Proposed Registration Decision for the New Active Ingredient

Xanthan Gum

A biochemical insecticide for use on food crops, turf, and ornamentals

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Approved by:

ELIZABETH VIZARD
Digitally signed by ELIZABETH VIZARD
Date: 2024.10.24 18:11:01 -04'00'

for Ed Messina, Esq.
Director, Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency

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1. Introduction

This document announces that the Environmental Protection Agency (EPA) has completed its initial evaluation of the new biochemical active ingredient (AI), xanthan gum, for use as an insecticide and has concluded that it meets the regulatory and safety standards under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). EPA is seeking public comments on its proposed decision during a 15-day public comment period.

Xanthan gum is a natural extracellular polysaccharide produced by most bacteria of the *Xanthomonas* genus as part of the capsule or outer covering of the cell. When dispersed in water, xanthan gum acts as a hydrocolloid and provides a gelling effect. Xanthan gum has an extensive history of human use; it is commonly consumed as a U.S. Food and Drug Administration (FDA) approved food additive and thickener in numerous food products and beverages (21 CFR 172.695); and it is regularly applied to the skin as a principal ingredient in cosmetics. Overall, xanthan gum has a low toxicological profile; and sustained exposures are unlikely as this natural gum degrades readily in the environment.

As a proposed active ingredient, xanthan gum is intended for use as a broad-spectrum insecticide to be applied by spray to crops, ornamentals, and turf. Xanthan gum works through a physical mode of action as a viscous dispersion able to entrap or engulf insects upon contact, immobilizing and/or suffocating target insects. The proposed end-use products (EP)s are liquid concentrates and are intended to be diluted and applied using standard equipment that includes ground, airblast, backpack, and aerial spray. The maximum application rate is 0.066 lb ai/A, and the products are applied at the first sign of infestation and then every 7 to 10 days as needed. The restricted-entry interval (REI) is 4 hours from the time of application. All occupational applicators and handlers are required to wear the following baseline attire: long-sleeved shirts, long pants, shoes and socks.

After reviewing the submitted and publicly available data and information for xanthan gum, EPA has concluded that there is a reasonable certainty of no harm from residues of this new active ingredient and that its use will not cause unreasonable adverse effects to human health or the environment. Therefore, the Agency is proposing to grant the unconditional registration of one manufacturing-use product (MP), Rhexalloid (EPA File Symbol: 92988-R) and three end-use products (EPs), IS-27 (EPA File Symbol: 92988-U), IS-29 (EPA File Symbol: 92988-G) and IS-39 (EPA File Symbol: 92988-E), containing the new active ingredient, xanthan gum, under FIFRA section 3(c)(5).

Additionally, an exemption from the requirement of a tolerance as an active and inert ingredient is already established for xanthan gum. The regulations at 40 CFR 180.950 (Tolerance exemptions for minimal risk active and inert ingredients) states: “Unless specifically excluded, residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation … are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices.” Further, the regulations at 180.950(e) state: ”*Specific chemical substances.* Residues

resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices." Xanthan gum is listed as a specific chemical substance that is tolerance-exempt. See [67 FR 36537, May 24, 2002].
https://www.federalregister.gov/citation/62-FR-66023
https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-D/section-180.950

2. Background

On August 13, 2021, EPA received applications from Attune Agriculture LLC for four pesticide products containing the new biochemical active ingredient xanthan gum. Attune Agriculture LLC provided a combination of guideline studies, data waiver requests, and scientific rationales supported by information from the open scientific literature to address product chemistry, human health, and ecological toxicity data requirements.

In the Federal Register of February 17, 2022, EPA published a Notice of Receipt (NOR) that announced receipt of four new product applications: one MP and three EPs, containing the new active ingredient, xanthan gum.

3. Evaluation

In evaluating a pesticide registration application, EPA assesses a variety of studies to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the use of the pesticide product. Risk assessments are developed to evaluate how the active ingredient might affect a range of non-target organisms, including humans and terrestrial and aquatic wildlife (plants and animals). Based on these assessments, EPA evaluates and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk. In this way, the pesticide's label helps to communicate essential limitations and/or mitigations that are necessary for public and environmental safety. In fact, it is a violation of FIFRA to use a registered pesticide in a manner inconsistent with the label.

3.1 Assessment of Risk to Human Health

To assess risks to human health from use of biochemical pesticides, EPA evaluates the potential toxicity of a product, and the likelihood, amount, and types of exposure users and bystanders are likely to experience. In conducting a risk assessment, EPA must consider: (1) the hazards of a substance and (2) the direct or indirect human exposure to that substance as a consequence of use. EPA uses this information to assess and characterize the risk(s) and predict the probability, nature, and magnitude of the adverse health effects that may occur from use of the substance in the manner described.

To evaluate the toxicity of biochemical pesticides, EPA typically requires a range of Tier I data:

acute toxicity data (acute oral toxicity, acute inhalation toxicity, acute dermal toxicity); irritation tests (primary eye irritation, primary dermal irritation, and dermal sensitization); subchronic testing (90-day oral, 90-day dermal, and 90-day inhalation); mutagenicity testing (bacterial reverse mutation test and in vitro mammalian cell assay); and developmental toxicity testing (prenatal development). Tiers II and III testing requirements are triggered only when there is indication, usually through lower tier testing, that a biochemical pesticide has unusual characteristics, such as subchronic toxicity, or is suspected or known to be a carcinogen.

3.1.1 Toxicological Data/Information

Adequate mammalian toxicology data/information are available to support the registration of xanthan gum. All toxicology data requirements for xanthan gum have been satisfied and an updated dietary risk assessment is available in the regulatory docket (search for "EPA-HQ-OPP-2022-0147" at http://www.regulations.gov).

The toxicology database used for the biopesticide risk assessment for xanthan gum includes guideline studies for acute oral toxicity, primary eye and dermal irritation, dermal sensitization; acceptable waiver requests for acute dermal toxicity and acute inhalation toxicity; scientific rationales for subchronic and chronic oral toxicity, prenatal development toxicity and genotoxicity. The 90-day dermal and 90-day inhalation rationales were reviewed by the Hazard and Science Policy Council (HASPOC), using a weight of the evidence (WOE) approach that considered all of the available hazard and exposure information. A literature search was also conducted using PubMed databases with the terms "xanthan gum" and "toxicity". The search returned 81 results. However, no additional toxicity information concerning human health was identified. After consideration of the database, the Agency conducted a qualitative risk assessment for xanthan gum based on the facts that no toxicity data for this active ingredient were identified in a search of the scientific literature and that no endpoints were indicated in the available toxicological data. Based on the available information from the database, EPA has determined that exposure to xanthan gum from use as a pesticide is expected to result in negligible risk to humans. The toxicology data requirements and the toxicological profile for xanthan gum are discussed in the following sections.

Acute Toxicity

Acute oral toxicity, primary eye irritation, primary dermal irritation, and dermal sensitization data requirements for xanthan gum were addressed with guideline studies. Acceptable waiver rationales were submitted for acute dermal toxicity and acute inhalation toxicity. The acute toxicity data indicate that xanthan gum is of low acute oral toxicity (Toxicity Category IV), is minimally irritating to the eye (Toxicity Category IV), slightly irritating to the skin (Toxicity Category IV), and is not a dermal sensitizer. The acute dermal toxicity requirement was waived based on Category IV acute oral toxicity and EPA guidance for waiving acute dermal toxicity tests for pesticide technical chemicals (EPA, 2020). Acute inhalation toxicity was also waived since xanthan gum cannot be aerosolized at an exposure concentration within the recommended median mass aerodynamic diameter (MMAD) size limits (1-4 µm). Toxicity categories for both acute dermal toxicity and acute inhalation toxicity were therefore not assigned.

Subchronic Toxicity (90-day oral toxicity, 90-day dermal toxicity, and 90-day inhalation toxicity)

Waiver rationales were submitted for the 90-day dermal toxicity and 90-day inhalation toxicity. The rationales were reviewed by OPP's HASPOC using a WOE approach that considered all of the available hazard and exposure information; both rationales were accepted by HASPOC on May 12, 2022. Multiple non-guideline studies were submitted to satisfy the 90-day oral toxicity requirement. A summary of EPA's subchronic toxicity assessment follows.

90-day oral toxicity

Four acceptable subchronic and chronic non-guideline dietary studies in both rats and dogs were determined to be acceptable, satisfying this data requirement. These studies indicated the no-observable-adverse-effect-level (NOAEL) is equal to or greater than the recommended limit dose of 1,000 mg/kg/day. The lowest-observable-adverse-effect-level (LOAEL) is associated with only minor toxicity seen at doses well above the limit dose (LOAEL = 2,000 mg/kg/day, based on reduced body weight, lowered serum cholesterol, red blood cell count and hemoglobin concentrations, and changed bowl function (diarrhea, enlarged and foul-smelling intestines). No toxicity was observed across the available studies at dose levels relevant for human health risk assessment.

*90-day dermal toxicit*y

A waiver rationale to fulfill the 90-day dermal toxicity data requirement was accepted by the HASPOC using a WOE approach that considered all of the available hazard and exposure information. The rationale is based on the following considerations: (1) Xanthan gum has a large molecular size (MW > 1×10^6 Da) and it is negatively charged, thus is unlikely to be absorbed dermally. (2) Xanthan gum is naturally occurring and has an extensive history of use in foods and cosmetics approved by FDA. It also is exempt from the requirement of a tolerance as a minimal risk active and inert ingredient (40 CFR 180.950(e)). (3) Xanthan gum has low acute mammalian toxicity. It has been assigned Toxicity Category IV for acute oral toxicity, primary eye irritation, and primary skin irritation. It is not a dermal sensitizer. (4) There was no systemic toxicity in subchronic and chronic studies with up to 1,000 mg/kg/day xanthan gum, the recommended limit dose for a guideline repeat-dose study. Further, a 6-week repeat-dose cutaneous irritation study in rabbits showed xanthan gum was very-well tolerated, and no signs of skin irritation were observed during the study. And (5) human health risk from occupational dermal exposure is expected to be minimal, as the maximum concentration reported in cosmetics is 6%, far exceeding the proposed active ingredient concentration (0.15%) in the EPs.

90-day inhalation toxicity

A waiver rationale to fulfill the 90-day inhalation toxicity data requirement was accepted by the HASPOC using a WOE approach that considered all of the available hazard and exposure information. The rationale is based on the following considerations: (1) xanthan gum has a non-toxic, physical mode of action specific to target insects. (2) Xanthan gum is naturally occurring

and has an extensive history of use. (3) Xanthan gum has low acute mammalian toxicity. Xanthan gum could not effectively be aerosolized at the required guideline particle size (MMAD 1-4 µm), with a minimum particle size of 10.4 µm (MMAD) at 2.38 mg/L. (4) There was no systemic toxicity in subchronic and chronic studies with up to 1,000 mg/kg/day xanthan gum, the recommended limit dose for a guideline repeat-dose study. (5) Human health risk from occupational inhalation exposure is expected to be minimal, as xanthan gum cannot be aerosolized at an exposure concentration within the recommended MMAD size limits.

Developmental Toxicity

The developmental toxicity data requirement for xanthan gum was satisfied with a three-generation non-guideline reproductive/developmental study in rats. No treatment-related effects were observed for parental, reproductive, and developmental outcomes at the highest dose tested (500 mg/kg/day). A NOAEL of 500 mg/kg/day can be considered for prenatal developmental toxicity.

Genotoxicity

The genotoxicity data requirements were satisfied by a non-guideline combined chronic dietary and carcinogenicity study in rats and supplemental toxicity data on xanthan gum. The combined study results indicated no carcinogenicity effects at the highest dose tested, 1,000 mg/kg/day (the recommended limit dose for guideline studies). Additionally, an assessment conducted by the European Food Safety Authority (EFSA, 2017) concluded that there is no dietary risk of concern with respect to genotoxicity based on the available toxicity information on xanthan gum and its negligible absorption.

3.1.2 Dietary and Occupational Exposure and Risks

Dietary and Drinking Water Exposure and Risk Characterization

Xanthan gum is to be applied on food crops, so there is the potential for food and drinking water exposures. However, xanthan gum is naturally occurring and has an extensive history of safe use in foods, beverages, and cosmetics approved by FDA. Moreover, xanthan gum is exempt from the requirement of a tolerance as a minimal risk active and inert ingredient (40 CFR 180.950(e)). Based on the physicochemical properties and toxicological profile of the proposed active ingredient xanthan gum, no dietary risks of concern are anticipated.

Residential (Non-occupational) Exposure and Risk Characterization

There are no proposed residential (non-occupational) uses associated with xanthan gum; however, there does exist the potential for residential post-application and handler exposure. Due to the low toxicity profile of xanthan gum, the EPA has determined there is no risk of concern that is associated with residential post-application exposure. Therefore, a residential handler and post-application exposure and risk assessment has not been conducted.

Occupational Exposure and Risk Characterization

Occupational handler exposure and post-application exposure to xanthan gum may occur from the proposed EPs that are to be used in commercial settings. Risk is not expected to be of concern based on the low toxicity of xanthan gum through all routes of exposure, the extensive history of human exposure without known toxicological incident, and the unlikelihood for systemic absorption. In short, no risks of concern have been identified relative to occupational exposures.

3.1.3 Cumulative Risk

EPA has not made a common mechanism of toxicity finding for xanthan gum and any other substances, and this biopesticide does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that xanthan gum has a common mechanism of toxicity with other substances.

3.1.4 Human Health Conclusions

EPA concludes that the use of xanthan gum will not result in unreasonable adverse effects to human health and that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of xanthan gum. EPA does not expect dietary (food and drinking water) or other non-occupational risks of concern from the use of xanthan gum as an active ingredient in pesticide products for food use. Data demonstrate that xanthan gum is of low toxicity for oral, dermal and inhalation routes of exposure, and that no significant exposures are anticipated when the product is used in accordance with label directions. Of additional note, no toxic endpoints have been established for xanthan gum.

The database of studies required to support the hazard assessment to human health is complete. For more information on the human health hazard assessment of xanthan gum, see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0147" at http://www.regulations.gov).

3.2 Assessment of Ecological Exposure and Risk

To assess ecological risks from use of biochemical pesticides, EPA evaluates the likely environmental impacts as a result of exposure of the chemical to plants and animals in the environment and to whether that exposure will cause harm or ecological effects. EPA uses this combined information and considers the overall toxicity to characterize the risk(s) in order to identify what levels may cause harmful effects on the plants and animals of concern that may occur from use of the substance in the manner described.

To evaluate toxicity, EPA initially requires that a wide range of studies including Tier I testing be done on the following non-target organisms: mammalian (acute, sub-chronic, prenatal developmental, and mutagenicity), birds (acute oral and dietary), fish (acute freshwater fish and aquatic invertebrates), plants, and insects. Testing is organized in a tiered structure, where Tier I studies test worst-case exposure scenarios and higher tiers (Tiers II and III) generally encompass definitive risk determinations and longer-term greenhouse or field testing. Higher tier testing is implemented only when unacceptable effects are seen at the Tier I screening level.

The database of studies required to support the hazard assessment to the environment is complete for xanthan gum. All nontarget toxicology data requirements for xanthan gum have been satisfied per 40 CFR 158.2060. To address these data requirements, the applicant submitted acceptable guideline studies for nontarget insect toxicity, avian acute oral toxicity and mammalian acute oral toxicity; and they submitted acceptable scientific rationales supported by toxicity studies identified in the scientific literature for freshwater fish toxicity, aquatic invertebrate toxicity, seedling emergence, vegetative vigor and avian dietary toxicity. The guideline studies submitted for the nontarget mammals, birds and insects indicated that xanthan gum was practically non-toxic to mammals, birds and nontarget insects. The scientific rationales for nontarget plants, based on field trials, indicated minimal phytotoxicity and demonstrated that plant cell walls are largely impermeable to xanthan gum, limiting the potentiality for any significant plant cell disruption. The scientific rationales for nontarget aquatic animals, fish and aquatic invertebrate, demonstrate that xanthan gum is readily diluted in aquatic environments, rendering it practically non-toxic to both aquatic animals and plants.

For more information on the environmental hazard assessment of xanthan gum, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0147" at http://www.regulations.gov).

3.2.1 Terrestrial Animals and Plants

Terrestrial Vertebrates

Birds and mammals may be exposed to xanthan gum as a result of the intended applications; however, the submitted data indicate that no significant effects are anticipated for nontarget birds or mammals.

An acceptable avian oral toxicity study of xanthan gum to Northern bobwhite was submitted to EPA. No observable abnormalities were seen in any bird at necropsy. An acute oral LD_{50} was determined to be greater than 2000 mg a.i./kg bw, which indicates practical dietary non-toxicity to birds. An acceptable scientific rationale was submitted to address the avian dietary toxicity data requirement. The rationale demonstrated that dietary testing was not necessary because: 1) the non-toxic physical mode of action of xanthan gum does not indicate accumulative or significant bioaccumulation potential; 2) there is already a history of safe use of xanthan gum as an inert ingredient in pesticide formulations; 3) avian oral toxicity tests, which generally result in a more sensitive endpoint for pesticides than the avian dietary test, were considered sufficient based on the EPA's guidance (USEPA, 2020); and 4) xanthan gum has been safely used in avian

vaccines and feed items, indicating that dietary toxicity would be highly unlikely.

An acceptable acute oral toxicity study on rats was submitted to EPA. There were no deaths and all animals gained weight for the duration of the study. An acute oral LD_{50} was determined to be greater than 5000 mg a.i./kg, which indicates that xanthan gum is practically non-toxic to wild mammals on an acute oral basis.

Nontarget Terrestrial Invertebrates

An acceptable guideline study on honeybee acute toxicity for xanthan gum was submitted to EPA. Study results indicated an LD_{50} value greater than 25 µg a.i./bee, indicating that xanthan gum was practically nontoxic to honeybees on a contact basis.

Nontarget Plants

Acceptable scientific rationales were submitted to EPA to address the nontarget plant toxicity data requirements (seedling emergence and vegetative vigor) for xanthan gum. The plant toxicity testing rationales include information about multiple field trials with EPs containing xanthan gum sprayed post-emergence at application rates that bracket the proposed rates (0.4 to 60 g a.i./acre). In these trials, no significant phytotoxicity was observed. Additionally, the rationales demonstrated that xanthan gum is not likely to permeate plant cell walls due to high molecular weights; and as such, it would be unlikely that xanthan gum would disrupt biological systems in plants. Furthermore, the rationales make clear that plants are not expected to be susceptible to xanthan gum's physical mode of action. Lastly, the rationales cite EPA's approval of xanthan gum as an inert ingredient permitted in exempted minimal risk pesticide products (40 CFR 152.25(2)) as an indication that xanthan gum is not expected to adversely affect nontarget plants. Altogether, the data indicate that no significant adverse effects are anticipated for nontarget plants relative to the use of xanthan gum as an active ingredient.

3.2.2 Aquatic Organisms

Freshwater Fish, Aquatic-Phase Amphibians, Aquatic Invertebrates and Aquatic Plants

Acceptable scientific rationales, supported by toxicity studies identified in the scientific literature, indicate that xanthan gum is practically non-toxic to freshwater fish and aquatic invertebrates. The rationale for toxicity to freshwater fish includes a publication, which discusses drilling fluid ecotoxicity data collected from the scientific literature. The publication identifies three 96-hr rainbow trout acute toxicity studies with xanthan gum. In these studies, 96-h LC_{50} values ranged from 420 to 2200 mg/L, indicating that xanthan gum is practically non-toxic to fish. The rationale for toxicity to freshwater invertebrates includes acute toxicity values from safety data sheets. In these data sheets, the xanthan gum 24- and 48-h LC_{50} values for *Daphnia magna* were 700 and 980 mg/L, respectively, indicating that the xanthan gum is practically non-toxic to aquatic invertebrates. These rationales are further supported by the fact that the xanthan gum has a history of safe use in pesticide formulations as an inert ingredient with a non-toxic, physical mode of action that is not expected to be efficacious in aquatic habitats due to dilution. The scientific

rationales indicate that xanthan gum is practically non-toxic to fish and aquatic invertebrates.

With regard to aquatic plants, no significant exposure is anticipated given the low estimated environmental concentration of xanthan gum and the rapid degradation of xanthan gum in the environment. As such, no significant risks are anticipated for any aquatic plants.

3.2.3 Listed Threatened and Endangered Species Conclusions

Xanthan gum is proposed for use as a broad spectrum, contact insecticide that entraps or engulfs insects upon contact, killing the insect by suffocation, immobilization, and/or exhaustion. Target insects susceptible to being entrapped are generally less than 4 mm. Xanthan gum is non-toxic to both terrestrial and aquatic taxa. Because xanthan gum is non-toxic and elicits its effects through entrapping or engulfing the target pest, its physical mode of action is limited to direct contact with terrestrial invertebrates at the time of the application. Therefore, direct effects from the proposed uses are only expected for terrestrial invertebrates.

The EPA made No Effect (NE) determinations for 682 listed species and 500 designated Critical Habitats (CHs). These NE determinations are made because either the species or designated CH is outside of the action area (based on overlap analysis) or no direct effects and no effects to the species' prey, pollination, habitat, or dispersal (PPHD) are expected based on the habitat of the species or life history of the species, suggesting that no effects are expected. The EPA also made Not Likely to Adversely Affect (NLAA) determinations for 1,046 listed species and 445 designated CHs because the species' range or designated CH has ≥1% overlap, indicating that there is a potential for xanthan gum exposure. The NLAA determinations for terrestrial invertebrates and their designated CHs were made due to the fact that 1) xanthan gum works via a physical mode of action, 2) exposure to xanthan gum is only expected during or shortly after the application, so its temporal impact is highly restricted and exposure is only expected for invertebrates on the field during this brief time period, 3) most listed terrestrial invertebrates are not expected to be on the treated use sites (*e.g.,* agricultural fields, commercial areas with turfgrass or ornamentals) during or shortly after application, and 4) xanthan gum is not effective on invertebrates >4 mm in size because these invertebrates cannot become engulfed and can extract themselves from the spray droplet. The off-field expectation is particularly true for listed species that obligately rely on native host plants and for listed species with highly specific habitats that are not represented by the proposed use sites. For non-invertebrate species that rely on terrestrial invertebrates for prey or pollination and for these species' designated CHs, the EPA made NLAA determinations because effects to the species' PPHD and the physical or biological features (PBFs) of the designated CHs are expected to be discountable based on physical mode of action and the narrow spatial and temporal window of effects to invertebrates. Because the effects of xanthan gum are expected to be largely localized to the treated field within 6 hours of an application and to invertebrates less than 4 mm in size, disruption of ecosystem services provided by non-target invertebrates to listed vertebrate and plant species is not expected and habitat quality of these species' designated CHs is not likely to be adversely affected.

Pursuant to the requirements of section 7(a)(2) of the Endangered Species Act (16 U.S.C. § 1536(a)(2)) and 50 C.F.R. § 402.13, EPA initiated consultation with the U.S. Fish and Wildlife

Service (FWS) on August 14, 2024.

The database of studies required to support the assessment of risk to the environment is complete at this time. For more information on the environmental risk assessment of xanthan gum, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0147" at http://www.regulations.gov).

4. Benefits

Xanthan gum is a biochemical insecticide with a low toxicity profile. It is a lower toxicity alternative to conventional insecticides such as organophosphates, organochlorines, carbamates and pyrethroids. End-use products containing xanthan gum can also be used in Integrated Pest Management (IPM) programs as a complement or replacement for the aforementioned conventional insecticides. Of additional note, xanthan gum biodegrades more rapidly than most alternative conventional pesticides, potentially making it a more environmentally protective choice. Altogether, pesticides containing xanthan gum have both environmental and human health benefits relative to many conventional insecticides, making them a valuable addition to the pesticide tool kit and an attractive alternative to conventional insecticides.

5. Public Comments

In the Federal Register of February 17, 2022, EPA published a Notice of Receipt (NOR) that announced receipt of four new product applications: one MP and three EPs, containing the new active ingredient, xanthan gum. No comments were received in response to the NOR.

Because this pesticide product contains a new active ingredient, xanthan gum, EPA is opening a 15-day public comment period. EPA is taking this action in accordance with a policy, first implemented in October 2009, designed to provide a more meaningful opportunity for the public to participate in major registration actions.

6. Proposed Registration Decision

The xanthan gum database is considered to be complete with regard to the human health and environmental fate and ecological data requirements. In considering the assessed risk to human health and the environment, the Agency concludes that xanthan gum meets the regulatory standard under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Therefore, the EPA is proposing to grant the unconditional registration of xanthan gum as a new active ingredient under Section 3(c)(5) of FIFRA.

EPA is proposing to register one MP, Rhexalloid (EPA File Symbol: 92988-R), containing 100% xanthan gum, and three EPs, IS-27 (EPA File Symbol: 92988-U), IS-29 (EPA File Symbol: 92988-G) and IS-39 (EPA File Symbol: 92988-E), each containing 0.15% xanthan gum. The EPs will be applied to crops, turf, and ornamental plants as a contact insecticide. An exemption from the requirement of a tolerance is already established for "xanthan gum" by name as a "specific

chemical substance" under 40 CFR 180.950(e).

In the endangered species assessment portion of its review of the proposal to register xanthan gum pesticide products, EPA made a "may affect, not likely to adversely affect" (NLAA) determination for discountable effects to listed terrestrial invertebrates and to taxa that depend upon terrestrial invertebrates (e.g., for diet or pollination), including listed birds, mammals, amphibians, reptiles, insects, arachnids, and plants. Therefore, as part of the registration of the MP and EPs containing xanthan gum, EPA initiated consultation with the FWS on August 14, 2024, and we are proposing to require the following term on both registrations:

"If, following consultation with the United States Fish and Wildlife Service, the Service identifies additional issues or needed modifications, EPA will determine whether any changes are needed to this registration or labeling and will notify Attune Agriculture LLC. in writing if any changes are necessary and whether they are required to submit an amendment application incorporating any required data or modification, including an amended label. Alternatively, Attune Agriculture LLC must submit a request for voluntary cancellation of the product. If this term of registration is not met, EPA may cancel the registration under an expedited process under FIFRA 6(e)."

The risk assessments and labels supporting this proposed decision can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0147" http://www.regulations.gov).

7. Registration Requirements

The EPA is registering the following products:

An MP: Rhexalloid (EPA File Symbol: 92988-R)
- 100 % Xanthan gum
- For Formulation into Insecticidal End-use Products for Agricultural and Commercial Use

An EP: IS-39 (EPA File Symbol# 92988-E)
- .015 % Xanthan gum
- Xanthan gum must be applied using nozzles and spray pressures that minimize the production of spray drops that are less than 105 microns in diameter.
- Xanthan gum must not be tank mixed with adjuvants containing surfactants, spreaders, wetting agents or organosilicones but can be tank mixed with hydrocolloid based adjuvants.

An EP: IS-29 (EPA File Symbol# 92988-G)
- .015 % Xanthan gum
- Xanthan gum must be applied using nozzles and spray pressures that minimize the production of spray drops that are less than 105 microns in diameter.
- Xanthan gum must not be tank mixed with adjuvants containing surfactants, spreaders, wetting agents or organosilicones but can be tank mixed with hydrocolloid based adjuvants.

An EP: IS-27 (EPA File Symbol# 92988-U)

- .015 % Xanthan gum
- Xanthan gum must be applied using nozzles and spray pressures that minimize the production of spray drops that are less than 105 microns in diameter.
- Xanthan gum must not be tank mixed with adjuvants containing surfactants, spreaders, wetting agents or organosilicones but can be tank mixed with hydrocolloid based adjuvants.

8. Supporting Documents

The risk assessments supporting this proposed decision and the draft product labels for the MP, Rhexalloid (EPA File Symbol: 92988-R) and three EPs, IS-27 (EPA File Symbol: 92988-U), IS-29 (EPA File Symbol: 92988-G) and IS-39 (EPA File Symbol: 92988-E), can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0147" at http://www.regulations.gov).

9. Future Data Requirements

Should the formulation of the end-use product or the application methods described in 'Section 7' of this document change in the future, or if new products are proposed containing xanthan gum, additional data may be required, and new risk assessments may need to be performed.