E 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 [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-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?*

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-2021-0422 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 [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-2021-0422, 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 April 28, 2022 (87 FR 25178 (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 0F8873) by Amoéba SA, 38 ave des Frères Montgolfier, F-69680 Chassieu, France. The petition requested that 40 CFR Part 180 be amended to establish an exemption from the requirement of a tolerance for residues of the

pesticide, when used as a fungicide and systemic resistance inducer for various food crops in fields and greenhouses, in accordance with label directions and good agricultural practices. That document referenced a summary of the petition prepared by the petitioner, Amoéba SA, which is available in the docket, *https://www.regulations.gov*. There were no relevant comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is establishing a tolerance exemption that varies from what the petitioner sought. The reason for the change is explained in full detail in Unit V.B.

**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 Lysate of *Willaertia magna* C2c Maky including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with Lysate of *Willaertia magna* C2c Maky follows.

*A. Toxicological Profile*

*Willaertia magna* C2c Maky is a non-genetically modified microorganism isolated from the thermal baths of Aix-les-Bains (France). It is a thermophilic free-living amoeba strain that belongs to the protozoan order, among eukaryotic unicellular mobile microorganisms (with flagella). It is a natural predator of bacteria, including *Legionella*, and other smaller amoebas. The lack of pathogenicity of this amoeba in human endothelial cells was demonstrated by cell culture.

With regard to the overall toxicological profile, *Willaertia magna* C2c Maky is of low toxicity. Based on acute studies, *Willaertia magna* C2c Maky is of low acute oral toxicity and acute inhalation toxicity (Toxicity Category III), 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. Subchronic 90-day oral toxicity, developmental toxicity, reproductive toxicity and mutagenicity data requirements were satisfied by guideline studies. There were no adverse subchronic effects for any oral 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. EPA granted waivers for the 90-day dermal and 90-day inhalation data

requirements based on a weight of the evidence approach (WOE) due to: 1) significant volatilization not being expected, 2) low overall acute toxicity (Toxicity Category III for inhalation), 3) its components are naturally-occurring and are similar to substances already present in mammalian cells, 4) the lysate of Willaertia magna C2c Maky being non-irritating to the skin and non-sensitizing to the skin and its physical/chemical properties indicate it is unlikely to be dermally absorbed,  and 5) no adverse effects were seen in neither the 90-day oral toxicity study up to the limit dose nor the prenatal developmental toxicity study up to the limit dose.

*B. Toxicological Points of Departure/Levels of Concern*

EPA did not identify any toxicological endpoints of concern for *Willaertia magna* C2c Maky.

*C. Exposure Assessment*

1. *Dietary exposure from food, feed uses, and drinking water*. As part of its qualitative risk assessment for lysate of *Willaertia magna* C2c Maky, the Agency considered the potential for dietary exposure to residues of lysate of *Willaertia magna* C2c Maky. EPA concludes that dietary (food and drinking water) exposures are possible. However, no toxicological endpoint of concern was identified for lysate of *Willaertia magna* C2c Maky, and therefore, a quantitative assessment of dietary exposure is not necessary.

2. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). There are currently no proposed residential uses for this active ingredient; therefore, a residential exposure assessment is not necessary.

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 lysate of *Willaertia magna* C2c Maky shares a common mechanism of toxicity with any other substances, and it does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed lysate of *Willaertia magna* C2c Maky 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/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 lysate of *Willaertia magna* C2c Maky because no dietary endpoints have been selected based on the lack of human-relevant adverse effects at limit doses in the 90-day oral toxicity study and prenatal developmental toxicity study.

*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 lysate of *Willaertia magna* C2c Maky, and that risks of concern are not anticipated from aggregate exposure to the substance. This conclusion is based on the low toxicity of the active ingredient.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the January 13, 2022, document entitled "BPPD Risk Assessment

91283-I, 91283-O and Tolerance Petition." 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 lysate of *Willaertia magna* C2c Maky.

## 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. Revisions to Petitioned-For Tolerance Exemption*

The petitioned-for tolerance exemption for lysate of *Willaertia magna* C2c Maky is different from that being established by EPA. EPA determined that based on the low toxicity of lysate of *Willaertia magna* C2c Maky, any possible residues from the use of this active ingredient as a pesticide are not expected to result in any risks of concern to humans. Therefore, EPA has determined that the broad exemption for all food commodities, when used in accordance with label directions, is appropriate.

## VI. Conclusions

Therefore, EPA is establishing an exemption for residues of lysate of *Willaertia magna* C2c Maky in or on all food commodities, when used 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: October 5, 2022.

**Edward Messina,**

*Director, 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. Add § 180.1394 to subpart D to read as follows:

### §180.1394 Lysate of *Willaertia magna* C2c Maky; Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of the pesticide, lysate of *Willaertia magna* C2c Maky, in or on all food commodities, when used in accordance with label directions.

[FR Doc. 2022-22045 Filed: 10/11/2022 8:45 am; Publication Date: 10/12/2022]