

The following Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

| Company No. | Company Name and Address |
|-------------|--|
| 000769 | SURECO, Inc., 10012 Dale Mabry, Suite 221, Tampa, FL 33618. |
| 005481 | AMVAC Chemical Corp., 4100 East Washington Blvd., Los Angeles, CA 90023. |
| 008660 | Pursell Industries, Inc., P.O. Box 540, Sylacauga, AL 35150. |
| 034704 | Platte Chemical Co., 419 18th Street, P.O. Box 667, Greeley, CO 80632. |

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: March 13, 1997.

Linda A. Travers,

Director, Program Management Support Division, Office of Pesticide Programs.

[FR Doc. 97-7063 Filed 3-25-97; 8:45 am]

BILLING CODE 6560-50-F

[PF-724; FRL-5594-7]

American Cyanamid Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the filing of a pesticide petition proposing the establishment of a tolerance for residues of dimethomorph [(E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]-morpholine] in or on the raw agricultural commodity potatoes and grape commodities. This notice contains a summary of the petition that was prepared by the petitioner, American Cyanamid Company.

DATES: Comments, identified by the docket control number [PF-724], must be received on or before April 25, 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.

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 in ASCII file format. All comments and data in electronic form must be identified by docket control number [PF-724]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as a 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: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-6226; e-mail: welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 7F4816) from American Cyanamid Company, Agricultural Products

Research Division, P.O. Box 400 Princeton, NJ 08543-0400 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 346a, to amend 40 CFR part 180 by establishing tolerances for residues of the fungicide, dimethomorph [(E,Z)4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]-morpholine] in or on the raw agricultural commodity potato at 0.05 parts per million (ppm) and a time-limited tolerance for residues of dimethomorph in or on the raw agricultural commodity grape at 2.0 ppm. The proposed analytical method for determining residues is a High Performance Liquid Chromatography (HPLC) method (FAMS 002-04). A confirmatory method (FAMS 022-03) also is available which provides for analysis by either Gas Chromatography/Nitrogen-Phosphorus Detection or by HPLC/UV Detection. EPA has determined that the 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.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, (Pub. L. 104-170), American Cyanamid included in the petition a summary of the petition and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. The summary represents the views of American Cyanamid; EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA has made minor edits to the summary for the purpose of clarity.

I. Petition Summary Prepared by American Cyanamid Company

A. Residue Chemistry

1. *Plant metabolism.* American Cyanamid believes that the results of the potato metabolism study show only negligible residues in tubers, 0.01-0.02 ppm total radioactive residues (TRR). This is in contrast to the aerial portions of the plant which were found to have up to 23.5 parts per million (ppm) TRR, thus demonstrating that translocation of dimethomorph within the plant was not significant. Almost all of the radioactive residue (97.8%) was extractable from the plant at harvest. In the aerial portion of the plant, approximately 70% of the TRR was identified as dimethomorph. No metabolites were identified that require regulation. There was no concentration of residue in the peel or tuber. The latter point indicates that during processing dimethomorph is not expected to concentrate to a level greater than that of the proposed tolerance for the raw agricultural commodity, potato tubers.

The results of the grape metabolism study showed that the TRR in/on grapes harvested 35 days following the last of four applications (0.8 lb active ingredient/application (ai/A) for 4 consecutive weeks) for a total rate of 3.2 lb ai/A (3x the proposed maximum seasonal rate) was 14.6 ppm. Unmetabolized dimethomorph accounted for 87.3% of the TRR (12.7 ppm). No metabolites were identified that require regulation.

2. *Analytical method.* A reliable method for the determination of dimethomorph residues in potatoes and grapes exists. This method (FAMS 002-04) is appropriate for enforcement purposes. FAMS 002-04 is a HPLC method. A confirmatory method (FAMS 022-03) also is available which provides for analysis by either Gas Chromatography with Nitrogen-Phosphorus Detection or by HPLC with UV Detection.

3. *Magnitude of residues.* The residue data for potato submitted to support this tolerance petition were collected from studies conducted in several European countries; these countries are representative of potato growing regions of the U.S. Dimethomorph residues observed in these field residue studies ranged from <0.01 ppm (the Limit of Quantitation of the method) to 0.04 ppm; however, most residues were <0.01 ppm. These trials were conducted using multiple applications (5-12) with a maximum seasonal rate of up to 2.56 lb ai/A. The proposed U.S. use pattern is five applications at a maximum treatment rate of 0.203 lb ai/A and a

maximum seasonal use rate of 1.015 lb ai/A. Residue levels in domestic potatoes would be expected to be similar or lower (< 0.01 ppm) than that observed in the European trials. Therefore, a tolerance of 0.05 ppm is appropriate.

The residue data for grape submitted to support this tolerance petition were collected from studies conducted in various regions of France; these sites are representative of grape growing regions of Europe. Dimethomorph residues observed in these field residue studies ranged from <0.01 ppm (the Limit of Quantitation of the method) to 1.81 ppm. These trials were conducted using multiple applications (3-11) with a maximum seasonal rate of up to 2.94 lb ai/A. In six studies conducted on the magnitude of residue in grape processed commodities, residues of dimethomorph did not concentrate in grape juice or wine. Therefore, a time-limited tolerance of 2.0 ppm in/on grape commodities is appropriate.

B. Toxicological Profile

American Cyanamid believes that the toxicity of dimethomorph has been studied extensively and there is a complete data base to address the acute and chronic effects, effects on genetic material, the potential for carcinogenicity or teratogenicity, and effects on reproductive performance or growth of offspring.

The toxicological data submitted to support the petition for a tolerance for dimethomorph on potatoes and for a time-limited tolerance on grape include:

1. *Acute toxicity.* i. An acute oral toxicity study in the Sprague-Dawley rat for dimethomorph technical with a LD₅₀ of 4,300 milligrams/kilograms (mg/kg) body weight (bwt) for males and 3,500 mg/kg bwt for females. Based upon EPA toxicity criteria, the acute oral toxicity category for dimethomorph technical is Category III or slightly toxic.

ii. Oral LD₅₀ studies were conducted on the two isomers (E and Z) alone:

a. An acute oral toxicity study in the Wistar rat for the E-isomer with a LD₅₀ greater than 5,000 mg/kg bwt for males and approximately 5,000 mg/kg bwt for females.

b. An acute oral toxicity study in the Wistar rat for the Z-isomer with a LD₅₀ greater than 5,000 mg/kg bwt for both males and females.

iii. An acute dermal toxicity study in the Wistar rat for dimethomorph technical with a dermal LD₅₀ greater than 5,000 mg/kg bwt for both males and females. Based on the EPA toxicity category criteria, the acute dermal toxicity category for dimethomorph is Category IV or relatively non-toxic.

iv. A 4-hour inhalation study in Wistar rats for dimethomorph technical with a LC₅₀ greater than 4.2 mg/L for both males and females. Based on the EPA toxicity category criteria, the acute inhalation toxicity category for dimethomorph technical is Category IV or relatively non-toxic.

2. *Genotoxicity.* i. Salmonella reverse gene mutation assays (2 studies) were negative up to a limit dose of 5,000 µg/plate. Chinese hamster lung cells were negative in V79 cells up to toxic doses in 2 studies.

ii. Two Chinese hamster lung structural chromosomal studies were reportedly positive for chromosomal aberrations at the highest dose tested (HDT) (160 µg/ml/-S9; 170 µg/ml/+S9). Dimethomorph induced only a weak response in increasing chromosome aberrations in this test system. These results were not confirmed in two micronucleus tests under *in vivo* conditions.

iii. Structural Chromosomal Aberration studies were weakly positive, in human lymphocyte cultures, but only in S9 activated cultures treated at the HDT (422 µg/ml) which was strongly cytotoxic. Dimethomorph was negative in the absence of activation at all doses. Furthermore, the positive clastogenic response observed under the *in vitro* conditions was not confirmed in two *in vivo* micronucleus assays.

iv. Micronucleus assay (2 studies) indicated that dimethomorph was negative for inducing micronuclei in bone marrow cells of mice following i.p. administration of doses up to 200 mg/kg or oral doses up to the limit dose of 5,000 mg/kg. Thus, dimethomorph was found to be negative in these studies for causing cytogenic damage *in vivo*.

v. Dimethomorph was negative for inducing unscheduled DNA synthesis, in cultured rat liver cells, at doses up to 250 µg/ml, a weakly cytotoxic level.

vi. Dimethomorph was negative for transformation in Syrian hamster embryo cells treated, in the presence and absence of activation, up to cytotoxic concentrations (265 µg/ml/+S9; 50 µg/ml/-S9).

3. *Reproductive and developmental toxicity.* i. A rat developmental toxicity study with a maternal toxicity Lowest-Observed-Effect Level (LOEL) of 160 mg/kg/day and a maternal toxicity No-Observed-Effect Level (NOEL) of 60 mg/kg/day. The NOEL for developmental toxicity is 60 mg/kg/day. Dimethomorph is not teratogenic in the Sprague-Dawley rat.

ii. A rabbit development toxicity study with maternal toxicity LOEL of 650 mg/kg/day and a NOEL of 300 mg/kg/day. The NOEL for developmental

toxicity is 650 mg/kg/day, the highest dose tested. Dimethomorph is not teratogenic in the New Zealand white rabbit.

iii. A multi-generational rat reproduction study with parental LOEL for systemic toxicity of 80 mg/kg/day and a NOEL of 24 mg/kg/day. The NOEL for fertility and reproductive function was 80 mg/kg/day, the highest dose tested.

4. *Subchronic toxicity.* i. A 90-day dietary study in Sprague-Dawley rats with a NOEL of greater than or equal to 73 mg/kg/day in males and 82 mg/kg/day in females, the highest doses tested.

ii. A 90-day dog dietary study with a NOEL 15 mg/kg/day and a LOEL 43 mg/kg/day.

5. *Chronic toxicity.* i. A 2-year chronic toxicity study in Sprague-Dawley rats with a NOEL 9 mg/kg/day for males and 12 mg/kg/day for females. The LOEL for systemic toxicity is 36 mg/kg/day for males and 58 mg/kg/day for females.

ii. A 1-year chronic toxicity study in dogs with a NOEL of 14.7 mg/kg/day and a LOEL of 44.6 mg/kg/day.

iii. A 2-year oncogenicity study in Sprague-Dawley rats with a NOEL for systemic toxicity of 9 mg/kg/day for males and 11 mg/kg/day for females. The LOEL for systemic toxicity was 34 mg/kg/day for males and 46 mg/kg/day for females. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOEL for oncogenicity is 95 mg/kg/day for males and 132 mg/kg/day for females, the highest dose tested.

iv. A 2-year oncogenicity study in mice with a NOEL for systemic toxicity of 100 mg/kg/day and a LOEL of 1,000 mg/kg/day. There was no evidence of increased incidence of neoplastic lesions in treated animals. The NOEL for oncogenicity is 1,000 mg/kg/day, the highest dose tested.

6. *Animal metabolism.* Results from the livestock and rat metabolism studies show that orally administered dimethomorph was rapidly excreted by the animals. The principal route of elimination is the feces.

7. *Metabolite toxicology.* There were no metabolites identified in potatoes or animal commodities which require regulation.

8. *Endocrine effects.* There is no evidence of effects of dimethomorph on the endocrine system. There were no changes noted in organ weights for the pituitary, thyroid, ovaries or testes. There was no increased incidence of mammary tumors observed. No effects on fertility or reproduction were noted and there was no evidence of related histopathological changes in

reproductive or endocrine system organs.

C. Aggregate Exposure

1. *Dietary (food) exposure.* Dietary exposure should be based solely upon the Theoretical Maximum Residue Concentration (TMRC) from the tolerance of 0.05 ppm dimethomorph in or on potato and the time-limited tolerance of 2.0 ppm dimethomorph in or on grape. The goat metabolism study demonstrates that there is no reasonable expectation of transfer of residues of dimethomorph to meat or milk from potatoes or from grapes. There are no potato or grape feed commodities fed to poultry. Therefore, no consumption data associated with meat, milk, poultry or eggs should be included in the calculation of the TMRC. There are no other established U.S. tolerances for dimethomorph, and there are no registered uses for dimethomorph on food or feed crops in the United States.

2. *Dietary (drinking water) exposure.* There is no available information about dimethomorph exposure via drinking water. However, exposure to dimethomorph from drinking water is not likely to occur as a result of use on potatoes. Dimethomorph dissipated fairly rapidly under field conditions with half lives ranging from 14 to 57 days. Laboratory and field studies demonstrate that dimethomorph is not mobile in soil. No movement below the top 4 inches was observed in the field studies. Laboratory leaching studies result in the classification of dimethomorph as having medium to high adsorption onto soil.

3. *Non-dietary exposure.* There are no other registered uses of dimethomorph in the U.S. Thus, there is no potential for non-dietary exposure.

D. Cumulative Effects

There is no information to indicate that any toxic effects produced by dimethomorph would be cumulative with those of any other chemical. The fungicidal mode of action of dimethomorph is unique; dimethomorph inhibits cell wall formation only in *Oomycete* fungi. The result is lysis of the cell wall which kills growing cells and inhibits spore formation in mature hyphae. This unique mode of action and limited pest spectrum suggest that there is little or no potential for cumulative toxic effects in mammals. In addition, the toxicity studies submitted to support this petition do not indicate that dimethomorph is a particularly toxic compound. No toxic end-points of potential concern were identified.

E. Safety Determination

1. *U.S. population.* The proposed reference dose (RfD) is 0.1 mg/kg bwt/day, based on a NOEL of 10 mg/kg bwt/day from a 2-year dietary toxicity study in rats that demonstrated decreased body weight and liver foci in females. The proposed RfD is also based on an uncertainty factor of 100. For potatoes, the TMRC from this proposed action is estimated at 0.000057 mg/kg bwt/day. This represents an aggregate exposure to the general population of the United States of 0.063 percent of the RfD. The TMRC for the most highly exposed group, children ages 1 to 6 is estimated at 0.000113 mg/kg bwt/day. This represents 0.125 percent of the RfD. Establishment of a tolerance for residues in/on grape commodities is not expected to significantly change the exposure estimate to the most highly exposed group since the commodity which is most extensively imported is wine. Since EPA generally has no concern for exposures below 100 percent of the RfD, EPA should conclude that there is a reasonable certainty that no harm will result from aggregate exposure to dimethomorph residues in or on potato and grape commodities.

2. *Infants and children.* American Cyanamid believes that the results of the studies submitted to support this package provide no evidence that dimethomorph caused reproductive, developmental or fetotoxic effects. No such effects were noted at dose levels which were not maternally toxic. The NOELs observed in the developmental and reproductive studies were 6 to 65 times higher than the NOEL used to establish the proposed RfD (10 mg/kg bw/day). There is no evidence to indicate that children or infants would be more sensitive than adults to toxic effects caused by exposure to dimethomorph.

F. International Issues

No Codex maximum residue levels (MRLs) have been established for dimethomorph to date.

II. Public Record

A record has been established for this notice under docket control number [PF-724] (including comments and data submitted electronically as described below). A public version of the 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 Room 1132 of the

Public Response and 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 an 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.

Dated: March 18, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-7494 Filed 3-25-97; 8:45 am]

BILLING CODE 6560-50-F

[PF-722; FRL-5592-8]

DowElanco; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice is a summary announces the filing of a pesticide petition proposing the establishment of a regulation for residues of cloransulam-methyl in or on soybeans. This notice contains a summary was prepared by the petitioner, DowElanco.

DATES: Comments, identified by the docket number [PF-722], must be received on or before April 25, 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. 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 in ASCII file format. All comments and data in electronic form must be identified by docket control number [PF-722]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below this document.

Information submitted as a 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:

Philip Errico, Product Manager (PM) 25, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M. St., SW., Washington, D.C. Office location, telephone number and e-mail address: Rm. 237, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 703-305-6027. e-mail: errico.phillip@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP 5F4560 from DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268-1054 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide N-(2-carboxymethyl-6-chlorophenyl)-5-ethoxy-7-fluoro[1,2,4] triazolo[1,5c]pyrimidine-2-sulfonamide, (cloransulam-methyl) in or on the raw agricultural commodity soybeans at 0.02 ppm, soybean forage at 0.1 part per million (ppm) and soybean hay at 0.2 ppm. The proposed analytical method is gas chromatography coupled with a mass selective detector (GC-MSD).

EPA has determined that the 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.

Availability of the analytical method: The proposal analytical method of enforcement which measures residues of cloransulam-methyl in soybeans, and soybean forage and hay discussed below has not been validated by the Agency. Public versions of the analytical method can be obtained from the Pesticide Docket, U.S. Environmental Protection Agency, Office of Pesticide Programs, 401 M. St., SW., Washington, D.C. 20460, (703) 305-5805.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, DowElanco included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of DowElanco; EPA, as mentioned above, is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

1. *Plant metabolism.* Nature of residue studies demonstrated that residues of cloransulam-methyl and its metabolites would not be expected to accumulate to significant levels in soybeans treated either pre-plant or post-emergence, and that it was appropriate to base the magnitude of total terminal residues and proposed tolerances only on residues of the parent compound, cloransulam-methyl. A rotational crop study showed no significant level of cloransulam-methyl or any structurally-related metabolite in any crop, or crop fractions, grown in rotation 120 days after soil treatment.

2. *Analytical method.* Residue analytical methods were validated based upon gas chromatography coupled with a mass selective detector (GC-MSD). The limit of detection of the methods is 0.005 ppm and a level of quantitation is 0.01 ppm.

3. *Magnitude of residues.* No detectable residues of cloransulam-methyl resulted in soybeans from either preplant incorporated or post emergence applications, in soybean forage or hay