ii. *Drinking water*. Unites States EPA's standard operating procedure (SOP) for drinking water exposure and risk assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct a screening level drinking water assessment. These tools include water models such as screening concentration ground water (SCI-GROW), generic expected environmental concentration (GENEEC), EPA's pesticide root zone model (PRZMS)/EXAMS, and monitoring data. If monitoring data is not available then the models are used to predict potential residues in surface and ground water and the highest value is assumed to be the potential drinking water residue. In the case of foramsulfuron monitoring data do not exist therefore model calculations were used to estimate a water residue. The calculated drinking water levels of concern (DWLOC) for chronic exposures for adults is 297,498 (ppb) parts per billion (297 ppm). The chronic DWLOC for children/toddlers is 84,999 ppb (84 ppm). The worst case chronic drinking water estimated concentration (DWEC) is 0.225 ppb based on a PRZM/EXAMS simulation of runoff into surface water in a standard EPA exposure assessment scenario for corn (MLRA 111, Ohio). The calculated DWLOCs for chronic exposures for all adults and children therefore greatly exceed the DWECs from the models.

2. *Non-dietary exposure*. Exposure to foramsulfuron for the mixer/loader/ground boom/aerial applicator was calculated using the pesticide handlers exposure data base (PHED). It was assumed that the product would be applied to a maximum of 50 hectares per day (125 A/day) by ground boom applicatior and 140 hectares per day (350 A/day) by aerial applicator at a maximum use rate of 45 grams a.i./ha. Normal work attire consisting of long-sleeved shirt, long pants, and protective gloves was assumed in the PHED assessment. Margins of exposure (MOEs) for a 70 kg operator were calculated utilizing a dermal NOAEL of 1,000 mg/kg bwt/day from the rat dermal toxicity study and an inhalation NOAEL of 50 mg/kg bwt/day based on an oral administration, developmental toxicity study in the rabbit. There were no signs of developmental toxicity in the rabbit developmental toxicity study. The combined MOE (inhalation plus dermal) for foramsulfuron was 126,000 for a ground operator undertaking mixing, loading, and spraying. For aerial application where the mixer/loader was assumed to be a different operator from the pilot combined MOEs were 60,400 for the mixer/loader and 1,425,000 for the pilot. The results indicate that large margins of safety exist for the proposed use of foramsulfuron.

The timing of foramsulfuron application to corn is such that field reentry shortly after spraying is atypical. Therefore estimations of worker reentry exposure were not considered necessary.

D. Cumulative Effects

There is no available data at this time to determine whether foramsulfuron has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Therefore a cumulative assessment was not done for this chemical.

E. Safety Determination

1. *U.S. population*. Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure, in this case food only, to the proposed uses of foramsulfuron will utilize <0.001% of the reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data and models are developed. EPA generally has no concern 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 risk to human health. DWLOC based on the dietary exposure are much greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to foramsulfuron.

2. *Infants and children*. No evidence of increased sensitivity to fetuses was noted in developmental toxicity studies in rats or rabbits. There has been no indication of reproductive effects or indication of increased sensitivity to the offspring in the 2–generation rat reproduction study. No additional safety factor to protect infants and children is necessary as there is no evidence of increased sensitivity in infants and children.

Using the conservative assumptions described in the exposure section above, the percent of the reference dose that will be used for exposure to residues of foramsulfuron in food for non-nursing infants (the most highly exposed sub group) is <0.001%. The children (1–6) exposure uses are also <0.001% of the reference dose. As in the adult situation, DWLOC are much higher than the worst case DWEC and are expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of foramsulfuron.

F. International Tolerances

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of foramsulfuron.

[FR Doc. 01–3093 Filed 2–6–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–994; FRL–6764–8]

Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

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 a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–994, must be received on or before March 9, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–994 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–994. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–994 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–994. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical 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 support granting of these petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: January 25, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

The 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 petitioner and represent the view of the petitioner. EPA is publishing the petitioner's summaries verbatim without editing it in any way. The petitioner's summaries 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.

Elf Atochem North America

PP 7F4867 and 7F4868

EPA has received pesticide petitions PP 7F4867 and PP 7F4868 from Elf Atochem North America, 2000 Market Street, Philadelphia, PA 19103 proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of endothall in or on the raw agricultural commodities cottonseed ((RAC) seed and processed seed) at 2.0 parts per million (ppm) and apples at 0.05 ppm. EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

1. PP 7F4867

A. Residue Chemistry

1. *Plant metabolism*. Acala cotton was treated by a single foliar application with ^{14}C-endothall formulated as the dipotassium salt. The study identified 84– >100% of the radioactivity in/on cotton calyx, forage, and lint. Endothall accounted for ca. 94% and 83% of total radioactive residue (TRR) in calyx and lint, respectively, harvested 4 days following application at 1x, and for ca. 99%, 102%, and 95% of TRR in calyx, forage and lint, respectively, harvested 14 days post-treatment. No other metabolites were identified in calyx and forage. The monomethyl and dimethyl ester of endothall were minor (< 10% TRR) metabolites in lint. No metabolites were identified in seed.

2. *Analytical method*. The analytical method for endothall in water is EPA/ORD method 548, ''Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction and Gas Chromatography with Electron-Capture Detection.'' The limit of detection (LOD) for this method is 0.015 ppm.

3. *Magnitude of residues*. Endothall was applied to cotton at a rate of 0.85 lb./acre with a 3–day pre-harvest interval (PHI). Residues in RAC seed were 0.46 ppm (0.071 to 1.1 ppm) and residues in RAC gin trash were 21 ppm (6.6 to 59 ppm).

B. Toxicological Profile

1. *Acute toxicity*. Endothall acid and the dipotassium salt of endothall are moderately toxic by oral ingestion and inhalation (toxicity category II), slightly toxic by dermal exposure (toxicity category III) and severely irritating to the eye. The diamine salt of endothall is moderately toxic by oral, dermal, and inhalation routes of exposure (toxicity category II) and is severely irritating to the eyes and skin.

2. *Genotoxicity*. A full battery of genetic toxicology studies were conducted for endothall. Endothall was not mutagenic.

3. *Reproductive and developmental toxicity*. In a teratology and postnatal behavioral study, pregnant Sprague Dawley rats were dose via oral gavage on gestation days 6 through 15 with endothall doses of 0, 10, 20, or 30 milligram/kilogram (mg/kg)/day. The maternal no observed adverse effect level (NOAEL) was 20 mg/kg/day due to mortality seen at 30 mg/kg/day. The developmental NOAEL was 30 mg/kg/day. In a subsequent developmental toxicity study, pregnant Sprague Dawley rats were orally dosed with 0, 6.25, 12.5, or 25.0 mg/kg/day from gestation day 6 through 15. The NOAEL for maternal toxicity was 12.5 mg/kg/day. The developmental NOAEL was 25.0 mg/kg/day.

A developmental toxicity study was conducted in female CD–1 mice. Groups of pregnant mice were orally dosed with 0, 5, 20, or 40 mg/kg/day on days 6 to 16 of gestation. The NOAEL for maternal toxicity was 5 mg/kg/day based on mortality seen at 20 mg/kg/day. The developmental NOAEL was 20 mg/kg/day. Developmental changes seen at 40 mg/kg/day were related to the severe maternal toxicity at that dose. A developmental toxicity study was conducted in New Zealand white rabbits by oral exposure. Preliminary studies indicated that the rabbit was extremely sensitive to endothall. Groups of pregnant rabbits were dose with 0, 0.3, 1.0, or 3.0 mg/kg/day on gestation days 6 through 19. The fetal and maternal toxicity NOAELs were 1.0 mg/kg/day. A 2–generation reproduction study was conducted in rats. In this study, groups of rats received dietary doses of 0, 30, 150, and 900 ppm (0, 1.9, 9.5, or 58.8 mg/kg/day for male and 0, 1.9–3.4, 9.6–18.5, or 59.0–106.5 mg/kg/day for female F_0 animals; 0, 2.1, 10.9, or 77.1 for male and 0, 1.8–3.1, 9.5–17.3, or 63.5–107.7 for female F_1 animals). The NOAEL for parental effects was 30 ppm based on dose related body weight effects. The NOAEL for reproductive toxicity was 900 ppm.

4. *Subchronic toxicity*. Male and female Sprague Dawley rats were exposed dermally to 0, 30, 100, and 300 mg/kg/day for 21 days. The lowest observed effect level (LOAEL) was 30 mg/kg/day based on decreased body weight gain and dermal irritation. A NOAEL was not established. Male and female Sprague Dawley rats were exposed to oral concentrations of 0, 150, 600, or 1,800 ppm (0, 10, 39, or 118 mg/kg/day for males; 0, 12, 51, or 153 mg/kg/day for females respectively) for 13 weeks. The LOAEL was 1,800 ppm based on decreases in body weight gain and food intake. The NOAEL was 600 ppm. Male and female Beagle dogs were exposed to oral concentrations of 0, 100, 400, or 1,000 ppm (0, 3.2, 11.7, or 27.5 mg/kg/day for males and 0, 3.2, 13.0, or 28.9 mg/kg/day for females respectively) for 13 weeks. The LOAEL was 1,000 ppm based on decreases in body weight gain and food intake. The NOAEL was 400 ppm.

5. *Chronic toxicity*. In a combined chronic toxicity and oncogenicity study, male and female Sprague Dawley rats were fed endothall dietary concentrations of 0, 150, 300, 900, and 1,800 ppm for 104 weeks. No evidence of carcinogenicity was seen in this study. The NOAEL was 150 ppm. The incidence of acanthosis and hyperkeratosis of the stomach was slightly higher than control for the 150 ppm males. This finding was not considered an adverse effect since the incidence of this finding in the 300 ppm males was similar to control. Beagle dogs were fed diets containing 0, 100, 300, or 800 ppm disodium endothall (equivalent to 0, 2, 6, or 16 mg/kg/day endothall) for 24 months. No clinical signs of toxicity were seen at any dose level. The 100 ppm dietary concentration (2 mg/kg/day) was the NOAEL.

In a 52–week oral toxicity study, groups of 4 male and 4 female Beagle dogs were fed diets containing 0, 150, 450, or 1,350/1,000 ppm (0, 5.7, 17.1, and 35.8 mg/kg/day for males; 0, 6.4, 18.8, and 36 mg/kg/day for females). The 1,350 ppm dietary level had to be 1,000 ppm after 6 weeks of treatment due to marked reductions in body weight, food consumption, and subsequent sacrifice of 5 animals from this group. Minimal to very mild gastric epithelial effects were seen in some of the dogs receiving 150 ppm. This effect

was considered as a low grade reaction to chronic epithelial irritation and 150 ppm is considered a NOAEL. In an 18–month oncogenicity study, Swiss Albino mice were fed in the diet at concentrations of 0, 50, 100, and 300 ppm (0, 8.1, 16.7, and 50 mg/kg/day for males; 0, 10.8, 22.4, and 68 mg/kg/day for females) for 92 weeks. The systemic NOAEL was 100 ppm based on decreased mean body weight in 300 ppm males. No evidence of carcinogenicity was seen in this study.

In a second 18–month dietary oncogenicity study, groups of 50 male and 50 female Swiss Albino mice were fed the disodium salt of endothall at dietary concentrations of 0, 750, and 1,500 ppm (0, 122, and 258 mg/kg/day for males; 0, 152, and 319 mg/kg/day for females). Toxicity results for the 1,500 ppm dietary level clearly shows that the maximum tolerance dose (MTD) was exceeded. At 750 ppm, compound-related effects consisted of decreased body weight gain, rectal prolapse and an increase in the incidence and severity of mucosal hyperplasia of the glandular stomach. Endothall was not considered carcinogenic in this study.

6. *Animal metabolism*. Following a single oral administration of ^{14}C-endothall to males and female rats, the majority of the radioactivity was excreted within 24 hours. The majority of the radioactivity was found in the feces. Chromatographic analysis of extracts of the urine, feces, cecum, and large intestine of both male and female rats gave a single radioactive component corresponding to unchanged endothall.

7. *Endocrine disruption*. Evaluation of the results from the 2–generation reproduction studies do not demonstrate any effects suggestive of disruption of hormonal stasis in the rat. Further, histopathologic evaluation of hormone sensitive tissues from chronically exposed rats, mice, and dogs did not reveal any changes suggestive of an endocrine-related effect.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Endothall exposure via the diet will occur from treated apples, sugar beets, potatoes, cotton, and hops (adults). Secondary residues are expected in meat, milk, and eggs as well as shellfish, fish, catfish, and crayfish.

ii. *Drinking water*. Drinking water exposure to endothall may be expected. However this exposure is not considered to be significant due to the seasonal intermittent use of the product for aquatic weed control, its low mobility in surface waters and rapid degradation.

2. *Non-dietary exposure*. There are no registered and proposed uses for endothall products which would result in non-occupational exposure.

D. Cumulative Effects

Elf Atochem has reviewed chemical structure data to determine if any other pesticide products are chemically similar to endothall and produce gastrointestinal changes specific to endothall. Endothall appears to be chemically and toxicologically dissimilar to existing chemical substances. Therefore, cumulative risk should not be an issue for this chemical.

E. Safety Determination

1. *U.S. population*. For chronic dietary risk, two scenarios were used. Scenario 1 used tolerance values on all registered and proposed crops, as well as secondary residues in meat, milk, and eggs, shellfish, fish, catfish, and crayfish. Under this scenario, less than 5% of the reference dose (RfD) for the total U.S. population was utilized. Because of the high milk consumption by children ages 1–6, this group represents the highest exposed subgroup. For children ages 1–6, approximately 12.4% of the RfD is utilized. In the second scenario which included the above food exposure from above plus tap water and non-food based water, 28.3% of the RfD was utilized for the total U.S. population. Because of high water consumption likely from reconstituted formula, all infants utilized 103.7% of the RfD and non-nursing infants utilized 130.7% of the RfD. This scenario, however, is not considered a realistic estimate of risk. It is unlikely that endothall residues would be significant in water considering its intermittent and seasonal use pattern, lack of movement in surface water, rapid degradation and label restriction for application within 600 feet of a potable water intake. The acute dietary risk analysis has been performed using TAS-Exposure software which gives a distributional analysis of exposure. For the total U.S. population, children aged 7–12, and women aged 13 to 50 all margins of exposure (MOE) exceeded 1,000 at the 95th percentile of exposure for the first scenario (excluding water). Under this scenario, all Infants, non-nursing infants < 1–year and children ages 1–6 had MOEs of 935, 852, and 988, respectively. When tap water and non-food based water are included in the analysis at tolerance level (0.2 ppm), the highest exposed subpopulation is again non-nursing infants with a MOE of 98 at the 95th percentile of exposure. For the total U.S. population the 95th percentile of exposure results in an MOE of 373. This analysis included all commodities, including water, at theoretical ''worst case'' levels resulting in an extreme over estimation of acute risk from dietary exposure to potential endothall residues. This analysis has not included estimates of anticipated residues, percent of crop treated, or the likelihood of residues in water accounting for endothall's use pattern, movement and degradation. Additionally, processing effects on residue levels have not been considered. Despite all of the worst case assumptions, the dietary exposure analysis for the U.S. population, and all population subgroups except all infants and non-nursing infants <1 year results in acceptable MOE, i.e., >100. The MOE for all infants and non-nursing infants <1 year were 99 and 98, respectively. Clearly these MOEs in this worst case assessment would exceed 100 if adjustments described above were applied.

2. *Infants and children*. The exposure to infants and children has been calculated in both the acute and chronic dietary assessments. In all cases, and all age groups of infants and children, the MOE is sufficient to protect the health of infants and children.

F. International Tolerances

No international tolerances have been established for endothall.

2. PP 7F4868

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of endothall was examined in three crops types: alfalfa, cotton, and sugarbeet. All three studies were conducted using C–2 and C–3–(^{14}C) endothall and showed the same pattern of metabolic breakdown. The parent compound endothall accounted for the majority of the total radioactive residue (85–110%), with the monomethyl and dimethyl esters of endothall present as minor metabolites (<10%).

2. *Analytical method*. The analytical method for endothall in water is EPA/ORD method 548, ''Determination of Endothall in Drinking Water by Aqueous Derivatization, Liquid-Solid Extraction and Gas Chromatography with Electron-Capture Detection.'' The limit of detection LOD for this method is 0.015 ppm.

3. *Magnitude of residues*. Residue trials in apples showed residue levels in the RAC of 0.0086 ppm (residue range of 0.005–0.023 ppm), 0.015 ppm (0.012–0.020 ppm) for the processed RAC, 0.019 ppm (0.012–0.026 ppm) for apple pomace, and 0.019 ppm (0.071–1.1 ppm) for apple juice.

B. Toxicological Profile

1. *Acute toxicity*. Endothall acid and the dipotassium salt of endothall are moderately toxic by oral ingestion and inhalation (toxicity category II), slightly toxic by dermal exposure (toxicity category III) and severely irritating to the eye. The diamine salt of endothall is moderately toxic by oral, dermal, and inhalation routes of exposure (toxicity category II) and is severely irritating to the eyes and skin.

2. *Genotoxicity*. A full battery of genetic toxicology studies were conducted for endothall. Endothall was not mutagenic.

3. *Reproductive and developmental toxicity*. In a teratology and postnatal behavioral study, pregnant Sprague Dawley rats were dose via oral gavage on gestation days 6 through 15 with endothall doses of 0, 10, 20, or 30 mg/kg/day. The maternal NOAEL was 20 mg/kg/day due to mortality seen at 30 mg/kg/day. The developmental NOAEL was 30 mg/kg/day. In a subsequent developmental toxicity study, pregnant Sprague Dawley rats were orally dosed with 0, 6.25, 12.5, or 25.0 mg/kg/day from gestation day 6 through 15. The NOAEL for maternal toxicity was 12.5 mg/kg/day. The developmental NOAEL was 25.0 mg/kg/day.

A developmental toxicity study was conducted in female CD–1 mice. Groups of pregnant mice were orally dosed with 0, 5, 20, or 40 mg/kg/day on days 6 to 16 of gestation. The NOAEL for maternal toxicity was 5 mg/kg/day based on mortality seen at 20 mg/kg/day. The developmental NOAEL was 20 mg/kg/day. Developmental changes seen at 40 mg/kg/day were related to the severe maternal toxicity at that dose. A developmental toxicity study was conducted in New Zealand white rabbits by oral exposure. Preliminary studies indicated that the rabbit was extremely sensitive to endothall. Groups of pregnant rabbits were dosed with 0, 0.3, 1.0, or 3.0 mg/kg/day on gestation days 6 through 19. The fetal and maternal toxicity NOAELs were 1.0 mg/kg/day. A 2–generation reproduction study was conducted in rats. In this study, groups of rats received dietary doses of 0, 30, 150, and 900 ppm (0, 1.9, 9.5, or 58.8 mg/kg/day for male and 0, 1.9–3.4, 9.6–18.5, or 59.0–106.5 mg/kg/day for female F_0 animals; 0, 2.1, 10.9, or 77.1 for male, and 0, 1.8–3.1, 9.5–17.3, or 63.5–107.7 for female F_1animals). The NOAEL for parental effects was 30 ppm based on dose related body weight effects. The NOAEL for reproductive toxicity was 900 ppm.

4. *Subchronic toxicity*. Male and female Sprague Dawley rats were exposed dermally to 0, 30, 100, and 300 mg/kg/day for 21 days. The LOAEL was 30 mg/kg/day based on decreased body weight gain and dermal irritation. A NOAEL was not established. Male and female Sprague Dawley rats were exposed to oral concentrations of 0, 150, 600, or 1,800 ppm (0, 10, 39, or 118 mg/kg/day for males; 0, 12, 51, or 153 mg/kg/day for female respectively) for 13 weeks. The LOAEL was 1,800 ppm based on decreases in body weight gain, and food intake. The NOAEL was 600 ppm. Male and female Beagle dogs were exposed to oral concentrations of 0, 100, 400, or 1,000 ppm (0, 3.2, 11.7, or 27.5 mg/kg/day for males and 0, 3.2, 13.0, or 28.9 mg/kg/day for females respectively) for 13 weeks. The LOAEL was 1,000 ppm based on decreases in body weight gain and food intake. The NOAEL was 400 ppm.

5. *Chronic toxicity*. In a combined chronic toxicity and oncogenicity study, male and female Sprague Dawley rats were fed endothall dietary concentrations of 0, 150, 300, 900, and 1,800 ppm for 104 weeks. No evidence of carcinogenicity was seen in this study. The NOAEL was 150 ppm. The incidence of acanthosis and hyperkeratosis of the stomach was slightly higher than control for the 150 ppm males. This finding was not considered an adverse effect since the incidence of this finding in the 300 ppm males was similar to control. Beagle dogs were fed diets containing 0, 100, 300, or 800 ppm disodium endothall (equivalent to 0, 2, 6, or 16 mg/kg/day endothall) for 24 months. No clinical signs of toxicity were seen at any dose level. The 100 ppm dietary concentration (2 mg/kg/day) was the NOAEL. In a 52–week oral toxicity study, groups of 4 male and 4 female Beagle dogs were fed diets containing 0, 150, 450, or 1,350/1,000 ppm (0, 5.7, 17.1, and 35.8 mg/kg/day for males; 0, 6.4, 18.8, and 36 mg/kg/day for females). The 1,350 ppm dietary level had to be 1,000 ppm after 6 weeks of treatment due to marked reductions in body weight and food consumption and subsequent sacrifice of 5 animals from this group. Minimal to very mild gastric epithelial effects were seen in some of the dogs receiving 150 ppm. This effect was considered as a low grade reaction to chronic epithelial irritation and 150 ppm is considered a NOAEL. In an 18–month oncogenicity study, Swiss Albino mice were fed in the diet at concentrations of 0, 50, 100, and 300 ppm (0, 8.1, 16.7, and 50 mg/kg/day for males; 0, 10.8, 22.4, and 68 mg/kg/day for females) for 92 weeks. The systemic NOAEL was 100 ppm based on decreased mean body weight in 300 ppm males. No evidence of carcinogenicity was seen in this study.

In a second 18–month dietary oncogenicity study, groups of 50 male and 50 female Swiss Albino mice were fed the disodium salt of endothall at dietary concentrations of 0, 750, and 1,500 ppm (0, 122, and 258 mg/kg/day for males; 0, 152, and 319 mg/kg/day for females). Toxicity results for the 1,500 ppm dietary level clearly shows that the MTD was exceeded. At 750 ppm, compound-related effects consisted of decreased body weight gain, rectal prolapse and an increase in the incidence and severity of mucosal hyperplasia of the glandular stomach. Endothall was not considered carcinogenic in this study.

6. *Animal metabolism*. Following a single oral administration of ^{14}C-endothall to males and female rats, the majority of the radioactivity was excreted within 24 hours. The majority of the radioactivity was found in the feces. Chromatographic analysis of extracts of the urine, feces, cecum and large intestine of both male and female rats gave a single radioactive component corresponding to unchanged endothall.

7. *Endocrine disruption*. Evaluation of the results from the 2–generation reproduction studies do not demonstrate any effects suggestive of disruption of hormonal stasis in the rat. Further, histopathologic evaluation of hormone sensitive tissues from chronically exposed rats, mice, and dogs did not reveal any changes suggestive of an endocrine-related effect.

C. Aggregate Exposure

1. *Dietary exposure*— i. *Food*. Endothall exposure via the diet will occur from treated apples, sugar beets, potatoes, cotton, and hops (adults). Secondary residues are expected in meat, milk, and eggs as well as shellfish, fish, catfish,and crayfish.

ii. *Drinking water*. Drinking water exposure to endothall may be expected. However this exposure is not considered to be significant due to the seasonal intermittent use of the product for aquatic weed control, its low mobility in surface waters and rapid degradation.

2. *Non-dietary exposure*. There are no registered and proposed uses for endothall products which would result in non-occupational exposure.

D. Cumulative Effects

Elf Atochem has reviewed chemical structure data to determine if any other pesticide products are chemically similar to endothall and produce gastrointestinal changes specific to

endothall. Endothall appears to be chemically and toxicologically dissimilar to existing chemical substances. Therefore, cumulative risk should not be an issue for this chemical.

E. Safety Determination

1. *U.S. population*. For chronic dietary risk, two scenarios were used. Scenario 1 used tolerance values on all registered and proposed crops, as well as secondary residues in meat, milk, and eggs, shellfish, fish, catfish, and crayfish. Under this scenario, less than 5% of the RfD for the total U.S. population was utilized. Because of the high milk consumption by children ages 1–6, this group represents the highest exposed subgroup. For children ages 1–6, approximately 12.4% of the RfD is utilized. In the second scenario which included the above food exposure from above plus tap water and non-food based water, 28.3% of the RfD was utilized for the total U.S. population. Because of high water consumption likely from reconstituted formula, all infants utilized 103.7% of the RfD and non-nursing infants utilized 130.7% of the RfD. This scenario, however, is not considered a realistic estimate of risk. It is unlikely that endothall residues would be significant in water considering its intermittent and seasonal use pattern, lack of movement in surface water, rapid degradation and label restriction for application within 600 feet of a potable water intake. The acute dietary risk analysis has been performed using TAS-Exposure software which gives a distributional analysis of exposure. For the total U.S. population, children ages 7–12, and women ages 13 to 50 all MOEs exceeded 1,000 at the 95th percentile of exposure for the first scenario (excluding water). Under this scenario, all infants, non-nursing infants <1–year and children ages 1–6 had MOEs of 935, 852, and 988, respectively. When tap water and non-food based water are included in the analysis at tolerance level (0.2 ppm), the highest exposed subpopulation is again non-nursing infants with an MOE of 98 at the 95th percentile of exposure. For the total U.S. population the 95th percentile of exposure results in an MOE of 373. This analysis included all commodities, including water, at theoretical ''worst case'' levels resulting in an extreme over estimation of acute risk from dietary exposure to potential endothall residues. This analysis has not included estimates of anticipated residues, percent of crop treated, or the likelihood of residues in water accounting for endothall's use pattern, movement and degradation. Additionally, processing effects on residue levels have not been considered. Despite all of the worst case assumptions, the dietary exposure analysis for the U.S. population, and all population subgroups except all infants and non-nursing infants <1–year results in acceptable MOE, i.e., >100. The MOE for all infants and non-nursing infants <1–year were 99 and 98, respectively. Clearly these MOEs in this worst case assessment would exceed 100 if adjustments described above were applied.

2. *Infants and children*. The exposure to infants and children has been calculated in both the acute and chronic dietary assessments. In all cases and all age groups of infants and children, the margins of exposure are sufficient to protect the health of infants and children.

F. International Tolerances

No international tolerances have been established for endothall.

[FR Doc. 01–3092 Filed 2–6–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–00697; FRL–6765–5]

Acute Toxicity Data Requirements For Granular Pesticide Products, Including those with Granular Fertilizers in the Product; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA is announcing the availability of guidance whichintends to streamline the acute toxicity review and classification process for certain granular pesticide products, including those products that contain granular fertilizers. The policies should achieve the following objectives: Significantly reduce the number of animals subject to testing; reduce the use of Agency resources while maintaining protection of the public health and environment, and decrease the time required to register qualifyinggranular pesticide products. Pesticide Registration (PR) Notice 2001–2 is effective now, but comments will be accepted for 30 days, after which the Agency may revise the notice.

DATES: Comments, identified by docket control number OPP–00697, must be received on or before March 9, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00697 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: John Redden,Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–1969; fax number: (703) 308–9382; e-mail address: redden.john@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are required to conduct testing of chemical substances under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document and the PR Notice from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides/. You can also go directly to the listings from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also godirectly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *Fax–on–demand*. You may request a faxed copy of the PR Notice titled, ''Acute Toxicity Data Requirements For Granular Pesticide Products, Including those with Granular Fertilizers in the Product,'' by using a faxphone to call (202) 401–0527 andselecting item 6136. You may also follow the automated menu.

3. *In person*. The Agency has established an official record for this action under docket control number OPP–00697. The official record consists of the documents specifically referenced