The C.P. Hall Company

PP 1E6257

EPA has received an amendment to a pending pesticide petition (1E6257) from The C.P. Hall Company, 311 S. Wacker, Suite 4700, Chicago, IL 60606. The pending pesticide petition proposes, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for N,N-dimethyloctanamide (CAS Reg. No. 1118–92–9) and N,N-dimethyldecanamide (CAS Reg. No. 14433–76–2) when used as an inert ingredient, as an emulsifier, solvent, and cosolvent in pesticide formulations applied only to growing crops. The original pesticide petition specified that the use of N,N-dimethyloctanamide and N,N-dimethyldecanamide should be limited to less than 15% of the total pesticide formulation by weight, and this 15% limit was reflected in the original Notice of Filing, published in the **Federal Register** (66 FR 57450) (FRL–6808–6) on November 15, 2001. Subsequent to the publication of that Notice of Filing, the petitioner requested to amend the pending pesticide petition to remove the limitation on the percentage of N,N-dimethyloctanamide and N,N-dimethyldecanamide used in formulated products. There are no other changes to the information presented by the petitioner in the November 15, 2001, Notice of Filing.

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.

[FR Doc. 03–28654 Filed 11–18–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0365; FRL–7334–3]

Aminoethoxyvinylglycine hydrochloride (aviglycine HCl); 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 identification (ID) number OPP–2003–0365, must be received on or before December 19, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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 Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2003–0365. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and

without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0365. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2003–0365. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2003–0365.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–0365. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 FFDCA 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.

Dated: November 7, 2003.

Phil Hutton,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

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

Valent BioSciences Corporation

PP 3F6772

EPA has received a pesticide petition (3F6772) from Valent BioSciences Corporation, 870 Technology Way, Libertyville, IL 60048, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the biochemical pesticide aminoethoxyvinylglycine hydrochloride (aviglycine HCl), formerly designated as aminoethoxyvinylglycine (AVG), in or on the stone fruits crop group, excepting cherries, at 0.170 part per million (ppm).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Valent BioSciences Corporation has submitted the following summary of new information, data, and arguments in support of their pesticide petition (3F6772). This summary was prepared by Valent BioSciences Corporation and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

In addition to the new data summarized below, however, Valent BioSciences Corporation also is relying on a summary of information, data, and arguments previously submitted by Abbott Laboratories, pursuant to section 408(d)(2)(A)(i) of the FFDCA as amended, in support of a prior Abbott Laboratories pesticide petition 9G5048 that sought temporary tolerances for residues of AVG in or on the stone fruit crop group. This Abbott Laboratories request, including the referenced summarized information, was published in the **Federal Register** of March 10, 1999 (64 FR 11872) (FRL–6067–5). EPA issued a final rule, published in the **Federal Register** of June 10, 1999 (64 FR 31124) (FRL–6080–4), in which it announced the establishment of the temporary tolerances requested by Abbott Laboratories for residues of aminoethoxyvinylglcine in or on the stone fruit crop group at 0.170 ppm, with an expiration date of April 1, 2001. Subsequently, Valent BioSciences Corportion submitted a pesticide petition (9G5048, transferred from Abbott Laboratories) that sought to extend the temporary tolerances for AVG in or on the stone fruit crop group originally obtained by Abbott Laboratories. Notice of this previous pesticide petition by Valent BioSciences Corporation, which also relied, in part, on the referenced summary of information previously prepared and submitted by Abbott Laboratories, was published in the **Federal Register** of March 28, 2001 (66 FR 16931) (FRL–6775–1). EPA issued a final rule, published in the **Federal Register** of July 12, 2001 (66 FR 36477) (FRL–6788–7), announcing the establishment of the temporary tolerances requested by Valent BioSciences Corporation for residues of the plant regulator AVG in or on the stone fruit crop group at 0.170 ppm, with an expiration date of December 21, 2003. It is the original summary of information previously submitted by Abbott Laboratories, and previously relied upon by Valent BioSciences Corporation, that Valent BioSciences Corporation once again is relying upon in connection with this new pesticide petition. EPA has not republished the summary of information initially submitted by Abbott Laboratories and published in the March 10, 1999 **Federal Register,** except where EPA believes such information would be helpful in understanding the new data.

A. Product Name and Proposed Use Practices

Aminoethoxyvinylglycine hydrochloride (aviglycine HCl), which was previously designated as aminoethoxyvinylglycine (AVG), is a plant growth regulator used in the harvest management of apples, pears, and stone fruit (excluding cherries). It is used at the rate of 50 grams active ingredient per acre. Applications to apples are made once a season at 4 weeks before harvest; proposed use on stone fruit (except cherries) is for application 7 to 10 days before harvest.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* A study designed to determine whether uptake, translocation and metabolism of aminoethoxyvinylglycine hydrochloride occurs in apples identified seven minor metabolites in addition to the primary metabolite, *N*-acetyl-aminoethoxyvinylglycine. The study was not meant as a measure of the amount of aminoethoxyvinylglycine hydrochloride residues and metabolites found in apples under normal field conditions. The only significant incorporation of aminoethoxyvinylglycine hydrochloride in apple tissues, following brush-on application at high rates, resulted from absorption from the peel rather than translocation from the leaves. Aminoethoxyvinylglycine hydrochloride is also metabolized in the tissues to form *N*-acetyl-aminoethoxyvinylglycine and several other minor metabolites, and is partially degraded on the apple surface to water-soluble products that may be formed due to microbial and/or photodegradative action.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Crops in residue trials were treated at maximum label rates, or above, and harvested at the specified minimum treatment to harvest intervals. Residue data for apples previously submitted by Abbott Laboratories and reviewed by EPA indicated that at the proposed use rates, no quantifiable residues were present in or on the food commodities at 21 days after treatment. Additional pome fruit residue data generated internationally has been provided to EPA by Valent BioSciences Corporation. Residues on representative stone fruit were typically below levels of quantitation, maximum residues on plums at 7 days were 0.142 ppm, and maximum residues on cherries were 0.490 ppm at 7 days. The proposed tolerance excludes use on cherries.

Analytical Enforcement Methodology. There is a practical method for detecting and measuring levels of aviglycine HCI in or on food with a limit of detection (LOD) that allows monitoring of food

with residues at or above the levels set in these proposed tolerances. Abbott Laboratories has submitted a practical analytical methodology for detecting and measuring levels of aviglycine HCl in or on raw agricultural commodities (RACs). The proposed analytical method for determining residues is by high-performance liquid chromatography (HPLC). The HPLC/fluorescence detector analytical method used in the apple residue studies has been validated by an independent laboratory and provided to the Food and Drug Administration (FDA). This method was modified slightly for analysis of residue on peaches, plums, and cherries. This modified method has been validated by an independent laboratory. The limit of quantitation (LOQ) was 0.080 ppm for all matrices analyzed by either method. It was determined that residues on treated commodities were stable for a period of 22 months in frozen storage.

C. Mammalian Toxicological Profile

1. *Acute toxicity*. Aviglycine HCl has low acute oral, dermal, and inhalation toxicity. The oral lethal dose $(LD)_{50}$ in rats is >5,000 milligrams/kilogram (mg/kg), the dermal LD_{50} is >2,000 mg/kg and the inhalation 4–hour lethal concentration $(LC)_{50}$ is >5.00 milligrams/Liter (mg/L) air. Aviglycine HCl is not a skin sensitizer in guinea pigs, and is not irritating to the skin and eyes of rabbits. End-use formulations of aviglycine HCl have similar low acute toxicity profiles.

2. *Genotoxicity*. Aviglycine HCl does not induce gene mutations in bacterial and mammalian cells, chromosome aberrations in mammalian cells or deoxyribonucleic acid (DNA) damage in bacterial cells in *in vitro* test systems. Similarly, it does not exhibit a clastogenic effect *in vivo* in the rat micronucleus test. Therefore, there is no evidence to suggest a genotoxic hazard at any of the three main levels of genetic organization.

3. *Reproductive and developmental toxicity*. In the rabbit developmental toxicity study with aviglycine HCl, there was no evidence of teratogenicity or other embryotoxic effects at the highest dose levels tested, although maternal toxicity was evident. The rabbit maternal no observed adverse effect level (NOAEL) was established at 0.4 mg a.i./kg body weight/day (mg a.i./kg bwt/day) based on reduced body weight gains and food consumption, and decreased defecation. The developmental NOAEL was established at 0.4 mg a.i./kg bwt/day based on fetal body weights. In the rat test the maternal NOAEL was established at 1.77 mg a.i./kg bwt/day based on inhibition of body weight gain and reduced food consumption. The developmental NOAEL was found to be 1.77 mg a.i./kg bwt/day based on decreased mean fetal body weights and reduced ossification. The developmental and maternal lowest observed adverse effect levels (LOAELs) were established at 8.06 mg a.i./kg bwt/day. Aviglycine HCl was evaluated in a rat 2–generation reproduction study submitted by Abbott Laboratories. Based on reductions in body weight, changes in organ weights, and an increased incidence of microscopic findings, the parental NOAEL was established at 0.8 mg a.i./kg bwt/day. The NOAEL for reproductive toxicity was established at 4.0 mg a.i./kg bwt/day and the neonatal toxicity NOAEL was established at 2.5 mg a.i./kg bwt/day.

4. *Subchronic toxicity*. Subchronic 90–day feeding studies were conducted with rats, mice, and dogs. In a 90–day feeding study in rats, the NOAEL was 0.4 mg a.i./kg bwt/day for males and females based on increased incidence of periportal hepatocellular vacuolation in the liver. In the 90–day feeding study in mice, the NOAEL was established at 10 mg a.i./kg bwt/day for males and females - based on decreased body weight and histopathological changes in the liver (both sexes), in the testis (males) and the adrenal (females) at 25 mg a.i./kg bwt/day. For dogs, the NOAEL was established at 0.6 mg a.i./kg bwt/day - based on inappetence, low body weight gain and centrilobular histopathological changes in the liver at 1.2 mg a.i./kg bwt/day. Note that the liver vacuolation is considered an adaptive change. Increased vacuolation of the liver was not observed in the 52–week chronic rat study or the 104–week rat oncogenicity study. A 21–day repeat dose dermal toxicity study in rats was carried out at 0, 100, 500, and 1,000 mg a.i./kg bwt/day. The NOAEL is 1,000 mg a.i./kg bwt/day; a LOAEL was not determined.

5. *Chronic toxicity*. Chronic studies with aviglycine HCl were conducted on rats to determine oncogenic potential and/or chronic toxicity of the compound. The NOAEL for the 1–year chronic study was 0.7 mg a.i./kg bwt/day for males and females based on decreases in body weights, food consumption, testicular tubular and epithelial vacuolation, and pancreatic acinar cell atrophy. The rat carcinogenicity study with aviglycine HCl confirmed the substance has no carcinogenic potential. There was no evidence of cell necrosis that could be a preliminary stage before tumor genesis, and time of death was similar to controls. During the 2–year carcinogenicity study, the administration of aviglycine HCl at 7 mg a.i./kg bwt/day was associated with body weight and food consumption reductions, increases in the incidence of adrenal focal medullary cell hyperplasia, testicular tubular atrophy, and other associated findings in the testis and epididymis, ocular cataracts, and pancreatic lobular/acinar cell atrophy. The NOAEL was established at 0.7 mg a.i./kg bwt/day.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Expected dietary exposures from residues of aviglycine HCl would occur through apples, pears, peaches, nectarines, plums, and processed pome and stone-fruits. Acute and chronic dietary exposure assessments were conducted using a Tier I approach. This Tier I assessment incorporated; tolerance level residues for all commodities; assumption of 100% crop-treated for all crops; default processing factors and consumption data from the 1994 through 1998 U.S. Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII) (USDA), 1994, 1995, 1996, and 1998). Estimates of chronic and acute dietary exposure were calculated using Dietary Exposure Evaluation Module Food Commodity Intake Database (DEEM-FCID™) software (Novigen, 2001). The resulting exposures were compared to a chronic reference dose (RfD) of 0.007 mg a.i./kg bwt/day and an acute NOAEL of 1.77 mg a.i./kg bwt/day. The RfD is based on the NOAEL of 0.7 mg a.i./kg bwt/day from the rat chronic toxicity study (52–week) and the rat carcinogenicity feeding study (104–week) with a 100–fold uncertainty factor (UF) to account for intraspecies and interspecies variations. The acute NOAEL is based on the rat oral developmental toxicity study.

Chronic dietary exposure estimates for the overall U.S. population and 24 population subgroups, including infants and children, are well below the chronic RfD. Estimated daily exposures from tolerance level residues and a 100% crop treated assumption for all crops were 15.9% of the RfD or less for all populations examined. Acute dietary exposure was estimated for the overall U.S. population and the population subgroups:

a. All infants.
b. Nursing infants.
c. Non-nursing infants.
d. Children 1 to 2 years of age.
e. Adult 20 to 49 years of age.
f. Females 13 t0 49 years of age.
g. Adults 50 years and older.

Estimated daily exposures from tolerance level residues (at the 95th percentile) and a 100% crop treated assumption for all crops resulted in margins of exposure (MOEs) greater than 430 for all population groups examined. The results of both the chronic and acute dietary exposure analyses clearly demonstrate a reasonable certainty that no harm will result from the proposed agricultural uses of aviglycine HCI.

ii. *Drinking water.* Aviglycine HCl is highly unlikely to contaminate ground water resources due to its high soil sorption, and short soil and water/sediment half-lives. Study results show that aviglycine HCl is easily adsorbed to soils, principally onto clay particles. Half-lives in soils vary between 1.7 and 4.7 days. Water-sediment studies have shown that aviglycine HCl will be readily adsorbed to sediment where it is mineralized and incorporated into the organic fraction of the sediment. Biodegradation occurs in both systems. The half-life of aviglycine HCl in the aqueous phase and total water/sediment system was calculated to be 1.5 and 4.3 days respectively. An aviglycine HCI water concentration assessment was conducted using EPA first tier screening models. FQPA Index Reservoir Screening Tool (FIRST) was used for surface water concentration assessment and screening concentration in ground water (SCI-GROW) was used for ground water assessment. There were no estimated ground water concentrations according to SCI-GROW. Peak surface water concentrations estimated using FIRST were 1,283 and the estimated annual average was 0.021 part per billion (ppb), assuming 87% crop treated. The contribution of drinking water to aggregate risk is considered to be negligible.

2. *Non-dietary exposure.* Aviglycine HCl has no product registrations for residential non-food uses. Non-occupational, non-dietary exposure for aviglycine HCl has thus been estimated to be extremely small. Therefore, the potential for non-dietary exposure is insignificant. The exposure from the commercial use is expected to be dermal in nature. A 21–day repeat dose dermal toxicity study resulted in no significant treatment related effects at 1,000 mg a.i./kg bwt/day, the highest dose tested (HDT).

E. Cumulative Exposure

Consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of aviglycine HCl would be cumulative with those of any other chemical compounds. Aviglycine HCl has a novel mode of action compared to other currently registered active ingredients. Therefore, Valent BioSciences Corporation believes it is appropriate to consider only the potential risks of aviglycine HCl in an aggregate risk assessment.

F. Safety Determination

1. *U.S. population.* Aviglycine HCl is an amino acid which has been generated through a fermentation of a soil microorganism. Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to aviglycine HCl for the U.S. population was calculated to be 2.2% of the RfD. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of aviglycine HCl in food and drinking water will not result in unacceptable levels of human health risk.

2. *Infants and children.* FFDCA section 408 (b)(2)(C)(i) provides that EPA shall apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the lack of completeness of the data base. Only when there is no indication of increased sensitivity of infants and children and when the data base is complete, may the extra safety factor be removed. In the case of aviglycine HCl, the toxicology data base is complete. There is no indication of increased sensitivity in the data base overall, and specifically, there is no indication of increased sensitivity in the developmental and multi-generation reproductive toxicity studies. Therefore, Valent BioSciences Corporation concludes that there is no need for an additional safety factor and a safety factor of 100 be used for the assessment. Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to aviglycine HCl for non-nursing infants, the most highly exposed population subgroup, was calculated to be 0.001110 mg a.i./kg bwt/day or 15.9% of the RfD. Daily exposure for the overall U.S. population was estimated to be 0.000153 mg a.i./kg bwt/day. The proposed tolerances will utilize 2.2% of the RfD for the U.S. population.

G. Effects on the Immune and Endocrine Systems

Lifespan, and multigenerational studies on mammals, and acute and subchronic studies on aquatic organisms and wildlife did not reveal any definite immune or endocrine effects. An immunotoxicity study in rats at 0, 1.25, 5, and 15 mg a.i./kg bwt/day presented a NOAEL of 5 mg a.i./kg bwt/day based on decreased primary antibody (igM) response to sheep red blood cells; decreased absolute and relative thymus weights; and decreased body weight, food consumption, and food efficiency at the high dose level. The LOAEL is 15 mg a.i./kg bwt/day. Any endocrine related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of aviglycine HCl is considered negligible.

H. Existing Tolerances

Time limited tolerances have been established for the residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl, formerly aminoethoxyvinylglycine (AVG)) in or on the following food commodities:

Commodity	Parts per million	Expiration date
Apple	0.08	December 21, 2003
Pear	0.08	December 21, 2003

Temporary tolerances have been established for the residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl, formerly aminoethoxyvinylglycine (AVG)) in or on the following food commodities:

Commodity	Parts per million	Expiration date
Fruit, stone, group 12	0.170	December 21, 2003

I. International Tolerances

There are no codex maximum residue limits for use of aminoethoxyvinylglycine hydrochloride on apples or pears, stone fruits, or on any other crop.

[FR Doc. 03–28913 Filed 11–18–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0325; FRL–7329–5]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only