

different sizes under a single registration number.

DATES: Written comments, identified by the document control number [OPP-00448], must be received on or before February 24, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Copies of the draft notice may be requested from the Public Response and Program Resources Branch by telephone (703) 305-5805 or by writing to the Washington, DC, address indicated above.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-00448]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Room 1128 at the Virginia address given above, from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: William W. Jacobs, Insecticide-Rodenticide Branch, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 259, CM

#2, 1921 Jefferson Davis Highway, Arlington, (703) 305-6406.

SUPPLEMENTARY INFORMATION:

EPA has established a record for this notice of availability under docket number [OPP-00448] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at: opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice of availability, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 18, 1996.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96-32798 Filed 12-24-96; 8:45 am]

BILLING CODE 6560-50-F

[PF-680; FRL-5576-7]

American Cyanamid Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice is a summary of a pesticide petition proposing the establishment of a regulation for residues of AC 299263 [(±)-2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(methoxymethyl)-3-pyridinecarboxylic acid] in or on soybean seed.

DATES: Comments, identified by the docket number [PF-680], must be received on or before, January 27, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in Unit II. of this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Robert Taylor, Product Manager (PM) 25, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, Telephone: 703-305-6027, e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 6F4649 from American Cyanamid Company, P.O. Box 400, Princeton, NJ 08543-0400, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FDDCA), 21 U.S.C. section 346a(d), to amend 40 CFR

part 180 by establishing a tolerance for residues of the herbicide AC 299263 in or on the raw agricultural commodity soybean seed at 0.1 ppm. The proposed analytical method is HPLC Method M2248.01.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, American Cyanamid Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by American Cyanamid Company and EPA has not fully evaluated the merits of the petition.

EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

On November 30, 1995, American Cyanamid Company petitioned the EPA, under pesticide petition (PP) 6F4649, for a permanent tolerance of 0.1 ppm for the residues of AC 299263 on soybean seed.

Section 408(b)(2)(A) of the amended FFDCA allows EPA to establish a tolerance only if the Administrator determines that there is a "reasonable certainty that no harm will result from the aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

All of the studies required for the proposed use pattern have been completed and submitted to EPA for review. The available information indicates there is a reasonable certainty that no harm will result from various types of exposure.

The following is a summary of the information submitted to EPA to support the establishment, under section 408(b)(2)(D) of the amended FFDCA, of a tolerance for AC 299263 on soybean seed.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of AC 299263 in soybeans is adequately understood. Parent compound is the only residue of concern. The requirement for a processing study was waived by EPA based on the results of field trials at rates up to 5x the maximum label rate. In these trials, there was no measurable residue of AC 299263 in soybean seed above the validated sensitivity of the method (0.05 ppm). In addition, results from the plant metabolism study showed no detectable residues of AC 299263 in oil obtained from soybean

seed which had been treated at an exaggerated use rate.

2. *Analytical method.* A practical analytical method (HPLC Method M2248.01) for detecting and measuring levels of AC 299263 in soybean seed has been submitted to EPA. This method is appropriate for enforcement purposes.

3. *Magnitude of residues.* No apparent residues of AC 299263 were observed in soybean seed at or above 0.05 ppm (the limit of quantitation for the analytical method). These field studies, conducted at 1–5x the highest intended label use rate, clearly support the proposed tolerance of 0.1 ppm.

B. Toxicological Profile

A complete battery of mammalian toxicity studies supports the tolerance for AC 299263 on soybean seed. The data base is complete, valid and reliable, and all studies have been submitted to EPA for review.

1. *Acute toxicity.* Based on EPA criteria, AC 299263 technical material is relatively non-toxic via the oral and inhalation routes of exposure (Category IV), and is only slightly toxic (Category III) via dermal exposure.

Acute oral toxicity in rats: LD50 > 5,000 mg/kg

Acute dermal toxicity in rabbits: LD50 > 4,000 mg/kg

Acute inhalation toxicity in rats: LC50 > 6.3 mg/l (analytical)

Primary eye irritation in rabbits:

Slightly to moderately irritating

Primary dermal irritation in rabbits:

Non-irritating to slightly irritating

Dermal sensitization in guinea pigs: Non-sensitizer

2. *Genotoxicity.* The results from a battery of three *in vitro* and one *in vivo* genetic toxicity tests with AC 299263 show that this compound is not mutagenic or genotoxic.

Gene mutation - Ames: Negative

In vitro structural chromosomal

aberration assay: Negative

In vitro CHO/HGPRT assay: Negative

In vivo micronucleus aberration assay: Negative

3. *Reproductive and developmental toxicity.* Results of these studies indicate that AC 299263 is not a reproductive toxicant, a developmental toxicant, or a teratogen.

Teratology in rats: NOEL (maternal) = 500 mg/kg/day NOEL (fetal/developmental) = 1000 mg/kg/day*

Teratology in rabbits: NOEL (maternal) = 300 mg/kg/day NOEL (fetal/developmental) = 900 mg/kg/day*

Two-Generation reproduction in rats: NOEL (parental and reproductive) = 20,000 ppm* (~ 1639 mg/kg/day)

* highest concentration tested

4. *Subchronic toxicity.* No treatment-related adverse effects were noted in

subchronic toxicity studies at the highest doses tested.

28-Day dermal in rats: NOEL = 1000 mg/kg/day*

13-Week oral feeding in rats: NOEL = 20,000 ppm* (~ 1661 mg/kg/day)

90-Day oral feeding in dogs: NOEL = 40,000 ppm* (~ 1368 mg/kg/day)

* highest concentration tested

5. *Chronic toxicity.* The low order of mammalian toxicity of AC 299263 technical is also evident from the chronic dietary toxicity studies. These studies showed no increased mortalities or clinical signs of toxicity attributed to AC 299263 treatment. There was no gross or microscopic evidence of treatment-related lesions or carcinogenicity in the three chronic studies conducted in dogs, mice, or rats.

1-Year chronic toxicity in dogs: NOEL = 40,000 ppm* (~ 1,165 mg/kg/day)

18-Month chronic toxicity and carcinogenicity in mice: NOEL = 7,000 ppm* (~ 1201 mg/kg/day)

24-Month chronic toxicity and carcinogenicity in rats: NOEL = 20,000 ppm* (~ 1,167 mg/kg/day)

* highest concentration tested

6. *Animal metabolism.* The qualitative nature of the residues of AC 299263 in animals is adequately understood. Based on metabolism studies with goats, hens and rats, there is no reasonable expectation that measurable AC 299263-related residues will occur in meat, milk, poultry or eggs from the proposed use.

7. *Metabolite toxicology.* No toxicologically significant metabolites were detected in plant or animal metabolism studies. Therefore, no metabolites are required to be regulated.

8. *Endocrine effects.* Collective organ weights and histopathological findings from the two-generation rat reproductive study, as well as from the subchronic and chronic toxicity studies in two or more animal species, demonstrate no apparent estrogenic effects or effects on the endocrine system. There is no information available which suggests that AC 299263 would be associated with endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure.*-- (i) *Food.* The Theoretical Maximum Residue Concentrations (TMRC) of AC 299263 on or in soybean seed are:

0.000036 mg/kg b.w./day for the general U.S. population

0.000252 mg/kg b.w./day for non-nursing infants

0.000064 mg/kg b.w./day for children 1 to 6 years of age

0.000050 mg/kg b.w./day for children 7 to 12 years of age

These TMRC values are calculated from the proposed 0.1 ppm tolerance of AC 299263 on soybean seed using a "worse case" estimate of dietary exposure. This conservative estimate assumes that 100 percent of all soybeans are treated with AC 299263 and that the residues of AC 299263 on soybean seed are at the tolerance level (0.1 ppm). In fact, no apparent residues were observed in soybean seed at or above the 0.05 ppm limit of quantitation of the residue method.

There are no other established tolerances for AC 299263, and there are no other registered uses for AC 299263 on food or feed crops.

(ii) *Drinking water.* There is no available information about AC 299263 exposures via levels in drinking water. Studies verify that the use of AC 299263 in soybeans, at the proposed application rate of 0.04 lb. ai/acre, has a low potential for ground water contamination. Results from field dissipation studies showed rapid initial degradation of AC 299263 in soil, and additional studies indicate that AC 299263 is resistant to desorption with time. Furthermore, AC 299263 soil metabolites suggest a "moderate to strong" soil binding potential.

EPA has not established a Maximum Concentration Level for AC 299263 in drinking water under the Safe Drinking Water Act, because it is unlikely to be found in ground water. Because of the very low level of mammalian toxicity of parent AC 299263 and its two major soil metabolites, there is no health risk to humans from exposure to parent or soil metabolites in ground water. A Lifetime Health Advisory level for AC 299263 in drinking water calculated by EPA procedures would be 81.55 mg/liter, assuming a 20% relative contribution from water.

There is a reasonable certainty that no harm will result from dietary exposure to AC 299263, because dietary exposure to residues on food will use only a small fraction of the Reference Dose (including exposure of sensitive populations), and exposure through drinking water is expected to be insignificant.

2. *Non-dietary exposure.* There is no available information quantifying non-dietary exposure to AC 299263. However, based on the physical and chemical characteristics of the compound, the proposed use pattern and available information concerning its environmental fate, non-dietary exposure is expected to be negligible.

D. Cumulative Effects

AC 299263 belongs to the imidazolinone class of compounds. The

herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxy acid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the extremely low toxicity of AC 299263 in mammals. Although other registered imidazolinones have a similar herbicidal mode of action, there is no information available to suggest that these compounds exhibit a similar toxicity profile in the mammalian system. Since AC 299263 is relatively non-toxic, cumulative effects of residues of AC 299263 and other compounds are not anticipated.

E. Safety Determination

1. *U.S. population.* Based on a RfD of 11.65 mg/kg b.w./day, supported by a NOEL of 40,000 ppm or 1165 mg/kg b.w./day from the 1-year dog study and a safety (uncertainty) factor of 100, the "worse case" estimate of chronic dietary exposure of AC 299263 in soybean seed will utilize approximately 0.0003 percent of the RfD for the general U.S. population. EPA generally has no concern for exposures below 100 percent 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. The complete and reliable toxicity data and the conservative chronic exposure assumptions support the conclusion that there is a "reasonable certainty of no harm" from aggregate exposure to AC 299263 residues.

2. *Infants and children.* The conservative estimates, as described above, indicate that dietary exposure of AC 299263 on soybeans will utilize approximately 0.002 percent of the RfD for non-nursing infants, approximately 0.0006 percent of the RfD for children ages 1 to 6, and approximately 0.0004 percent of the RfD for children ages 7 to 12.

No developmental, reproductive, or fetotoxic effects were noted at the highest doses of AC 299263 tested in guideline studies. The only maternal effects in the rat and rabbit teratology studies were decreased body weights, body weight gains, and absolute and relative feed consumption in the higher dose groups of each study.

Based on the current toxicological data requirements, the data base relative to pre- and post-natal effects for children is complete, valid, and reliable. Results from the teratology studies and the two-generation reproduction study, which

support NOELs for fetal/developmental effects or reproductive/offspring effects, respectively, equivalent to the highest concentrations tested, suggest that there is no additional sensitivity of infants and children to residues of AC 299263. Therefore, an additional safety (uncertainty) factor is not warranted, and the RfD of 11.65 mg/kg b.w./day, which utilizes a 100-fold safety factor, is appropriate to assure a reasonable certainty of no harm to infants and children.

F. International Tolerances

There is no Codex maximum residue level established for residues of AC 299263 on soybean seed.

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the document control number, [PF-680]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address give above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket number [PF-680] including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address

in "ADDRESSES" at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 17, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96-32796 Filed 12-24-96; 8:45 am]

BILLING CODE 6560-50-F

[OPPT-59357; FRL-5581-7]

Certain Chemical; Approval of a Test Marketing Exemption

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-97-3. The test marketing conditions are described below.

DATES: This notice becomes effective December 19, 1996. Written comments will be received until January 10, 1997.

ADDRESSES: Written comments, identified by the docket number [OPPT-59357] and the specific TME number [TME 97-3] should be sent to: TSCA nonconfidential center (NCIC), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NEB-607 (7407), 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by [OPPT-59357]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on these notices may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under "SUPPLEMENTARY INFORMATION".

FOR FURTHER INFORMATION CONTACT:

Darlene Jones, New Chemicals Branch, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-447, 401 M St. SW., Washington, DC 20460, (202) 260-2279; jones.darlene@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Section 5(h)(1) of TSCA 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 human 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.

EPA hereby approves TME-97-3. EPA has determined that test marketing of the new chemical substance described below, under the conditions set out in the TME application, and for the time period and restrictions specified below, will not present an unreasonable risk of injury to human health or the environment. Production volume, use, and the number of customers must not exceed that specified in the application. All other conditions and restrictions described in the application and in this notice must be met.

A notice of receipt of the application was not published in advance of approval. Therefore, an opportunity to submit comments is being offered at this time. EPA may modify or revoke the test marketing exemption if comments are received which cast significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury.

The following additional restrictions apply to TME-97-3. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. In addition, the Company shall maintain the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. The applicant must maintain records of the quantity of the TME substance produced and the date of manufacture.
2. The applicant must maintain records of dates of the shipments to

each customer and the quantities supplied in each shipment.

3. The applicant must maintain copies of the bill of lading that accompanies each shipment of the TME substance.

TME-97-3.

Date of Receipt: October 30, 1996.

Close of Review Period: December 20, 1996 (inclusive of a voluntary suspension). The extended comment period will close January 10, 1997.

Applicant: Confidential.

Chemical: (G) Ammonium Benzophenonecarboxylate.

Use: (G) Dispersing Agent.

Production Volume: Confidential.

Number of Customers: Confidential.

Test Marketing Period: Confidential.

Risk Assessment: EPA identified no significant human health or environmental concerns. Therefore, the test market activities will not present an unreasonable risk of injury to health or the environment.

The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information come to its attention which casts significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury to health or the environment.

A record has been established for this notice under docket number OPPT-59357 (including comments and data submitted electronically as described above). A public version of this record, including printed page versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA nonconfidential information center (NCIC), Rm. NEB-607, 401 M St., SW., Washington, DC 20460. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official records for these notices, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

List of Subjects

Environmental protection, Test marketing exemption.