

## PRE-PUBLICATION NOTICE

On Thursday, October 7, 2020, Andrew R. Wheeler, the EPA Administrator, signed the following document:

Action: Proposed rule.

Title: Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products; Proposed rule.

FRL #: 10009-24

Docket ID #: EPA-HQ-OPP-2019-0701

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 152**

**[EPA-HQ-OPP-2019-0701; FRL-10009-24]**

**RIN 2070-AK56**

**Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to add the substance commonly referred to as chitosan (also known by its chemical name: poly-D-glucosamine) (CAS Reg. No. 9012-76-4) to the list of active ingredients allowed in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Tidal Vision Products, LLC submitted a petition to EPA requesting that chitosan be added to both the lists of active and inert ingredients allowed in exempted minimum risk pesticide products. At this time, EPA is deferring a decision on whether to add chitosan to the list of allowable inert ingredients.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by the docket identification (ID) number EPA-HQ-OPP-2019-0701, through the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information

(CBI) or other information whose disclosure is restricted by statute.

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

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Anne Overstreet, Deputy Director, 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](mailto:BPPDFRNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. Minimum risk pesticide products are exempt from registration and other FIFRA requirements and are described in 40 CFR 152.25(f). 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:

- Pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (NAICS code

311119), cosmetics (NAICS code 325620), and soap and detergents (NAICS code 325611).

- Manufacturers who may also be distributors of these products, including farm supplies merchant wholesalers (NAICS code 424910), drug and druggists merchant wholesalers (NAICS code 424210).

- Retailers of minimum risk pesticide products (some of who may also be manufacturers), including nursery, garden center, and farm supply stores (NAICS code 444220); outdoor power equipment stores (NAICS code 444210); and supermarkets (NAICS code 445110).

- Users of minimum risk pesticide products, including the public in general, exterminating and pest control services (NAICS code 561710), landscaping services (NAICS code 561730), sports and recreation institutions (NAICS code 611620), and child daycare services (NAICS code 624410). Many of these entities also manufacture minimum risk pesticide products.

*B. What action is the Agency taking?*

EPA is proposing to add the substance commonly referred to as chitosan (also known by its chemical name poly-D-glucosamine) (CAS Reg. No. 9012-76-4) to the list of active ingredients allowed in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

*C. What is EPA's authority for taking this action?*

This action is issued under the authority of FIFRA, 7 U.S.C. 136 *et seq.*, particularly FIFRA sections 3 and 25.

*D. Why is EPA taking this action?*

EPA may exempt from the requirements of FIFRA any pesticide that is "...of a character

which is unnecessary to be subject to [FIFRA]” (FIFRA section 25(b)). Pursuant to this authority, EPA has exempted from the pesticide registration and requirements of FIFRA certain pesticide products if they are composed of specified ingredients (recognized active and inert substances which are listed in the regulations (40 CFR part 152)) and labeled according to EPA's regulations in 40 CFR 152.25(f). EPA created the exemption for minimum risk pesticides to eliminate the need for the Agency to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment.

*E. What are the estimated incremental impacts of the proposal?*

EPA has evaluated the potential incremental impacts of this proposed exemption in the document entitled “Cost Analysis of the Proposed Modification to the Minimum Risk Pesticide Listing Program. Prepared by Biological and Economic Analysis Division, Office of Pesticide Programs” (Ref. 1), which is available in the docket and is briefly summarized here.

Without this exemption, the petitioner would be required to register the chitosan product(s) as a pesticide under FIFRA. This could entail generating supporting data, incurring submission costs, and paying registration fees. In addition, the petitioner could incur annual maintenance fees on the registrations. EPA estimates the cost savings of listing chitosan as an active ingredient that can be used in minimum risk pesticide products under 40 CFR 152.25(f) to be between \$53,000 and \$116,000 initially and about \$3,400 per year thereafter for each pesticide product registered containing chitosan as explained in the following paragraph.

EPA has previously estimated the costs of guideline studies (Ref. 2) and registration fees (Ref. 3) are available on EPA’s website. EPA estimates the cost of submitting an application for a product registration to be about \$1,300 (Ref. 4). For a new product, data generation costs could be as much as \$109,000 and fees would be \$5,363; including submission costs, the petitioner

could avoid registration costs of nearly \$116,000. For products that are substantially similar to existing registered products, data generation costs could be around \$51,000 with fees of \$1,342; including submission costs, the petitioner could avoid registration costs of about \$53,000. (Ref. 1). Tidal Vision Products, LLC, indicated in its petition that it plans to register six chitosan pesticide products. Assuming the six products meet all the criteria for exemption (exempt products must only contain substance listed in 40 CFR 152.25(f), list all ingredients on the label, and may not make any claims to control public health pests), EPA estimates the total savings to be between \$318,000 and \$696,000 initially and about \$20,000 per year thereafter in maintenance fees. There may be additional savings if production establishments and production levels do not have to be registered or reported under FIFRA section 7. The magnitude of savings depends, in part, on whether Tidal Vision, LLC., would normally be eligible for reductions in fees that are available to a small business. (Ref.1)

For EPA, this action may reduce the Agency's level-of-effort that would otherwise be spent on registering pesticide products with little risk. However, PRIA fees are meant to support the Agency's work, so this action has negligible impact on overall resources. The impact on State regulatory costs is uncertain, as States have wide variability in how they regulate conventional pesticide products versus minimum risk pesticide products; this Federal action, however, is unlikely to significantly change how States register chitosan-containing pesticide products.

In the absence of an exemption, manufacturers may forego development and production of chitosan-based products. Thus, the exemption may ultimately benefit consumers who may see more of these products available at lower costs. An analysis of the cost and savings of adding chitosan to the list of active ingredients that can be used in minimum risk pesticide products

under 40 CFR 152.25(f) can be found in the docket for this action.

*F. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

As authorized by FIFRA section 25(b), EPA has exempted from the requirement of registration certain pesticide products if they are composed of specified ingredients (recognized active and inert substances which are listed in the regulations) and labeled according to EPA's regulations in 40 CFR 152.25(f). EPA created the exemption for minimum risk pesticides to eliminate the need for the Agency to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment.

Chitosan is a naturally occurring substance that is produced in nature and is found in the cell walls of many fungi. Chitin and its derivative chitosan also occur naturally in the shells of all crustaceans (e.g., crab, shrimp, and lobster) and in the exoskeletons of most insects. Microorganisms in nature produce enzymes that break down chitosan, resulting in sugars that are

metabolized as a carbon and nitrogen source.

On October 10, 2018, EPA received a petition from Tidal Vision Products, LLC, requesting that the substance commonly known as chitosan (also known by its chemical name poly-D-glucosamine) (CAS Reg. No. 9012-76-4) be added to the list of active ingredients allowed in exempted minimum risk pesticide products under 40 CFR 152.25(f)(1). (Ref. 5). Subsequently, on April 4, 2019, EPA received an amendment to Tidal Vision Products, LLC's petition, requesting that chitosan also be added to the list of inert ingredients allowed in exempted minimum risk pesticide products under 40 CFR 152.25(f)(2). (Ref. 6)

This proposed rule addresses the 2018 petition and EPA is currently deferring a decision on the 2019 petition regarding whether to add chitosan to the list of allowable inert ingredients.

### **III. Proposal to Add Chitosan to the Minimum Risk Active Ingredient List**

#### *A. EPA's Decision on Tidal Vision Products, LLC's 2018 Petition*

EPA finds that Tidal Vision Products LLC's 2018 petition to add chitosan to the list of active ingredients in 40 CFR 152.25(f)(1) has merit. Therefore, the Agency is granting the 2018 petition and proposing this rulemaking to add chitosan to the list of active ingredients allowed in exempted minimum risk pesticide products in 40 CFR 152.25(f)(1). EPA has determined that there is sufficient scientific evidence to support a conclusion of minimum risk for chitosan.

#### *B. EPA's Scientific Review Supporting Its Decision*

Based on all the information available to the Agency, there are low risk concerns for human health or the environment if chitosan is intended for use as a minimum risk pesticide. This conclusion is supported by information in EPA's reviews of registered pesticide products containing chitosan as an active ingredient. The conclusions are documented in EPA's August 23, 2019, scientific review memorandum, entitled "Science review in support of the addition of

Chitosan (Poly-D-Glucosamine) to the list of minimum risk pesticides (MRPs) contained in 40 CFR 152.25(f),” (Ref. 7), the Chitin and Chitosan Summary Document Registration Review: Initial Docket September 2007, (Ref. 8), the Chitin and Chitosan Final Registration Review Decision Case 6063. December 11, 2008, (Ref. 9) and in the Chitin and Chitosan Final Work Plan Registration Review - Case 6063, January 2008, (Ref. 10).

#### **IV. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. “Cost Analysis of the Proposed Modification to the Minimum Risk Pesticide Listing Program.” Prepared by Biological and Economic Analysis Division, Office of Pesticide Programs, EPA. July 2020.
2. EPA. “Cost Estimates of Studies Required for Pesticide Registration.” 2018. Accessed on September 30, 2019 at <https://www.epa.gov/pesticide-registration/cost-estimates-studies-required-pesticide-registration>.
3. EPA. “PRIA Fee Category Table – Biopesticides Division – New Products: Table 13”. 2019b. Accessed on October 4, 2019 at <https://www.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-new-products>.
4. EPA. “Application for New and Amended Pesticide Registration: Supporting Statement for An Information Collection Request (ICR).” 2015. Accessed on October 16, 2019

at <https://www.federalregister.gov/documents/2016/07/01/2016-15737/agency-information-collection-activities-information-collection-request-submitted-to-omb-for-review>.

5. 2018 Petition. Tidal Vision Products, LLC. Petition to list the material Chitosan CAS# 9012-76-4 on the U.S. EPA FIFRA Minimum Risk List 40 CFR 152.25(f). October 10, 2018.

6. 2019 Petition (Amendment). Tidal Vision Products, LLC amendment to add Chitosan to the Minimum Risk Pesticide Inert Ingredient List at the same time as adding Chitosan to the Minimum Risk Pesticide Active Ingredient List; Re: Petition to list the material Chitosan CAS# 9012-76-4 on the U.S. EPA FIFRA Minimum Risk Pesticide List 40 CFR 152.25(f). April 4, 2019.

7. EPA. Science review in support of the addition of Chitosan (Poly-D-Glucosamine) to the list of minimum risk pesticides (MRPs) contained in 40 CFR 152.25(f). August 23, 2019.

8. EPA. Chitin and Chitosan Summary Document Registration Review: Initial Docket September 2007. Submitted to Docket EPA-HQ-EPA-2006-0566.

9. EPA. Chitin and Chitosan Final Registration Review Decision Case 6063. Signed December 11, 2008. Submitted to Docket EPA-HQ-EPA-2007-0566.

10. EPA. Chitin and Chitosan Final Work Plan Registration Review - Case 6063. January 2008. Submitted to Docket EPA-HQ-EPA-2007-0566.

## **V. FIFRA Review Requirements**

In accordance with FIFRA section 25(a), EPA submitted a draft of this proposed rule to the United States Department of Agriculture (USDA) and the FIFRA Scientific Advisory Panel (SAP) for review. A draft of the proposed rule was also submitted to the appropriate Congressional Committees.

USDA responded without comments. The FIFRA SAP waived review of this proposed

rule, concluding that the proposed rule does not contain scientific issues that warrant scientific review by the Panel.

## **VI. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

### *A. Executive Order 12866: Regulatory Planning and Review; and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

### *B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs*

This action is expected to be an Executive Order 13771 deregulatory action (82 FR 9339, February 3, 2017). Details on the estimated cost savings of this proposed rule can be found in EPA's cost analysis (Ref. 1), which are briefly summarized in Unit I.E.

### *C. Paperwork Reduction Act (PRA)*

This action does not impose any new information collection requirements that require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities required under the proposed exemption are covered by the existing Information Collection Request (ICR), entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b)" (OMB Control No. 2070-0187; EPA ICR No. 2475.03). The existing ICR estimates the burden of displaying mandatory active and inert ingredient and producer information on the labels of minimum risk pesticide products. To maintain exemption status, an exempt pesticide product must display the following information

on its label; the label display name and the percentage (by weight) of all active ingredients, the label display name of all inert ingredients, and the name of the producer or the company for whom the product was produced, along with the producer/company's contact information. Labels provide important regulatory information for the Federal, State, and Tribal authorities that regulate or enforce minimum risk pesticide products.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule.

This proposal to add a substance to the list of active ingredients allowed in exempted minimum risk pesticide products reduces existing regulatory burden and will not have a significant economic impact on a substantial number of small entities. The cost savings are summarized in Unit I.E. We have therefore concluded that this action will relieve/have no net regulatory burden for all directly regulated small entities.

*E. Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector Accordingly, this action is not subject to the requirements of UMRA.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government (Executive Order 13132 (64 FR 43255, August 10, 1999)).

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or the distribution of power and responsibilities between the Federal government and Indian tribes. Currently, there are no known instances where a Tribal government is the producer of a minimum risk pesticide product exempt from regulation. Thus, Executive Order 13175 does not apply to this action.

*H. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

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FR Document entitled: “Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products; Proposed Rule” (FRL-10009-24)

*J. National Technology Transfer and Advancement Act (NTTAA)*

NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this proposed rule because it does not involve technical standards.

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This rule proposes to add the substance commonly referred to as chitosan the list of active ingredients allowed in minimum risk pesticide products.

**List of Subjects in 40 CFR Part 152**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting, and recordkeeping requirements.

Dated: Click or tap to enter eSignature date.

**Andrew Wheeler,**

*Administrator.*

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

**Part 152—[Amended]**

1. The authority citation for part 152 continues to read as follows:

**Authority:** 7 U.S.C. 136–136y; and 31 U.S.C. 9701.

2. Add alphabetically the entry for “Chitosan, Poly-D-glucosamine (CAS No. 9012-76-4)” to the table in paragraph 152.25(f)(1) to read as follows:

**§152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.**

\* \* \* \* \*

**Table 1 of paragraph (f)(1).**

<b>Label display name</b>	<b>Chemical name</b>	<b>Specifications</b>	<b>CAS No.</b>
*	*	*	*
Chitosan	Poly-D-glucosamine		9012-76-4
*	*	*	*

\* \* \* \* \*