

estimated by the GENEEC model, the large margin of exposure (38x-116x), and the similar use patterns of dimethomorph on commodities of the cited crops, the additional proposed uses of dimethomorph are not expected to reach a level of concern for residues in drinking water.

ii. *Hops*. For this use, the DWLOC from chronic exposure to dimethomorph was estimated by EPA to be 3,400 ppb for the U.S. population and for males 13 years and older, 2,900 ppb for females 13 years and older, and 960 ppb for children (1–6 years of age). Given the low levels of dimethomorph residues as estimated by the GENEEC model and the large margin of exposure (40x-142x), the additional use of dimethomorph on hops is not expected to reach a level of concern for residues in drinking water.

2. *Infants and children*. The TMRC for all commodities covered in this petition is minimal. The consumption of residues of dimethomorph on lettuce (head and leaf), cucurbit vegetables (crop group 9), and bulb vegetables (crop group 3) will use approximately 7.0% of the cPAD for children ages 1–6. The TMRC for residues of dimethomorph in hops as consumed by infants, non-nursing infants, children ages 1–6, and children ages 7–12 are each estimated to be 0.00% of the cPAD. Moreover, the combined TMRC values for all current and pending dimethomorph tolerances will utilize less than 10% of the cPAD for each of the subgroups.

The results of the studies submitted to support this package provide no evidence that dimethomorph caused reproductive, developmental or reproductive effects. No such effects were noted at dose levels that were not maternally toxic. The NOAELs observed in the developmental and reproductive studies were 6 to 65 times higher than the NOAEL used to establish the cPAD. There is no evidence to indicate that children or infants would be more sensitive than adults to toxic effects caused by exposure to dimethomorph.

Therefore, the registrant believes that the results of the toxicology and metabolism studies support both the safety of dimethomorph to humans based on the intended use as a fungicide on domestically produced hops, lettuce (head and leaf), cucurbit vegetables (crop group 9), and bulb vegetables (crop group 3) and the granting of the requested tolerances.

F. International Tolerances

There are no Canadian, Mexican, or codex MRLs established for dimethomorph for the commodities

associated with this request; consequently, a discussion of international harmonization is not relevant.

[FR Doc. 02–21279 Filed 8–16–02; 4:19 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0170; FRL–7190–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP–2002–0170, must be received on or before September 20, 2002.

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 ID number OPP–2002–0170 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	32532	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,” “Regulations and Proposed Rules,” 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 ID number OPP–2002–0170. 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 ID number OPP-2002-0170 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.

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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 ID 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 a pesticide petition 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 this petition contains 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 the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

August 15, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the Interregional

Research Project Number 4 (IR-4), and represents the view of IR-4. EPA is publishing the petition summary verbatim without editing it 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.

Interregional Research Project Number 4 (IR-4)

PP 2E6404

EPA has received a pesticide petition 2E6404 from Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.473 by establishing a tolerance for residues of the herbicide glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-, monoammonium salt) and its metabolite, 3-methylphosphinopropionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid in or on the raw agricultural commodities blueberry, lingonberry, junberry, and salal at 0.10 part per million (ppm). This notice includes a summary of the petition prepared by Aventis CropScience U.S.A., P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of residues found in plants as a result of a treatment of glufosinate-ammonium is well understood.

2. *Analytical method.* The enforcement analytical method utilizes gas chromatography for detecting and measuring levels of glufosinate-ammonium and metabolites with a general limit of quantification of 0.05 ppm. This method allows detection of residues at or above the proposed tolerances.

3. *Magnitude of residues.* Field residue trials were conducted at sites in New Jersey, New Hampshire, North Carolina, and Michigan. The treatment regime was selected to represent the use

pattern that is the most likely to result in the highest residues. Glufosinate-ammonium derived residues did not exceed 0.072 ppm in blueberries when sampled at 14 days or more after the last treatment.

B. Toxicological Profile

1. *Acute toxicity.* Glufosinate-ammonium has been classified as toxicity category III for acute oral, dermal, and inhalation toxicity and for eye irritation. Glufosinate-ammonium is not a dermal irritant (toxicity category IV) nor is it a dermal sensitizer. The oral lethal dose (LD)₅₀ is 2 grams/kilogram (g/kg) in male rats and 1.62 g/kg in female rats.

2. *Genotoxicity.* Based on results of a complete genotoxicity data base, there is no evidence of mutagenic activity in a battery of studies, including: *Salmonella* spp., *E. coli*, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, groups of 20 pregnant female Wistar rats were administered glufosinate-ammonium by gavage at doses of 0, 0.5, 2.24, 10, 50, and 250 milligrams/kilogram/day (mg/kg/day) from days 7 to 16 of pregnancy. The no observed adverse effect level (NOAEL) for maternal toxicity is 10 mg/kg/day; the LOAEL is 50 mg/kg/day based on vaginal bleeding and hyperactivity in dams. In the fetus, the NOAEL is 50 mg/kg/day, based on dilated renal pelvis observations at the lowest observed adverse effect level (LOAEL) of 250 mg/kg/day.

In a developmental toxicity study, groups of 15 pregnant female Himalayan rabbits were administered glufosinate-ammonium by gavage at doses of 0, 2.0, 6.3, or 20.0 mg/kg/day from days 7 to 19 of pregnancy. In maternal animals, decreases in food consumption and body weight gain were observed at the 20 mg/kg/day dose level. The NOAEL for maternal toxicity was 6.3 mg/kg/day and that for developmental toxicity was 20 mg/kg/day.

In a multi-generation reproduction study, glufosinate-ammonium was administered to groups of 30 male and 30 female Wistar/Han rats in the diet at concentrations of 0, 40, 120, or 360 ppm. The LOAEL for systemic toxicity is 120 ppm based on increased kidney weights in both sexes and generations. The systemic toxicity NOAEL is 40 ppm. The LOAEL for reproductive/developmental toxicity is 360 ppm based on a decreased number of viable

pups at this dose. The NOAEL is 120 ppm.

4. *Subchronic toxicity.* In a subchronic oral toxicity study, glufosinate-ammonium was administered to 10 NMRI mice/sex/dose in the diet at levels of 0, 80, 320, or 1,280 ppm (equivalent to 0, 12, 48 or 192 mg/kg/day for 13 weeks. Significant ($p < 0.05$) increases were observed in serum aspartate aminotransferase and in alkaline phosphatase in high-dose (192 mg/kg/day) males. Also observed were increases in absolute and relative liver weights in mid-(48 mg/kg/day) and high-dose males. The NOAEL is 12 mg/kg/day, the LOAEL is 48 mg/kg/day based on the changes in clinical biochemistry and liver weights.

5. *Chronic toxicity.* In a combined chronic toxicity/carcinogenicity study, glufosinate-ammonium was administered to 50 Wistar rats/sex/dose in the diet for 130 weeks at dose levels of 0, 40, 140, or 500 ppm (mean compound intake in males was 0, 1.9, 6.8, and 24.4 mg/kg/day and for females was 0, 2.4, 8.2, and 28.7 mg/kg/day, respectively). A dose-related increase in mortality was noted in females at 140 and 500 ppm; whereas in males, increased absolute and relative kidney weights were noted at 140 ppm and 500 ppm. The NOAEL was considered to be 40 ppm. No treatment-related carcinogenic response was noted.

In a carcinogenicity study, glufosinate-ammonium was administered to 50 NMRI mice/sex/dose in the diet at dose levels of 0, 80, 160 (males only), or 320 (females only) ppm for 104 weeks. The NOAEL for systemic toxicity is 80 ppm (10.82/16.19 mg/kg/day in males/females (M/F), and the LOAEL is 160/320 ppm (22.60/ 63.96 mg/kg/day in M/F), based on increased mortality in males, increased glucose levels in males and females, and changes in glutathione levels in males. No increase in tumor incidence was found in any treatment group.

In a chronic feeding study, technical glufosinate-ammonium was fed to male and female beagle dogs for 12 months in the diet at levels of 2.0, 5.0, or 8.5 mg/kg/day. The NOAEL is 5.0 mg/kg/day based on clinical signs of toxicity, reduced weight gain and mortality at the 8.5 mg/kg/day dose level. In a rat carcinogenicity study, glufosinate-ammonium was administered to Wistar rats (60/sex/group) for up to 24 months at 0, 1,000, 5,000, or 10,000 ppm (equivalent to 0, 45.4, 228.9, or 466.3 mg/kg/day in males and 0, 57.1, 281.5, or 579.3 mg/kg/day in females). The LOAEL for chronic toxicity is 5,000 ppm (equivalent to 228.9 mg/kg/day for male rats and 281.5 mg/kg/day for

females), based on increased incidences of retinal atrophy. The chronic NOAEL is 1,000 ppm. Under the conditions of this study, there was no evidence of carcinogenic potential. Dosing was considered adequate based on the increased incidence of retinal atrophy.

6. *Animal metabolism.* Studies conducted in rats using ¹⁴C-glufosinate-ammonium have shown that the compound is poorly absorbed (5-10%) after oral administration and is rapidly eliminated primarily as the parent compound. The highest residue levels were found in liver and kidney tissues.

The metabolic profile and the quantitative distribution of metabolites were very similar in both goat and hen. The vast majority of the dose was excreted, primarily as parent compound. The very limited residues found in edible tissues, milk and eggs were comprised principally of glufosinate and 3-methylphosphinopropionic acid (Hoe 061517), with lesser amounts of N-acetyl-L-glufosinate (Hoe 099730) and 2-methylphosphinopropionic acid (Hoe 064619).

7. *Metabolite toxicology.* Additional testing has been conducted with the major metabolites, 3-methylphosphinopropionic acid, and N-acetyl-L-glufosinate. Based on subchronic and developmental toxicity study results, a profile of similar or less toxicity was observed for the metabolites as compared to the parent compound, glufosinate-ammonium.

8. *Endocrine disruption.* No special studies have been conducted to investigate the potential of glufosinate-ammonium to induce estrogenic or other endocrine effects. However, no evidence of estrogenic or other endocrine effects have been noted in any of the toxicology studies that have been conducted with this product and there is no reason to suspect that any such effects would be likely.

C. Aggregate Exposure

1. *Dietary exposure.* Tolerances have been established (40 CFR 180.473) for the combined residues of glufosinate-ammonium and metabolites in or on a variety of raw agricultural commodities. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicity studies. EPA has, therefore, not established an acute reference dose (RfD) for the general population including infants and children. An acute RfD of 0.063 mg/kg/day was established, however, for the females 13+ subgroup. Therefore, an acute dietary analysis was conducted for this subpopulation; whereas, chronic dietary

analysis was conducted for the usual populations.

i. *Food.* An acute dietary analysis was conducted using the Dietary Exposure Evaluation Model™ (DEEM) software and the 1994–1996 CSFII consumption data base. The analysis assumed tolerance level residues for all commodities and 100% of crop treated for all registered or pending uses. This tier one analysis resulted in an exposure of 0.007552 mg/kg bwt/day (95th percentile) for the female 13+ subpopulation (the only population of concern) representing 36% utilization of the acute reference dose (RfD).

Chronic dietary analysis was conducted to estimate exposure to potential glufosinate-ammonium residues in or on registered and proposed commodities. The DEEM software and the 1994–1996 USDA food consumption data were used. Tolerance level residues were assumed for all commodities. Percent crop treated values generated by the agency were incorporated as follows: Tree nuts 1%; apples, 1%; field corn, 2.6%; grapes, 1%; and soybeans, 1%. Aventis CropScience estimates that an upper bound value for cotton at market maturity is 20% and that for potato is 10%. All other crops are included at 100% of crop treated. Chronic dietary exposure estimates from residues of glufosinate-ammonium for the U.S. population represented approximately 25% of the chronic RfD; whereas that for children 1–6, the subpopulation with the highest exposure, represented approximately 61% of the chronic RfD. This analysis was based on highly conservative assumptions, yet still indicates that dietary exposures for all segments of the population are well within the chronic RfDs. The Agency has no concerns with RfD utilization up to 100%.

ii. *Drinking water.* EPA's standard operating procedure for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. The models Screening Concentration in Ground Water (SCI-GROW) and EPA's Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM-EXAMS) were used to estimate the concentration of glufosinate-ammonium that might occur in water. The acute drinking water level of comparison (DWLOC) for females 13+ is 403 parts per billion (ppb). In comparison, the acute drinking water estimated concentrations (DWELOC) calculated by the Generic Expected Environmental Concentration (GENEEC) is 127 ppb.

The chronic DWLOC calculated for adults is 185 ppb and that for children/

toddlers is 41 ppb. The chronic DWELOC calculated using a worst case scenario is 31 ppb (GENEEC). The DWLOCs are based on highly conservative dietary (food) exposures and are expected to be much higher in real world situations reducing further the percent utilization of the DWLOC.

2. *Non-dietary exposure.* Glufosinate-ammonium is currently registered for use on the following non-food sites: areas around ornamentals, shade trees, Christmas trees, shrubs, walks, driveways, flower beds, farmstead buildings, in shelter belts, and along fences. It is also registered for use as a post-emergent herbicide on farmsteads, areas associated with airports, commercial plants, storage and lumber yards, highways, educational facilities, fence lines, ditch banks, dry ditches, schools, parking lots, tank farms, pumping stations, parks, utility rights-of-way, roadsides, railroads, and other public areas and similar industrial and non-food crop areas. It is also registered for lawn renovation uses.

EPA has determined that there are no acute or chronic non-dietary exposure scenarios. Further, the Agency has determined that it is not appropriate to aggregate short- and intermediate-term non-dietary exposure with dietary exposures in risk assessments because the end-points are different.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has indicated that, at this time, the Agency does not have available data to determine whether glufosinate-ammonium has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, glufosinate-ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that glufosinate-ammonium has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above and based on the completeness and reliability of the toxicity data, it is concluded that chronic dietary exposure

to the registered and proposed uses of glufosinate-ammonium will utilize at most 25% of the chronic RfD for the U.S. population. The actual exposure is likely to be significantly less than predicted by this analysis as data and models that are more realistic are developed. Exposures below 100% of the RfD are generally assumed to be of no concern because the RfD dose represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health.

The acute population of concern, female 13+ utilizes 36% of the acute RfD. This is a tier one highly conservative assessment and actual exposure is likely to be far less. DWLOCs based on dietary exposures are 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, drinking water and nonresidential) to residues of glufosinate-ammonium and metabolites.

2. *Infants and children.* The toxicological data base is sufficient for evaluating prenatal and postnatal toxicity for glufosinate-ammonium. There are no prenatal or postnatal susceptibility concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproduction study. Based on clinical signs of neurological toxicity in short and intermediate dermal toxicity studies with rats, EPA has determined that an added FQPA safety factor of 3x is appropriate of assessing the risk of glufosinate-ammonium derived residues in crop commodities. Using the conservative assumptions described in the exposure section above, the percent of the chronic reference dose that will be used for exposure to residues of glufosinate-ammonium in food for children 1–6 years old (the most highly exposed subgroup) is 61%. Infants utilize 37% of the chronic RfD. As in the adult situation, DWLOCs are higher than the worst case drinking water estimated concentrations 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 glufosinate-ammonium.

F. International Tolerances

The codex maximum residue limit for glufosinate-ammonium and metabolite in or on berries and other small fruits (except for currants) has been

established by the Codex Alimentarius Commission at 0.10 ppm.

[FR Doc. 02-21280 Filed 8-16-02; 4:19 pm]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0177; FRL-7191-6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP-2002-0177, must be received on or before September 20, 2002.

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 ID number OPP-2002-0177 in the subject line on the first page of your response.

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