common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. In the meeting of September 30, 1993, the OPP RfD Peer Review Committee recommended that the RfD for this chemical be based on a NOAEL of 20 mg/kg/day for a dose-related increase in size and altered tinctorial properties of centrilobular hepatocytes in males and females at 60 and 200 mg/kg/day in a chronic toxicity study in rats. An uncertainty factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated to be 0.20 mg/kg/day. The TMRC from existing tolerances is 0.001845 mg/kg/day. Existing tolerances utilize >1% of the RfD. It should be noted that no regulatory value has been established for this chemical by the World Health Organization (WHO) up to this date. The committee classified picloram as a ''Group E'' chemical, no evidence of carcinogenicity for humans.

Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to picloram will utilize approximately 1% of the RfD for the U.S. population. Generally, exposures below 100% of the RfD are of no concern because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to picloram residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of picloram, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat were considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism during prenatal development resulting from pesticide exposure to one or both parents. Reproduction studies provide (1) information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and (2) data on systemic toxicity.

Developmental toxicity was studied using rats and rabbits. The developmental study in rats resulted in a developmental NOAEL of >298 mg/kg/day and a maternal toxicity NOAEL of 280 mg/kg/day. A study in rabbits resulted in a maternal NOAEL of 34 mg/kg/day and a developmental NOAEL of 344 mg/kg/day. Based on all of the data for picloram, there is no evidence of developmental toxicity at dose levels that do not result in maternal toxicity.

In a 2-generation reproduction study in rats, The NOAEL for parental systemic toxicity is 200 mg/kg/day. There was no effect on reproductive parameters at 1,000 mg/kg/day nor was there an adverse effect on the morphology, growth or viability of the offspring; thus, the reproductive NOAEL is 1,000 mg/kg/day.

FDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. Therefore, it is concluded that an additional uncertainty factor is not warranted and that the RfD at 0.2 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumption previously described, it is concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of picloram will be less than 4% of the RfD for all populations and subgroups. Since this estimate represents the 'worst case' exposure for a given population (Non-nursing infants, >1 year old), exposures will be less for all other sub-populations e.g. children, 1-6 years. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to picloram residues.

F. International Tolerances

There are no Codex maximum residue levels established for residues of picloram.

G. Other Considerations

Data Gaps. Residue data for sorghum aspirated grain fractions is currently being generated. Based on the toxicological data and the levels of exposure, EPA has determined that the proposed tolerances will be safe.

[FR Doc. 98–31067 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–832; FRL–6027–6]

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–832, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, 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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office Location, telephone number, and e-mail address: Rm. 707A, CM #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–8380, e-mail: gandhi.bipin@epamail.epa.gov.

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–832] (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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–832] and appropriate petition number. Electronic comments on this 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: October 22, 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. EDM Corp

PP 8E4968

EPA has received a pesticide petition (8E4968) from EDM Corp 2278 So. Indiana Porterville, CA 93257 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 to establish an exemption from the requirement of a tolerance for Yucca Extract in or on the raw agricultural commodity when used in accordance with good agriculture practice as an inert ingredient in pesticide formulations applied to growing crops, the 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*. No plant metabolism studies have been submitted in support of this tolerance exemption petition since yucca extract, a sarsasaponin is present in most plant life.

2. *Analytical method*. Since the petitioner has requested a tolerance exemption, a residue analytical method is not required.

3. *Magnitude of residues*. No yucca extract residue studies were conducted since yucca extract is naturally found at significant levels (> .68 ppm) in many different types of food. In addition, residue trials are not practical since it is very difficult to distinguish Sarsaponin residues naturally occurring versus sapsaponin residues from yucca extract.

B. Toxicological Profile

1. *Acute toxicity— Study #6176-P320 acute oral toxicity*. The acute oral LD_{50} for a 70% solution of yucca extract is > 5,000 milligrams/kilogram (mg/kg). Accordingly, yucca extract relatively non-toxic by the oral route.

The petitioner has requested that the Agency waive all sub-chronic, chronic/oncogenicity, mutagenicity, developmental and reproductive toxicity study requirements for yucca extract. There is an overwhelming lack of evidence for any chronic effects induced by dietary ingestion of yucca extract.

C. Aggregate Exposure

1. *Food*. The FDA title 21 under CFR 172.510, FEMA #3121, No Limitations. Food. Sarsasaponin is naturally found in several types of foods, such as fruits and vegetables,(asparagrus, legumes ect) at various levels.

2. *Drinking water*. Degradation of sarsasaponin in water.

D. Cumulative Effects.

No cumulative adverse effects are expected from long-term exposure to yucca extract.

E. Safety Determination

1. *U.S. population*. Yucca has been approved for uses in food and beverages by the FDA title 21 CFR 172.510, FEMA number 3121, with no limits. Approval of this petition will not increase dietary exposure to yucca extract. Accordingly, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population to yucca extract.

2. *Infants and children*. Since yucca extract is also an additive in soft drinks, root beer etc. the daily exposure to children is anticipated to be trivial, no adverse effects on infants or children are expected.

F. International Tolerances

There are no approved CODEX maximum residue levels (MRLS) established for residues of yucca extract.

Previously submitted Yucca extract data:

1. THERM-70 Study #6176-P320 Acute Oral Toxicity.

2. Regarding the use of the inert ingredient Yucca extract:

A-350 tons raw materials are used for all usese in the United States.

B- 300,000 lbs of raw material makes 4,630 gallons of THERMX-70 for pesticidal uses.

C- CELLU-CON, INC. Received raw material in 1997 from Mexico (85%) and U.S. 15%.

D- Yucca already approved for uses in food and beverages by the FDA title 21 CFR 172.510, FEMA number 3,121, no limits.

E- We would like to waive Yucca (Schidigera) to be approved under title 40 CFR in section 180.1001 as an Inert Ingredient.

3. This is to advise you regarding EDM's use of Yucca. We will not be using more than 6% THERMX-70 as a wetting in our product MIRAGE.

Enclosed is a packet of information to assist you in studying this material.

A- FDA 21 CFR 172.510
B- COMMERCIAL FEED LICENSE
C- THERMX-70 label
D- THERMX-70 MSDS sheet
E- Sarsaponin (Micro-Aid)

4. DESERT PRIDE label Yucca Herbal Food Tablets has been sold in stores since 1974.

2. Hercules, Incorporated

PP 6E4782

EPA has received a pesticide petition (PP 6E4782) from Hercules, Incorporated, 1313 North Market Street, Wilmington, Delaware, 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 to establish an exemption from the requirement of a tolerance for polymers of α-pinene and/or *B*-pinene in or on raw agricultural commodities. 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

1. *Acute toxicity.* An acute oral intubation test was conducted. Two male and two female rats were administered four dose levels of oligomeric copolymer ranging from 10.2 to 34.6 g/kg. No deaths resulted. The oral LD_{50} in rats is therefore >34.6 g/kg. An acute eye irritation study was conducted. Two rabbits were treated with 0.1 milliliter (ml) of undiluted oligomeric copolymer material instilled in each eye. One eye of each animal was rinsed with running water after one minute. The unwashed eye showed moderate irritation to the iris and conjunctiva which persisted for 4 days after treatment. Irritation in the washed eyes was mild and persisted for 3 days after treatment.

2. *Reproductive and developmental toxicity.* Petitioner has not identified a reproduction study in which the test substance was an α-pinene based polymer. In the interest of complete disclosure, Petitioner is aware of a limited reproduction study dated 1960 that was conducted at the LaWall & Harrisson Laboratories in connection with a larger 2-year feeding study. The test substance was Hercules Piccolyte S125 Polyterpene Resin, a *B*-pinene-based resin which is derived from the polymerization of a terpene feedstock containing a minimum *B*-pinene content of 80% and an α-pinene content of between 5% and 9%. Groups of six female Sprague-Dawley rats were fed the test substance at 0%, 3%, or 10% of the diet. After 4 months of exposure, the rats were mated with similarly treated males. All females bore litters except one from the untreated control group. All litters were normal in size and a few stillborn pups were noted in each group. There were some deaths among the pups, but survival to weaning was equal in all groups. Indices of reproductive and developmental performance were not calculated. The dietary level of 10% was considered the no-observed-adverse-effect level (NOAEL) in this limited reproduction study.

3. *Subchronic toxicity— i. Study No. 1.* In a study conducted in 1968, groups of 10 male and 10 female Charles River rats were fed diets containing 0%, 1%, 3%, or 5% of an α-pinene based resin for 3 months. Criteria of evaluation for possible toxic effects included general appearance and behavior, growth, food consumption, survival, clinical laboratory results, absolute and relative organ weights, and gross and microscopic pathology. Effects seen at the 5% dietary concentration include increases in relative liver weight in both sexes, and absolute liver weight in females only. Increased relative thyroid weight in males was noted at the 5% and 3% dosage levels. In the absence of histopathological alterations, these changes are regarded as adaptive and not of toxicological significance. The dietary level of 5%, equivalent to an overall average of 3,967 milligrams/kilogram/day (mg/kg/day) is considered the NOAEL in this study.

ii. *Study No. 2.* Groups of ten male and ten female Sprague-Dawley rats were fed diets containing 0%, 0% (i.e., two untreated controls), 0.01%, 0.05%, 0.2%, 1%, or 5% of Terpene AP for 90 days. Criteria of evaluation included appearance and behavior, growth, survival, hematology and urinalysis, organ weights and gross and microscopic pathological evaluation. A paired feeding study was conducted in conjunction with the main study to evaluate the significance of diet rejection vs. compound-related toxicity in weight gain reduction associated with high concentrations of Terpene AP. In the paired feeding study, each rat fed 5% Terpene AP (Test Group) was matched with a rat of the same sex and similar weight. Each of the Paired Feeding Control Group received the same amount of diet in each 24-hour period as the corresponding treated rat during the preceding reference 24-hour period, but without the test material. Two deaths occurred during the study. They were not dosage-related and were attributed to respiratory infection and not to compound-related toxicity. Decreased body weight gain and increased liver weight were consistent findings. Final body weights were reduced 16% in males and 11% in females at the highest dosage level. The paired-feeding study demonstrated that the effect was due to food rejection based on poor palatability and not due to systemic toxicity of the test material. Liver weight, as absolute weight and liver/brain weight ratios, increased in a dosage-related fashion. At the 5% dietary levels, 39% and 83% absolute weight increases were noted in males and females, respectively. Lesser increases were noted at the 1% and 0.2% dietary levels of the test material. Liver weight/body weight ratios were increased artifactually because of the growth depression. Since there were no adverse histological findings associated with the liver weight increases, the finding is attributed to generalized physiologic stress and not to organ-specific toxicity. Thyroid hyperplasia noted in some rats at the 5% and 1% levels is a secondary effect of the liver weight increase. The dietary concentration of 0.05% Polyterpene was a NOAEL in this 90-day study. Because food consumption was not evaluated, an equivalent mg/kg/day NOAEL could not be calculated in this study. Based on analyses of food consumption data from similar studies, an approximate dosage equivalent would be 37.5 mg/kg/day.

4. *Chronic toxicity*— i. *Study No. 3.* A terpene resin was fed to beagle dogs, three per sex per group, at dietary levels of 0%, 0.2%, 1% and 5% for 2 years. Criteria of effect included appearance and behavior, growth and survival, food consumption, hematology, clinical chemistry, urinalysis, absolute and relative organ weights and gross and microscopic pathology. Effects seen at the 5% dietary level included moderate reduction in growth and increased absolute and relative liver weight at 1 year and 2 years, and minimal hepatocellular fatty changes at 1 year but not 2 years. Similar liver effects were seen at the 1% dietary concentration. The dietary levels of 0.2% terpene resin equivalent to an overall average of 51 mg/kg/day, a NOAEL in this 2-year study.

ii. *Study No. 4.* Groups of 30 male and 30 female Sprague Dawley rats were fed diets containing 0%, 0.2%, 1%, or 5% terpene resin for 2 years. The terpene resin was a copolymer of α- and *B*-pinene. No differences from controls were noted in any test groups with respect to appearance and behavior,

food consumption, growth, survival, tumor incidence, hematology and urinalysis. All means were within the range of normal variation. Significant elevations of absolute and relative liver weight were noted in females after 12 months on the 1% and 5% diets. In males, absolute liver weight was elevated at the 5% level and relative liver weights were elevated at both the 1% and 5% levels. After 24 months of treatment, relative liver weights were elevated in males at 5% and in females at 1% and 5%. Histological examinations after 2 years showed only effects anticipated in untreated animals. Liver enlargement in the absence of histopathological changes results from compensatory effects. The highest dietary concentration of 5% terpene resin, equivalent to an overall average of 3,100 mg/kg body weight per day, is regarded as the NOAEL in this study.

5. *Endocrine disruption*. A comprehensive literature search has revealed no reports associating pinene monomers or polymers with endocrine effects. Petitioner has not undertaken any testing to explore further the possibility that pinene polymers or monomers could cause endocrine effects and understands that EPA will implement a screening program for endocrine effects in the future.

C. Aggregate Exposure

1. *Dietary exposure*. Synthetic terpene resin, consisting of polymers of α-pinene, *B*-pinene, and/or dipentene, is currently cleared by the Food and Drug Administration for use as an ingredient of chewing gum base and for use in a variety of food-contact or food packaging applications. The range of materials that are used in these applications under the name ''synthetic terpene resin'' will vary in composition and molecular weight. These existing food applications result in some small amount of dietary exposure to pinene monomers, oligomers, and polymers. This exposure can be expected to be quite small given that only a small amount, if any, of the synthetic terpene resin present in a food-contact article will migrate into food. Similarly, the insoluble gum base portion of chewing gum is ordinarily discarded after chewing, and like the other components of gum base, synthetic terpene resin is not extracted to any significant degree by saliva. Petitioner has presented calculations showing very roughly that even if the total annual U.S. production volume of terpene resins were incorporated directly into the diet, this would result in a per capita consumption of α-pinene and α-pinene repeating units of only 1.7 mg/kg body weight per day for a 60-kg adult. Actual intake will be significantly less than this number, given that not all synthetic terpene resin is used in food applications, and that very little migration and ingestion can be attributed to the existing food-contact and chewing gum applications.

2. *Food*. Petitioner does not manufacture sticker formulations and therefore has not conducted studies to show the actual quantity of pinene polymers that will remain on harvested food crops. Based on the conservative assumption that all pinene polymer will remain on food crops at the time of harvest, Petitioner has presented calculations showing that the resulting dietary exposure will not exceed 0.43 mg/kg body weight per day for a 60-kg adult. Actual intake will be less than his number. Petitioner notes that this intake is a subset of the worst-case aggregate exposure number, 1.7 mg/kg body weight per day.

3. *Drinking water*. Due to its relative insolubility, only trace amounts of pinene polymer, if any, will be found in drinking water. Some amount of pinene polymer will enter the soil in fields where it is applied as part of a pesticide formulation. Any pinene polymer present in the soil could potentially reach ground water, as is the case with agricultural chemicals generally. In the case of pinene polymers, Petitioner notes that they can be expected to adhere to the soil due to their adhesive properties and that they may biodegrade before reaching ground water. Petitioner further notes that any drinking water exposure will be within the worst-case aggregate exposure estimate, 1.7 mg/kg body weight per day.

4. *Non-dietary exposure*. Outside of food applications, pinene polymers are used in various adhesive applications including construction adhesives used, for example, to lay floor tile. Pinene polymers present in adhesives are not volatile and will therefore not be inhaled. The only human exposure will be that associated with accidental skin contact. It would be difficult to assign a numerical value to this non-occupational exposure for a typical person. Exposures from all sources cannot exceed 1.7 mg/kg body weight per day for a typical adult, given the total production volume of α-pinene polymers.

D. Cumulative Effects

No identified risks are associated with exposure to pinene polymers. The mechanism or mode of action associated with pinene polymers is simply that the substance is physically sticky.

E. Safety Determination

1. *U.S. population*. Petitioner estimates that exposure to α-pinene polymers and repeating units attributable to the requested action will be less than 0.43 mg/kg body weight per day in a 60-kg adult. This number is based on a set of conservative assumptions, and actual exposure is expected to be much less. In no event will aggregate exposure, by all routes and from all sources, exceed 1.7 mg/kg body weight, given the total production volume of α-pinene polymers. In several of the available animal feeding studies, the NOAEL was found to be 5% or more of the diet (greater than 3,000 mg/kg body weight per day). The lowest reported NOAEL of which the petitioner is aware is 37.5 mg/kg body weight, which is somewhat of an outlying value.

2. *Infants and children*. Infants and children will not experience higher levels of exposure to pinene polymers than the rest of the population as a result of the action requested in this petition. Furthermore, no chronic or acute effects are associated with pinene polymers, for which infants and children could be particularly sensitive. Petitioner expects pesticide sticker formulations containing pinene polymers to be used on a variety of food crops, which will lead to low levels of residues distributed evenly throughout the food supply. Considering this variety of uses, exposure should be spread evenly over the entire population and not concentrated in any particular sub-population. Dietary exposure in adults will not exceed 0.43 mg/kg body weight per day from the requested application, and aggregate exposure from all sources and routes cannot exceed 1.7 mg/kg body weight per day. These estimates correspond to an adult weighing 60 kg and consuming 1,500 grams of solid food per day. The numbers can be adjusted to account for the weight of a child. For example a child weighing 30 kg and consuming 1,000 g of solid food per day will be exposed to no more than 0.56 mg/kg body weight per day from the requested application and no more than an aggregate of 3.3 mg/kg body weight per day from all routes and all sources. Exposure estimates thus adjusted for children compare favorably with the NOAEL reported in the animal feeding studies.

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