ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300853; FRL–6078–4]

RIN 2070–AB78

Sulfosulfuron; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of sulfosulfuron: 1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron in or on wheat grain at 0.02 parts per million (ppm), wheat straw at 0.1 ppm, wheat hay at 0.3 ppm, wheat forage at 4.0 ppm, milk at 0.006 ppm, fat and meat of cattle, goat, swine, horse, and sheep at 0.005 ppm, and meat by-products of cattle, goat, swine, horse, and sheep at 0.05 ppm. Monsanto Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 19, 1999. Objections and requests for hearings must be received by EPA on or before July 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300853], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300853], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300853]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Tompkins, 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. 237, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, Tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 23, 1998 (63 FR 71126) (FRL–6047–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) announcing the filing of a pesticide petition (PP) 7F4840 for tolerance by Monsanto Company. This notice included a summary of the petition prepared by the Monsanto Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the herbicide sulfosulfuron in or on wheat grain at 0.02 part per million (ppm), wheat straw at 0.1 ppm, wheat hay at 0.3 ppm, wheat forage at 4.0 ppm, milk at 0.006 ppm, fat and meat of cattle, goat, swine, horse, and sheep at 0.005 ppm, and meat by-products of cattle, goat, swine, horse, and sheep at 0.05 ppm.

I. Background and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of Sulfosulfuron and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of 1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron on wheat grain at 0.02 parts per million (ppm), wheat straw at 0.1 ppm, wheat hay at 0.3 ppm, wheat forage at 4.0 ppm, milk at 0.006 ppm, fat and meat of cattle, goat, swine, horse, and sheep at 0.005 ppm, and meat by-products of cattle, goat, swine, horse, and sheep at 0.05 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by sulfosulfuron are discussed in this unit.

1. Several acute toxicity studies place technical sulfosulfuron in Toxicity Categories III or IV. Technical sulfosulfuron is not a dermal sensitizer.

2. In a rat subchronic oral toxicity study, sulfosulfuron was administered in the diet for 13 weeks at a dose levels of 0, 20, 200, 2,000, 6,000, or 20,000 ppm (equivalent to average daily intake of 0, 1.2, 12.1, 123.2, 370.3 or 1,277.5 miligrams/kilograms/day (mg/kg/day) for males and 0, 1.5, 14.6, 144.3, 447.5 or 1,489.1 mg/kg/day for females). The systemic toxicity lowest observed adverse effect level (LOAEL) is 20,000 ppm (1,277.5 mg/kg/day), based on decreased body weight/weight gain in males, possible decreased weight gain in pregnant females during gestation days 14–21, and possible renal lesions related to formulation of calculi. The no observed adverse effect level (NOAEL) is 6,000 ppm (370.3 mg/kg/day).

3. In a dog subchronic oral toxicity study, sulfosulfuron was administered by gelatin capsule at dose levels of 0, 30, 100, 300, or 1,000 mg/kg/day for 90 days. The systemic toxicity LOAEL is 300 mg/kg/day, based on lesions in the urinary bladder in females occurring subsequent to urinary crystal formation and on abnormal urinary crystals in males and females. The NOAEL for systemic toxicity is 100 mg/kg/day.

4. In a 28–day rat dermal study, sulfosulfuron was applied dermally at dose levels of 0,100, 300 or 1,000 mg/kg/day for 5 days/week for 4 weeks. The NOAEL is ≧ 1,000 mg/kg/day the highest dose tested for males and females.

5. In a 1–year dog chronic feeding study, sulfosulfuron was administered by gelatin capsule at dose levels of 0, 5, 20, 100 or 500 mg/kg/day, 5 days/week, for 1 year. The LOAEL is 500 mg/kg/day based on the presence of abnormal urinary crystals and bladder pathology secondary to formation of urinary tract calculi in males. The NOAEL is 100 mg/kg/day.

6. In a rat chronic feeding/carcinogenicity study, sulfosulfuron was administered in the diet at dose levels of 0, 50, 500, 5,000 and 20,000 ppm (females only) for 22 months. Surviving males at 20,000 ppm were sacrificed on day 259 due to excessive mortality. The average daily intake of test material was 0, 2.4, 24.4 or 244.2 mg/kg/day(males up to 5,000 ppm); 1,178.3 mg/kg/day, males at 20,000 ppm until day 259) and 3.1, 30.4, 314.1 or 1,296.5 mg/kg/day for females. The LOAEL is 5,000 ppm (244.2 mg/kg/day), based on increased incidence of urinary tract gross/microscopic lesions, mineralization in several tissues (males), abnormal urine crystals and possibly decreased albumin (males, termination). The NOAEL is 500 ppm (24.4 mg/kg/day) Transitional cell papilloma and carcinoma of the urinary bladder occurred at 1,296.5 mg/kg/day (5,000 ppm) in females. These tumors were determined to be treatment related.

7. In a mouse carcinogenicity study, sulfosulfuron was administered in the diet at dose levels of 0, 30, 700, 3,000, or 7,000 ppm (0, 4.0, 93.4, 393.6 or 943.5 mg/kg/day to males or 0, 6.5 153.0 634.9 or 1,388.2 mg/kg/day to females) for 18 months. The LOAEL is 3,000 ppm (393.6 mg/kg/day), based on gross and microscopic effects related to urinary calculus formation in the urinary bladder of males. The NOAEL is 700 ppm (93.4 mg/kg/day) Benign mesenchymal tumors of the urinary bladder occurred in males at 943.5 mg/kg/day (7,000 ppm). These tumors also occurred in one male at 393.6 mg/kg/day (3,000 ppm), one control female and one female at 1,388.2 mg/kg/day (7,000 ppm). Incidences of renal tubular adenoma were observed in one male and one female at 943.5 and 1,388.2 mg/kg/day or 7,000 ppm. The mesenchymal tumors and adenoma in females were determined to be treatment related.

8. In a 2–generation rat reproduction study, sulfosulfuron was administered in the diet at dose levels of 0, 50, 500, 5,000 or 20,000 ppm during premating (equivalent to average daily intake for P adults of 0, 3.1, 31.6, 312.1 or 1,312.8 mg/kg/day, males and 0, 3.6, 36.2. 363.2 or 1,454.1 mg/kg/day, females; for F1a adults, 0, 3.1, 31.1, 315.8, 1,378.8 mg/kg/day, males and 0, 3.7, 37.7, 377.8 or 1,598.0 mg/kg/day, females). The reproductive toxicity NOAEL is ≧ 20,000 ppm (1,312.8 mg/kg/day) and the LOAEL is > 20,000 ppm. The parental systemic toxicity LOAEL is 20,000 ppm based on decreased parental body weight and/or weight gain during premating, gestation and lactation, mortality (males) and increased incidence of urinary tract pathology related calculus formation. The parental systemic NOAEL is 5,000 ppm (312.1 mg/kg/day). The offspring toxicity LOAEL is 20,000 ppm (1,312.8 mg/kg/day) based on decreased body weight gain in postweaning adolescent rats, and the offspring NOAEL is 5,000 ppm (312.1 mg/kg/day).

9. In a rat developmental study, sulfosulfuron was administered by gavage at dose levels of 0, 100, 300, and 1000 mg/kg/day to females from day 6 through 15 of gestation. The NOAELs for maternal and developmental toxicity were greater than 1,000 mg/kg/day, the highest dose tested.

10. In a rabbit developmental study, sulfosulfuron was administered by gavage at dose levels of 0, 50, 250, or 1,000 mg/kg/day from day 7 through 19 of gestation. The NOAEL for maternal toxicity is greater than 1,000 mg/kg/day the highest dose tested. No LOAEL for developmental toxicity was observed in this study.

11. In an acute rat oral neurotoxicity screening study, sulfosulfuron was administered by gavage at dose levels of 0, 125, 500, or 2,000 mg/kg/day. No treatment-related effects on clinical signs, body weight, food consumption, functional observational battery parameters, motor activity, gross pathology or neuropathology were observed. The NOAEL is ≧ 2,000 mg/kg/day. The LOAEL > 2,000 mg/kg/day.

12. In a rat subchronic neurotoxicity study, sulfosulfuron was administered in the diet at dose levels of 0, 200, 2,000, 20,000 ppm (corresponding to average daily doses of 0, 12, 122, or 1,211 mg/kg/day in males and 0, 14, 141, or 1,467 mg/kg/day in females). The NOAEL is 20,000 ppm (1,211 mg/kg/day), based on marginal reductions in body weight/weight gain of males. The LOAEL is > 20,000 ppm (> 1,211 mg/kg/day).

13. Mutagenicity data included a gene mutation bacterial reverse gene mutation with Salmonella (negative for inducing reverse gene mutation); an *in vitro* mammalian forward gene mutation with Chinese hamster ovary cells (negative for inducing forward gene mutations at the HGPRT locus in Chinese hamster ovary (CHO) with and without S9 activation); *in vitro* chromosome aberration study on human lymphocytes (did not induce structural chromosome damage); and an *in vivo* structural chromosome aberration micronucleus test (negative).

14. Based on the results of the rat metabolism study, more than 90% of the administered radioactivity was excreted by 72–hours post-dosing. Between 77% to 87% was excreted in the urine in all low dose groups. Feces was the major route of elimination at the high dose. In all dose groups minimal radioactivity was retained in the tissue. Metabolism of sulfosulfuron in all groups was minimal and most was excreted unmetabolized.

B. Toxicological Endpoints

1. *Acute toxicity.* A dose and endpoint were not selected for the acute dietary risk assessment because there were no effects attributable to a single dose (exposure) observed in oral toxicity studies including developmental toxicity studies in the rat and rabbit (up to 1,000 mg/kg/day) and an acute neurotoxicity study in rat (up to 2,000 mg/kg). The acute oral, dermal and inhalation toxicity of sulfosulfuron is very low.

2. *Short- and intermediate-term toxicity.* No short- or intermediate-term dermal or inhalation endpoints were

identified. No dermal or systemic toxicity was seen following dermal applications in the 28–day dermal toxicity study with rats up to 1,000 mg/kg/day.

Based on the low acute inhalation toxicity (Toxicity Category IV, no mortality at 3.0 mg/liter (l), the formulation of the product as wettable granules and the low application rates from the proposed use patterns, there is minimal concern for potential inhalation exposure and risk.

3. *Chronic toxicity*. EPA has established the RfD for sulfosulfuron at 0.24 mg/kg/day. This Reference Dose (RfD) is based on the rat chronic toxicity/carcinogenicity study NOAEL of 24.0 mg/kg/day and an uncertainty factor of 100.

4. *Carcinogenicity*. In accordance with the Agency's Proposed Guidelines for Carcinogenic Risk Assessment (April 10, 1996), the HED Cancer Assessment Review Committee (CARC) classified sulfosulfuron as a likely human carcinogen. The weight-of-evidence for this classification are as follows: (i) occurrence of rare transitional cell papilloma and carcinoma of the urinary bladder in female rats; (ii) occurrence of rare benign mesenchymal tumors of the urinary bladder in male as well as one renal adenoma in both male and female mice; and (iii) the relevancy of the observed tumors to human exposure. The Committee recommended that a linear low-dose approach (Q_1*) for human risk characterization and extrapolation of risk should be based on the incidence of benign mesenchymal bladder tumors in male mice. The unit risk, Q_1* (mg/kg/day), of sulfosulfuron based upon male mouse urinary bladder mesenchymal tumor rates is 1.03×10^{-3} $^{(mg/kg/day)-1}$ in human equivalents.

C. Exposures and Risks

1. *From food and feed uses*. No tolerances have been established for sulfosulfuron. Risk assessments were conducted by EPA to assess exposures from sulfosulfuron as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. An acute risk from the proposed use is not expected because no effect attributed to a single dose (exposure) were observed in oral toxicology studies including developmental toxicity in the rat and the rabbit and an acute neurotoxicity study in the rat. The Agency concludes with reasonable certainly that sulfosulfusulfuron does not elicit an acute toxicological response.

ii. *Chronic exposure and risk*. A chronic dietary exposure analysis was performed using the RfD of 0.24 mg/kg/day based on a chronic toxicity NOAEL of 24.0 mg/kg/day and an uncertainly factor of 100, assuming tolerance level residues and 100 % crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 28 subgroups. The TMRC for the all population subgroups represent <1% of the RfD. This is a highly conservative risk estimate since no refinements for percent crop treated or anticipated residues were made.

iii. *Carcinogenicity exposure and risk*. A cancer exposure analysis was performed (DEEM) software, USDA 1989–91 Nationwide Continuing Surveys for Food Intake by Individuals (CSFII) using tolerance level residues and 100% crop treated information to estimate the lifetime cancer risk for the general population. The lifetime risk was 8.45×10^{-8} for a 70–year exposure. The lifetime risk was 1.05×10^{-7} for infants, 2.55×10^{-7} for childern (1–6) and 1.47×10^{-7} for childern (7–12). The Agency considers risks in the range of 1×10^{-6} as negligible risk. The cancer dietary risk associated with sulfosulfuron is below the Agency's level of concern.

2. *From drinking water*. Tier I estimated environmental concentrations (EEC) were calculated for both surface water ((Generic expected environmental concentration) GENEEC model) and ground water ((Screening Concentration in GROund water) SCI-GROW). Tier I models represent the most conservative estimates of potential residues in drinking water. Drinking water levels of comparison (DWLOCs) for acute and chronic dietary risk from drinking water were calculated for both surface and ground water. Estimated environmental concentrations (EECs) for surface and ground water were 1.73 parts per billion (ppb) and 0.295 ppb, respectively.

A DWLOC is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxic endpoint, with drinking water consumption, and body weights. Different populations will have different DWLOCs. OPP uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

i. *Acute exposure and risk*. An acute risk from the proposed use is not expected because no effect attributed to a single dose (exposure) were observed in oral toxicology studies including developmental toxicity in the rat and the rabbit and an acute neurotoxicity study in the rat.

ii. *Chronic exposure and risk*. The DWLOC s calculated for adults and children were 8,400 ppb and 2,400 ppb, respectively. These are higher than the EEC s of 1.73 ppb for surface water and 0.295 ppb for ground water.

iii. For cancer exposure to sulfosulfuron, the adult DWLOC is 27 ppb, which is above the EECs of 1.73 ppb for surface water and 0.0295 ppb for ground water.

3. *From non-dietary exposure*. Based on the proposed use of sulfosulfuron on turf at playgrounds, parks, and residential areas by professional applicators, potential for residential exposure exists, from post-application scenarios.

i. *Acute exposure and risk*. An acute risk from the proposed use is not expected because no effects attributed to a single dose (exposure) were observed in oral toxicology studies including developmental toxicity in the rat and the rabbit and an acute neurotoxicity study in the rat.

ii. *Chronic exposure and risk*. A chronic exposure is not expected for use of sulfosulfuron on agricultural, and non-agricultural areas, because exposure does not continuously (daily) occur more than 180 days.

iii. *Short- and intermediate-term exposure and risk*. No short-term or intermediate term dermal or inhalation endpoints were identified. The Agency concludes that exposures form residential uses of sulfosulfuron are not expected to pose undue risk.

iv. *Cancer exposure and risk*. Post-application exposures resulting from the proposed application of sulfosulfuron to recreational areas, parks, and residential areas (lawns) are not expected to pose an undue cancer risk.

A typical cancer risk for a residential adult was calculated for a Tc = 1,000 cm^2/hr (high activity for 1 hr.) and for a Tc = 500 cm^2/hr (low activity for 1 hr.). An average is usually used for cancer assessments. This assessment is based on conservative assumptions (due to the assessment using 50 years of exposure, and utilizing an estimated 20% (default) of dislodgeable foliar residues (DFR) from the turf; which is

derived from the maximum application rate). An average of 14 days of DFRs was used for this cancer assessment; this would be considered a 10% decrease each day (from dilution by rain, and mowing of the grass) of the 20% residue for at least 14 days, and then taking the mean value of this 14 day exposure. The Life time Average Daily Dose (LADD) = 6.0×10^{-5} mg/kg/day for a Tc = 1,000 cm^2/hr (high activity for 1 hr.) and for a Tc = 500 cm^2/hr (low activity for 1 hr.) is equal to 3.0×10^{-5} mg/kg/day. The cancer risks are 6.0×10^{-8} (for Tc =1,000 cm^2/hr, high activity) and 3.0×10^{-8} (for Tc = 500 cm^2/hr (low activity for 1 hr.)). The highest residential calculated level of cancer risk on day zero for a Tc =1,000 cm^2/hr (high activity for 1 hr.) is equal to 1.2×10^{-7}, and for a Tc = 500 cm^2/hr (low activity for 1 hr.) is equal to 6.0×10^{8}. This risk is considered minimal.

The cancer risk assessment for dermal post-application exposure for toddlers is based on conservative assumptions (due to the assessment using 12 years of exposure at maximum rate, for 14 days a year without a 10 % dissipation each day after day zero, and a high transfer coefficient (Tc); default for toddlers = 8,700 cm^2/hr (high activity for 2 hrs, Tier I.). It also utilizes dislodgeable foliar residues (DFR) derived from the maximum application rate and an estimated 20 % (upper percentile, default) of this residue remaining on the turf). The calculated level of cancer risk is 1.0×10^{6}. This is considered as a worst case scenario for toddlers, because the toddler default Tc = 8,700 cm^22/hr (high activity for 2 hrs, Tier I.), and an average of exposure over time is usually used for cancer assessments (which would be considered much less due to a 10% decrease each day, from dilution by rain and mowing of the grass, of the 20% residue for at least 14 days, and then taking the mean value of this 14 day exposure). This risk is considered minimal.

Although it is likely that toddlers also would be exposed to sulfosulfuron from incidental ingestion of grass, soil, or hand-to-mouth transfer, no risk assessment was performed for these scenarios because no relevant oral toxicological endpoints have been identified. There was no acute dietary endpoint identified for sulfosulfuron.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether sulfosulfuron has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, sulfosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that sulfosulfuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. An acute risk from the proposed use is not expected because no effects attributed to a single dose (exposure) were observed in oral toxicology studies including developmental toxicity in the rat and the rabbit and an acute neurotoxicity study in the rat.

2. *Chronic risk*. Using the theoretical maximum residue contribution exposure assumptions described in this unit, EPA has concluded that aggregate exposure to sulfosulfuron from food will utilize <1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is discussed below. EPA generally 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. Despite the potential for exposure to sulfosulfuron in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to sulfosulfuron residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

Short- term and intermediate-term dermal and inhalation is not a concern due to the lack of significant toxicological effects observed with sulfosulfuron under these exposure scenarios.

4. *Aggregate cancer risk for U.S. population*. The cancer aggregate risk which includes food, water, and the lifetime average daily dose from post application exposure for the general population is 2.05×10^{-7} which is lower than the Agency's negligible risk of 1×10^{-6}.

Aggregrate cancer risk for infants and childern. The aggregrate cancer risk for infants and childern which includes food, water, and lifetime average daily dose from post-application exposure is 1.1×10^{-6} which is considered negibile risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to sulfosulfuron residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general*. In assessing the potential for additional sensitivity of infants and children to residues of Sulfosulfuron, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not

raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Pre- and post-natal sensitivity*. The developmental and reproductive toxicity data did not indicate increased susceptibility to *in utero* and/or postnatal exposure.

iii. *Conclusion*. There is a complete toxicity database for Sulfosulfuron and exposure data is complete or is estimated based on data that reasonably accounts for potential exposures.

Based on these data, there is no indication that the developing fetus or neonate is more sensitive than adult animals. Acceptable acute and subchronic neurotoxicity studies in rats have been submitted to the Agency. There were no data gaps for the assessment of the neurotoxic potential of sulfosulfuron. There was no evidence of neurotoxicity in other studies (including a rat 90–day feeding toxicity study, rat 2–year chronic toxicity/carcinogenicity study, dog oral (capsule) 90–day study and a dog 1 year oral (capsule) toxicity study, conducted on sulfosulfuron. The Agency believes that reliable data support the use of the standard 100–fold uncertainly factor, and that a tenfold (10x) uncertainty factor to protect the safety of infants and children should not be retained.

2. *Acute risk*. There are no acute toxicological endpoints for sulfosulfuron. The Agency concludes that establishment of the proposed tolerances would not pose an unacceptable aggregate risk.

3. *Chronic risk*. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to Sulfosulfuron from food will utilize < 1% of the RfD for infants and children. EPA generally 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. Despite the potential for exposure to Sulfosulfuron in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- or intermediate-term risk*. Short-term and intermediate-term dermal and inhalation risk is not a concern due to lack of significant toxicological effects observed with sulfosulfuron under these exposure scenarios.

5. Aggregrate cancer risk for infants and childern. The aggregrate cancer risk for infants and childern which includes food, water, and lifetime average daily dose from post-application exposure is 1.1×10^{-6} which is considered negibile risk.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to Sulfosulfuron residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The guideline requirement for an animal metabolism study is satisfied. Sulfosulfuron is rapidly excreted, primarily unmetabolized. Excretion at low dose occurred primarily in the urine, whereas at high dose, a large percentage of the administered dose was excreted in the feces. Sulfosulfuron was not retained in tissues to any significant extent.

The nature of the residue in plants is understood. The sulfonyl urea bond is cleaved in soil prior to uptake by wheat and Pd-metabolites are taken up less readily than Im-metabolites. Metabolite formation appears to occur by demethylation and cleavage of sulfonyl urea bond.start

B. Analytical Enforcement Methodology

An interim adequate enforcement methodology (example - gas chromatography) is available to enforce the tolerance expression. The method is undergoing modification to improve the method. The improved method, when available, may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229. The interim method is available from the Analytical Chemistry Lab, BEAD (7503C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, (703) 305–2905.

C. Magnitude of Residues

Residues of 1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites that are converted to 2-(ethylsulfonyl)-imidazol[1,2-a]pyridine and calculated as sulfosulfuron are not expected to exceed on wheat grain 0.02 ppm, wheat straw 0.1 ppm, wheat hay 0.3 ppm, wheat forage 4.0 ppm, milk 0.006 ppm, fat and meat of cattle, goat, swine, horse, and sheep 0.005 ppm, and meat by-products of cattle, goat, swine, horse, and sheep at 0.05 ppm.

D. International Residue Limits

No Codex or Mexican MRLs are established for sulfosulfuron. Canadian MRLs exist for sulfosulfuron on wheat grain at 0.02 mg/kg; milk at 0.006 mg/kg, meat and fat of cattle, goat, swine, horse , sheep and poultry at 0.005 mg/kg, eggs at 0.0005 mg/kg; and meat by products of cattle, goat, swine, horse, sheep and poultry at 0.05 mg/kg. The Canadian MRLs are the same as the United States tolerances. No Canadian MRLs exist for wheat straw, wheat hay, and wheat forage. These tolerances are necessary to support use patterns in the United States.

E. Rotational Crop Restrictions

Based on the results of the confined accumulation in rotational crops study, the appropriate plantback intervals are: 30 days for leafy and root crops. Limited rotational field trials are required to determine the appropriate rotation intervals for all other crops (except wheat).

IV. Conclusion

Therefore, the tolerances are established for residues of sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron, in wheat grain at 0.02 ppm, wheat straw at 0.1 ppm, wheat hay at 0.3 ppm, wheat forage at 4.0 ppm, milk at 0.006 ppm, fat and meat of cattle, goat, swine, horse, and sheep at 0.005 ppm, and meat by-products of cattle, goat, swine, horse, and sheep at 0.05 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 19, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ''ADDRESSES'' section (40

CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300853] (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 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov.

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR

27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: May 6, 1999.

Susan B. Hazen,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.552 is added to subpart C to read as follows:

§ 180.552 Sulfosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide sulfosulfuron, 1–(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl) sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine and calculated as sulfosulfuron in or on the raw agricultural commodities.

Commodity	Parts per million
Cattle, fat	0.005
Cattle, meat	0.005
Cattle, meat by-products	0.05
Goat, fat	0.005
Goat, meat	0.005
Goat, meat by-products	0.05
Horse, fat	0.005
Horse, meat	0.005
Horse, meat by-products	0.05
Milk	0.006
Sheep, fat	0.005
Sheep, meat	0.005
Sheep, meat by-products	0.05
Swine, fat	0.005
Swine, meat	0.005
Swine, meat by-products	0.05
Wheat, forage	4.0
Wheat, grain	0.02
Wheat, hay	0.3
Wheat, straw	0.1

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 99–12247 Filed 5–18–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300856; FRL–6079–7]

RIN 2070–AB78

Emamectin Benzoate; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for combined residues of the insecticide emamectin benzoate, 4′-epi-methylamino- 4′-deoxyavermectin B_1 benzoate (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and a maximum of 10% 4′-epi-methlyamino-4′deoxyavermectin B_{1b} benzoate) and its metabolites 8,9 isomer of the B_{1a} and B_{1b} component of the parent insecticide (8,9 ZMA); 4′-deoxy-4′-epi-amino-avermectin B_1 (AB_{1a}); 4′deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_1(FAB_{1a}) (CAS No. 137512–74–4) in or on Brassica, head & stem subgroup (5-A), head lettuce and celery. Novartis Crop Protection, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective May 19, 1999. Objections and requests for hearings must be received by EPA on or before July 19, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300856], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300856], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.