

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

Com- pany No.	Company Name and Address
062719	DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268.

### 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: October 23, 1996.

Oscar Morales,

*Acting Director, Program Management and Support Division, Office of Pesticide Programs.*

[FR Doc. 96-28419 Filed 11-5-96; 8:45 am]

BILLING CODE 6560-50-F

[PF-670; FRL-5571-4]

### Pesticide Tolerance Petition; Notice of 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 sulfentrazone in or on soybeans.

**DATES:** Comments, identified by the docket number [PF-670], must be received on or before, December 6, 1996.

**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 in 5.1 file format or ASCII file format. All comments and data in electronic form

must be identified by the docket number [PF-670]. 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 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 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Joanne Miller (PM23) Rm., 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. 703-305-6224, e-mail: miller.joanne@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition (PP 4F4407) from FMC Corporation, 1735 Market Street, Philadelphia, PA 19103, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide sulfentrazone (*N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]-methanesulfonamide in or on the raw agricultural commodity soybeans at 0.05 ppm and rotational crop tolerances in cereal grains from 0.1 to 0.5 ppm. The proposed analytical method is gas chromatography with electron detection.

Pursuant to section 408(d)(2)(A)(I) of the FFDCA, as amended, FMC Corporation has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by FMC Corporation 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. FMC Petition Summary

1. *Sulfentrazone uses.* Sulfentrazone is the first herbicide in a new aryl triazolinone chemical class. Weeds found resistant to other herbicides are not cross resistant to sulfentrazone. The unique mode of action of sulfentrazone provides economic control for a wide spectrum of grass and broadleaf weeds, with exceptional strength on morningglory and nutsedge species.

Sulfentrazone will be used on soybeans to control Broadleaves (including cocklebur, lambsquarter, morningglory, pigweed and velvetleaf); Grasses (including barnyardgrass, crabgrasses, foxtail, goose grass, johnsongrass and panicum); Sedges (including purple and yellow nutsedge and annual sedge).

Sulfentrazone will be applied to the soil preemergent to the soybean crop. The product controls emerging weeds and also has postemergent burn-down activity to small exposed weeds. A single application will be made using standard low pressure ground herbicide boom sprayer equipped with suitable nozzles and screens. Application rates for sulfentrazone alone range from 0.25 to 0.375 lb active ingredient per acre dependent on soil texture, organic matter, and geography. Combinations with selected products may further reduce the application rate to 0.15 lb active ingredient per acre. Applications can be made up to 30 days before crop emergence in either conventional or no-till situations. Authority 75DF or 4F may be applied early preplant, preplant incorporated or preemergence.

2. *Sulfentrazone safety.* FMC has submitted over 40 separate toxicology studies in support of tolerances for sulfentrazone. According to FMC, sulfentrazone is not a carcinogen or a mutagen and has low oral and dermal toxicity to mammals. Although laboratory experiments at the higher rates tested have shown some developmental and reproductive effects, risk assessment calculations indicate the margins of safety for agricultural

workers and the population in general far exceed the EPA required level of 100.

The following mammalian toxicity studies have been conducted to support the tolerance of sulfentrazone:

A rat acute oral study with an LD<sub>50</sub> of 3,034 mg/kg (male) and 2,689 mg/kg (female).

A rabbit acute dermal LD<sub>50</sub> of >2,000 mg/kg.

A rat acute inhalation LC<sub>50</sub> of >4.13 mg/L.

A primary eye irritation study in the rabbit which showed mild irritation.

A primary dermal irritation study which showed no irritation.

A primary dermal sensitization study which showed no sensitization.

An acute neurotoxicity study with a No-Observed Effect Level (NOEL) of 250 mg/kg and no neuropathological findings at any dose.

A 28-day feeding study in the rat with a NOEL of 1,000 ppm based on hematology effects.

A 90-day feeding study in the rat with a NOEL of 1,000 ppm based on hematology findings.

A 28-day feeding study in the mouse with a NOEL of 800 ppm based on effects on hematology parameters.

A 90-day feeding study in the mouse with a NOEL of 300 ppm based on hematology parameters.

A 90-day subchronic neurotoxicity study in the rat with a neurotoxicity and overall NOEL of 500 ppm; no histopathological effects on the peripheral or central nervous system were observed.

A 24-month chronic feeding/ oncogenicity study in the rat with an overall NOEL of 600 ppm in females and 1,000 ppm in males based on hematology effects and reduced body weights. There was no evidence of an oncogenic response.

A 4 week range-finding study in dogs with a NOEL of 900 ppm based on hematology effects.

A 90-day feeding study in dogs with a NOEL of 300 ppm based on liver histopathology.

A 12-month feeding study in dogs with a NOEL of 800 ppm based on hematology effects and microscopic liver changes.

A mouse oncogenicity study with a NOEL of 600 ppm based on decreased hemoglobin. There was no evidence of oncogenicity.

An oral teratology study in the rat with a maternal NOEL of 25 mg/kg/day based on body weight effects and a fetal NOEL of 10 mg/kg/day based on reduced body weights and delayed skeletal effects at higher doses.

A supplemental teratology study conducted to test for cardiac effects at

the request of the EPA did not reveal any significant effects on fetal cardiac development.

A dermal teratology study in the rat with a maternal NOEL of 250 mg/kg/day and a fetal NOEL of 100 mg/kg/day based on an increase in fetal and litter incidence of skeletal effects.

An oral teratology study in the rabbit with a maternal and fetal NOEL of 100 mg/kg/day based on decreased body weights for the does and fetal effects at higher doses.

A two generation reproduction study in the rat with a NOEL for systemic and reproductive/developmental parameters of 200 ppm. Male fertility in the F1 generation was reduced at higher doses; litter size, pup survival and pup bodyweight for both generations were also effected at higher doses.

A supplemental rat reproduction study with a NOEL for reproductive parameters of 200 ppm.

Ames Assay: Negative; Mouse lymphoma: Negative with activation, equivocal without activation.

Mouse Micronucleus Assay: Negative.

3. *Threshold effects—chronic effects.* Based on the available chronic toxicity data, FMC believes the Reference Dose (RfD) for sulfentrazone should be 0.05 mg/kg/day. The RfD for sulfentrazone is based on a multigeneration reproduction study in rats with a threshold No-observed Effect Level (NOEL) of 14 mg/kg/day and an uncertainty factor of 100, with an additional modifying factor of 3 to account for the nature of the effects.

*Acute toxicity.* EPA recently proposed a tiered approach to estimate acute dietary exposure. The methods proposed by the EPA were reviewed and supported by the FIFRA scientific advisory panel (SAP, 1995). EPA's Tier 1 method is based on the assumption that residue concentrations do not vary. The analysis assumes that all residues have the same magnitude, typically the highest field trial residue or tolerance value. This value is assumed for all points along the consumption distribution, resulting in a distribution of dietary exposure.

For the acute analysis for sulfentrazone, a Tier 1 analysis was conducted for the overall U.S. population, infants, children 1 to 6 years of age, females 13 years and older, and males 13 years and older. Using the NOEL of 10 mg/kg/day derived from the oral teratology study in rats, the following margins of exposure were calculated (Margins of exposure of 100 or more are considered satisfactory):

Population Group	Margin of Exposure
U.S. Population .....	2,180
Infants .....	760
Children 1 to 6 .....	2,052
Females 13 years and older .....	3,640
Males 13 years and older .....	3,219

4. *Non-threshold effects—Carcinogenicity.* Using the Guidelines for Carcinogen Risk Assessment, FMC believes sulfentrazone to be in Group E for carcinogenicity — no evidence of carcinogenicity — based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month feeding study in mice and a 2-year feeding study in rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment should not be necessary.

5. *Aggregate exposure.* For purposes of assessing the potential dietary exposure, FMC has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from the tolerances for sulfentrazone on soybeans at 0.05 ppm and rotational crop tolerances in cereal grains from 0.1 to 0.5 ppm. (The TMRC is a worse case estimate of dietary exposure since it is assumed that 100 percent of all crops for which tolerances are established are treated and that pesticide residues are present at the tolerance levels.) Dietary exposure to residues of sulfentrazone in or on food will be limited to residues on soybeans and cereal grains. Forage and straw from cereal grains are fed to animals; thus exposure of humans to residues might result if such residues carry through to meat, milk, poultry or eggs. However, FMC believes that there is no reasonable expectation that measurable residues of sulfentrazone will occur in meat, milk, poultry or eggs from this use. There are no other established U.S. tolerances for sulfentrazone, and there are no registered uses for sulfentrazone on food or feed crops in the U.S. In conducting this exposure assessment, very conservative assumptions—100% of soybeans and cereal grains will contain sulfentrazone residues and those residues would be at the level of the tolerances have been used which results in an overestimate of human exposure.

Other potential sources of general population exposure to residues of pesticides are residues in drinking water and exposure from non-occupational sources. While the majority of field studies with sulfentrazone indicate that movement into groundwater will not occur, a single study in very vulnerable

soil has shown that a small percentage of material could reach shallow groundwater under extreme conditions. Based on this worst case situation, the maximum exposure to residues of sulfentrazone in drinking water resulting from product use at extremely vulnerable sites would be less than 50 ppb. There is no established Maximum Contaminant Level (MCL) for residues of sulfentrazone in drinking water under the Safe Drinking Water Act. However, a reasonable estimate of the sulfentrazone MCL using the appropriate methodology would be 350 ppb. The dietary contribution from these residues is included in the safety determination for both the U.S. population and infants (shown below).

Non-occupational exposure for sulfentrazone has not been estimated since the current registration for sulfentrazone is limited to commercial soybean production. The potential for nonoccupational exposure to the general population is, thus, insignificant.

EPA consideration of a common mechanism of toxicity is not appropriate at this time since EPA does not have information to indicate that toxic effects produced by sulfentrazone would be cumulative with those of any other chemical compounds.

6. *Determination of safety for U.S. population—Reference Dose.* Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, the aggregate exposure to sulfentrazone will utilize 4.5 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the Reference Dose (RfD). Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, FMC, concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sulfentrazone, including all anticipated dietary exposure and all other non-occupational exposures.

7. *Determination of safety for infants and children.* Developmental toxicity was observed in developmental toxicity studies using rats and rabbits. The NOELs for developmental effect were established at 10 mg/kg/day in the rat study and 100 mg/kg/day in the rabbit study. The developmental effect observed in these studies is believed to be a secondary effect resulting from decreased oxygen transport to the fetus.

*Reference Dose.* Using the conservative exposure assumptions described above, FMC has concluded that the percent of the RfD utilized by aggregate exposure to residues of

sulfentrazone ranges from 4.3 percent for children 1 to 6 years old, up to 13.5 percent for non-nursing infants. EPA generally has no concern for exposure below 100 percent of the Reference Dose. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, FMC concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of sulfentrazone, including all anticipated dietary exposure and all other non-occupational exposures.

8. *Estrogenic effects.* No specific tests have been conducted with sulfentrazone to determine whether the pesticide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

9. *Chemical residue.* The qualitative nature of the residues in plants and animals is adequately understood for the purposes of registration. Residues of sulfentrazone do not concentrate in the processed commodities. There are no Codex maximum residue levels established for residues of sulfentrazone on soybeans. FMC has submitted a practical analytical method for detecting and measuring levels of sulfentrazone in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. EPA will information on this method to the Food and Drug Administration. The method is available to anyone who is interested in pesticide residue enforcement from the Field operations Division, Office of Pesticide Programs.

Forty separate residue trials have been conducted with sulfentrazone on soybeans. Analysis of these trials shows that the maximum total combined residue for sulfentrazone and its major metabolite will be below 0.05 ppm. Virtually no detectable residues of sulfentrazone were found in soybean meal, soapstock and oil treated at an exaggerated rate. Because of the very low level of these residues, no food additive tolerances are being proposed for these processed commodities.

Tolerances have been requested for residues of sulfentrazone and its major metabolite on soybean seed at the low level of 0.05 ppm. In addition, tolerances for residues of sulfentrazone and its major metabolites have been requested to cover inadvertent residues found in rotational crops of the cereal grain crop grouping (excluding sweet corn). For these rotational crop tolerances, the requested levels are as follows: 0.1 ppm in or on grain; 0.2 ppm in or on hay; 0.6 ppm in or on straw;

0.2 ppm in or on forage; 0.1 ppm in or on stover and 0.2 ppm in or on bran.

The proposed tolerance levels are adequate to cover residues likely to be present from the proposed use of sulfentrazone. Therefore, no special processing to reduce the residues will be necessary. There is no need for tolerances in animal meat, milk, poultry or eggs since there is no reasonable expectation of residues in these materials. This is based on the results of goat and poultry metabolism studies, as well as the soybean metabolism and crop rotation studies. Calculated transfer factors are extremely low and maximum expected residues in meat, milk, poultry and eggs would be in the part per trillion range. Since the level of detection of the available methods would be higher than the maximum expected level in each of the matrixes, no detectable residues would be found.

10. *Environmental fate.* Laboratory studies indicate that sulfentrazone has the potential to persist in soil and be mobile. However, the results of field dissipation studies run in the three largest soybean producing states (Iowa, Illinois, Arkansas) indicate that downward movement of sulfentrazone is limited, with no quantifiable residues being found below 18. In a single field study conducted under highly vulnerable conditions (very high sand content and low organic matter), small amounts of sulfentrazone were detected in shallow groundwater when sulfentrazone was applied at exaggerated rates. The site for this study received excessive record rainfall early during the study which contributed to the movement observed.

Sulfentrazone has been found to be stable to chemical hydrolysis in the pH range of environmental concern. However, the compound is subject to rapid extensive degradation in water in the presence of natural sunlight. Under these conditions, sulfentrazone residues rapidly break down, with more than 50% of the residue disappearing in 1 hour at environmental pH. Under aerobic conditions in soil, the major metabolic pathway for sulfentrazone is oxidation of the methyl group on the triazolinone ring. A minor metabolic pathway under aerobic conditions is the cleavage of the sulfonamide group on sulfentrazone. Sulfentrazone residues do not bioaccumulate in fish.

## 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-670]. All written comments filed in response to this

petition will be available, in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice of filing under docket number [PF-670] 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 a.m. to 4:30 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 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 notice of filing, 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 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: October 21, 1996.

Peter Caulkins,

*Acting Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 96-28422 Filed 11-5-96; 8:45 am]

BILLING CODE 6560-50-F

[FRL-5646-9]

#### **Clean Water Act Class II: Proposed Administrative Penalty Assessment and Opportunity To Comment Regarding Corning Municipal Utilities, Corning, IA**

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

**ACTION:** Notice of proposed administrative penalty assessment and opportunity to comment regarding Corning Municipal Utilities, Corning, Iowa.

**SUMMARY:** EPA is providing notice of opportunity to comment on the proposed assessment.

Under 33 U.S.C. 1319(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue such orders after filing a Complaint commencing either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessment pursuant to 33 U.S.C. 1319(g)(4)(A).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 CFR part 22. The procedures by which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the procedures by which a respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty (30) days after issuance of this public notice.

On September 26, 1996, EPA commenced the following Class II proceeding for the assessment of penalties by filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, (913) 551-7630, the following Complaint:

In the Matter of Corning Municipal Utilities, CWA Docket No. VII-96-W-0004.

The Complaint proposes a penalty of Fourteen Thousand (\$14,000) dollars for the discharge of 127 gallons of No. 2 diesel fuel into or upon the East Nodaway River and for failure to prepare an SPCC Plan in writing and in accordance with 40 CFR 112.7, in violation of Section 311(b)(3) and 311(j) of the Clean Water Act.

#### **FOR FURTHER INFORMATION CONTACT:**

Persons wishing to receive a copy of EPA's Consolidated Rules, review the Complaint or other documents filed in this proceeding, comment upon the proposed penalty assessment, or otherwise participate in the proceeding should contact the Regional Hearing Clerk identified above.

The administrative record for the proceeding is located in the EPA Regional Office at the address stated above, and the file will be open for public inspection during normal business hours. All information

submitted by Corning Municipal Utilities is available as part of the administrative record, subject to provisions of law restricting public disclosure of confidential information.

In order to provide opportunity for public comment, EPA will issue no final order assessing a penalty in this proceeding prior to thirty (30) days from the date of this notice.

Dated: October 23, 1996.

William Rice,

*Acting Regional Administrator.*

[FR Doc. 96-28425 Filed 11-5-96; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5647-1]

#### **Clean Water Act Class II: Proposed Administrative Penalty Reinhold Development, Inc., St. Louis, MO**

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

**ACTION:** Notice of proposed administrative penalty assessment and opportunity to comment regarding Reinhold Development, Inc., St. Louis, Missouri.

**SUMMARY:** EPA is providing notice of opportunity to comment on the proposed assessment.

Under 33 U.S.C. 1113(g), EPA is authorized to issue orders assessing civil penalties for various violations of the Act. EPA may issue such orders after filing a Complaint commencing either a Class I or Class II penalty proceeding. EPA provides public notice of the proposed assessment pursuant to 33 U.S.C. 1319(g)(4)(A).

Class II proceedings are conducted under EPA's Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 CFR part 22. The procedures by which the public may submit written comment on a proposed Class II order or participate in a Class II proceeding, and the procedures by which a respondent may request a hearing, are set forth in the Consolidated Rules. The deadline for submitting public comment on a proposed Class II order is thirty (30) days after issuance of this notice.

On September 30, 1996, EPA commenced the following Class II proceeding for the assessment of penalties by filing with the Regional Hearing Clerk, U.S. Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, (913) 551-7630, the following Complaint: