

2% gel formulation indicate that less than 1% of the dose is dermally absorbed after 10-hours. In addition, the Agency has reviewed risk assessments and accepted the existence of more than adequate margins of exposure ((MOE) of 658 for both commercial and homeowner applicators and MOEs of >540 for post-application homeowner exposures) for other hydramethylnon-based products, containing up to 2% active ingredient. Thus, this new use pattern does not present any incremental risk of exposure to hydramethylnon residues.

D. Cumulative Effects

To the best of our knowledge, hydramethylnon is the only registered pesticide which belongs to a unique chemical class, the pyrimidinones (amidinohydrazones). Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hydramethylnon does not appear to produce a toxic metabolite produced by other substances. Therefore, the potential for cumulative effects of hydramethylnon and other chemicals having a common mechanism of toxicity should not be of concern and for the purposes of this tolerance action, it is assumed that hydramethylnon does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*— i. *Acute risk*. An acute endpoint has not been identified. The Agency's Hazard Identification Committee determined that this risk assessment is not required.

ii. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to hydramethylnon from food will utilize <1% of the RfD of 0.01 mg/kg/day for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. In view of the negligible potential for exposure to hydramethylnon in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure is not expected to exceed 100% of the RfD. EPA has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to hydramethylnon residues. According to Agency policy, the residential uses of hydramethylnon do not fall under a chronic exposure scenario. Thus, it can be concluded that there is a reasonable certainty that no harm will result from

chronic aggregate exposure to hydramethylnon residues.

iii. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Although hydramethylnon has residential uses, this new use pattern does not present any incremental risk of exposure to hydramethylnon residues. As discussed previously in section C. 4., the vapor pressure of hydramethylnon is less than 2×10^{-8} mm of Hg at 35 and 45 °C; thus, the potential for non-occupational exposure by inhalation is insignificant. Moreover, based on the physical and chemical properties of hydramethylnon, exposure from drinking water is not likely. Although there may be short- and intermediate-term occupational and non-occupational dermal exposures, the Agency has reviewed risk assessments and accepted the existence of more than adequate (MOEs of 658 for both commercial and homeowner applicators and MOEs of >540 for post-application homeowner exposures) for other hydramethylnon-based products, containing up to 2% active ingredient. Thus, as in the case for chronic exposure scenarios, it can be concluded that there is a reasonable certainty that no harm will result from short and intermediate-term exposures to hydramethylnon residues.

2. *Infants and children*—i. *Chronic risk*. Using the TMRC exposure assumptions described above, EPA has concluded that aggregate exposure to hydramethylnon from food will utilize only 0.2% of the RfD of 0.01 mg/kg/day for non-nursing infants <1 year old.

ii. *Safety factor for infants and children*— a. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of hydramethylnon, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. EPA has concluded that the toxicological database for hydramethylnon is adequate and does not indicate an increased sensitivity of perinatal animals to pre- and/or post natal exposures. Therefore, no additional uncertainty factor for protection of infants and children are warranted for hydramethylnon.

b. *Developmental toxicity studies*. In the rat developmental toxicity study, the developmental NOEL was 10 mg/kg/bwt/day with a NOEL for maternal toxicity of 3.0 mg/kg/bwt/day. In the rabbit developmental toxicity study the developmental NOEL was 5 mg/kg/bw/

day with a NOEL for maternal toxicity of less than 5 mg/kg bwt/day.

c. *Reproductive toxicity study*. A 2-generation reproduction study with hydramethylnon was conducted in rats. The data support a NOEL for reproductive toxicity of 50 ppm (4.2 mg/kg/bwt/day), while the NOEL for paternal toxicity was 25 ppm (2.1 mg/kg/bwt/day). No adverse effects were observed in the pups.

These values are significantly higher than the NOEL used to calculate the RfD for the general U.S. population which is 0.01 mg/kg/bwt/day. These results demonstrate that there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to hydramethylnon.

F. International Tolerances

There are no Codex, Canadian or Mexican residue limits established for hydramethylnon in/on pineapple. Thus, harmonization is not an issue for this petition.

[FR Doc. 98-21902 Filed 8-13-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-822; FRL-6019-8]

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-822, must be received on or before September 14, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), 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
Mark Dow	Rm. 214, CM #2, 703-305-5533, e-mail:dow.mark@epamail.epa.gov.	1921 Jefferson Davis Highway, Arlington, VA
Bipin Gandhi (PM 22)	Rm. 707A, CM #2, 703-308-8380, e-mail:gandhi.bipin@epamail.epa.gov.	1921 Jefferson Davis Highway, 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 Cosmetic 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-822] (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: August 5, 1998.

Arnold E. Layne,

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. Bayer Corporation

PP 4F4330

EPA has received a pesticide petition (PP 4F4330) from Bayer Corporation, 8400 Hawthorn Road, PO Box 4913, Kansas City MO, 64120-2000 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 cyfluthrin, (Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in or on the raw agricultural commodity potato 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 metabolism of cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

2. *Analytical method.* Adequate analytical methodology (gas/liquid chromatography with an electron capture detector) is available for enforcement purposes.

3. *Magnitude of residues.* Cyfluthrin is the active ingredient in the registered end-use product Baythroid 2 Emulsifiable Pyrethroid Insecticide, EPA Reg. No. 3125-351. Data to support the proposed tolerances have been submitted to the Agency.

B. Toxicological Profile

The database for cyfluthrin is current and complete. Toxicology data cited in support of these tolerances include:

1. *Acute toxicity.* There is a battery of acute toxicity studies for cyfluthrin supporting an overall toxicity Category II for the active ingredient.

2. *Genotoxicity.* Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary(CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

3. *Reproductive and developmental toxicity.* An oral developmental toxicity study in rats with a maternal and fetal NOEL of 10 milligram/ kilograms/body weight/day (mg/kg/bw/day) (highest dose tested (HDT)).

An oral developmental toxicity study in rabbits with a maternal NOEL of 20 mg/kg bw/day and a maternal lowest effect level (LEL) of 60 mg/kg bw/day, based on decreased body weight gain

and decreased food consumption during the dosing period. A fetal NOEL of 20 mg/kg bw/day and a fetal LEL of 60 mg/kg bw/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

A 3-generation reproduction study in rats with systemic toxicity NOELs of 7.5 and 2.5 mg/kgbw/day for parental animals and their offspring, respectively. At HDTs, the body weights of parental animals and their offspring were reduced.

4. *Subchronic toxicity.* A subchronic toxicity feeding study using rats demonstrated a NOEL of 22.5 mg/kg bw/day, the HDT.

A 6-month toxicity feeding study in dogs established a NOEL of 5 mg/kg bw/day. The LEL was 15 mg/kg bw/day based on clinical signs and reduced thymus weights.

5. *Chronic toxicity.* A 12-month chronic feeding study in dogs established a NOEL of 4 mg/kg bw/day. The LEL for this study is established at 16 mg/kg bw/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

A 24-month chronic feeding/carcinogenicity study in rats demonstrated a NOEL of 2.5 mg/kg bw/day and LEL of 6.2 mg/kg bw/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

A 24-month carcinogenicity study in mice was conducted. Under the conditions of the study there were no carcinogenic effects observed. A 24-month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism.* A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Metabolite toxicology.* No toxicology data have been required for cyfluthrin metabolites. The residue of concern is cyfluthrin.

8. *Endocrine disruption.* No evidence of endocrine effects was observed in any of the studies conducted with cyfluthrin, thus, there is no indication at this time that cyfluthrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure—Food.* Dietary exposure was estimated using Novigen's Dietary Exposure Evaluation Model (DEEMä) software; results from field trial and processing studies;

consumption data from the USDA Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1989 through 1992; and information on the percentages of the crop treated with cyfluthrin.

Cyfluthrin is currently registered for use in alfalfa, citrus, sweet corn, cotton, sorghum, sunflower, sugarcane, carrots, peppers, radishes and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments and in combination with another active ingredient, for use in field corn, pop corn and sweet corn.

Considering all current registered uses with the addition of potatoes, chronic dietary exposure estimates for the overall U.S. population were 0.8% of the RfD (0.008 mg/kg bw/day). For the most highly exposed population subgroup, children 1 to 6 years of age non-nursing infants (<1 year), the exposure was estimated to be 0.000153 mg/kg bw/day, or 1.9% of the RfD.

Acute dietary exposures were estimated for the overall U.S. population, females 13-years and older, children, ages 1-6 and 7-12 years, infants, non-nursing and nursing. The exposure was compared to the NOEL of 20 mg/kg bw/day to estimate the Margins of Exposures (MOEs).

For the overall U.S. population the 95th, 99th and 99.9th percentile of exposure the MOEs were calculated as 11,751; 6,882; and 4,439 respectively.

For women aged 13-years and older the 95th, 99th and 99.9th percentile of exposure the MOEs were calculated as 19,719; 13,147 and 7,165 respectively.

Lastly, for the potentially highest exposed population subgroup, non-nursing infants, the 95th, 99th and 99.9th percentile of exposure to the MOEs were calculated at 6,201; 4,595; and 2,933, respectively.

2. *Drinking water.* Cyfluthrin is immobile in soil, therefore, will not leach into groundwater. Additionally, due the insolubility and lipophilic nature of cyfluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water.

A screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM3). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at 2 meters are essentially zero (<0.001 parts per billion (ppb)). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System

(EXAMS) using Standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 52 parts per trillion (ppt). Concentration in actual drinking water would be much lower. Based on these analyses, the contribution of water to the dietary risk estimate is negligible.

3. *Non-dietary exposure.* Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Pursuant to the requirements of FIFRA as amended by the Food Quality Protection Act (FQPA) of 1996 non-dietary and aggregate risk analyses for cyfluthrin were conducted. The analyses include evaluation of potential non-dietary acute application and post-application exposures. Non-occupational, non-dietary exposure was assessed based on the assumption that a flea infestation control scenario represents a "worst case" scenario. For the flea control infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst-case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose no-observed-effect-level (NOEL). Results for each potential exposed subpopulation (of adults, children 1-6 years, and infants <1 year) were compared to the systemic absorbed dose NOEL for cyfluthrin to provide estimates of MOE.

The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,600, and 2,400 for adults, children (1-6 years), and infants (<1 year), respectively. When chronic dietary exposure is aggregated with non-dietary exposure, the aggregate MOE for adults is relatively unchanged approximately 3,800 and the MOEs for infants and children exceed 2,400.

The non-dietary methods used in the analyses can be characterized as highly conservative. This is due to the conservatism inherent in the calculation procedures and input assumptions. An

example of this is the conservatism inherent in the jazzercise methodology over representation of residential post-application exposures. It is important to acknowledge that these MOEs are likely to significantly underestimate actual MOEs due to a variety of conservative assumptions and biases inherent in the derivatization of exposure by this method. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the FQPA of 1996 and supports the continued registration and use of residential, commercial, and agricultural products containing cyfluthrin.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA at 62 FR 42020 (August 4, 1997) and other EPA publications pursuant to the FQPA.

E. Safety Determination

1. *U.S. population.* Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to cyfluthrin from all uses will utilize less than 2% of the RfD for chronic dietary exposures and that margins of exposure in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. MOE 100 or more (300 for infants and children) also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive

capability of mating animals through 2-generations, as well as any observed systemic toxicity.

The toxicology data which support these tolerances include: toxicity study in rats with a maternal and fetal NOEL of 10 mg/kg bw/day (HDT).

An oral developmental toxicity study in rabbits with a maternal NOEL of 20 mg/kg bw/day and a maternal LEL of 60 mg/kg bw/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOEL of 20 mg/kg bw/day and a fetal LEL of 60 mg/kg bw/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

An oral developmental toxicity study performed with beta-cyfluthrin, the resolved isomer mixture of cyfluthrin, has been submitted to the Agency and is currently under review.

A developmental toxicity study in rats exposed via inhalation to liquid aerosols of cyfluthrin revealed developmental toxicity, but only in the presence of maternal toxicity. The developmental NOEL was 0.46 mg/m³ on the basis of reduced placental and fetal weights, and delayed ossification. The NOEL for overt maternal toxicity was <0.46 mg/m³, the LDT.

A 3-generation reproduction study in rats with systemic toxicity NOELs of 7.5 and 2.5 mg/kg bw/day for parental animals and their offspring, respectively. At HDLs, the body weights of parental animals and their offspring were reduced. Another multiple-generation reproduction study in rats has been submitted to the Agency and is currently under review.

The Agency used the rabbit developmental toxicity study with a maternal NOEL of 20 mg/kg bw/day to assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups. Since this toxicological endpoint pertains to developmental toxicity the population group of concern for this analysis was women aged 13 and above, the subgroup which most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOEL to the exposure. The Agency calculated the MOE to be over 600. The Tier III acute dietary analysis calculated an MOE over 7,000 for this age group. Generally, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk.

FFDCA Section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal effects and the completeness of the toxicity database.

The results of the 3-generation study in rats provided evidence suggesting that, with respect to effects of cyfluthrin on body weight, pups were more sensitive than adult rats. Thus, the Agency determined that an additional 3-fold uncertainty factor (UF) should be used in risk assessments to ensure adequate protection of infants and children.

Generally, EPA considers margins of exposure of at least 100 to indicate an adequate degree of safety. With an additional 3x uncertainty factor, this would be 300 for infants and children. Using the exposure assessments described above and based on the described toxicity data aggregate exposure to infants and children indicate a MOE in excess of 2,500. Thus, it can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

F. International Tolerances

There are no Codex maximum residue levels (MRLs) currently established for residues of cyfluthrin on potatoes commodities.

The available data indicate that there is reasonable certainty of no harm from the aggregate exposure from all currently registered uses of cyfluthrin. Thus consistent with the provisions of the FFDCA as amended August 3, 1996, the time limitations on established cyfluthrin tolerance should be removed. (Mark Dow).

2. Huntsman Petrochemical Corporation

PP 5E4487

EPA has received a pesticide petition (PP 5E4487) from Huntsman Petrochemical Corporation, 3040 Post Oak Blvd., Houston, TX 77056 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 a C₍₁₂₋₁₆₎ linear alcohol, propoxylated aminated, and ethoxylated, also known as SURFONIC AGM550, applied to growing crops or to raw agricultural commodities 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. Residue Chemistry

1. *Plant metabolism.* The plant metabolism of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated has not been investigated. However, due to their structural similarity, the metabolic pathway for C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated is expected to be similar to that of other alkyl amine ethoxylates which have been previously granted an exemption from tolerances.

2. *Analytical method.* Huntsman proposes a reverse phase liquid chromatography using RI detection method for C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated, giving a limit of detection of 0.2 to 1%. Although a method has not been developed to determine the low level concentrations of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated, it is believed that a liquid chromatography/mass spectroscopy method could be developed for this product.

3. *Magnitude of residues.* Given the extensive and widespread use of structurally similar cationic surfactants in herbicide formulations, the added use of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated will not contribute significantly to the total use-volume of these materials. The expected concentration of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated, when used in a herbicide formulation, will be much lower than the concentration of any co-formulated pesticide active ingredient. Thus, the comparable application rate, on an grams/acre basis, will be significantly lower than that of any co-formulated active ingredient. Therefore, it is reasonable to assume that any potential residues resulting from the use of this material in a pesticide formulation would be insignificant.

B. Toxicological Profile

1. *Acute toxicity.* The results of acute toxicity testing using C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated have provided the following toxicity information: a rat acute oral toxicity study with an LD₅₀ of 1.5 g/kg; a rabbit acute dermal toxicity study with an LD₅₀ of greater than 2.0 g/kg; a primary irritation study in rabbits showing severe irritation/corrosion; and an eye irritation study in rabbits showing C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated to produce only slight ocular irritation. A delayed contact hypersensitivity study (Buehler method) in guinea pigs showed C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and

ethoxylated to be negative (not a dermal sensitizer) when induced at 6% and challenged at 4%.

2. *Genotoxicity.* C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated did not induce point mutations *in vitro* in the Ames/*Salmonella-E. coli* reverse mutation assay in either the plate incorporation method or in the liquid pre-incubation method. In addition, C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated did not induce chromosomal aberrations or polyploidy in cultured human lymphocytes with and without metabolic activation.

3. *Reproductive and developmental toxicity.* A rat developmental toxicity study using C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated administered via the oral (gavage) route of exposure at dosages of 0, 25, 75, and 150 mg/kg/day, resulted in a No Adverse Effect Level (NOAEL) of 25 mg/kg/day for maternal toxicity, and a NOEL of 75 mg/kg/day for developmental toxicity. Primary effects observed in this study were decreased food consumption and decreased weight gain for the dams in both the 75 and 150 mg/kg/day dose groups, and reduced fetal body weights with related changes in the incidences of three skeletal variants (ossification) in the pups at the 150 mg/kg/day dose level.

4. *Subchronic toxicity.* A rat subchronic (90-day) toxicity study using C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated administered in the diet at target concentrations of 0, 20, 100, 1,000 or 3,000 ppm in males and 0, 20, 100, 500 or 1,000 ppm in females, resulted in a NOEL of 100 ppm in males and 500 ppm in females, corresponding to calculated dosages of 5.84 and 35.39 mg/kg/day, respectively. Primary effects observed in this study were decreased food consumption and decreased weight gain.

5. *Chronic toxicity.* C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated has not been tested in animal carcinogenicity assays. However, due to lack of response in the genotoxicity assays conducted on this material, and the lack of any obvious pre-neoplastic changes observed in the 90-day subchronic studies, C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated is not expected to be a carcinogen in animal assays.

6. *Animal metabolism.* The animal metabolism of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated has not been investigated. However, due to their structural similarity, the metabolic pathway for C₍₁₂₋₁₆₎ linear alcohol, propoxylated,

aminated, and ethoxylated is expected to be similar to that of other alkyl amine ethoxylates which have previously been granted an exemption from tolerances.

7. *Metabolite toxicology.* The animal metabolism of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated has not been investigated, and the metabolites have not been identified. However, due to their structural similarity, the metabolites of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated are expected to be similar to those of other alkyl amine ethoxylates which have previously been granted an exemption from tolerances.

8. *Endocrine disruption.* No effects on endocrine or reproductive tissues were observed in rat and dog 90-day subchronic studies and in the rat teratology study conducted with C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated.

C. Aggregate Exposure

1. *Dietary exposure.* The results of acute, genotoxic, subchronic and developmental toxicity testing has shown C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated to be of low toxicity. Structurally and functionally similar alkyl amine ethoxylates, which currently have an exemption from tolerances, have also been shown to be of low toxicity in animal studies, and have been widely and extensively used in food-use herbicide products for many years. Any possible chronic dietary exposure of the general population from potential residues of these materials has existed historically, for a considerable period of time, with no evidence of adverse human health effects. Thus, the use of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated as an inert ingredient in a pesticide formulation is not expected to result in adverse health effects from potential aggregate exposures.

2. *Food.* Exposures to C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated from ingestion of food are not expected to occur.

3. *Drinking water.* Exposures to C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated from ingestion of drinking water are not expected to occur.

4. *Non-dietary exposure.* This class of surfactants, of which C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated is part, is used extensively in a number of consumer household and personal care products which may be applied directly to the body. These uses are expected to result in much higher exposure than any exposure that would

result from the trace residue levels resulting from application to growing crops at relatively low concentrations. Therefore, the use of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated in pesticide formulations would not be expected to significantly increase the existing background exposure level.

D. Cumulative Effects

C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated, and other similar alkyl amine ethoxylates, have not been shown to produce specific target organ toxicity, thus there is no evidence of a common mechanism of toxicity with any other substance. There is no reason to expect that the use of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated in pesticide products will contribute to any cumulative toxicity resulting from exposures to other substances having a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population.* The results of acute, genotoxic, subchronic, and developmental toxicity testing have shown C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated to be of low toxicity. Similar alkyl amine ethoxylates, in both structure and function, which have previously been granted an exemption from tolerances, have also been shown to be of low toxicity in animal studies. The use of C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated is not expected to produce significant residue levels resulting from its application, at relatively low concentrations, to growing crops, and would thus, not be expected to significantly increase the existing background exposure level to alkyl amine ethoxylates. In addition, there is no evidence of adverse human health effects in any segment of the population from the historical exposure to these materials from a wide variety of products and uses. Therefore, Huntsman believes that there is a reasonable certainty that no harm will result to the general population (including infants and children) from aggregate exposures to C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated.

2. *Infants and children.* For the reasons outlined above, Huntsman believes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposures to C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated.

F. International Tolerances

No tolerances or exemptions from tolerances have been previously sought by Huntsman for C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated in agricultural applications. A maximum residue level has not been established for C₍₁₂₋₁₆₎ linear alcohol, propoxylated, aminated, and ethoxylated by the Codex Alimentarius Commission. (Bipin Gandhi).

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ENVIRONMENTAL PROTECTION AGENCY

[PF-782A; FRL-6023-3]

Notice of Filing of a Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of pesticide petition (PP 6F4772), 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-782A, must be received on or before September 14, 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: Joanne Miller, Product Manager (PM-23) Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location/telephone and e-mail address: Rm. 237, CM #2, 1921 Jefferson Davis Hwy, Arlington, VA, 703-305-6224, e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition 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-782A] (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-782A] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.