 1940's as a medicinal feed additive for poultry and swine with no reported incidents of hypersensitivity among workers.

2. *Genotoxicty*. Arsanilic acid is not mutagenic to five strains of *Salmonella typhimurium*. In the mouse micronucleus test, arsanilic acid (99.6% purity) was devoid of micronucleus inducing potential in the bone marrow of male and female CD-1 mice when tested to maximum tolerated doses. Arsanilic acid was determined to be weakly mutagenic in mouse lymphoma L51178Y cells in the presence of S9 mix, when tested at concentrations extending into the toxic range. However, evidence of mutagenicity in the absence of S9 mix was inconclusive.

3. *Reproductive and developmental toxicity*. A review of three studies detailing the effects of arsanilic acid on reproduction in swine found no adverse effects on the fertility, fecundity, or health and survival of swine dams and their offspring at an arsanilic acid feed concentration of 100 ppm. Furthermore, at the 100 ppm arsanilic acid feeding level, no gross abnormalities or adverse effects were found on organ weights or pathology. To the contrary, arsanilic acid in the diet improved the overall health, improved weight gain, and increased survival of swine.

No developmental effects were found in rats exposed *in utero* to arsanilic acid at levels up to and including that which produced overt maternal toxicity. Arsanilic acid was administered orally by gavage to pregnant rats at nominal dose levels of up to 60 mg/kg/day. Reduced body weight gains early in the treatment period, reduced food consumption, and the presence clinical signs (60 mg/kg/day group) were considered evidence of maternal toxicity. No developmental toxicity was apparent at any dose level. A no observable effect level (NOEL) for maternal effects (reduced food consumption) was considered to be less than 6 mg/kg/day (based on a 60.0% of target concentration analysis of the 10 mg/kg/day formulation used during the first 5 days of dose administration). The NOEL for maternal clinical signs was 30 mg/kg/day. The NOEL for developmental toxicity of rats was 60 mg/kg/day.

No developmental effects were noted in rabbits exposed *in utero* to arsanilic acid (100%) at levels up to and including that which produced overt maternal toxicity. Arsanilic acid (Pro-Gen(r)) was administered orally by gavage to pregnant rabbits at nominal dose levels up to 6 mg/kg/day. Maternal effects were observed only in the 6 mg/kg/day dosed dams and were limited to reductions in mean body weight gain and food consumption. No maternal effects were apparent at dose levels of 1 and 3 mg/kg/day. No developmental toxicity was expressed at any dose level. The NOEL for maternal effects was 3 mg/kg/day. The NOEL for developmental toxicity was 6 mg/kg/day.

4. *Subchronic toxicity*. No mortality occurred during a 91-day feeding study in which male and female rats were fed nominal concentrations of up to 750 ppm arsanilic acid in the diet. Some signs of toxicity (behavior, locomotion and excreta) were observed at feeding levels of 375 ppm and above. No definite treatment effects were observed in animals receiving 50 ppm arsanilic acid in the diet. The NOEL was determined to be 50 ppm (3.77 mg/kg/day for males and 4.76 mg/kg/day for females).

No mortality occurred during a 90-day feeding study in which male and female beagles were fed arsanilic acid at up to 200 ppm in diet. No ophthalmoscopic abnormalities were observed at any level. Clinical signs of toxicity were observed in some dogs receiving 200 ppm arsanilic acid in diet. While there was no observable indication of toxicity in animals receiving up to 100 ppm arsanilic acid in the diet, microscopic evaluation of the kidneys revealed dose-related abnormalities. The NOEL for female beagle dogs was 50 ppm (1.7 mg/kg/day). The NOEL for male beagle dogs was 25 ppm (0.7 mg/kg/day).

5. *Chronic toxicity*. Arsanilic acid is not carcinogenic to rats. Arsanilic acid is approved by the FDA for use as a medicinal feed supplement for swine and poultry at concentrations up to 0.01% of the ration and has been extensively used in commercial rations since the 1940's.

Arsanilic acid was fed to rats (two separate studies) at concentration levels of 100, 500 and 1,000 ppm in the diet for 106 to 116-weeks. In both studies, the presence of arsanilic acid in the diet was reported to have caused no gross abnormalities or adverse effects on organ weights, pathology, incidence of tumors or health of rats.

Long term feeding of 0.01% arsanilic acid in pig feed for up to 51 months during a multigeneration study resulted in increased survival and overall improved health of arsanilic acid-treated pigs.

6. *Animal metabolism*. Arsanilic acid uniformly labeled with ^{14}C in the benzene ring was used to determine the metabolic fate of arsanilic acid fed to pigs and chickens. Arsanilic acid was well absorbed by both species. Urine was the predominant route of excretion. The bile was a minor (<5% of the dose) route of excretion in pigs (was not measured in chickens). Arsanilic acid and two other metabolites, N-acetylarsanilic acid and (4-acetamidophenyl)dimethylarsine oxide, were identified in the pig urine. In pigs, somewhere between 17-39% of the urinary ^{14}C metabolites was excreted as arsanilic acid, 15-29% as N-acetylarsanilic acid and <5% as (4-acetamidophenyl)dimethylarsine oxide. Only 2-5% of the radio-labeled arsanilic acid dose remained in the carcass or liver of pigs while less than 1% remained in the chicken carcasses (liver included). There was no evidence of any biotransformation of arsanilic acid in chickens. The study authors also note that the results of this study corroborate earlier research showing that chickens rapidly excrete arsanilic acid with no biotransformation.

7. *Metabolite toxicology*. There is no known information about the toxicity of any of the currently identified metabolites of arsanilic acid.

8. *Endocrine disruption*. Arsanilic acid is not considered to be an endocrine disruptor. Several studies in which different species were administered high levels of arsanilic acid have shown no effect on the time-to-mating or on mating and fertility indices. Radiolabelled [^{14}C]-arsanilic acid fed to chickens (laying hens) had no effect on the ability of the hens to produce eggs. Multigeneration reproduction studies in swine, developmental toxicity studies in rats and rabbits, chronic studies in rats plus long term medicinal use in animal husbandry amply demonstrates that arsanilic acid does not affect the estrous cycle, mating behavior, male or female fertility, or male or female reproductive tracts.

C. Aggregate Exposure

1. *Dietary exposure—Food—* i. *From medicinal feed additive use*. Arsanilic acid has been utilized under FDA approval as a medicinal feed additive in pig, chicken and turkey feeds since the 1940's. However, the feed additive tolerances established by the FDA are expressed in terms of total residues of combined arsenic (calculated as As) instead of as arsanilic acid (21 CFR 558.62 and 556.60). Because arsanilic acid may be the sole dietary contributor that necessitates the feed additive tolerances for arsenic, these tolerances can be converted to total arsanilic acid equivalents by using a conversion factor of 2.9, the ratio of the molecular weight of arsanilic acid (217.04) to that of its arsenic content (74.92).

Total Residues as Arsenic (ppm)	Total Residues as Arsanilic Acid (ppm)	Commodity
0.5	1.45	eggs, chicken
0.5	1.45	muscle, chicken
2.0	5.8	edible by-products, chicken
0.5	1.45	eggs, turkey
0.5	1.45	muscle, turkey
2.0	5.8	edible by-products, turkey
2.0	5.8	liver, swine
2.0	5,8	kidney, swine
0.5	1.45	muscle, swine
0.5	1.45	by-products, swine

ii. *From proposed use on fresh market grapefruit grown only in Florida*. In the amended petition for a Saleable Experimental Use Permit, the following temporary tolerance is proposed for total residues of arsanilic acid expressed as arsanilic acid, *per se*, in or on fresh market grapefruit.

0.5 ppm in/on grapefruit (whole fruit)

Because the treated fruit are prohibited from being processed under the amended Experimental Use Permit, no dietary exposure is anticipated from the processed commodities nor are any temporary tolerances proposed for the processed commodities, grapefruit juice, dried grapefruit pulp or grapefruit citrus oil.

iii. *From livestock consumption of treated grapefruit and/or processed products*. Under the amended petition for Experimental Use Permits (EUP), treated fruit may not be fed to livestock. The amended EUP also restricts livestock grazing or consumption of forage or hay from Pro-Gen(r) treated orchards. Therefore, no dietary exposure to arsanilic acid is anticipated from livestock consumption of Pro-Gen(r) under the auspices of the proposed EUP.

2. *Drinking water*. No exposure to arsanilic acid is expected from consumption of drinking water. Arsanilic acid is not proposed for application to sources of drinking water. Additionally, hydrolysis, soil metabolism and soil adsorption/desorption studies have shown that arsanilic acid is stable to environmental degradation and binds tightly and irreversibly to the organic and mineral fractions of soils. Any arsanilic acid that

might be excreted by poultry or swine administered arsanilic acid for medicinal purposes will be tightly bound to soil if incorporated in to the soil as a fertilizer. Consequently, potential exposure of surface and/or ground water to arsanilic acid will be minimized.

3. *Non-dietary exposure*. There are no known sources of non-dietary exposure to arsanilic acid, outside of occupational exposure in the manufacturing and packaging of Pro-Gen(r)/arsanilic acid in its current usage in animal husbandry, or in its proposed use in Florida fresh market grapefruit production. There is little concern that children would be exposed to non-dietary sources of arsanilic acid.

D. Cumulative Effects

For cumulative exposure considerations, Fleming Laboratories believes it is appropriate to consider only the potential risks of arsanilic acid noted in the discussion of aggregate exposure (above), based on the current approaches used by the FDA and EPA for regulating organic arsenical compounds in animal husbandry and crop production.

Arsanilic acid is an organic arsenical compound. FDA regulations have established feed additive tolerances, expressed as ppm total combined arsenic, for the following medicinal organoarsenical compounds, arsanilic acid, arsanilate sodium, nitarsone, carbarsone, and roxarsone.

Although FDA has authorized the use of these compounds as medicinal feed additives, only one of these organoarsenicals may be used at a time as the sole source of organic arsenic in the feed. Therefore, there is no exposure from multiple organic arsenicals in animal feeds.

With regards to crop protection, the only known organic arsenicals registered in the U.S. are the herbicides: cacodylic acid, a cotton defoliant; and disodium or monosodium methanearsonic acid, contact herbicides used in cotton and citrus production. With regard to residue tolerances for these herbicides, residues of cacodylic acid are regulated discretely for that compound under 40 CFR 180.311. While, residues of disodium and monosodium methanearsonic acid are regulated simultaneously as methanearsonic acid under 40 CFR 180.289. Since these compounds are regulated discretely, it can be assumed that EPA considers them to have distinct metabolic pathways and modes of action.

Since arsanilic acid has a considerably different chemical structure (containing a phenyl ring) from these other straight-chained organic arsenical herbicides, it is reasonable to assume that arsanilic acid will have a unique mode of action compared to the straight chain herbicides. The proposed use of arsanilic acid as a plant growth regulator further illustrates the differences when comparing arsanilic acid to these herbicides.

Therefore, for cumulative exposure considerations, Fleming Laboratories believes it is appropriate to consider only the potential risks of arsanilic acid noted in the discussion of aggregate exposure (above).

E. Safety Determination

U.S. population. The Acceptable Daily Intake (ADI) is the amount of pesticide residue that can be ''safely'' ingested by humans and still be protective of the health of all segments of the population. An ADI must be established for any pesticide that results in a residue on crops used for human consumption. The ADI, sometimes referred to as the Reference Dose (RfD), is a mathematically derived figure based on the NOEL of a chronic or subchronic toxicity study and safety or uncertainty factors. Uncertainty factors are used to compensate for inter- and intra-species differences, type of study, etc. when extrapolating from toxicity data (animal or human) to human risk assessments.

For arsanilic acid, the ADI will be based on the results of the dog subchronic feeding study. The ADI is equal to the NOEL times a safety or uncertainty factor (UF). It is customary to use a UF of 100 fold (100x) to account for the species differences from dog to human, as well as for extrapolating from a subchronic study to chronic exposure of humans. Assuming that EPA concurs with an uncertainty factor of 100x, the ADI based on the most sensitive NOEL can be calculated as follows:

NOEL = 25 ppm arsanilic acid in diet of dogs = 0.75 mg/kg/day

Then the ADI or RfD = 0.75 mg/kg/day x (1/100) = 0.0075 mg/kg/day

Based on EPA's total diet survey, sensitive populations, such as infants, have little or no intake of grapefruit or grapefruit juice. Therefore the ADI is based on consumption of grapefruit and grapefruit juice by 70 kg adult humans. Therefore, if the ADI is 0.0075 mg/kg/day, a 70 kg adult could safely consume 0.525 mg arsanilic acid /day (0.0075 mg/kg/day x 70 kg).

F. Dietary Risk Assessment

The dietary risk assessment evaluates how much of the ADI would be ''used up'' when residue tolerances are proposed for pesticide-bearing crop or animal commodities that may be consumed by humans. To conduct the risk assessment for arsanilic acid under the tenets of the proposed amended Experimental Use Permit for Florida-grown, fresh market fruit only, one needs to know how much grapefruit would typically be consumed by humans and the amount of arsanilic acid residues in or on the fruit. Additionally, human exposure from consumption of swine and poultry products from medicinally treated animals must be considered.

For estimating grapefruit dietary consumption, EPA's Total Diet Study, which is used to calculate exposure and dietary risk for pesticides, reveals that 25-30 year-old men have the highest consumption of grapefruit compared to all other age and sex groupings. Consumption rates in this group are listed as 4.3 grams of grapefruit per day. Consumption of whole grapefruit (4.3 grams/day) contributes to less than 0.08% of the total diet in this age and sex category.

Dietary exposure from grapefruit consumption will be reduced by the limited use of Pro-Gen(r) to grapefruit grown in Florida. According to the Florida Citrus Summary 1993-94, Florida produced 816,800 tons of grapefruit in 1993-1994, which was 66.10% of the total U.S. production of grapefruit. This means that grapefruit grown in Florida would contribute to less than 0.053% (i.e. 0.08% of diet x 66.1% of grapefruit = 0.053%) of the total diet for the highest consumers of grapefruit, 25-30 year-old men.

For estimating the dietary consumption of swine and poultry products, EPA's Total Diet Study reveals that 25-30 year-old men have the highest consumption of pork (39.5 grams/day) and poultry (chicken plus turkey; 28.7 grams/day). (Gram servings of pork, chicken and turkey kidneys and livers were not included). While 60-65 year old men have the highest consumption of eggs, the 25-30 year-old men have the second highest consumption rate (31 grams/day). Total consumption of pork, poultry and eggs accounts for 3.23% of the diet of 25-20 year-old men. In comparison, the same commodities comprise 3.1% of the diet of 2 year-old children, 2.7 % for females 14-16 years-old, 2.9% for males 14-16 years-old and 2.8% for 25-30 year-old women.

For conducting a dietary risk assessment and to provide conservative estimates: (1) the total consumption of fruit has been adjusted up from an estimated 4.3 grams to 5 grams grapefruit consumed per day (2); total

residues of arsanilic acid in or on whole fruit are considered to be 0.5 ppm, based on the proposed temporary tolerance for total residues of Pro-Gen(r) in or on treated grapefruit (3); the total consumption of pork, poultry and eggs has been adjusted from the estimated 39.5 grams/day to 40 grams/day; and (4) total FDA allowed residues of arsanilic acid in pork or poultry products (with the exception of kidneys and liver) is 1.45 ppm. Since the estimated gram quantities of pork and poultry organ meats (kidneys and livers) were not provided using the estimated daily consumption of 2.8 g beef liver provides an extremely conservative estimate for pork and poultry livers with FDA allowed arsanilic acid residues of 5.8 ppm.

If it is assumed that all grapefruit in Florida are treated with Pro-Gen(r), which results in total arsanilic acid residue levels of 0.5 ppm in fruit, and a 70 kg adult consumes 5 grams of grapefruit per day of which 66.1% is from Florida, then the total dietary intake per day can be calculated as follows:

5 grams/day grapefruit consumed = 0.005 kg/day grapefruit consumed

0.005 kg/day grapefruit x 0.661 = 0.00331 kg/day Florida fresh market grapefruit consumed

Total residues of 0.5 ppm arsanilic acid = 0.5 mg total arsanilic acid residues /kg food

(Amount of Florida fruit consumed) x (residue level) = 0.00331 kg fruit/day x 0.5 mg total arsanilic acid residues /kg fruit = 0.00166 mg total arsanilic acid/ day in grapefruit

If it is assumed that all swine and poultry received arsanilic acid-treated, then the total dietary intake per day of arsanilic acid from pork and poultry products except organ meats, can be calculated as follows:

40 grams/day pork, poultry and eggs consumed = 0.04 kg/day animal products consumed

X total residues of 1.45 ppm arsanilic acid = 1.45 mg total arsanilic acid residues /kg food

(Amount of pork, poultry and eggs consumed) x (residue level) = 0.04 kg/ day x 1.45 mg total arsanilic acid residues /kg food = 0.058 mg total arsanilic acid/day in pork, poultry and eggs.

If it is assumed that all swine and poultry received arsanilic acid-treated, then the total dietary intake per day of arsanilic acid from pork and poultry kidneys and liver can be calculated as follows:

2.8 grams/day pork and poultry organs consumed = 0.0028 kg/day organs consumed

Total residues of 5.8 ppm arsanilic acid = 5.8 mg total arsanilic acid residues /kg food

(Amount of kidneys and liver consumed) x (residue level) = 0.0028 kg total arsanilic acid /day x 5.8 mg/kg = 0.016 mg total arsanilic acid/day in pork and poultry kidneys and liver.

Total dietary intake of total arsanilic acid = 0.00166 + 0.058 + 0.016 = 0.07566 mg total arsanilic acid residues per day

This estimate of total dietary intake represents only 14% of the allowable daily consumption of 0.525 mg arsanilic acid/day for a 70 kg adult, established by a NOEL of 25 ppm and an ADI of 0.0075 mg/kg/day. The estimated dietary intake of total arsanilic acid residues from Pro-Gen(r)-treated fresh market grapefruit is only 0.03% of the ADI of 0.0075 mg/kg/day.

Infants and children. Based on EPA's total diet survey, sensitive populations, such as infants, have little or no intake of grapefruit or grapefruit juice. Therefore, the proposed use of Pro-Gen(r) on Florida grapefruit will pose no additional risk of adverse effects to infants or children beyond that which already exists from consumption of poultry and swine products from animals medicinally treated with arsanilic acid. Even so, it is appropriate to consider the results of the developmental, reproductive, and chronic studies. The available data clearly show that there is no increased risk to neonates or young when arsanilic acid is ingested. Therefore, Fleming Laboratories concludes that

An additional safety factor for the protection of infants and children is not needed and

The ADI or RfD of 0.0075 mg/kg/day is appropriate for assessing arsanilic acid risks to infants and children.

G. International Tolerances

The Applicant is not aware of any international tolerances or Codes Maximum Residue Limits (MRLs) for arsanilic acid on any crop or livestock commodities. (Cynthia Giles-Parker)

2. ICI Surfactants

PP 8E4965

EPA has received a pesticide petition (PP 8E4965) from ICI Surfactants, 3411 Silverside Road, Wilmington, DE, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) and (e) to establish an exemption from the requirement of a tolerance for oxirane, methyl-, polymer with oxirane, mono[2-(2-butoxyethoxy)ethyl]ether (CAS Registry No. 85637-75-8) when used as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest or to animals. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency 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.

A. Residue Chemistry

Magnitude of residues. No residue chemistry data or environmental fate data are presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient.

B. Toxicological Profile

1. *Acute toxicity*. ICI believes sufficient information was submitted in the petition to assess the hazards of oxirane, methyl-,polymer with oxirane, mono[2-(2-butoxyethoxy)ethyl]ether. No toxicology data were presented in the petition as the Agency does not generally require some or all of the listed studies to rule on the exemption from the requirement of a tolerance for an inert ingredient. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with toxicity.

2. *Endocrine disruption*. ICI has no information to suggest that oxirane, methyl-, polymer with oxirane, mono[2-(2- butoxyethoxy)ethyl]ether will have an effect on the immune and endocrine systems. EPA is not requiring information on the endocrine effects of this substance at this time; Congress has allowed 3-years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

C. Cumulative Effects

ICI believes sufficient information was submitted in the petition to assess the hazards of oxirane, methyl-,polymer with oxirane, mono[2-(2-butoxyethoxy)ethyl]ether. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with cumulative effects.

D. Safety Determination

1. *U.S. population*. ICI believes sufficient information was submitted in

the petition to assess the hazards of oxirane, methyl-,polymer with oxirane, mono[2-(2-butoxyethoxy)ethyl]ether. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to adults.

2. *Infants and children*. ICI believes sufficient information was submitted in the petition to assess the hazards of oxirane, methyl-,polymer with oxirane, mono[2-(2-butoxyethoxy)ethyl]ether. Based on this polymer conforming to the definition of a polymer and meeting the criteria of a polymer under 40 CFR 723.250 ICI believes there are no concerns for risks associated with any potential exposure to infants and children. (Bipin Gandhi)

3. KIM-C1, LLC

PP 7G4906

EPA has received a pesticide petition (PP 7G4906) from KIM-C1, LLC, 6333 East Liberty Avenue, Fresno, CA 93727 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of N-(2-chloro-4-pyridinyl)-N-phenylurea in or on the raw agricultural commodities grape, kiwi, almond, apple, blueberries, cranberries, figs, plums, pears, and olives at 0.01 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency 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.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues of CPPU in almonds, apples, blueberries, cranberries, figs, grapes, kiwis, olives, pears and plums are adequately understood. Three ^{14}C radiolabeled plant metabolism studies conducted in apples, grapes and kiwis shows CPPU leaves the same residue pattern in all three crops, representing three unrelated botanical species. These studies show that the residue is in the low parts per billion (ppb) range at harvest and that the residue is primarily associated with the skin. CPPU does not translocate any significant distance in the plant, not moving from the leaves to the fruit nor from the fruit to the leaves. The use level of 10 to 20 grams of CPPU *per acre* assures that only low residues will occur. Residue analysis on grapes and kiwis confirm the radiolabel findings. In grapes and kiwis the residue level was below the level of quantification (LOQ) in all cases and generally below the level of validated detection. The LOQ in whole grape was 0.01 ppm; the level of detection (LOD) was 0.003 ppm. In grape juice, the LOQ was 0.002 ppm and the LOD was 0.0007 ppm (0.7 ppb). In raisins the LOQ was 0.01 ppm and the LOD was 0.003 ppm.

2. *Analytical method*. The analytical method extracted the parent material and analyzed it using HPLC analysis with UV fluorescence at wavelength 265 nm.

3. *Magnitude of residues*. The magnitude of the residues in the crops are anticipated to be below the level of quantification which, based on whole fruit, will be 0.01 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Based on EPA criteria, CPPU would be placed in EPA toxicity Category III generally, while the dermal irritation results would be placed in EPA Category IV.

Acute Oral	81-1	LD_{50} 4.9 gr/kg
Acute Dermal	81-2	LD_{50} >2000 mg/kg
Acute Inhalation	81-3	LC_{50} >3.0 mg/l (the higest conc achievable)
Eye Irritation	81-4	Mildly irritating; No corneal or iridial irritation noted
Dermal Irritation	81-5	Non-irritating
Skin Sensitization	81-6	Non-sensitizing

2. *Genotoxicity*. The results from a battery of three genetic toxicity tests with CPPU show that this compound is not mutagenic or genotoxic.

Gene mutation - Ames: Slightly Positive

In-vivo structural chromosomal aberration assay: Negative

In-vivo micronucleus aberration assay: Negative

3. *Reproductive and developmental toxicity*. Results of these studies indicate that CPPU is not a reproductive toxicant, developmental toxicant, or a teratogen.

Teratology in rats: NOAEL (maternal) = 100 mg/kg/day; no observed adverse effect level (NOAEL) (fetal/development) = 200 mg/kg/day

Teratology in rabbits: NOAEL (maternal) = 25 mg/kg/day; NOAEL (fetal/development) = 100 mg/kg/day

2-Generation reproduction in rats: NOAEL (parental) = 150 ppm; NOAEL (reproductive) = 2,000 ppm (115 mg/kg/day - males) (205 mg/kg/day - females).

4. *Subchronic toxicity*. No treatment-related adverse effects were noted in subchronic toxicity studies at the highest doses tested.

28 - Day dietary in rats: NOEL 1,000 ppm

13 - Week dietary in rats: NOEL 200 ppm

28 - Day dietary in dogs: NOEL 2,500 ppm

13 - Week Dietary in dogs: NOAEL 500 ppm 13 - Week dietary in mice: NOAEL 3,500 ppm.

5. Chronic toxicity 1-year chronic toxicity in dogs: not required for EUP; Test initiated.

18 -month chronic toxicity and carconogeniscity in mice: not required for EUP will be initiated section 3 reg.

24-month chronic toxicity and carcinogenicity in rats: NOAEL 150 ppm (8 mg/kg/day); NOAEL 7,500 ppm (435 mg/kg/day).

6. *Animal metabolism*. Study will be completed prior to section 3 registration requirement. (Not required for an Experiment Use Permit.)

7. *Metabolite toxicology*. Metabolites occur at levels below 0.1 ppm and therefore are below levels required to be assayed in animal testing. The ^{14}C radiolabel plant studies show metabolites to be glucosides of the parent material.

8. *Endocrine disruption*. Collective weights and histopathological findings from the 2-generation rat reproductive study, as well as from the subchronic

and chronic toxicity studies in two or more animal species, demonstrate no apparent effects on the endocrine system. There is no information available which suggests that CPPU would be associated with endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure—Food.* A reference dose (RfD) was calculated using the most sensitive species data available from the toxicological testing. This RfD 0.08 mg/kg/day/based on a temporary tolerance of 0.01 ppm, was used to calculate the impact of the estimated residue levels with results from treatment of the indicated crops. The table below shows the Theoretical Maximum Residue Concentrations (TMRC) of CPPU on or in the listed crops requested in this EUP request.

Theoretical Maximum Residue Concentrations for CPPU for the crops listed in the EUP request.

	All-Apples	All+Apples	Total Exposure	
			mg/kg body wt/ day	Percent of RfD
General U.S. Populations, all seasons	0.000005	0.000011	0.000016	0.02
Non-nursing infants	0.000029	0.000064	0.000093	0.12
Children 1 to 6-years of age	0.000010	0.000048	0.000058	0.07
Children 7 to 12-years of age	0.000005	0.000017	0.000022	0.03

The anticipated use rate of 17 grams of CPPU per acre applied once per year yielding residue levels in the very low ppb range indicates that less than 1% of the reference dose would be consumed in aggregate with all of these crops. The crop contributing greatest to the percent of the reference dose related to the most sensitive of the population i.e. all nursing infants (less than 1-year old), non-nursing infants (less than 1-year old), children (1 to 6 years old) would represent 1/10th of 1% of the reference dose. Making the same risk exposure calculations, it is shown that no significant impact on reducing the RfD by using blueberries, cranberries, cranberry juice, grapes-raisins, pears, pears dried, cherries, cherries dried, cherry juice, plums (Damsons), plums as prunes (dried), plum/prune juice, figs, kiwifruit, grapes-wine and sherry, cranberry juice concentrate, pear nectar in aggregate. Combining the RfD consumption from the large group of crops with that of the apples would exceed 1% of the reference dose only slightly if the total acreage of all of these crops were treated. The intention of this experimental use permit is not to treat all of the various crops listed; the table below shows the requested acreage of each crop.

Crop	Acreage Requested	% Total Acreage
Grape	3,500	0.53
Kiwi	1,000	14.08
Almond	50	0.01
Apple	50	0.14
Blueberries	50	
Cranberries	50	
Figs	50	0.40
Plums	50	0.03
Pears	50	0.15
Olives	50	0.05

This program would permit development of requisite data to assure safe and efficacious use and, yet, not subject any segment of the public to a health risk.

2. *Dietary exposure - drinking water.* The very low use rate of CPPU i.e. 17 grams or less per acre, if used constantly for 20-years, would apply only 3/4 of a pound of CPPU per acre during that 20-year period. Computer modeling, using the conservative pesticide root zone model (PRZM) means of analysis has shown that no CPPU would reach ground water, even in sandy loam soils. The results of this risk analysis supported an unambiguous conclusion of ''essentially zero risk to ground water'' even under reasonable worst case assumptions. Concentrations are not predicted to exceed 15 to 20 ppb of CPPU in the soil in the upper soil horizons, even following yearly applications for as long as 30 years. No secondary exposure is anticipated as a result of contamination of drinking water.

3. *Non-dietary exposure.* No non-dietary exposure is expected since CPPU is not anticipated to be found in the drinking water. It does not translocate in plants and thus secondary exposure through plants growing in soil receiving CPPU is not anticipated. The extremely low application rates will not result in significant buildup in the environment.

D. Cumulative Effects

There are no cumulative effects expected since CPPU is not taken up by plants from the soil. It slowly degrades to mineral end points. Its low use rate is not conducive to buildup in the environment.

E. Safety Determination

1. *U.S. population.* As pointed out above in dietary exposure-food the percentage of the reference dose consumed by treating the subject crops represents only slightly more than 1% of the estimated safe level for the most sensitive segment of the population, non-nursing infants.

2. *Infants and children.* No developmental, reproductive or fetotoxic effects have been associated with CPPU. The calculation of safety margins with respect to these segments of the population were taken into consideration in the TMRC estimates with respect to the risk associated with the percentage of the reference dose being consumed.

F. International Tolerances

There is no Codex maximum residue level established for CPPU. However, CPPU is registered for use on grapes and other crops in Japan, Chile, Mexico, and South Africa. (Cynthia Giles-Parker)

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–6131–5]

Notice of Proposed NPDES General Permit for Discharges From Ready-Mixed Concrete Plants, Concrete Products Plants and Their Associated Facilities in Texas (TXG110000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of draft NPDES general permit.

SUMMARY: EPA Region 6 is proposing to issue a general NPDES permit authorizing discharges of facility waste water and contact storm water from ready-mixed concrete plants, concrete products plants and their associated facilities in Texas. This permit covers facilities having Standard Industrial Classification (SIC) Codes 3273