Individuals requiring special accommodation at SAB meetings, including wheelchair access, should contact the appropriate DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: June 30, 1998.

A. Robert Flaak,

Acting Staff Director, Science Advisory Board.

[FR Doc. 98–17965 Filed 7–6–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–814; FRL–5795–6]

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–814, must be received on or before August 6, 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. 119, 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 5)	Rm. 4W53, CS #2, 703–308–8380, e-mail:gandhi.bipin@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Cynthia Giles-Parker (PM 22).	Rm. 229, CM #2, 703–305–7740, e-mail: giles-parker.cynthia@epamail.epa.gov.	Do.

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–814] (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. Comment 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: June 24,1998.

Peter Caulkins, Acting

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. Rhodia Inc.

PP 6E4714

EPA has received a pesticide petition (PP 6E4714) from Rhodia Inc., CN 7500 Cranbury NJ 08512-7500 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 to establish an exemption from the requirement of a tolerance for Sucroglycerides derived from 21 CFR-approved fats and oils in or on the raw agricultural commodity after harvest. 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. Toxicological Profile

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305) (FRL 3190-1), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an inert ingredient.

The data we believe supports establishing an exemption from tolerances is summarized below. More detailed information has been provided to the Agency in previous submissions.

Sucroglycerides are a mixture of substances, primarily of mono- and di-glycerides and sucrose esters of fatty acids. The product is produced through a process of transesterification of an edible fat or oil with sucrose in the presence of a solvent. The resulting crude mixture is purified by vacuum distillation, counter-current extraction, and further distillation to remove solvent and other impurities.

Rhodia has conducted studies on the physicochemical characteristics of a sucroglyceride derived from palm oil. The studies evaluated the product chemistry, solubility, and the octanol/water partition coefficient of sucroglycerides.

1. *Acute toxicity*. The LD_{50} of palm oil-derived sucroglyceride is estimated to be greater than 30 grams/kg. In addition, early studies of sucroglycerides use in the diets of bottle-feeding calves indicated a lack of toxic response and an increased weight gain and improved food utilization.

Sucrose esters of fatty acids are approved for food use and mono- and di-glycerides are GRAS-approved additives; sucroglycerides are GRAS-approved and approved for food use in Europe; sucrose esters of fatty acids and mono- and di-glycerides are unlikely to be dermally absorbed.

Preliminary attempts to examine the potential environmental toxicity of Sucroglycerides have been made, but were not possible due to the physicochemical properties of the material. Sucroglycerides have the consistency of wax at low temperatures and petroleum jelly when warmed. In addition, as can be seen from the determination of the octanol/water partition coefficient, sucroglycerides are not water soluble (estimated Ko/w > 3.38 x 106), thereby precluding aquatic toxicity testing.

2. *Genotoxicty*. The components of sucroglycerides already have regulatory acceptance as agricultural inerts exempted from tolerance; sucroglycerides are a complex mixture of sucrose esters of fatty acids and mono- and di-glycerides derived from FDA-approved edible fats and oils. None of the components of sucroglycerides are genotoxic.

3. *Reproductive and developmental toxicity*. An early study of the potential effects of Sucroglycerides on reproduction in rats indicated that there were no effects on reproduction, pup survival and development, or pup anomalies at dietary dose levels up to 2%.

4. *Subchronic toxicity*. In 1980 a 13-week subchronic toxicity study of Sucroglycerides with an 8-week ''recovery period'' was conducted in beagle dogs. This study utilized doses as high as 20% of the total dietary intake. Decrease body weight gains (bwt) were observed in the 10% and 20% dose groups. These animals showed a significant weight gain recovery during the post-treatment period. No dose-related changes were noted in hematology, urinalysis, ophthalmoscopy, gross pathology or organ weights. Increased alkaline phosphatase and SGPT levels and fatty changes in the liver were noted for some animals in the high dose group, but most returned to normal during the recovery phase. Results should be interpreted keeping in mind that 20% of sucroglycerides in the diet represents a significant change in the normal dietary composition and could possibly cause changes in the nutritional status of the animals.

5. *Chronic toxicity*. A chronic toxicity/carcinogenicity study of Sucroglycerides was conducted in rats in 1982. Sprague-Dawley rats received 0%, 5%, 10%, or 20% sucroglycerides in the diet for 2-years. Clinical observations associated with treatment were pale feces and poor grooming. Survival was greater among treated rats than controls. Treated rats showed a dose-related decrease in weight gain during the early part of the study, particularly in males. Weight gain then became similar to that of controls until the last few weeks of the study when control rats lost more weight than did treated rats. Alkaline phosphatase and SGPT levels were elevated for high dose animals until week 25, but were comparable to controls during weeks 51-102. No treatment-related changes in hematology, ophthalmoscopy, gross pathology, organ weights, or tumorigenesis were reported.

6. *Animal metabolism*. Sucroglycerides are derived from a variety of 21 CFR-approved edible fats and oils including, but not limited to, lard, tallow, palm oil, rapeseed (canola) oil, and coconut oil. Mono- and di-glycerides are GRAS substances 21 CFR 184.1505 and already have regulatory acceptance as agricultural inerts and adjuvants exempted from tolerance requirements (under 40 CFR 80.1001(c)), as do sucrose, fatty acids conforming to 21 CFR 172.860, methyl esters of edible fats and oils, and sucrose esters of fatty acids such as sorbitan fatty acid esters.

7. *Metabolite toxicology*. The components of sucroglycerides and related substances already have regulatory acceptance as agricultural inerts exempted from tolerance requirements

8. *Endocrine disruption*. Sucroglycerides are not derived from, nor contain any compounds which are known to be, or are suspected to be, endocrine disruptors. Sucroglycerides are derived from a variety of 21 CFR-approved edible fats and oils including, but not limited to, lard, tallow, palm oil, rapeseed (canola) oil, and coconut oil. Mono- and di-glycerides are GRAS substances 21 CFR 184.1505 and already have regulatory acceptance as agricultural inerts and adjuvants exempted from tolerance requirements (under 40 CFR 180.1001(c)), as do sucrose fatty acids conforming to 21 CFR 172.860, methyl esters of edible fats and oils, and sucrose esters of fatty acids such as sorbitan fatty acid esters.

B. Aggregate Exposure

Consistent with section 408(c)(2)(B) of FFDCA, Rhodia, Inc. believes that, based on our prior submissions (as Rhone-Poulenc, Inc.), EPA now has sufficient data to assess the hazards of sucroglycerides and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerance exemptions for the residues of sucroglycerides on growing crops, raw agricultural commodities after harvest and animals.

1. *Dietary exposure*—i. *From food and feed uses, drinking water, and non-dietary exposures*. For the purposes of assessing the potential dietary exposure under these exemptions, Rhodia, Inc. considered that under these exemptions sucroglycerides could be present in all raw and processed agricultural commodities although, due to a lack of water solubility (octanol/water partition coefficient was estimated as Ko/w > 3.38 x 106) no drinking water exposure

was possible. Non-occupational, non-dietary exposure is highly unlikely given that the inhalation potential or dermal absorption of these substances are not feasible. No concerns for risks associated with any potential exposure scenarios are reasonably foreseeable.

ii. Sucroglycerides are derived from a variety of 21 CFR-approved edible fats and oils including, but not limited to, lard, tallow, palm oil, rapeseed (canola) oil, and coconut oil. Mono- and di-glycerides are GRAS substances 21 CFR.184.1505 and already have regulatory acceptance as agricultural inerts and adjuvants exempted from tolerance requirements (under 40 CFR 180.1001(c)), as do sucrose fatty acids conforming to 21 CFR 172.860, methyl esters of edible fats and oils, and sucrose esters of fatty acids such as sorbitan fatty acid esters.

iii. Sucroglycerides derived from edible fats and oils have been granted Self-Affirmed GRAS status in the U.S and are approved for food use in Europe and by the WHO Joint Expert Committee on Foods (JECFA), with an Acceptable Daily Intake (ADI) of 0-20 mg/kg/day. Sucroglycerides are currently marketed by Rhodia, Inc. for food use. Sucroglycerides, including those derived from palm oil, hydrogenated palm oil, tallow, rapeseed oil, castor oil, and coconut oil have been used safely in foods in Europe since the early 1960s.

2. *Drinking water.* Sucroglycerides are insoluble in water, hence exposure from drinking water is not considered to be a route of exposure.

3. *Non-dietary exposure.* Non-occupational, non-dietary exposure is highly unlikely given that the inhalation potential or dermal absorption of these substances are not feasible. No concerns for risks associated with any potential exposure scenarios are reasonably foreseeable.

C. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.'' In the case of sucroglycerides, the lack of observed toxicity of these substances after acute and chronic exposure would suggest that a cumulative risk assessment is therefore not necessary.

D. Safety Determination

1. *U.S. population.* Sucroglycerides derived from edible fats and oils have been granted Self-Affirmed GRAS status in the U.S and are approved for food use in Europe and by the WHO Joint Expert Committee on Foods (JECFA), with an Acceptable Dietary Intake (ADI) of 0-20 mg/kg/day. Sucroglycerides are derived from a variety of 21 CFR-approved edible fats and oils including, but not limited to, lard, tallow, palm oil, rapeseed (canola) oil, and coconut oil. Mono- and di-glycerides are GRAS substances 21 CFR 184.1505 and already have regulatory acceptance as agricultural inerts and adjuvants exempted from tolerance requirements (under 40 CFR 180.1001(c)), as do sucrose, fatty acids conforming to 21 CFR 172.860, methyl esters of edible fats and oils, and sucrose esters of fatty acids such as sorbitan fatty acid esters.

Based on these materials' low-risk profiles, there is a reasonable certainty that no harm to the U.S. population will result from aggregate exposure to sucroglycerides.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Due to the extensive available toxicology database including a reproductive toxicity study and studies of sucroglycerides in the diets of bottle-fed calves, and the low expected toxicity of these compounds, Rhodia, Inc. does not believe a safety factor analysis is necessary in assessing the risk of these compounds. For the same reasons we believe the additional safety factor is unnecessary.

E. International Tolerances

Sucroglycerides derived from edible fats and oils are approved for food use in Europe and by the WHO JECFA, with an ADI of 0-20 mg/kg/day. Sucroglycerides are currently marketed by Rhodia, Inc. for food use. Sucroglycerides, including those derived from palm oil, hydrogenated palm oil, tallow, rapeseed oil, castor oil, and coconut oil have been used safely in foods in Europe since the early 1960s.

There are no Codex Alimentarius Commission (Codex), Canadian or Mexican residue limits for sucroglycerides, which have been granted self-affirmed GRAS status in the U.S.

F. Conclusion

Based on the information and data considered, Rhodia, Inc. proposes that exemption from the requirements of a tolerance be established for Sucroglycerides derived from 21 CFR-approved fats and oils when used in accordance with good agricultural practice as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest (under 40 CFR.180.1001(c)).

2. Rhone-Poulenc Ag Company

PP 8F4969

EPA has received a pesticide petition (PP 8F4969) from Rhone-Poulenc Ag Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. 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 fosetyl-Al (aluminum tris(O-ethylphosphonate) in or on the raw agricultural commodity bananas at 3.0 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 metabolism of fosetyl-Al in plants is adequately understood. Adequate data on the nature of the residues in plants, including identification of major metabolites and degradates of fosetyl-Al, are available. Radiolabeled studies on the uptake, translocation and metabolism in plants show that the chemical proceeds through hydrolytic cleavage of the ethyl ester. The major residues are fosetyl-Al, phosphorus acid and ethanol. The tolerances are established for the parent only, that is fosetyl-Al. There is no reasonable expectation of residues occurring in eggs, milk, and meat of livestock and poultry since there are no livestock feed items associated with commodities treated with fosetyl-Al. Relating specifically to the proposed tolerance on bananas, no processed food or livestock feed items are associated with this commodity. Accordingly, tolerances in meat, animal byproducts and milk are not necessary.

2. *Analytical method*. Adequate methods are available for enforcement purposes. There are two analytical methods acceptable for determining residues of fosetyl-Al in plants: a gas chromatography method is available for enforcement of tolerance in pineapple and is listed as Method I in PAM, Vol. II; a GC/phosphorus specific flame photometric detector (FPD-P) method (Rhone-Poulenc Method No. 163) for citrus has undergone a successful method tryout on oranges and has been sent to the FDA for inclusion in PAM as Method II.

3. *Magnitude of residues*. Seven field sites in six Latin American countries were treated in two applications at the rate of 4.8 Kg/ha/application. Two of the seven trials also included a 2x rate application. Applications were made by two methods: foliar spray by ground equipment and tree injection into the pseudostem. The applications were made approximately 70-days apart with a PHI of 0- days for the foliar treatments and 1-day for the injection treatments. Each plot included both bagged and unbagged bunches. Fosetyl-Al residues greater than the LOT were found in 22 of the 96 treated banana samples. Residues were highest in the 1x and 2x foliar unbagged treatments, averaging 0.45 ppm from the 1x treatment and 0.69 ppm from the 2x treatment. Residues were very low from all foliar bagged and all injection treatments, averaging at or below the LOT. Residues from all treated samples ranged from no detects to 1.99 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Fosetyl-Al presents a minimal acute hazard. The acute toxicity data support that acute exposure is unlikely to constitute any significant risk. A complete battery of acute toxicity studies for fosetyl-Al technical have been conducted. The LD_{50} from the acute oral rat is 5.4 g/kg and the LD_{50} from an acute dermal rabbit study is >2 g/kg. The LC_{50} for a rat inhalation study is >1.73 mg/L. The acute oral rat and primary dermal irritation studies indicate category IV toxicity. A guinea pig dermal sensitization study shows fosetyl-Al is not a skin sensitizer. The primary eye irritation study in rabbits shows fosetyl-Al to be an eye irritant with Category I toxicity.

2. *Genotoxicity*. Fosetyl-Al is neither mutagenic nor genotoxic. The genetic toxicity potential of fosetyl-Al was assessed in several assays. Eight mutagenicity tests performed with fosetyl-Al were negative. The tests included two Ames assays with S. typhimurium, two phase induction assays using *E. coli*, two micronucleus studies in mice, one DNA repair assay using *E. coli* and one mutation assay in Saccharomyces cereviseae.

3. *Reproductive and developmental toxicity*. Fosetyl-Al is not a reproductive toxicant and shows no evidence of estrogenic or androgenic related effects. In a 3-generation reproduction study, fosetyl-Al was administered to rats at dietary levels of 0, 6,000, 12,000 or 24,000 ppm. No adverse effects on reproductive performance or pup survival were observed in any dose group. The LEL was established at 12,000 ppm based on effects on animal weights and urinary tract changes. The NOEL for all effects was 6,000 ppm. Developmental toxicity studies were conducted with technical grade fosetyl-Al in rats and rabbits. These studies are summarized below.

i. *Rat*. A teratology study in rats dosed via oral gavage at 500, 1,000 or 4,000 mg/kg/day showed a developmental NOEL of 1,000 mg/kg. At 4,000 mg/kg, there was maternal toxicity, as evidenced by effects on animal weights, maternal deaths, increased resorptions and delayed fetal ossification.

ii. *Rabbit*. A rabbit teratology study showed no toxic effects at oral doses up to 500 mg/kg. Effects of fosetyl-Al on fetal development were observed only in the rat at a dose producing severe maternal toxicity. In the absence of maternal toxicity, no adverse effects on fetal development were observed, i.e. at 1,000 milligram/kilograms/day (mg/kg/day) in rats or at 500 mg/kg/day in rabbits.

4. *Subchronic toxicity*. In subchronic studies, no significant toxicity was observed even at doses exceeding the limit of 1,000 mg/kg/day.

i. A 21-day dermal study in rabbits showed mild to moderate skin irritation and a NOEL of 1.5 g/kg/day.

ii. A 90-day feeding study in rats showed a NOEL of >5,000 ppm; the LEL was 25,000 ppm with extramedullary hematopoiesis in the spleen.

iii. A 90-day dog feeding study showed a NOEL of 10,000 ppm and a LEL at 50,000 ppm, at which the test animals had a lower serum potassium level than untreated animals.

5. *Chronic toxicity*. Chronic toxicity studies have been conducted in dogs and rats.

i. *Dog*. Fosetyl-Al was fed to dogs for 2-years at concentrations of 0, 10,000, 20,000, and 40,000 ppm. The NOEL was 10,000 ppm, equivalent to 250 mg/kg/day. The LEL was 20,000 ppm based on a slight degenerative effect on the testes. These testicular changes, as well as a few scattered clinical changes, were seen in the high dose dogs. No effects were observed in the urinary tract.

ii. *Rat*. Fosetyl-Al was administered via admixture in the diet to CD rats at target levels of 0, 2,000, 8,000, and 30,000/40,000 ppm for approximately 2-years. Based on these levels, respective doses were 100, 400 and 2,000/1,500 mg/kg/day. After 2-weeks at 40,000 ppm, this dietary level was reduced to 30,000 ppm due to the occurrence of red coloration of the urine and a decrease in body weight gain. Although these findings were no longer apparent after week 2, analytical verification of dietary levels revealed that the highest dietary level ranged from approximately 38,000 to 61,000 ppm during the first 32 weeks of the study. No significant differences in bwt or food consumption were noted at 2,000 or 8,000 ppm. No biologically significant differences were observed in ophthalmoscopy, hematology, clinical chemistry, or urinalysis for treated and control animals. Calculi in the urinary bladder were observed for several male and female rats in the high dose group. Non-neoplastic findings consisted of epithelial hyperplasia and inflammation in the urinary bladders of males at 30,000/40,000 ppm. Increased incidences of hydronephrosis, inflammation, and epithelial hyperplasia in the kidney were also observed in males from the high dose group. Females from the same group exhibited increased incidences of epithelial hyperplasia in the urinary bladder and hydronephrosis in the kidney. The NOEL in the chronic rat study was 8,000 ppm (400 mg/kg/day).

iii. *Conclusion*. The lowest NOEL for chronic effects of fosetyl-Al is 10,000 ppm (250 mg/kg/day) based on the dog study. This NOEL is based on minor changes at 20,000 ppm. In the rat, calculi in the urinary bladder and related histopathological changes in the bladder and kidneys of males and females were observed at 30,000/40,000 ppm.

6. *Carcinogenicity*. Long-term feeding studies were conducted with technical grade fosetyl-Al in mice and rats and with monosodium phosphite, the primary urinary metabolite of fosetyl-Al, in rats. These studies, in addition to a mechanistic study in rats, are described below:

i. *Rat*. Fosetyl-Al was administered via admixture in the diet to CD rats at target levels of 0, 2,000, 8,000, and 30,000/40,000 ppm for approximately 2-years. After 2-weeks at 40,000 ppm, this dietary level was reduced to 30,000 ppm due to the occurrence of red coloration of the urine and a decrease in body weight gain. Although these findings were no longer apparent after week 2,

analytical verification of dietary levels revealed that the highest dietary level ranged from approximately 38,000 to 61,000 ppm during the first 32 weeks of the study. Calculi in the urinary bladder were observed for several male and female rats at 30,000/40,000 ppm. Microscopic examination revealed transitional cell carcinomas and papillomas in the urinary bladders of high dose males. In addition, a statistically significant increase in adrenal pheochromocytomas (benign and malignant combined) was observed in males at 8,000 and 30,000/40,000 ppm. The adrenal slides were independently reread by two consulting pathologists who found no significant dose-related increases in the incidence of pheochromocytomas or hyperplasia. The NOEL for fosetyl-Al in the chronic rat study was 8,000 ppm. A subsequent mechanistic study in rats conducted with dietary levels of 8,000, 30,000 and 50,000 ppm demonstrated that the massive doses of 30,000 and 50,000 ppm fosetyl-Al alter calcium/phosphorous homeostasis resulting in severe acute renal injury, similar to that observed in the chromic rat study, and the formation of calculi in kidneys, ureters, and bladder. Under conditions of chronic exposure, these effects could lead to the formation of bladder tumors as seen in the chronic rat study. At 8,000 ppm, no evidence of renal injury was observed, a result consistent with the absence of bladder tumors. Thus, the bladder tumors induced by fosetyl-Al were the result of acute renal injury followed by a chronic toxic reaction rather than a true carcinogenic effect. An oncogenicity study in rats was conducted with monosodium phosphite administered via dietary mixture at levels of 2,000, 8,000, and 32,000 ppm. No evidence of oncogenicity was observed in this study.

ii. *Mouse*. A 2-year feeding/carcinogenicity study was conducted in mice fed diets containing fosetyl-Al at 0, 2,500, 10,000, or 20,000/30,000 ppm. The 20,000 ppm dose was increased to 30,000 ppm during week 19 of the study. The NOEL for all effects was 20,000/30,000 ppm (3,000/4,500 mg/kg/day). There were no carcinogenic effects observed under the conditions of this study.

iii. *Conclusion*. The Office of Pesticide Programs', Health Effects Division, Carcinogenicity Peer Review Committee (CPRC) concluded in their report of June 29, 1993 that the pesticidal use of fosetyl-Al is unlikely to pose a carcinogenic hazard for humans given that:

a. Tumors develop in rats under extreme conditions that are unlikely to be achieved other than under laboratory conditions (at a dose in excess of the OPP dose limit for carcinogenicity studies).

b. Tumors in rats are believed to develop only at doses that produce stones.

c. Human dietary exposure to fosetyl-Al is only about one-500,000th of the NOEL for stone formation in the rat (the most sensitive experimental model).

d. The dose of fosetyl-Al which can be absorbed dermally by applicators is also probably too low to result in stone formation. EPA has therefore chosen to use the Reference Dose (RfD) to quantify dietary risk to humans.

7. *Neurotoxicity*. No evidence of neurotoxic potential has ever been observed with fosetyl-Al. Fosetyl-Al does not have a chemical function associated with neurotoxicity. No signs of neurotoxicity have been recorded in any study conducted with fosetyl-Al.

8. *Animal metabolism*. Rat metabolism studies showed that most of the radiolabel rapidly appeared in exhaled carbon dioxide. There was also some radiolabel excreted in the urine as phosphite, along with a smaller amount as the unchanged parent compound. It appears that fosetyl-Al is essentially completely absorbed after ingestion and extensively hydrolyzed to carbon dioxide which is exhaled. The phosphite is excreted in the urine without further oxidation to phosphate. Aluminum does not appear to be absorbed to a significant extent from the gastrointestinal tract.

9. *Metabolite toxicology*. There are no metabolites of toxicological concern. The tolerances are established for the parent only, that is fosetyl-Al.

10. *Endocrine disruption*. No evidence of estrogenic or androgenic effects were noted in any study with fosetyl-Al. No adverse effects on mating or fertility indices and gestation, live birth, or weaning indices were noted in a 3-generation rat reproduction study at doses well above EPA's limit of 1,000 mg/kg/day. Therefore, fosetyl-Al does not have any effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Chronic risk*. Based upon all available data, EPA has established an RfD of 3.0 mg/kg/day using a 100 fold safety factor to account for inter- and intra-species differences and a NOEL of 250 mg/kg/bwt/day from a 2-year feeding study in dogs. A chronic dietary risk assessment was prepared using established and proposed tolerance residue levels, 1987 food consumption data, and 100% crop treated. The calculated potential exposure for the U.S. population is 0.065760 mg/kg bwt/day. Potential exposure for nursing and non-nursing infants less than 1-year old, children aged 1 to 6-years, and children aged 7 to 12-years is calculated to be 0.022485, 0.134076, 0.116682, and 0.069637 mg/kg bwt/day, respectively. This results in utilization of 2.2, 4.5, 3.9, and 2.3% of the RfD for the whole U.S. population, non-nursing infants less than 1-year old, children aged 1 to 6- years, and children aged 7 to 12-years, respectively. Thus, the dietary exposure for fosetyl-Al is well below the RfD of 3.0 mg/kg/day and is negligible for all segments of the population including infants and children.

ii. *Acute risk*. Based on a lack of acute toxicity and the large margins of exposure in the chronic dietary assessment, fosetyl-Al does not pose any acute dietary risks.

2. *Food*. The dietary exposure assessment accounts for all anticipated dietary exposure for a tolerance of 3.0 ppm on bananas, which is the subject of this request, and all other active and pending tolerances for fosetyl-Al. The active tolerances are for asparagus, avocados, blueberries, brassica, caneberries, citrus, cucurbits, ginseng, hops (dried), leafy vegetables, pineapple, onions (dry bulb), pome fruit, strawberries, and tomatoes. Pesticide petitions proposing the establishment of tolerances for Fosetyl-Al on grapes and macadamia nuts (IR-4) have also been submitted to the Agency.

3. *Drinking water*. There is no established maximum contaminant level (MCL) or health advisory level (HAL) for fosetyl-Al. The potential for ground water and/or surface water contamination by fosetyl-Al and its degradates is expected to be very low, in most cases, due to the rapid degradation of the compound in soil to non-toxic degradates under both aerobic and anaerobic conditions. Under aerobic laboratory conditions, the half-life of fosetyl-Al is between 1 and 1.5 hours in loamy sand, silt loam, and clay loam and 20 minutes in sandy loam soil. The degradation proceeds through the hydrolysis of the ethyl ester bond, resulting in the formation of phosphorous acid and ethanol. The ethanol is further degraded into carbon dioxide. Based on the short half-life of fosetyl-Al and the known fate of phosphates under anaerobic conditions, EPA determined that an anaerobic soil metabolism study was not necessary. An anaerobic aquatic soil metabolism study was conducted. When anaerobic conditions were established by flooding soil, the half-life was 40 hours with silty

clay loam, and 14 hours with sandy loam soil.

4. *Non-dietary exposure*. In addition to agricultural uses, fosetyl-Al is registered on ornamentals and turf under the brand names CHIPCO Aliette WDG, and Aliette HG. CHIPCO Aliette WDG is sold to professional applicators only, which includes lawn care operators (LCO). All residential uses of CHIPCO Aliette WDG are applied by an LCO. Typically, LCOs use fungicides for ornamentals and turf on an as needed basis only in part because of high cost, variable performance, and little residual control. In 1994, LCOs made an estimated 206,200 acre treatments in total for all fungicides representing less than 1% of the available acreage of 32,740,000 assuming each acre was treated once (Kline & Company, Inc.). CHIPCO Aliette WDG is estimated to have been used on less than 3% of the acres treated with commercial landscapes (turf and ornamentals) constituting the majority of the use by LCOs. Therefore, fosetyl-Al is used by LCOs on less than 0.03% of the total available acres. Aliette HG is not currently being sold but plans are to introduce this product on the market in 1998 on a limited geographical scale. The product will be available to the home consumer in single dose packages for residential use on turf and ornamentals. Available market research information indicates that a total of 1.7 million pounds fungicide (active ingredient) are sold annually for use by the home owner. Since Aliette HG will just be entering the market, only very small quantities of the product are expected to be sold. The maximum amount expected to be sold for the next few years is approximately 1% of the total 1.7 million pounds of fungicide products available to the home owner for residential use on turf and ornamentals. This use of the product is therefore expected to have a negligible impact on the aggregate exposure for fosetyl-Al.

5. *Conclusion*. Considering that fosetyl-Al is applied by LCOs on about 0.03% of available lawn acres (the majority being commercial landscapes), the likelihood of post application exposure occurring, particularly in a residential situation, is extremely low. The use of fosetyl-Al by the homeowner constitutes a minor use of the product since only small quantities are expected to be sold in 1998. Other applications by professional operators, e.g. golf courses, nurseries, sod farms, present only very limited exposure to a limited population of adults but do not pose any exposure to small children. Thus, the ornamental and turf uses are not expected to add significantly to the aggregate exposure for fosetyl-Al, and only dietary exposure has been taken into consideration for risk assessment purposes.

D. Cumulative Effects

Effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. The formation of calculi and bladder tumors in rats is the only significant toxicological effect observed with fosetyl-Al. These effects were observed in rat only at a dose which not only exceeds estimated human exposure by several orders of magnitude but is in excess of the OPP dose limit for carcinogenicity studies. Therefore, an aggregate assessment based on common mechanisms of toxicity is not appropriate as exposure to humans will be well below the levels producing calculi and bladder tumors in rats. Further, considering the rapid elimination of fosetyl-Al in the rat metabolism study, any effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. Based on these reasons, only the potential risks of fosetyl-Al are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. Based upon all available data, EPA has established an RfD of 3.0 mg/kg/day using a 100 fold safety factor to account for inter- and intra-species differences and a NOEL of 250 mg/kg bwt/day from a 2-year feeding study in dogs. A chronic dietary risk assessment using established and proposed tolerance residue levels, 1987 food consumption data, and 100% crop treated results in utilization of 2.2, 4.5, 3.9, and 2.3% of the RfD for the whole U.S. population, non-nursing infants less than 1-year old, children aged 1 to 6-years, and children aged 7 to 12-years, respectively. Thus, the dietary exposure for fosetyl-Al is well below the RfD of 3.0 mg/kg/day and is negligible for all segments of the population including infants and children.

2. *Infants and children—Adequate margin of safety*. In assessing the potential for additional sensitivity of infants and children to residues of fosetyl-Al, the available developmental and reproductive toxicity studies and the potential for endocrine modulation were considered. Developmental toxicity studies in two species indicate that fosetyl-Al has no teratogenic potential at any dose level. Further, no adverse effects on fetal development were observed in rabbits at doses up to 500 mg/kg/day or in rats at doses up to 1,000 mg/kg/day. In a 3-generation rat reproduction study, no adverse effects on reproductive performance or pup survival were observed up to 24,000 ppm (equivalent to a dose well above EPA's limit dose of 1,000 mg/kg/day). Maternal and developmental NOELs and LELs were comparable in all studies indicating no increase in susceptibility of developing organisms. Further, fosetyl-Al has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies. Since registration of fosetyl-Al in 1983, EPA has assessed the safety of this molecule several times and has concluded repeatedly that the level of dietary exposure is sufficiently low to provide ample margins of safety to guard against any potential adverse effects of fosetyl-Al. Considering the conservative exposure assumptions in setting the tolerances and the dietary risk assessment assuming 100% crop treated, less than 5% of the RfD is utilized for non-nursing infants less than 1-year old, children aged 1 to 6-years, and children aged 7 to 12-years. The probability of non-occupational sources of exposure to fosetyl-Al is negligible. Therefore, based upon the completeness and reliability of the toxicity data and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from exposure to the residues of fosetyl-Al and no additional uncertainty factor is warranted.

F. International Tolerances

There are presently no Codex maximum residue levels established for residues of fosetyl-Al on any crop.

[FR Doc. 98–17808 Filed 7–6–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6121–3]

Proposed CERCLA Administrative De Minimis Contributor Settlement With Mesa Oil, Inc.—Rocky Flats Industrial Park Site in Jefferson County, Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and request for public comment.

SUMMARY: In accordance with the requirements of section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative *de minimis*