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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0308; FRL-9965-71]

EPTC; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of EPTC, S-ethyl dipropylthiocarbamate in or on grass, forage at 0.60 ppm and grass, hay at 0.50 ppm. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0308, is available at <https://www.regulations.gov> or at the

Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).

- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0308 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any

Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0308, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerances

In the **Federal Register** of Friday, July 17, 2015 (80 FR 42462) (FRL-9929-13), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F8355) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide EPTC, S-ethyl

dipropylthiocarbamate, in or on grass grown for seed, forage at 0.6 parts per million (ppm) and grass grown for seed, hay at 0.5 ppm. That document referenced a summary of the petition prepared by Gowan Company, the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA 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 and to make a determination on aggregate exposure for EPTC, including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with EPTC 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.

On an acute exposure basis, EPTC is highly toxic via inhalation and is moderately toxic via the oral and dermal routes of exposure. It is slightly irritating to eyes and minimally-irritating to skin. It is a weak skin sensitizer.

EPTC is an S-alkylthiocarbamate, which consistently produced cardiomyopathy and neuronal cell necrosis in studies of varying length of treatment and in different species. Cardiotoxicity was observed in subchronic and long-term studies, and in general, the severity and incidence of the lesion increased with increasing doses of EPTC. In 90-day feeding and inhalation studies and in two chronic feeding/oncogenicity studies, histopathological evaluation revealed myocardial degeneration. Myocardial degeneration in adult rats was also observed in two separate two-generation reproduction studies. In two chronic dog studies, degenerative changes in the cardiac muscle were observed when EPTC was administered in a capsule, but not when administered (at comparable doses) in the diet. In both dog studies, electrocardiograms were taken, but only one high-dose male

in the capsule study had changes which were described as “potentially’ treatment-related.

EPTC, as well as other thiocarbamates (molinate, cycloate, pebulate, vernolate and butylate), have toxic effects on the central and peripheral nervous systems. With EPTC, there was an increased incidence and severity of neuronal necrosis/degeneration in both the central and peripheral nervous systems of rats and dogs. In the rat neurotoxicity studies, dose-related increases in the incidence of neuronal necrosis were observed in the brains after acute and subchronic exposure to EPTC. In the rat developmental neurotoxicity study, a marginal decrease in absolute (not relative) pup brain weight (4-6%) was observed in only one sex (male pups) and at only one time point (PND63). Furthermore, this marginal effect had no dose-response, was not seen after perfusion, and had no corresponding necrosis. Therefore, this effect was considered marginal at best and not robust. In both of the combined chronic toxicity/carcinogenicity studies in the rat and in the chronic (capsule) study in the dog, treatment-related neuromuscular lesions were observed. In all of these studies, hindquarter weakness with corresponding histopathology findings of atrophy and degeneration of the skeletal muscle were observed. In the dog study, the lesions were described as Wallerian-type degeneration in the spinal cords and various peripheral nerves.

EPTC is a reversible acetylcholinesterase (AChE) inhibitor. Toxicology studies with EPTC did not show any consistent pattern of AChE-inhibition between different species, length of treatment, or the type of AChE enzyme measured. In some studies, brain AChE activity was inhibited without any effect on either plasma or erythrocyte AChE activities. In other studies, erythrocyte AChE was inhibited with no inhibition of

either plasma or brain AChE. AChE-inhibition was observed at comparable or higher doses than where cardiac/neuronal effects were observed.

There is no evidence of increased susceptibility following *in utero* exposure to EPTC in either the rat or rabbit developmental toxicity study or following *in utero* and/or postnatal exposure in the 2-generation reproduction study in rats. EPTC is classified as “Not Likely to be Carcinogenic to Humans.” This is based on the lack of carcinogenic potential noted in the available studies. There are no concerns for mutagenicity or clastogenicity. There is also no concern for immunotoxicity.

Specific information on the studies received and the nature of the adverse effects caused by EPTC as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <https://www.regulations.gov> in document *EPTC: Human Health Risk Assessment for the Proposed Section 3 Registration for Use on Grasses Grown for Seed Production* in docket ID number EPA-HQ-OPP-2015-0308.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are

identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for EPTC used for human risk assessment is shown in Table 1 of this unit.

Table 1. -- Summary of Toxicological Doses and Endpoints for EPTC for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (all populations including infants and children)	LOAEL = 200 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF/UF _L = 10x	aRfD/aPAD = 0.2 mg/kg/day	<u>Acute neurotoxicity rat study</u> NOAEL not established in males. LOAEL = 200 mg/kg/day based on neuronal cell necrosis in the brain in males.
Chronic dietary (all populations)	POD = 5 mg/kg/day UF _A = 10x	cRfD/cPAD = 0.05	<u>Co-critical, chronic/carcinogenicity</u>

including infants and children)	UF _H = 10x FQPA SF = 1x	mg/kg/day	<u>and 2-generation reproduction in rats</u>
Incidental oral (short- and intermediate-term)	POD = 5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE=100	<u>Chronic toxicity/carcinogenicity rat study</u> NOAEL = 5 mg/kg/day LOAEL = 25 mg/kg/day based on decreased body weight and increased incidences of myocardial and neuromuscular lesions.
Dermal (short- and intermediated-term)	POD = 5 mg/kg/day Dermal absorption factor= 5% UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE=100	<u>2-generation reproduction toxicity rat study</u> Parental NOAEL = 2.5 mg/kg/day Parental LOAEL = 10 mg/kg/day based on decreased body weight and cardiomyopathy. Developmental NOAEL = 10 mg/kg/day Developmental LOAEL = 40 mg/kg/day based on decreased mean pup weight during lactation days 4 to 21. Reproductive NOAEL = 40 mg/kg/day Reproductive LOAEL > 40 mg/kg/day
Inhalation (short- and intermediated-term)	BMDL ₁₀ =5.05 mg/m ³ mg/kg/day	LOC for MOE=30	<u>90-day inhalation toxicity study in rats</u> <u>BMD₁₀=10.84 mg/m³</u>

	$UF_A = 3x$ $UF_H = 10x$ FQPA SF = 1x		<u>based on brain cholinesterase inhibition in males.</u>
	Residential bystander HEC= 2.288 mg/m ³ Occupational Handler HEC=9.609 mg/m ³ ; HED=0.91 mg/kg/day		
Cancer (oral, dermal, inhalation)	Classified as “Not Likely to be Carcinogenic to Humans.” based on the lack of carcinogenic potential noted in the available studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram per kilogram per day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). POD = point of departure. RfD = reference dose (a = acute, c = chronic). UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. HEC= human equivalent concentration. HED= human equivalent dose.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to EPTC, EPA considered exposure under the petitioned-for tolerances as well as all existing EPTC tolerances in 40 CFR 180.117. EPA assessed dietary exposures from EPTC in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and 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. Such effects were identified for EPTC. In estimating acute dietary exposure, EPA used food consumption

information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA incorporated tolerance-level residues (adjusted for metabolites at 15X, to estimate the concentration of residues of toxicological concern), 100 percent crop treated (PCT) for all commodities, and default processing factors for all processed commodities except for potato granules (1.4X) and for sugar beets (4X).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the same food consumption data and food residue level information as described above for acute dietary exposure.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that EPTC does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for EPTC. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.*

The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for EPTC in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of EPTC. Further information regarding EPA drinking water models used in pesticide exposure

assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the Tier II Surface Water Concentration Calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM-GW) model, the highest estimated drinking water concentration (EDWC) of EPTC for acute exposure is estimated to be 378 parts per billion (ppb) from ground water. For chronic exposure, the highest EDWC is estimated to be 335 ppb from ground water. These EDWCs were directly entered into the dietary exposure models for both acute and chronic dietary risk assessments to assess the contribution from drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). EPTC is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA 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.” Although thiocarbamates share some chemical and toxicological characteristics, the toxicological database does not support a testable hypothesis for a common mechanism of action. Therefore, for the purposes of this tolerance action EPA has assumed that EPTC does not have 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 EPA's website at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* As discussed in Unit III.A., there was no qualitative or quantitative evidence of increased susceptibility to developing fetuses following *in utero* exposure to EPTC in the rabbit and rat developmental toxicity studies, or to offspring in the rat two-generation reproduction toxicity study. Although there was evidence of increased qualitative and quantitative susceptibility of offspring observed in the rat developmental neurotoxicity study. The effect on a marginal decreased absolute brain weight was observed only in male pups at one time-point on postnatal day 63. This effect was considered marginal and not robust since it had no dose-response, was not seen after perfusion, and had no corresponding necrosis. Therefore, there is low concern for susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for assessing chronic dietary exposure but retained at 10X for assessing acute dietary exposure to account for extrapolating a NOAEL from a LOAEL. That decision is based on the following findings:

i. The toxicity database for EPTC is complete and adequate to assess potential risk to infants and children.

ii. There is indication that EPTC has toxic effects on the central and peripheral nervous systems. Neuronal necrosis and degeneration were observed in both the central and peripheral nervous systems of rats and dogs after acute and subchronic exposure. Treatment-related neuromuscular lesions were also observed in chronic rat and dog studies. In all of these studies hindquarter weakness was noted, and at necropsy evaluation atrophy and degeneration of the skeletal muscle was observed. In the dog study, the lesions were described as Wallerian-type degeneration in the spinal cords and various peripheral nerves. AChE inhibition was also seen in a number of toxicology studies; however, no consistent pattern was witnessed across studies with respect to AChE inhibition between different species, length of treatment, or the type of AChE enzyme measured. All studies provide clear NOAELs and LOAELs, except the acute neurotoxicity study, and because the Agency is relying on that study for selection of the acute dietary exposure endpoint, EPA is retaining the 10X FQPA safety factor to account from the extrapolation from the LOAEL to the NOAEL.

iii. There is no evidence that EPTC results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the two-generation reproduction study. Evidence of increased susceptibility to offspring was observed in the developmental neurotoxicity study; however, this effect was considered marginal and not robust. Therefore, there is low concern for the susceptibility.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to EPTC in drinking water. These assessments will not underestimate the exposure and risks posed by EPTC.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to EPTC will occupy 46% of the aPAD for children between 1-2 years old, the population subgroup receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to EPTC from food and water will utilize 65% of the cPAD for children between 1-2 years old, the population subgroup receiving the greatest exposure. There are no residential uses for EPTC.

3. *Short- and intermediate-term risks.* Short- and intermediate-term aggregate exposures takes into account short-term (1 to 30 days) and intermediate-term (1 to 6 months) residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, EPTC is not registered for any use patterns that would result in residential exposure. Because there is no residential exposure and chronic dietary exposure has already been assessed under the appropriately protective PADs (which is at least as protective as the PODs used to assess short- and intermediate-term risks), no further assessment of short- and intermediate-term risks are necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risks for EPTC.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, EPTC is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to EPTC residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate gas chromatography with micro coulometric (GLC/MC) detection method (RR-50) listed under Method A in the Pesticide Analytical Manual (PAM Volume II, Section 180.117; is available for enforcing tolerances of EPTC *per se* in plant commodities. For the determination of hydroxylated metabolites (free or conjugated) of EPTC in or on plant commodities, an adequate gas chromatography with nitrogen-phosphorus detection (GC/NPD) enforcement method (Method RR-96-089B) is also available.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA

explain the reasons for departing from the Codex level. The Codex has not established any MRLs for EPTC.

C. Revisions to Petitioned-For Tolerances

The Agency is establishing tolerances for the forage and hay forms of “grass” rather than “grass grown for seed” as requested to conform with its food and feed commodity vocabulary. Also, the Agency is establishing the tolerance levels to conform with its policy of significant figures.

V. Conclusion

Therefore, tolerances are established for residues of EPTC, S-ethyl dipropylthiocarbamate, including its metabolites and degradates, in or on grass, forage at 0.60 ppm and grass, hay at 0.50.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) 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). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any

information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances 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.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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 action 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: August 16, 2017.

Michael L. Goodis

Director, Registration Division, 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), 346a and 371.

2. In § 180.117, add alphabetically the commodities to the table in paragraph (a) to read as follows:

§ 180.117 S-ethyl dipropylthiocarbamate; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	*
Grass, forage	0.60
Grass, hay	0.50
* * * * *	*

* * * * *