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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0825; FRL-9960-37]

Topramezone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of topramezone in or on sugarcane, cane. BASF Corporation requested this tolerance 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-2015-0825, is available at *http://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 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*.

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-2015-0825 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-2015-0825, by one of the following methods:

• *Federal eRulemaking Portal*: *http://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 *http://www.epa.gov/dockets/contacts.html*.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 22, 2016 (81 FR 40594) (FRL-9947-32), 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 5F8421) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.612 be amended by establishing a tolerance for residues of the herbicide topramezone, [3-(4,5-dihydro-isoxazol-3-yl)-4-methylsulfonyl-2-methylphenyl](5-hydroxyl-1-methyl-1*H*-pyrazol-4-yl)methanone, in or on sugarcane, cane at 0.01 parts per million (ppm). That document referenced a summary of the petition prepared by BASF

Corporation, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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 topramezone including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with topramezone 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.

Topramezone inhibits the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is involved in the catabolism of the amino acid tyrosine. HPPD-inhibition causes blood levels of tyrosine to rise (tyrosinemia), resulting in ocular, liver, kidney, and developmental effects in laboratory animals.

Similar to other HPPD inhibiting chemicals, the rat was the most sensitive species and males were found to be more sensitive than females (in rats and dogs). In rat subchronic and chronic oral studies, topramezone produced ocular (corneal vascularization, opacity, and keratitis) and kidney (microscopic findings and increased organ weights) effects, which are consistent with the mammalian toxicity profile for HPPD inhibitors caused by high tyrosine levels in the blood. Histopathological findings in the thyroid were frequently observed in rats and dogs following topramezone exposure. Thyroid tumors via a non-linear mode of action involving thyroid hormone disruption were seen in the rat; however, topramezone is classified as "not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." Additional histopathological findings were seen in the pancreas of rats and the urinary bladder in dogs. Body weight decrements were also noted in all species, including the mouse, which did not exhibit any other adverse effects in the database.

There was evidence of increased prenatal susceptibility following *in utero* exposure to topramezone in the developmental toxicity studies in rats and rabbits, with fetal skeletal variation and abnormalities observed in both species that were consistent with those reported in the toxicological databases for other HPPD inhibiting chemicals and typically seen in the absence of maternal toxicity or less severe maternal adverse effects. In the mouse developmental toxicity study, elevated tyrosine blood levels were noted in maternal animals; however, there were no developmental effects observed. There was evidence for increased qualitative offspring susceptibility in the rat developmental neurotoxicity study, where neurobehavioral and neuropathological changes were observed in the presence of limited maternal toxicity (corneal opacity). There was no evidence of increased pre- or postnatal susceptibility in the rat reproduction toxicity study.

While neurobehavioral and neuropathological offspring effects were observed in the developmental neurotoxicity study, which are indicators of potential neurotoxicity, no neurotoxic effects were observed in the acute neurotoxicity study up to the limit dose or the subchronic neurotoxicity study, where systemic effects were consistent with the rest of the toxicological database.

Topramezone is classified as having low acute toxicity (Toxicity Category III or IV) via the oral, dermal, and inhalation routes). It was found to be a slight eye and dermal irritant, but it was not found to be a dermal sensitizer.

Specific information on the studies received and the nature of the adverse effects caused by topramezone 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 http://*www.regulations.gov* in document *Topramezone: Human Health Risk Assessment for New Use on Sugarcane* in docket ID number EPA-HQ-OPP-2015-0825.

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 *http://www.epa.gov/pesticides-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

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

Table --Summary of Toxicological Doses and Endpoints for Topramezone 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 (Females 13-49 years old)	NOAEL = 0.5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	aRfD = 0.005 mg/kg/day aPAD = 0.005 mg/kg/day	*Rabbit Developmental Toxicity Study* Developmental LOAEL = 5 mg/kg/day based on alterations in skeletal ossification sites and increased number of pairs of ribs.
Acute dietary (General population including infants and children, excluding females 13-49 years old)	LOAEL = 8 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF/UF_L = 10x	aRfD = 0.08 mg/kg/day aPAD = 0.008 mg/kg/day	*Rat Developmental Neurotoxicity Study* LOAEL = 8 mg/kg/day based on decreased maximum auditory startle reflex response, decreased brain weights, and changes in brain morphology.
Chronic dietary (All populations)	NOAEL= 0.4 mg/kg/day UF_A = 10x	cRfD = 0.004 mg/kg/day	*Rat Chronic Toxicity/Carcinogenicity Study* LOAEL = 3.6 mg/kg/day based on

	UF_H = 10x FQPA SF = 1x	cPAD = 0.004 mg/kg/day	increased incidences of corneal opacity, decreased body weight and body-weight gains in males and histopathological evaluations in the eyes, thyroid, and pancreas of both sexes.
Incidental oral short-term (1 to 30 days) and intermediate (1-6 months) term	NOAEL= 0.4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100	*Rat Two-Generation Reproduction Study* Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F_2 generation and increased time to preputial separation in the F_1 male (offspring).
Dermal short-term (1 to 30 days) and intermediate (1-6 months) term	NOAEL = 0.4 mg/kg/day (dermal absorption rate = 2.6% UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100	Rat Two-Generation Reproduction Study in Rats] Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F_2 generation and increased time to preputial separation in the F_1 male (offspring).

Inhalation short-term (1 to 30 days) and intermediate (1-6 month) term	NOAEL= 0.4 mg/kg/day (inhalation assumed equivalent to oral) UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = <100	Rat Two-Generation Reproduction Study in Rats] Parental/Offspring LOAEL = 4.2 mg/kg/day based on decreased body weight, increased thyroid and kidney weights, and microscopic findings in eyes, kidney, and thyroid of both sexes (parental); and decreases in body weights in the F_2 generation and increased time to preputial separation in the F_1 male (offspring).
Cancer (Oral, dermal, inhalation)	In accordance with the 2005 EPA Guidelines for Carcinogen Risk assessment, topramezone was classified as "not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis." EPA has determined that the thyroid tumors arise through a non-linear mode of action and the cRfD of 0.004 mg/kg/day, which is derived from the NOAEL of 0.4 mg/kg/day from the rat chronic/carcinogenicity study, is not expected to alter thyroid hormone homeostasis nor result in thyroid tumor formation.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). 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.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to topramezone, EPA considered exposure under the petitioned-for tolerance as well as all

existing topramezone tolerances in 40 CFR 180.612. EPA assessed dietary exposure from topramezone 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 one-day or single exposure. Such effects were identified for topramezone. 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 used tolerance levels and 100 percent crop treated (PCT) for the acute dietary exposure assessment.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance levels and 100 PCT for the chronic dietary exposure assessment.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that topramezone 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 topramezone. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used the highest drinking water concentration expected to result from the currently-registered use of topramezone for direct, aquatic applications. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*. For acute and chronic dietary risk assessments, the water concentration value of 45 ppb was used to assess the contribution to drinking water, based on the maximum allowable topramezone concentration in water bodies with potable water intakes from direct aquatic use.

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).

Topramezone is currently registered for turf and golf course uses that could result in residential exposures. Topramezone is also currently registered for use in direct aquatic applications that could result in exposure during recreational swimming activities. The following residential exposure scenarios were used for assessing aggregate exposures: short-term dermal post-application exposure resulting from the physical activities on turf for adults, short-term dermal and incidental oral (hand-to-mouth) post-application exposures resulting from the physical activities on turf for children 1< 2 years, and intermediate-term incidental oral exposure resulting from soil ingestion from turf use for children 1<2 years. These post-application exposure estimates from the turf use are protective of post-application exposure for older children more likely to engage in recreational swimming activities. Further information regarding EPA standard

assumptions and generic inputs for residential exposures may be found at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

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."

EPA has not found topramezone to share a common mechanism of toxicity with any other substances, and topramezone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that topramezone 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 Food Quality Protection Act Safety Factor (FQPA 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*. There was evidence of increased quantitative prenatal susceptibility following *in utero* exposures to rats and rabbits. Fetal skeletal variations and abnormalities were observed in all of the rat and rabbit developmental studies, typically in the absence of maternal toxicity or in the presence of less severe maternal effects. Increased qualitative susceptibility was also observed in the developmental neurotoxicity study where offspring neurobehavioral and neuropathological changes were observed in the presence of limited maternal toxicity (corneal opacity). Concern is low since the effects are well-characterized and endpoints selected for risk assessment are protective of all observed offspring effects. There was no evidence of increased offspring sensitivity in the two-generation rat reproduction toxicity study.

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 all exposure scenarios except for acute dietary exposure. The FQPA SF of 10X was retained for acute dietary exposure to account for the extrapolation of a NOAEL from a LOAEL. This decision is based on the following findings:

i. The toxicity database for topramezone is adequate to assess the risk of aggregate exposure to topramezone. While a subchronic inhalation study is not available

for topramezone, EPA concluded, using a weight-of-evidence approach, that this study is not required at this time.

ii. Although there was evidence of potential neurotoxicity in the developmental neurotoxicity study (e.g., changes in neurobehavioral and neuropathological observations in offspring), there was no additional evidence of neurotoxicity in the rest of the toxicological database and the selected endpoints are protective of the observed effect up to the limit dose.

iii. Although there was evidence of increased prenatal susceptibility as discussed in Unit III.D.2., there are clear NOAELs associated with those effects, and the Agency's selected points of departure are protective of those effects. Therefore, there is no need to retain the FQPA 10X SF to adequately protect infants and children from these effects.

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. The maximum allowable concentration in potable water intakes was used to assess exposure to topramezone in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by topramezone.

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 topramezone will occupy 98 % of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure, and 50% of the aPAD for females 13-49 years old.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to topramezone from food and water will utilize 62% of the cPAD for all infants less than 1-year-old, the population group receiving the greatest exposure.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for residential turf uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to topramezone. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 220 for adults and 120 for children 1-2 years old (a subgroup predicted to have the highest residential and aggregate exposure). Because EPA's level of concern for topramezone is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Topramezone is currently registered for turf uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to topramezone for children that are 1-2 years old that may ingest soil on treated turf. Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 270 for children 1-2 years old. Because EPA's level of concern for topramezone is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population*. EPA has concluded that topramezone does not pose a cancer risk at exposure levels that do not alter thyroid hormone homeostasis. The chronic aggregate assessment, which utilized a cRfD that is protective of those effects did not indicate a chronic risk above EPA's level of concern; therefore, topramezone is not expected to pose a cancer risk to humans.

6. *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 topramezone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass-spectrometry detection (LC/MS/MS), BASF method D0007) is available to enforce the tolerance expression for sugarcane.

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 FFDCA 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for topramezone in or on sugarcane.

V. Conclusion

Therefore, tolerances are established for residues of topramezone, including its metabolites and degradates, in or on the following commodity. Compliance with the following tolerance levels is to be determined by measuring only topramezone ([3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone) in or on the following commodity: Sugarcane, cane at 0.01 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 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.

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: May 15, 2017.

Michael L. Goodis, P.E.

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 § 180.612, add alphabetically "Sugarcane, cane" in the table in paragraph (a) to read as follows:

§ 180.612 Topramezone; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * *	* * *
Sugarcane, cane	0.01

* * * * *

[FR Doc. 2017-15744 Filed: 7/27/2017 8:45 am; Publication Date: 7/28/2017]