ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0551; FRL–9348–01–OCSPP]

Tetraacetylethylenediamine (TAED) and Its Metabolite Diacetylethylenediamine (DAED); Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an exemption from the requirement of a tolerance for residues of tetraacetylethylenediamine (TAED) and its metabolite diacetylethylenediamine (DAED) by expanding its use in or on all food commodities, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices. The Lubrizol Corporation, 29400 Lakeland Blvd., Wickliffe, OH 44092, submitted a petition, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.1327. 40 CFR 180.1327 currently provides for an exemption from the requirement of a tolerance for residues of the pesticide, tetraacetylethylenediamine (TAED), and its metabolite diacetylethylenediamine (DAED), in or on rice and strawberries, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices. This regulation eliminates the need to establish a maximum permissible level for residues of tetraacetylethylenediamine (TAED) or its metabolite diacetylethylenediamine (DAED) when used in accordance with this exemption.

DATES: This regulation is effective March 17, 2022. Objections and requests for hearings must be received on or before May 16, 2022 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–2021–0551, 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.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title40.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2021–0551 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 May 16, 2022. 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–2021–0551, 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/contacts.html.*

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

II. Background and Statutory Findings

In the **Federal Register** of September 22, 2021 (86 FR 52624) (FRL–8792–03–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F8781) by The Lubrizol Corporation, 29400 Lakeland Blvd., Wickliffe, OH, 44092. The petition requested that 40 CFR 180.1327 be amended by amending the existing exemption from the requirement of a tolerance for residues of tetraacetylethylenediamine (TAED) and its metabolite diacetylethylenediamine (DAED) by expanding it to in or on all food commodities, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices. That document referenced a

summary of the petition prepared by the petitioner, The Lubrizol Corporation, 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(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that 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 establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. If EPA is able to determine that a tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 TAED and DAED including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with TAED and DAED follows.

A. Toxicological Profile

TAED is an analiphatic amide that is approved as a pesticide active ingredient for food and non-food uses. It is also is listed by the Food and Drug Administration (FDA) for use as a bleaching agent in the manufacture of food-contact paper and paperboard products (21 CFR 176.170).

TAED rapidly degrades to form diacetylethylenediamine (DAED), peroxyacetic acid (PAA), and hydrogen peroxide when exposed to water. DAED is considered to be of similar or less toxicity than TAED. Hydrogen peroxide and peroxyacetic acid are exempt from the requirement of a tolerance under 40 CFR 180.1197 and 180.1196(c), respectively. Food uses for TAED in or on rice and strawberries are supported by 40 CFR 180.1327, which currently provides for an exemption from the requirement of a tolerance for residues TAED and DAED in or on rice and strawberries, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices. As a non-food pesticidal use, TAED is used on various non-bearing fruit trees, ornamentals and grasses. For all uses, dietary exposure to TAED is expected to be minimal due to TAED's physical and chemical properties and ready biodegradation in the environment.

With regard to the overall toxicological profile, TAED is of minimal toxicity. Based on acute studies, TAED is of low acute oral toxicity and acute inhalation toxicity (Toxicity Category IV), low acute dermal toxicity (Toxicity Category III) and is non-irritating to the skin and eye (Toxicity Category IV). The chemical is not a skin sensitizer. DAED is considered to be of similar or less toxicity than TAED. All data requirements were satisfied by guideline studies for subchronic toxicity (90-day oral, 90-day inhalation and 90-day dermal), developmental toxicity, reproductive toxicity and mutagenicity data requirements. There were no adverse subchronic effects for any oral or dermal routes of exposure. The active ingredient was determined to be non-mutagenic, and no adverse effects were identified relative to either developmental toxicity or reproductive toxicity. Based on this toxicological profile, EPA did not identify any toxicological endpoints of concern for TAED.

B. Toxicological Points of Departure/ Levels of Concern

No toxicological endpoint of concern has been identified for TAED or DAED.

C. Exposure Assessment

1. *Dietary exposure from food, feed uses, and drinking water.* As part of its qualitative risk assessment for TAED, the Agency considered the potential for dietary exposure to residues of TAED and its degradate, DAED. EPA concludes that dietary (food and drinking water) exposures are likely to be negligible, due to the short half-life and biodegradable nature of TAED and DAED. Further, biodegradation of TAED and DAED yields the products water, nitrate, and ammonia, which are all found naturally in the environment and readily metabolized by microorganisms.

2. *From non-dietary exposure.* A revaluation of the risk of occupational and residential (non-dietary) exposure to TAED and DAED was not conducted at this time. Previous EPA risk assessments support the uses on currently approved TAED product labels.

3. *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 that TAED or DAED share a common mechanism of toxicity with any other substances, and they do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed TAED and DAED do 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/pesticides/cumulative.*

D. Safety Factor for Infants and Children

FFDCA Section 408(b)(2)(C) provides that EPA shall retain 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. An FQPA safety factor is not required at this time for TAED and its metabolite, DAED, because EPA has conducted a qualitative dietary assessment based on low toxicity and anticipated negligible exposure to the active ingredient.

E. Aggregate Risk

Based on the available data and information, the EPA has concluded that a qualitative aggregate risk assessment is appropriate to support the pesticidal use of TAED and its metabolite, DAED, and that risks of concern are not anticipated from aggregate exposure to the substance or its metabolite, DAED. This conclusion is based on the low toxicity of the active ingredient and expected rapid degradation of TAED and DAED in the environment.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the July 22, 2021, document entitled ''Human Health Dietary Risk Assessment to Support a Tolerance Exemption Amendment for Warwick AG610 (EPA Reg. No. 59825–6), Containing 92% Tetraacetylethylenediamine as its Active Ingredient.'' This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Determination of Safety for U.S. Population, Infants and Children

Based on the Agency's assessment, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of TAED.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

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 an MRL for tetraacetylethylenediamine (TAED) or its metabolite diacetylethylenediamine (DAED).

VI. Conclusions

Therefore, EPA is amending the currently established exemption for residues of tetraacetylethylenediamine (TAED) and its metabolite diacetylethylenediamine (DAED) to include use in or on all food commodities—no longer limiting food use to strawberries and rice, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices.

VII. Statutory and Executive Order Reviews

This action amends an exemption from the requirement of 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).

VIII. 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: March 10, 2022.

Charles Smith,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Revise § 180.1327 to read as follows:

§ 180.1327 Tetraacetylethylenediamine (TAED) and its metabolite Diacetylethylenediamine (DAED); Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide, tetraacetylethylenediamine (TAED), and its metabolite diacetylethylenediamine (DAED), in or on all food commodities, when used as a fungicide and bactericide in accordance with label directions and good agricultural practices.

[FR Doc. 2022–05530 Filed 3–16–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 102

RIN 0991–AC33

Annual Civil Monetary Penalties Inflation Adjustment

AGENCY: Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalty amounts in its regulations, under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015; adding references to new penalty authorities; and making technical changes to correct errors in the regulation.

DATES:

Effective date: This final rule is effective March 17, 2022.

Applicability date: The adjusted civil monetary penalty amounts apply to penalties assessed on March 17, 2022, r if the violation occurred on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Katrina Brisbon, Acting Deputy Assistant Secretary, Office of Acquisitions, Office of the Assistant Secretary for Financial Resources, Room 536–H, Hubert Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201; (202) 260–6677.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74) (the ''2015 Act'') amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 104 Stat. 890 (1990)), which is intended to improve the effectiveness of civil monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the CMPs for inflation annually.

The Department of Health and Human Services (HHS) lists the CMP authorities and the amounts administered by all of its agencies in tabular form in 45 CFR 102.3, which was issued in an interim final rule published in the September 6, 2016, **Federal Register** (81 FR 61538). Annual adjustments were subsequently published on February 3, 2017 (82 FR 9175), October 11, 2018 (83 FR 51369), November 5, 2019 (84 FR 59549), January 17, 2020 (85 FR 2869), and November 15, 2021 (86 FR 62928).

II. Calculation of Annual Inflation Adjustment

The annual inflation adjustment for each applicable CMP is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each CMP was most recently established or modified. In the December 15, 2021, Office of Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M–22–07, ''Implementation of Penalty Inflation Adjustments for 2022, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,'' OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2022, based on the CPI–U for the month of October 2021, not seasonally adjusted, is 1.06222. The multiplier is applied to each applicable penalty amount that was updated and published for fiscal year (FY) 2021 and is rounded to the nearest dollar.

III. Other Revisions

In addition to the inflation adjustments for 2022, this final rule updates the table in 45 CFR 102.3 to add references to new, applicable civil money penalty authorities that were established or implemented since the publication of the November 15, 2021 update and that are being updated in this rule. The rule also corrects several technical errors to regulatory citations in the table and updates descriptions for clarification and accuracy. The following technical errors were identified and are corrected in the table at 45 CFR 102.3:

- The citation to, and description of, 42 U.S.C. 299c–3(d) are revised for accuracy.
- The regulatory reference of 42 CFR 1003.210(a)(5) implementing 42 U.S.C. 1395cc(g) which was inadvertently omitted from the regulation and is added.
- The description of the CMP at 42 U.S.C. 1320a–7a(o) is revised for accuracy.
- The regulatory reference to 45 CFR 155.206(i) [1] implementing 42 U.S.C. 18041(c)(2) [2] which was inadvertently omitted from the regulation is added. Additionally, the amount for this CMP was not included in the 2021 inflation adjustment rule. 86 FR 62928, 62943 (Nov. 15, 2021). Thus, we are updating the inflation amount at this time.
- The first description tied to 42 U.S.C. 1395mm(i)(6)(B)(i) is revised from ''is such plan'' to ''if such plan''.
- The regulatory reference to 85 FR 71142 (Nov. 6, 2020) implementing CARES Act, Pub. L. 116–136, section 3202(b)(2), is revised to read 45 CFR 182.70.

++ The 2022 adjusted amount is calculated by applying the 2021 multiplier to 1.06222 percent and this adjusted amount is reflected in the table of the regulation at 45 CFR 102.3.

[1] The Department recently proposed a technical correction to 45 CFR 155.206(i) to add language that would cross-reference to the authority to implement annual inflation-related increases to CMPs pursuant to the 2015 Act. See Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023; Proposed Rule, 87 FR 584 at 640–641, 721 (Jan. 5, 2022). To date, no CMPs have been imposed under this authority, but any that are would reflect the current inflationary adjusted amount as required by the 2015 Act and would be calculated in accordance with applicable OMB guidance to all Executive Departments on the implementation of the 2015 Act.

[2] See, *e.g.,* the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule, 79 FR 30239 at 30262–30270 (May 27, 2014).