

therefore need to be reflected in the quantitative benefit assessment.

While developing the primary benefit estimates for reduced fatal cancer risks in the proposed radon rule, questions arose regarding the implementation of adjustments for some factors, but not others. For example, would it ever be appropriate to adjust only for latency periods, and not other factors, in the valuation of reduced cancer deaths? The Agency is requesting the SAB's counsel to help answer this and related questions regarding the valuation of cancer risks.

#### Charge to the Committee

The Agency has requested a review by the SAB-EEAC of its "white paper" on approaches to estimating the benefits of reduced fatal cancer risks. The principal questions for the Science Advisory Board are:

(a) Does the white paper accurately describe the empirical economic literature relevant to the benefit transfer issues that ensue when using the VSL literature to estimate the VSCF in a benefit-cost analysis?

(b) Does the white paper present the important risk and demographic factors that can affect benefit transfer approaches that use VSL estimates for VSCF?

(c) Does the white paper accurately describe attempts in the economic literature to measure VSCF directly?

(d) There are two numeric case studies of environmental cancer risks developed for the white paper. Each presents risk assessment information that forms the basis for quantifying the number of statistical cancer fatalities that will be reduced as a consequence of a hypothetical proposed environmental policy. The case studies are used to illustrate the outcome of using direct measures of the VSCF and benefit transfer adjustments to VSL estimates in order to calculate the VSCF.

(1) Which of the valuation approaches applied to the case study designated as ALPHA are valid to use? Does this case study omit any credible alternative protocols for valuing reductions in fatal cancer risks for benefit-cost analyses of environmental programs?

(2) Which of the valuation approaches applied to the case study designated as OMEGA are valid to use? Does this case study omit any credible alternative protocols for valuing reductions in fatal cancer risks for benefit-cost analyses of environmental programs?

(e) Which economic methods illustrated with the case studies, or additional methods identified by the Committee under charge question d), serve as credible protocols for the

Agency to use in representing quantitative data, qualitative information, and sensitivity analyses for the economic value of reduced fatal cancer risks reported in benefit-cost analyses?

**FOR FURTHER INFORMATION:** Members of the public desiring additional information about the meeting should contact Mr. Thomas Miller, Designated Federal Officer, Environmental Economics Advisory Committee (EEAC), USEPA Science Advisory Board (1400A), Room 6450, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone/voice mail at (202) 564-4558; fax at (202) 501-0582; or via e-mail at <millertom@epa.gov>. For a copy of the draft meeting agenda, please contact Ms. Dorothy Clark, Management Assistant at (202) 564-4537 or by FAX at (202) 501-0582 or via e-mail at <clark.dorothy@epa.gov>. Single copies of the background document, *Valuing Fatal Cancer Risk Reductions* can be obtained by contacting Mr. Brett Snyder, U.S. Environmental Protection Agency, Office of Policy and Reinvention (Mail Drop 2172), 1200 Pennsylvania Ave., NW, Washington, DC, 20460, (202) 260-5610, FAX (202) 260-2685, or via email at: <snyder.brett@epa.gov>.

#### Providing Oral or Written Comments

Members of the public who wish to make a brief oral presentation to the Committee must contact Mr. Thomas Miller, Designated Federal Officer for the Environmental Economics Advisory Committee, *in writing* (by letter or fax) no later than 4:00 pm Eastern Time, Thursday, February 17, 2000, at the address noted above in order to be included on the agenda. The request should identify the name of the individual who will make the presentation, the organization (if any) they will represent, any audio-visual equipment (e.g., overhead projector, 35 mm projector, chalkboard, etc.), and at least 35 copies of an outline of the issues to be addressed or the presentation itself. To discuss technical aspects of the meeting, please contact Mr. Miller by telephone at (202) 564-4558. For a copy of the draft agenda please contact Ms. Dorothy Clark, Management Assistant, at (202) 564-4537, or by FAX at (202) 501-0582 or via e-mail at <clark.dorothy@epa.gov>.

#### Providing Oral or Written Comments at SAB Meetings

The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. In general, each individual

or group making an oral presentation will be limited to a total time of ten minutes. Written comments (at least 35 copies) received in the SAB Staff Office sufficiently prior to a meeting date (usually one week before the meeting), may be mailed to the relevant SAB committee or subcommittee; comments received too close to the meeting date will normally be provided to the committee at its meeting, or mailed soon after receipt by the Agency. Written comments may be provided to the relevant committee or subcommittee up until the time of the meeting.

Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (<http://www.epa.gov/sab>) and in the Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564-4533 or via fax at (202) 501-0256.

#### Meeting Access

Individuals requiring special accommodation at this meeting, including wheelchair access, should contact the appropriate DFO at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: January 28, 2000.

**Donald G. Barnes,**

*Staff Director, Science Advisory Board.*

[FR Doc. 00-2477 Filed 2-3-00; 8:45 am]

**BILLING CODE 6560-50-P**

## ENVIRONMENTAL PROTECTION AGENCY

[PF-908; FRL-6398-9]

### Novartis Crop Protection; Notice of Filing a Pesticide Petition To Establish a Tolerance for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-908, must be received on or before March 6, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.**

To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-908 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker (PM 22), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7740; and e-mail address: giles-parker.cynthia@epamail.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:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufac-turing

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

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

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

2. *In person.* The Agency has established an official record for this action under docket control number PF-908. 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 (CM #2), 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-908 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, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

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

3. *Electronically.* You may submit your comments electronically by e-mail to: "[opp-docket@epa.gov](mailto:opp-docket@epa.gov)," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in

Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-908. Electronic comments may also be filed online at many Federal Depository Libraries.

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

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

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

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

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food,

Drug, and 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 supports 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: January 24, 2000.

**James Jones,**

Director, Registration Division, Office of Pesticide Programs.

#### Summary of Petition

9F6004

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 petitioner and represents the view of the petitioner. 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.

EPA has received a pesticide petition (9F6004) from Novartis Crop Protection, P.O. Box 18300, Greensboro, NC 27419 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 by establishing a tolerance for residues of 1,2,3-benzothiadiazole-7-carbothioic acid S-methyl ester (acibenzolar-S-methyl) in or on the raw agricultural commodity brassica leafy vegetables crop group and bananas at 1.0 and 0.1 parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

1. *Plant metabolism.* Novartis believes the metabolism of acibenzolar-S-methyl has been well characterized. Only 4.6% and 14.9% of the total radioactive

residue (TRR) was non-extractable in lettuce at the recommended application rate and three times the recommended application rate, respectively. Non-extractables were also low in a tomato metabolism study; 3.4% and 7.4% in tomatoes and foliage, respectively. The metabolism in these crops proceeded via hydrolysis of benzo [1,2,3] thiadiazole-7-carbothioic acid S-methyl ester to benzo [1,2,3] thiadiazole-7-carboxylic acid (BTCA), followed by conjugation as ester, glycoside and/or other plant constituents. The metabolism profile supports the use of an analytical enforcement method that accounts for acibenzolar-S-methyl and metabolites containing the benzo [1,2,3] thiadiazole-7-carboxylic acid (BTCA) moiety.

2. *Analytical method.* Novartis Analytical Method AG-671A is a practical and valid method for the determination and confirmation of CGA-245704 (acibenzolar-S-methyl) in raw agricultural commodities (RAC) and processing substrates from the tobacco, leafy (including brassica) and fruiting vegetable crop groups at a limit of quantitation (LOQ) of 0.02 ppm. The method involves extraction, solid phase cleanup of samples with analysis by high performance liquid chromatography (HPLC) with ultraviolet (UV) detection or confirmatory LC/MS. The validity is demonstrated by the acceptable accuracy and precision obtained on numerous procedural recovery samples (radiovalidation and field trial sample sets), and by the extractability and accountability obtained by the analysis of weathered radioactive substrates using Analytical Method AG-671A. Novartis Analytical Method REM 172.11 is a practical and valid method for the determination and confirmation of CGA-245704 in RAC of bananas at a LOQ of 0.02 ppm. The method involves hydrolytic extraction, partitioning, and solid phase cleanup of samples with analysis by two-column HPLC switching with UV detection. The validity is demonstrated by the acceptable accuracy and precision obtained on numerous procedural recovery samples (banana, tomatoes, cucumbers, and milk).

3. *Magnitude of residues.* This petition is supported by 17 field trials conducted on representative members of the brassica leafy vegetable crop groupings. All samples were analyzed for by the total residue method (AG-671A) to determine the combined residues of acibenzolar-S-methyl and metabolites which contain the benzo [1,2,3] thiadiazole-7-carboxylic acid (BTCA) moiety. In brassica leafy vegetables, the maximum residues

found on representative commodities were 0.63 ppm, 0.57 ppm, 0.31 ppm, 0.64 ppm, and 0.80 ppm, for broccoli (flower, head and stem), cabbage head (with wrapper leaves), cabbage head (without wrapper leaves), cabbage wrapper leaves, and mustard greens leaves, respectively. A tolerance of 1.0 ppm for the brassica leafy vegetable crop group has been proposed. This petition is supported by 14 field trials conducted on bananas. Banana samples were analyzed for by the total residue method REM 17.11 to determine the combined residues of acibenzolar-S-methyl and metabolites which contain the benzo [1,2,3] thiadiazole-7-carboxylic acid (BTCA) moiety. The maximum residue found in bananas was 0.08 ppm. A tolerance of 0.1 ppm in bananas has been proposed.

#### B. Toxicological Profile

1. *Acute toxicity.* The risk from acute dietary exposure to acibenzolar-S-methyl is considered to be very low. CGA-245704 and the formulated 50 WG product have low orders of acute toxicity by the oral, dermal and inhalation exposure routes. Results from acute studies all fall within toxicity rating categories of III or IV. CGA-245704 technical has a low order of acute toxicity, is only slightly irritating to skin and eyes, but may cause sensitization by skin contact. An LD<sub>50</sub> of greater than 5,000 milligrams/kilograms (mg/kg) was observed for the acute oral toxicity study in rats. The lowest no observed adverse effect level (NOAEL) in a short-term exposure scenario, identified as 50 mg/kg in the rabbit and rat teratology studies, is 10-fold higher than the chronic NOAEL. Based on worst case assumptions, the chronic exposure assessments (see below) did not result in any margin of exposure (MOE) less than 3,330 for even the most impacted population subgroup. Novartis believes the MOE is greater than 100 for any population subgroups; EPA considers MOEs of 100 or more as satisfactory. The following are results from the acute toxicity tests conducted on the technical material:

- i. Rat oral LD<sub>50</sub> > 5,000 mg/kg/bwt male/female (M/F) toxicity Category IV.
- ii. Rat dermal LD<sub>50</sub> > 2,000 mg/kg/bwt (M/F) toxicity Category III.
- iii. Acute inhalation LC<sub>50</sub> > 5,000 mg/L (M/F) toxicity Category IV.
- iv. Rabbit eye irritation: Minimally irritating—toxicity Category III.
- v. Rabbit dermal irritation: Slightly irritating—toxicity Category IV.
- vi. Dermal sensitization: Sensitizer.

2. *Genotoxicity.* CGA-245704 technical was not mutagenic or clastogenic and did not provoke unscheduled DNA

synthesis when tested thoroughly in a battery of standard *in vivo*, and *in vitro* independent assays, using both eukaryotes and prokaryotes, and with or without metabolic activation. These tests are summarized below:

- i. Microbial/Microsome Mutagenicity Assay: Non-mutagenic.
- ii. Mammalian Cell Chinese Hamster Ovary (CHO) Mutagenicity Assay: Non-mutagenic; Non-clastogenic.
- iii. Chinese Hamster (CH) Bone marrow: Non-clastogenic; negative for chromosome aberrations.
- iv. Mouse Micronucleus Test: Non-clastogenic; negative for chromosome aberrations.
- v. DNA Damage and Repair Rat hepatocyte: Negative.

3. *Reproductive and developmental toxicity.* Acibenzolar-S-methyl is not a teratogenic hazard except at, or close to, the maximum tolerated dose. In the rat multigeneration study, CGA-245704 (acibenzolar-S-methyl) technical had no effect on rat reproductive parameters including gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and sex organ histopathology. At 4,000 ppm, parental body weights (bwt) were reduced. This demonstrated by the results of the following studies:

- i. Rat oral teratology—Maternal NOAEL of 200 mg/kg based on embryotoxicity and teratogenic effects; fetal NOAEL of 50 mg/kg.
- ii. Rabbit oral teratology study—Maternal NOAEL of 50 mg/kg based on maternal toxicity and slightly delayed ossification; fetal NOAEL of 300 mg/kg based on changes in bwt.
- iii. Rat 2-generation reproduction study—NOAEL of 25 mg/kg based on weight development in adults at 4,000 ppm and pups during lactation at 2,000 ppm and above. No adverse effects on reproduction or fertility.

4. *Subchronic toxicity.* No signs of neurotoxicity were noted with CGA-245704 in both acute and subchronic studies even at the highest dose levels of 800 mg/kg and 8,000 ppm, respectively. The evaluated parameters included functional observation battery, motor activity measurement and neurohistopathologic assessment. These tests are summarized below:

- i. Rat 28-day dermal study—NOAEL of 1,000 mg/kg/day.
- ii. Dog 90-day feeding study—NOAEL of 10 mg based on reduced bwt gain at 50 mg/kg/day.
- iii. Mouse 90-day feeding—NOAEL of < 30 mg/kg based on reduced bwt development at 1,000 ppm and above.
- iv. Rat 90-day feeding study—NOAEL of 25 mg/kg based on inappetence and

reduced bwt development at higher dose levels (4,000, and 8,000 ppm).

5. *Chronic toxicity.* Based on the available chronic toxicity data, Novartis Crop Protection, Inc. believes the Reference Dose (RfD) for acibenzolar-S-methyl is 0.05 mg/kg/day. Acibenzolar-S-methyl is not oncogenic in rats or mice and is not likely to be carcinogenic in humans. No carcinogenic activity was detected in mice and rats at the Maximum Tolerated Dose (MTD). There was no evidence of carcinogenicity in an 18-month feeding study in mice and a 24-month feeding study in rats. Dosage levels in both the mouse and the rat studies were adequate for identifying a cancer risk. Novartis believes acibenzolar-S-methyl should be classified as a "Not Likely" carcinogen based on the lack of carcinogenicity in rats and mice.

6. *Animal metabolism.* Metabolism proceeded primarily via hydrolysis to form the corresponding carboxylic acid (BTCA) which was subsequently conjugated with several amino acids including glycine, lysine and ornithine. Elimination was rapid in all cases. Oxidation of the aromatic ring of the acid was a very minor pathway observed in goats. The metabolic fate of CGA-245704 in plants paralleled that observed in animals. The major metabolite in all test systems was the same hydrolysis product BTCA. Thus, the metabolism profile supports the use of an analytical enforcement method that accounts principally for parent and BTCA.

7. *Metabolite toxicology.* In short-term toxicity studies in rats, CGA-210007 was found to be of, at most, equal or less toxicity than the parent compound. As with parent CGA-245704, the subchronic NOAEL for CGA-210007 was 100 mg/kg bwt.

8. *Endocrine disruption.* Acibenzolar-S-methyl does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that acibenzolar-S-methyl might have any effects on endocrine function related to development and reproduction. Acibenzolar-S-methyl is not a teratogenic hazard except at, or close to, the maximum tolerated dose. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

#### C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Novartis has estimated

aggregate from the previously requested tolerances for the raw agricultural commodities: leafy vegetables (excluding spinach) at 0.25 ppm; spinach at 1.0 ppm; and fruiting vegetables at 1.0 ppm (PP 8F4974); and the requested tolerances for brassica leafy vegetables at 1.0 ppm and bananas at 0.1 ppm (PP 9F6004). Maximum expected chronic exposure to CGA-245704 in the diets of the most sensitive sub-population, children (1–6 years), was calculated to be 0.5% of the RfD. For the U.S. population (48 contiguous States) chronic exposure was 0.3% of the RfD. Acute dietary exposure is also minimal. Exposure to the most sensitive sub-population, children (1–6 years), was 2.17% of the acute RfD (aRfD). Acute exposure to the U.S. population was 1.2% of the aRfD. Dietary exposure analyses for CGA-245704 (and CGA-210007) were conducted using anticipated residues generated from field trials conducted at the maximum use rate and minimum pre-harvest interval (PHI). In addition, actual dietary exposure would be much less than the estimates made herein since significant residue reduction often takes place in commerce and during food preparation and cooking. Projected market share was included on all commodities except bananas. One hundred percent market share was assumed for bananas. These results (minimal exposure) show more than a reasonable certainty of no harm.

ii. *Drinking water.* The potential for exposure to CGA-245704 through drinking water (surface or ground water) is slight due to the minimal level of this chemical anticipated to reach these bodies of water. This expectation is based on the rapid degradation of CGA-245704 and the recommended low use rates that will further restrict the amount of chemical available for leaching or run-off. A Maximum Contaminant Level Goal (MCLG) of 350 parts per billion (ppb) has been calculated for CGA-245704. This calculated safe exposure value is substantially above the levels that are likely to be found in the environment under proposed conditions of use.

2. *Non-dietary exposure.* Novartis believes that the potential for non-occupational exposure to the general public is unlikely except for potential residues in food crops discussed above. The proposed uses for acibenzolar-S-methyl are for agricultural crops and the product is not used residentially in or around the home.

#### D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate

at this time since there is no information to indicate that toxic effects produced by acibenzolar-S-methyl would be cumulative with those of any other chemicals. Acibenzolar-S-methyl is a plant activator and no other compounds in this class are registered in the United States. Consequently, Novartis is considering only the potential exposure to acibenzolar-S-methyl in its aggregate risk assessment.

#### E. Safety Determination

1. *U.S. population.* For the U.S. population (48 contiguous States) chronic exposure was 0.3% of the RfD. Acute dietary exposure is also minimal. Acute exposure to the U.S. population was 1.2% of the aRfD. EPA usually has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to acibenzolar-S-methyl residues.

#### 2. Infants and children.

Embryotoxicity and fetotoxicity were apparent at maternally toxic doses of CGA-245704 technical in rats and rabbits. The lowest NOAEL for this effect was established in the 2-generation reproduction study at 25 mg/kg (200 ppm).

Maximum expected chronic exposure to CGA-245704 in the diets of the most sensitive sub-population, children (1–6 years), was calculated to be 0.5% of the RfD. Acute dietary exposure is also minimal. Exposure to the most sensitive sub-population, children (1–6 years), was 2.17% of the aRfD.

Additionally, CGA-245704 is not a reproductive toxin. Some signs of teratogenicity were found at, or close to, maternally toxic doses. No neurotoxic effects or oncogenic activity has been observed with CGA-245704. From these available toxicology data, no special susceptibility of infants or children is anticipated.

Dietary exposure analyses for CGA-245704 (and CGA-210007) were conducted using anticipated residues generated from field trials conducted at the maximum use rate and minimum pre-harvest interval (PHI). In addition, actual dietary exposure would be much less than the estimates made herein since significant residue reduction often takes place in commerce and during food preparation and cooking. Projected market share was included on all commodities except bananas. One hundred percent market share was assumed for bananas. These results

(minimal exposure) show more than a reasonable certainty of no harm.

#### Acute Dietary Exposure for the U.S. Population and the Most Sensitive Population Sub-Groups at the 99.9th Percentile

Population Sub-group	% aRfD (Diet Only)
U.S. Population - 48 contiguous states - all seasons.	1.20%
All infants (<1 year) .....	1.54%
Nursing infants (<1 year) .....	0.41%
Non-nursing infants (<1 year) ..	1.80%
Children (1–6 years) .....	2.17%
Children (7–12) .....	1.37%

Exposure to residues of CGA-245704 and CGA-210007 in consumed food is minimal. Both chronic and acute exposure estimates demonstrate the use of CGA-245704 on crops results in more than a reasonable certainty of no harm. The results herein are conservative since field trial residues utilized in these assessments were generated under maximum label use rates and minimum pre-harvest intervals.

#### F. International Tolerances

Codex maximum residue levels (MRLs) have not been established for residues of CGA-245704 in or on raw agricultural commodities from the fruiting vegetable and leafy vegetable crop groups. Maximum residue levels of 0.1 ppm have been established for CGA-245704 on wheat in Switzerland and Hungary. Proposed CODEX MRLs of 1.0 ppm on tomatoes and 0.1 ppm on bananas, cereals, wheat, spring barley, and rice have been proposed (Japan).

[FR Doc. 00-2484 Filed 2-3-00; 8:45 am]

BILLING CODE 6560-50-F

#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-6533-5]

#### The QTRACER Program for Tracer-Breakthrough Curve Analysis for Karst and Fractured-Rock Aquifers; and A Lexicon of Cave and Karst Terminology with Special Reference to Environmental Karst Hydrology

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability of two final documents and CD-ROM.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) announces the availability of two final documents, The QTRACER Program for Tracer-Breakthrough Curve Analysis for Karst and Fractured-Rock Aquifers (EPA/600/

R-98/156a, February 1999) and CD-ROM (EPA/600/R-98/156b, February 1999), and A Lexicon of Cave and Karst Terminology with Special Reference to Environmental Karst Hydrology (EPA/600/R-99/006, January 1999), prepared by the National Center for Environmental Assessment—Washington Office (NCEA-W), within the Office of Research and Development.

The QTRACER program was developed to provide a fast and easy method for evaluating tracer-breakthrough curves generated from tracing studies conducted in karst and fractured-rock aquifers. The results may then be applied in solute-transport modeling and risk assessment studies. The QTRACER document will serve as a technical guide to various groups who must address potential and/or existing ground-water contamination problems in karst and fractured-rock terranes. Tracing studies are always appropriate and probably necessary, but analyses can be difficult and tedious. This document and associated computer programs alleviate some of these problems.

A Lexicon of Cave and Karst Terminology with Special Reference to Environmental Karst Hydrology was prepared to satisfy the need to understand the terminology common to the field of karst. This document is a glossary of most terms that have some relationship to the field of environmental karst, as well as specific karst terms. It includes many foreign terms because much karst research is conducted in foreign countries and published using local terminology. In many instances common environmental terms are defined in such a way as to specifically reference karstic phenomena. This document will serve as a technical guide for those who must read the karst literature or hold discussion with karst researchers. It is intended to remove much of the confusion surrounding many karst terms.

**ADDRESSES:** These documents are being made available electronically from the NCEA web site at <http://www.epa.gov/ncea>. A limited number of copies of the printed and CD-ROM version of the QTRACER document is available from EPA's National Service Center for Environmental Publications (NSCEP) in Cincinnati, Ohio (telephone: 1-800-490-9198, or 513-489-8190; facsimile 513-489-8695). Please provide the title and EPA number when ordering from NSCEP. Paper copies of both documents also may be purchased from the National Technical Information Service