TABLE 3 TO PARAGRAPH (e)(1)(i)

Unit	SO_2 emission limit	Time period/operating scenario
Boilers 1, 2, and 3 (combined)	420 lbs/hr	Daily average.
Boilers 1, 2, and 3 (combined)	1839.6 tons per year	12-month rolling time period.
Boilers 1, 2, and 3 and Flares 1 and 2 (combined)	840 lbs/hr	Daily average.
Boilers 1, 2, and 3 and Flares 1 and 2 (combined)	2947.7 tons per year	12-month rolling time period as determined at the end of each calendar month.

(ii) [Reserved]

(2) *Monitoring requirements.* (i) The owner or operator shall maintain and operate in a satisfactory manner a device to monitor and record the SO_2 emissions from Boilers 1, 2, and 3 on a continuous basis. Installation and operation of each CEMS shall meet the timelines, requirements and reporting detailed in 40 CFR part 60, appendix F. If the owner or operator chooses to use a Predictive Emissions Monitoring System (PEMS) in lieu of a CEMS to monitor SO_2 emissions, the permittee shall follow the protocol delineated in Performance Specification 16 in appendix B of 40 CFR part 60.

(ii) The owner or operator shall verify compliance with the emission limits for Boilers 1, 2 and 3 and Flares 1 and 2 (combined) by following the procedures and methodologies contained in the document entitled ''Protocol for Demonstrating Continuous Compliance with the Emission Limitations of ROP MI–ROP–N6631–2004'' dated May 31, 2011, or subsequent revisions to this document approved by EPA.

[FR Doc. 2022–21662 Filed 10–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0774; FRL–10239–01–OCSPP]

Dimethyl Sulfoxide; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of dimethyl sulfoxide (CAS Reg. No. 67–68–5) when used as an inert ingredient (solvent, co-solvent), in pesticide formulations for pre-harvest applications, including post-emergence use. Exponent, Inc., on behalf of Gaylord Chemical Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of dimethyl sulfoxide for pre-harvest applications.

DATES: This regulation is effective October 12, 2022. Objections and requests for hearings must be received on or before December 12, 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–2021–0774, 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 and OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; 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 40 CFR part 180 through the Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2021–0774 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 December 12, 2022. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b), although the Office of the Administrative Law Judges, which houses the Hearing Clerk, encourages parties to file objections and hearing requests electronically. *See https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf.*

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–

2021–0774, 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. Petition for Exemption

In the **Federal Register** of February 25, 2022 (87 FR 10760) (FRL–9410–01), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11603) by Exponent, Inc., 1150 Connecticut Ave., Suite 1100, Washington, DC 20036, on behalf of Gaylord Chemical Company, LLC, 106 Galeria Boulevard, Slidell, LA 70458. The petition requested that 40 CFR 180.920 be amended by modifying an exemption from the requirement of a tolerance for residues of dimethyl sulfoxide (CAS Reg. No. 67–68–5) by allowing its use as an inert ingredient (solvent, co-solvent) in pesticide formulations applied for pre-harvest applications, including post-emergence use. That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of Gaylord Chemical Company, the petitioner, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. 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 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. . . .''

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 appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, 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 dimethyl sulfoxide including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with dimethyl sulfoxide follows.

A. Toxicological Profile

The toxicological profile of dimethyl sulfoxide remains unchanged from the Toxicological Profile in Unit IV.A. of the October 9, 2015, rulemaking (80 FR 61125) (FRL–9934–17). Refer to that section for a discussion of the toxicological profile of dimethyl sulfoxide.

B. Toxicological Points of Departure/Levels of Concern

The toxicological points of departure/levels of concern of dimethyl sulfoxide remains unchanged from the Toxicological Points of Departure/Levels of Concern discussion in Unit IV.B. of the October 9, 2015, rulemaking (80 FR 61125) (FRL–9934–17). No endpoints of concern were identified. Refer to that section for a discussion of the toxicological points of departure/levels of concern of dimethyl sulfoxide.

C. Exposure Assessment

The exposure assessment for dimethyl sulfoxide remains unchanged from the discussion in Unit IV.C. of the October 9, 2015, rulemaking and supporting human health risk assessment (September 11, 2015). Refer to that section for a discussion of the exposure assessment for dimethyl sulfoxide.

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.''

Based on the lack of toxicity in the available database, EPA has not found dimethyl sulfoxide to share a common mechanism of toxicity with any other substances, and dimethyl sulfoxide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance exemption, therefore, EPA has assumed that dimethyl sulfoxide 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

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 (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.

Because there are no threshold effects associated with dimethyl sulfoxide, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of dimethyl sulfoxide EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

The aggregate exposure assessment for dimethyl sulfoxide remains unchanged from the discussion in Unit IV.E. of the October 9, 2015, rulemaking and supporting human health risk assessment. Refer to that section for a detailed discussion of the aggregate assessment for dimethyl sulfoxide (these documents can be found at *https://www.regulations.gov* under docket ID numbers EPA–HQ–OPP–2014–0630 and EPA–HQ–OPP–2021–00774). In summary, qualitative dietary, residential and aggregate assessments were performed due to the lack of toxicity endpoints of concern. There was no dietary, residential or aggregate risks of concern for the U.S. population and all subpopulations. Based on this human health risk assessment, an exemption from the requirement of a tolerance was established for residues of dimethyl sulfoxide under 40 CFR 180.920 for use before crop emerges from soil or prior to formation of edible parts of food plants; for pesticide formulations used after crop emerges but before harvest. This limitation was based on concerns regarding the chemical properties of dimethyl sulfoxide that could result in increased active ingredient residues. However, the petitioner submitted a comparative field trial residue study showing that dimethyl sulfoxide as an inert ingredient in pesticide formulations does not increase active ingredient residues. EPA has concluded that the use of dimethyl sulfoxide as an inert ingredient in pesticide formulations does not increase active ingredient residues; nor is it expected to result in active ingredient residue levels that exceed established tolerances. Therefore, since there is no concern for increased active ingredient residues on treated crops due to dimethyl sulfoxide and there are no endpoints of concern for dimethyl sulfoxide, the qualitative dietary, non-dietary risk, and aggregate assessments performed in 2015 are appropriate and remain unchanged. As a result, the Agency has determined that a tolerance is not necessary to protect public health.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to dimethyl sulfoxide.

V. Other Considerations

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.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for dimethyl sulfoxide (CAS Reg. No. 67–68–5) when used as an inert ingredient (solvent, co-solvent) in pesticide formulations pre-harvest applications, including post-emergence use.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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 exemption 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: October 5, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 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. In § 180.920, amend table 1 by:

■ a. Removing the entry for ''Dimethyl sulfoxide''; and

■ b. Revising the entry ''Dimethyl sulfoxide (CAS Reg. No. 67–68–5)''.

The revision reads as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.920

Inert ingredients	Limits	Uses
* * * * * * *		
Dimethyl sulfoxide (CAS Reg. No. 67–68–5)		Solvent/co-solvent.
* * * * * * *		

[FR Doc. 2022–22129 Filed 10–11–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0422; FRL–9994–01–OCSPP]

Lysate of Willaertia magna C2c Maky; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of Lysate of *Willaertia magna* C2c Maky in or on raw agricultural commodities and processed food, when used in accordance with label directions and good agricultural practices. The Amoéba SA, 38 ave des Frères Montgolfier, F–69680 Chassieu, France, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Lysate of *Willaertia magna* C2c Maky when used in accordance with this exemption.

DATES: This regulation is effective October 12, 2022. Objections and requests for hearings must be received on or before December 12, 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–2021–0422, 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 and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1400; 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, greenhouse owner, 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?

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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–2021–0422 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 December 12, 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