V. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHERINFORMATION CONTACT**, postmarked before June 3, 2005. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

VI. Provisions for Disposition of Existing Stocks

Upon the close of the comment period for this Notice, EPA expects to issue an order granting the requests for voluntary cancellation and amendments for the products identified in Tables 1 and 2, and to include in the order provisions regarding the status of existing stocks of the pesticides. Existing stocks are defined in EPA's existing stocks policy (56 FR 29362, June 26, 1991) as those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation or amendment of their registration. Any distribution, sale, or use of existing stocks, except as provided in the amendment or cancellation order, would be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA.

In any order issued in response to these requests for cancellation or amendment to terminate certain uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products identified or referenced in Table 1 or 2:

1. *Distribution or sale of products by the registrant labeled for use on apples, broccoli raab, cabbage, collards, fennel, grapes, head lettuce, lespedeza, spinach, tomatillo, and trefoil*:

The registrant of any product listed in Table 1 or 2 may distribute or sell existing stocks of the product bearing labels for use on apples, broccoli, raab, cabbage, collards, fennel, grapes, head lettuce, lespedeza, spinach, tomatillo, or trefoil for 1 year after the effective date of the cancellation or amendment order. The distribution or sale of existing stocks by the registrant of any product listed in Table 1 or 2 will not be lawful under FIFRA 1 year after the effective date of the cancellation or amendment order, except for the purposes of shipping such stocks for export consistent with section 17 of FIFRA or for proper disposal.

2. *Distribution, sale, or use of products by persons other than the registrant labeled for use on apples, broccoli raab, cabbage, collards, fennel, grapes, head lettuce, lespedeza, spinach, tomatillo, and trefoil:*

Any person other than the registrant may distribute, sell, and use existing stocks of any product listed in Table 1 or 2 that is labeled for use on apples, broccoli raab, cabbage, collards, fennel, grapes, head lettuce, lespedeza, spinach, tomatillo, and trefoil after the effective date of the cancellation or amendment order and until such existing stocks are exhausted.

List of Subjects

Environmental protection, Pesticides and Pests.

Dated: April 26, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 05–8865 Filed 5–3–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0111; FRL–7710–6]

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–2005–0111, must be received on or before June 3, 2005.

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 identification (ID) number OPP–2005–0111. 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, 1801 S. Bell St., 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 the EPA 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–2005–0111. 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–2005–0111. 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 –2005–0111.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0111. 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: April 18, 2005.

Janet L. Anderson,

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 Corp.

PP 6F4632

EPA has received a pesticide petition 6F4632 from Valent BioSciences Corp.,870 Technology Way, Libertyville, Il. 60048, 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 part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide Aminoethoxyvinylglycine hydrochloride (Aviglycine HCI or AVG) in or on walnut and cucumber.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Valent BioSciences Corp. has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Valent BioSciences Corp. 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.

A. Product Name and Proposed Use Practices

Aviglycine HCl (AVG) is a plant growth regulator used in preventing pistillate flower abortion (PFA) in walnuts, thereby increasing yield. AVG is the active ingredient (ai) in ReTain Plant Growth Regulator (EPA Reg. 73049–45) and ReTain Plant Growth Regulator for California (EPA Reg. No. 73049–58). The proposed use is for a single application to orchards when 5 to 10% of each of the trees is in bloom in order to increase the fruit set in walnut cultivars that suffer a high incidence of PFA. The proposed use rate for walnuts is 50 - 100 grams a.i./acre (0.73 - 1.46 lbs of ReTain® per acre targeting 125 parts per million (ppm) AVG in the spray solution) in a spray volume of 100 gallons per acre for small trees, 200 gallons per acre for large trees.

Aviglycine HCl is a plant growth regulator effective in inducing staminate (male) flowers on gynoecious (all female) breeding lines of curcubits used in seed production. AVG is the ai in ReTain Plant Growth Regulator (EPA Reg. 73049–45) and ReTain Plant Growth Regulator for California (EPA Reg. No. 73049–58). The proposed use is for one to four applications of ReTain to cucumber plants at early first leaf stage through to the tenth leaf stage. The proposed use rate for cucumbers is 19 to 48 grams a.i./acre (0.28 - 0.7 lbs of ReTain® per acre targeting 250 to 500 ppm AVG in the spray solution) in a spray volume of 10 to 25 gallons per acre to ensure good coverage.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. A study designed to determine whether uptake, translocation and metabolism of AVG occurs in apples identified seven minor metabolites in addition to the primary metabolite, *N*-acetyl aviglycine HCl. The study was not meant as a measure of the amount of AVG residues and metabolites found in apples under normal field conditions. The only significant incorporation of AVG in apple tissues, following brush-on application at high rates, resulted from absorption from the peel rather than translocation from the leaves. AVG is also metabolized in the tissues to form *N*-acetyl aviglycine HCl 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*. It is improbable that the proposed early season use of aviglycine HCl, as a means of preventing PFA, would result in measurable residues in the meat of walnuts. The proposed timing of application to walnut trees is early to mid-bloom. The use precludes direct applications to walnut fruit which are not yet present on the trees and are harvested 3–5 months after application. The edible portion of the nut is further protected by the hull and shell surrounding the nut. Translocation

of aviglycine HCl residues within treated plants was examined in studies of AVG metabolism in apple trees. There is minimal translocation of aviglycine HCl within plants. Residues of AVG will degrade over time on and in treated plant tissue. As a result, the potential for measurable residues of aviglycine HCl on the harvested edible portion of walnuts following application of ReTain to control PFA in walnuts is negligible.

The proposed use of aviglycine HCl on cucumbers is for seed production only. The proposed use is for an early season application to immature plants. There is minimal translocation of aviglycine HCl within plants. Residues of AVG will degrade over time on and in treated plant tissue. Therefore it is unlikely residual AVG will be present in the fruit or seed at the time the seed is harvested. There are also two generations between the seed production use of ReTain and generation of a commercial edible plant product from that seed. Curcubit seed is mechanically harvested with specialized equipment that destroys the fruit to obtain the seed. As a result, the potential for measurable residues of aviglycine HCl on the harvested edible portion of commercially grown cucumbers following application of ReTain as a means of inducing male flowers in seed production 2–generations before commercial harvest is negligible. Analytical methods for the detection of aviglycine HCl have been submitted to EPA in support of petitions for tolerances on pome and stone fruit. An analytical method for detection of aviglycine HCl residues in or on walnuts or cucumbers is not required. There is negligible potential for measurable residues of aviglycine HCl on walnuts or cucumbers as a result of the proposed use of ReTain and an exemption from the requirements of a tolerance for both walnuts and cucumbers is being sought.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for detection of aviglycine HCl residues in walnuts or cucumbers is not required. The proposed uses of aviglycine HCl on walnuts is for a single season application of ReTain at a rate of 50 to 100 g a.i./acre, applied to walnut trees early to mid-bloom to control pistillate flower abortion. It is highly unlikely that this early season application at low rates would result in measurable residues in the harvested meat of walnuts. Therefore, it should not be necessary to establish a tolerance for this use. Residue studies, methods supporting the analysis and methods of analysis for purpose of enforcement would similarly not be required.

The proposed use of aviglycine HCl is one to four early season applications of ReTain to breeding lines of cucumbers for seed production. ReTain is not proposed for use on cucumbers destined for commercial harvest and it is highly unlikely that application to cucumbers grown for seed production could or would result in measurable residues in the cucumbers grown commercially from progeny of that seed. Therefore, it should not be necessary to establish a tolerance for this use. Residue studies, methods supporting the analysis and methods of analysis for purpose of enforcement would similarly not be required.

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. AVG is not a skin sensitizer in guinea pigs, and is not irritating to the skin and eyes of rabbits. End-use formulations of AVG have similar low acute toxicity profiles.

2. *Genotoxicity.* AVG 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 AVG, there was no evidence of teratogenicity or other embryotoxic effects at the highest dose levels, although maternal toxicity was evident. The rabbit maternal no obvserved adverse effect level (NOAEL) was established at 0.4 mg a.i./kg/day based on reduced body weight gains and food consumption, and decreased defecation. Developmental NOAEL was established at 0.4 mg a.i./kg/day based on fetal body weights. In the rat test the maternal NOAEL was established at 1.77 mg a.i./kg/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/day based on decreased mean fetal body weights and reduced ossification. The developmental and maternal LOELs were established at 8.06 mg/kg/day.

AVG 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/day. The NOAEL for reproductive toxicity was established at 4.0 mg a.i./kg/day and the neonatal toxicity NOAEL was established at 2.5 mg a.i./kg/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/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/day. For dogs, the NOAEL was established at 0.6 mg a.i./kg/day based on inappetence, low body weight gain and centrilobular histopathological changes in the liver at 1.2 mg a.i./kg/day.

A 21 day repeat dose dermal toxicity study in rats was carried out at 0, 100, 500, and 1,000 mg/kg/day. The no observed effect level (NOEL) is 1,000 mg/kg/day; a lowest observed effect level (LOEL) was not determined.

5. *Chronic toxicity.* Chronic studies with AVG 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/kg/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 AVG 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 AVG at 7 mg a.i/kg/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/kg/day.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. There is no expected dietary exposure to residues of aviglycine HCl from the proposed early to mid-bloom use of ReTain on walnuts. No residues are expected on the commodity. Additionally, the contribution of walnuts as a percent of total diet is relatively small. It is estimated that walnuts contribute 0.009% of the diet of the general population and 0.005% to the diet of non-nursing infants. There is no expected dietary exposure to residues of aviglycine HCl from the proposed use of ReTain on cucumbers for seed production. No residues are expected on any cucumbers produced for consumption from the proposed use. Expected dietary exposures from residues of AVG would occur through apples, pears, peaches, nectarines, plums, processed pome, and stone-fruits (excluding cherries). 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 (CT) for all crops, default processing factors and consumption data from the 1994 through 1998 United States Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII 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 database was used to determine chronic exposure estimates for the overall U.S. population and 24 population subgroups and acute exposure estimates for the overall U.S. population and 10 population subgroups.

The resulting exposures were compared to a chronic reference dose (RfD) of 0.007 mg a.i./kg/day and an acute NOEL of 1.77 mg/kg bwt/day. The RfD is based on the NOAEL of 0.7 mg a.i./kg/day from the rat chronic toxicity study (52 week) and the rat carcinogenicity feeding study (104–week) with a 100-fold uncertainty factor to account for intra-species and inter-species variations. The acute NOEL 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% CT 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: (i) all infants, (ii) nursing infants, (iii) non-nursing infants, (iv) children 1 to 2 years of age, (viii) adults 20 to 49 years of age, (ix) females 13 to 49 years of age and (x) adults 50 years and older. Estimated daily exposures from tolerance level residues (at the 95th percentile) and a 100% CT assumption for all crops resulted in MOEs (Margin of Exposure) greater than 430 for all population groups examined.

The proposed agricultural uses of aviglycine HCl will not alter the results of the chronic and acute dietary exposure analyses conducted for pome fruit and stone fruit applications, which clearly demonstrated a reasonable certainty that no harm will result from the agricultural uses of AVG.

ii. *Drinking water*. AVG is highly unlikely to contaminate groundwater resources due to its high soil sorption, and short soil and water/sediment half-lives. Study results show that AVG is easily adsorbed to soils, principally onto clay particles. Half-lives in soils vary between 0.6 and 4.3 days. Water-sediment studies have shown that AVG 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 AVG in the aqueous phase and total water/sediment system was calculated to be approximately 1.2 and 2.3 days respectively. An AVG water concentration assessment was conducted using the EPA first Tier screening models. FIRST was used for surfacewater concentration assessment and forscreening concentration in groundwater, SCI-GROW was used for groundwater assessment. There were no estimated groundwater concentrations according to SCI-GROW. Peak surfacewater concentrations estimated using FIRST were 1.283 and the estimated annual average was 0.021 parts per billion (ppb), assuming 87% CT. The contribution of drinking water to aggregate risk is considered to be negligible.

2. *Non-dietary exposure*. AVG has no product registrations for residential non-food uses. Non-occupational, non-dietary exposure for AVG 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 milligrams/kilogram/day (mg/kg/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 AVG would be cumulative with those of any other chemical compounds. AVG has a novel mode of action compared to other currently registered active ingredients. Therefore, Valent BioSciences Corp. 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. The proposed use of aviglycine HCL on walnuts prior to fruit development is not expected to result in measurable residues on the walnuts harvested for consumption approximately 4 months following application. Using the chronic exposure assumptions for pome and stone fruit and the proposed RfD described above, the dietary exposure to AVG 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 AVG in food and drinking water will not result in unacceptable levels of human health risk.

2. *Infants and children*. FFDCA section 407 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 database. 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 database is complete. There is no indication of increased sensitivity in the database overall, and specifically, there is no indication of increased sensitivity in the developmental and multi-generation reproductive toxicity studies. Therefore, Valent BioSciences Corp. 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 AVG for non-nursing infants, the most highly exposed population subgroup, was calculated to be 0.001110 mg/kg bwt/day or 15.9% of the reference dose. Daily exposure for the overall U.S. population was estimated to be 0.000153 mg/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/kg/day with a NOAEL of 5 mg/kg/day based on decreased primary antibody (igM) response to sheep red blood cells; decreased absolute and relative thymus weights; decreased body weight, food consumption and food efficiency at the high dose level. The LOEL is 15 mg/kg/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 AVG is considered negligible.

H. Existing Tolerances

Tolerances have been established for the residues of AVG in or on the following food commodities:

Commodity	Parts per million
Apples	0.08
Fruit, stone, group 12, (except cherry)	0.170
Pears	0.08

I. International Tolerances

There are no Codex maximum residue limits for use of aviglycine HCl on apples or pears, or on any other crop.

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ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2005–0026; FRL–7713–6]

Approval of Test Marketing Exemption for a Certain New Chemical

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of an application for test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated this application as TME–05–3. The test marketing conditions are described in the TME application and in this notice.

DATES: Approval of this TME is effective April 27, 2005.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Adella Underdown, Program Manager, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–9364; e-mail address: *underdown.adella@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed in particular to the chemical manufacturer and/or importer who submitted the TME to EPA. This action may, however, be of interest to the public in general. 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 technical 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 identification (ID) number OPPT–2005–0026. 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 EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

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.

II. What is the Agency's Authority for Taking this Action?

Section 5(h)(1) of TSCA and 40 CFR 720.38 authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes, if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

III. What Action is the Agency Taking?

EPA approves the above-referenced TME. EPA has determined that test