OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

Proposed Registration Decision for the New Active Ingredient

Linseed Oil

An insecticide and miticide for use on crops, turf, and ornamental plants

PC Code: 031603

Approved by:

Digitally signed by EDWARD MESSINA
Date: 2024.07.15 14:52:00 -04'00'

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), linseed oil, for use as an insecticide and miticide, 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 comment on its proposed decision regarding linseed oil during a 15-day public comment period.

Linseed oil, also known as flaxseed oil, is a colorless to yellowish oil obtained from the dried, ripened seeds of the flax plant (*Linum usitatissimum*). Linseed oil has a non-toxic mode of action and can smother certain insects or mites in many life stages and reduce their rate of population development, which in turn reduces crop damage and protects crop yield. Linseed oil has a long history of use in consumer products, including dietary supplements and cosmetic products. Linseed oil is also often blended with combinations of other oils, resins or solvents as an impregnator, drying oil finish or varnish in wood finishing, as a pigment binder in oil paints, as a plasticizer and hardener in putty, and in the manufacture of linoleum. Linseed oil is on the Agency's minimum risk pesticides list (40 CFR 152.25(f)) and is approved for use in pesticide products as an inert ingredient (food, non-food, and fragrance uses).

After reviewing the submitted and publicly available data and information for linseed oil, 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 three products (one manufacturing-use product (MP) and two end-use products (EP)): Raw Linseed Oil Technical (EPA File Symbol: 94473-R), CROPCOAT (EPA File Symbol: 94473-E), and CROPCOAT CX1098 (EPA File Symbol: 94473-G), containing the new active ingredient, linseed oil, under FIFRA section 3(c)(5). The MP is for use in manufacturing and formulating end-use products. CROPCOAT and CROPCOAT CX1098 are liquid biopesticide products intended to be applied to crops, turf, and ornamental plants as insecticides/miticides. The EPs must be applied using properly calibrated non-agitating (conventional ground spray and ground boom as well as handheld and backpack sprayers) or agitating sprayer tanks. Sufficient water volume must be used to obtain thorough uniform coverage of all plant surfaces, and all leaf and fruit surfaces must be thoroughly treated to the point of runoff. The maximum application rate is 23.6 lbs/A EP. There is a 4-hour restricted-entry interval (REI) on both labels. Personal Protective Equipment (PPE) requirements include long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks.

An exemption from the requirement of a tolerance is already established for linseed oil. 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." During its review, EPA determined that linseed oil is an "edible oil" per 40 CFR 180.950(c) and is therefore exempt from the requirement of a tolerance under FFDCA section 408. The tolerance petition submitted with this application has therefore been withdrawn by the applicant on April 2, 2024.

2. Background

Linseed oil was classified as a biochemical pesticide by the EPA's Biochemical Classification Committee on June 19, 2018, due to its natural occurrence, history of exposure to humans and the environment, and non-toxic mode of action to the target pest(s).

On October 29, 2021, EPA received applications from Crop Enhancement, Inc., for the registration of three pesticide products – one manufacturing product (MP) and two end-use products (EPs) – containing the new biochemical active ingredient linseed oil. Crop Enhancement, Inc. also submitted a petition [1F8959] to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for residues of linseed oil when used as an insecticide and miticide on crops, turf, and ornamental plants, in accordance with label directions and good agricultural practices. To support the FIFRA section 3 registration applications, Crop Enhancement, Inc. provided 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 (87 FR 57494) of September 20, 2022, EPA published a Notice of Receipt (NOR) per FIFRA section 3(c)(4), of three new pesticide registration applications, including one MP and two EPs containing the new active ingredient linseed oil. In the Federal Register (87 FR 58047) of April 22, 2021, EPA published a Notice of Filing (NOF) per FFDCA section 408 that announced a request to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of linseed oil in and on all food commodities when used as a plant regulator and an inducer of local and systemic resistance in accordance with label directions and good agricultural practices. No comments were received in response to this NOF. Subsequently, as noted above, EPA determined that linseed oil is an "edible oil" per 40 CFR 180.950(c) and is exempt from the requirement of a tolerance under the FFDCA section 408, if such use is in accordance with good agricultural or manufacturing processes. Based on the EPA's determination, on April 2, 2024, the applicant requested to withdraw the tolerance petition from the EPA's files.

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 that the directions for use and safety measures appropriately

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 a food-use registration of linseed oil on all food commodities. All toxicology data requirements for linseed oil have been satisfied and a qualitative risk assessment is available in the regulatory docket (search for "EPA-HQ-OPP-2022-0504" at http://www.regulations.gov).

The toxicology database used for the biopesticide risk assessment for linseed oil includes: 1) guideline acute toxicity studies; 2) guideline 90-day oral toxicity, prenatal developmental toxicity, and genotoxicity studies; 3) a non-guideline 14-day oral gavage dose-range finding study and a prenatal dose-range finding study; and 4) waiver rationales to satisfy the 90-day dermal toxicity and 90-day inhalation toxicity data requirements. Tier II and III testing (e.g., carcinogenicity, reproduction and fertility effects, etc.) are triggered only when there is indication, usually through the lower tier testing, that a biochemical pesticide has unusual characteristics such as subchronic toxicity, or is suspected or known to be a carcinogen.

Acute Toxicity

All acute toxicity data requirements were satisfied by guideline studies and indicate a low toxicity profile. The data submitted for linseed oil support the active ingredient being classified as Toxicity Category IV for acute oral, inhalation, and dermal toxicities; in addition, the primary

eye and primary dermal irritation studies showed the technical material is non-irritating (Toxicity Category IV). The signal word "CAUTION" will be used on the MP and EP labels containing the active ingredient linseed oil.

Linseed oil tested positive in the guideline local lymph node assay (LLNA) for skin sensitization. However, there is some evidence that chemicals with unsaturated carbon-carbon double bonds may result in a higher number of false positive results in the LLNA compared to the guinea pig maximization test (GPMT) (Kreling et al. 2008). It is unlikely that raw linseed oil is a contact skin sensitizer, given the negative results of its free fatty acids in the GPMT and the suitability of the LLNA assay for testing of unsaturated fatty acids. Additionally, it is important to note that one of the proposed EPs was tested and was not considered a dermal sensitizer in the LLNA test.

Subchronic Toxicity

14-day Oral Gavage Dose Range-Finding Study (rat)

A 14-day oral gavage dose-range finding study was performed. Dose levels included 0, 250, 500, and 1000 mg/kg/day. No mortality or morbidity was observed during the study period. No treatment-related changes in any of the tested parameters (including body weight, body weight change, food consumption, hematology, and clinical chemistry) were observed. Gross necropsy resulted in no observation of lesions of pathological significance. The no observed adverse effect level (NOAEL) was 1000 mg/kg/day (highest dose tested).

90-day Oral Toxicity Study (rat)

A guideline 90-day oral toxicity guideline study was performed. Dose levels included 0, 100, 300, and 1000 mg/kg/day. No mortality or morbidity was observed during the study period. No treatment-related changes were observed in any of the tested parameters. Gross necropsy resulted in no observation of lesions of pathological significance. The NOAEL was 1000 mg/kg/day (highest dose tested).

90-day Dermal Toxicity

A waiver rationale to fulfill the 90-day dermal toxicity data requirement was assessed by OPP's Hazard and Science Policy Council (HASPOC), using a weight of the evidence (WOE) approach that considered all of the available hazard and exposure information. The rationale was determined to be acceptable based on the following considerations: (1) linseed oil has a low overall toxicity profile, is non-irritating to the skin, and is classified as Toxicity Category IV for acute dermal toxicity; in addition, there were no adverse effects observed up to limit doses in the guideline 90-day oral and developmental toxicity studies, and genotoxicity results were negative in both assays; (2) linseed oil is derived from naturally occurring flax seeds and has a long history of exposure without significant adverse reactions; (3) linseed oil is approved for inert ingredient (food, non-food and fragrance) use in pesticide products and has an exemption from the requirement of a tolerance (40 CFR 180.950); (4) linseed oil is used to treat wounds and has been shown to be anti-inflammatory, anti-oxidative, and therapeutic for atopic dermatitis

patients; and (5) linseed oil is on the 25b minimum risk pesticides list in 40 CFR 152.25(f).

90-day Inhalation Toxicity

A waiver rationale to fulfill the 90-day inhalation toxicity data requirement was assessed by OPP's Hazard and Science Policy Council (HASPOC), using a
WOE approach that considered all of the available hazard and exposure information. The rationale was determined to be acceptable based on the following considerations:
(1) low vapor pressure; (2) linseed oil is derived from naturally occurring flax seeds and has a long history of exposure without significant adverse reactions; (3) the technical material is of low acute inhalation toxicity (Toxicity Category IV) and is non-irritating to the eye and skin (Toxicity Category IV), no adverse effects were observed up to limit doses in the guideline 90-day oral and developmental toxicity studies, and genotoxicity results were negative in both assays; (4) linseed oil is approved for inert ingredient (food, non-food and fragrance) use in pesticide products and has an exemption from the requirement of a tolerance (40 CFR 180.950); and (5) linseed oil is on the 25b minimum risk pesticides list in 40 CFR 152.25(f).

Prenatal Developmental Toxicity Study (rat)

In a guideline study, raw linseed oil was administered by gavage daily from gestation day (GD) 5 to 19 to 25 female rats per group at dose levels of 0, 250, 500, and 1000 mg/kg/day.
The evaluated parameters included mortality, clinical signs (signs/evidence of physical or behavioral changes together with any overt signs of toxicity including abortion/resorption, etc.), body weight, body weight gain, food consumption, gross pathology, thyroid hormone analysis, weight of the gravid uterus and thyroid, histological examination of thyroid gland, number of viable and nonviable fetuses, early and late resorptions, number of total implantation sites, number of corpora lutea, and fetal body weight. All fetuses were examined for external malformations and variations; half of all fetuses were examined for visceral malformations and variations, and the remaining half were examined for skeletal malformations and variations.
There were no treatment-related effects on survival, clinical signs, body weight, food consumption, or cesarean parameters. The NOAEL for both maternal and developmental toxicity was 1000 mg/kg/day.

Dose Range-finding Prenatal Developmental Oral Toxicity Study

In a non-guideline study, raw linseed oil was administered by gavage daily from gestation day (GD) 5 to 19 to 8 mated female rats per group at dose levels of 250, 500, and 1000 mg/kg/day. No mortality or morbidity or clinical signs of toxicity were observed. The NOAEL was 1000 mg/kg/day.

Genotoxicity

In vitro Bacterial Gene Mutation

In a guideline study, Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and Escherichia coli WP2uvrA were exposed to linseed oil dissolved in dimethyl sulfoxide (DMSO) in a standard plate incorporation assay in which all bacterial strains were exposed to concentrations of 0, 1.58, 5.0, 15.8, 50, 158, 500, 1580 and 5000 µg/plate without and with activation. The maximum dose level of the test item in the first experiment was selected as the maximum recommended dose level of 5000 µg/plate. There was no visible reduction in the growth of the bacterial background lawn at any dose level, either in the presence or absence of metabolic activation (S9-mix), in the first mutation test (plate incorporation method). Consequently, the same maximum dose level was used as the maximum dose in the second mutation test. Similarly, there was no visible reduction in the growth of the bacterial background lawn at any dose level, either in the presence or absence of metabolic activation (S9-mix), or in the second mutation test (pre-incubation method). No test item precipitate was observed on the plates at any of the doses tested in either the presence or absence of S9-mix. There were no biologically relevant increases in the frequency of revertant colonies recorded for any of the bacterial strains, with any dose of the test item, either with or without metabolic activation (S9-mix) in Experiment 1 (plate incorporation method). Similarly, no biologically relevant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test item, either with or without metabolic activation (S9-mix) in experiment 2 (pre-incubation method).

In vitro Mammalian Cell Assay

In a guideline study, an in vitro mammalian cell gene mutation assay at the Hprt locus, Chinese hamster ovary (CHO-K1) cells cultured in vitro were exposed to linseed oil dissolved in DMSO for 4 hours at concentrations of 0, 0.313, 0.625, 1.25, 2.5 and 5 µL/mL in the absence and presence of metabolic activation. The AI was tested up to the concentration limit for the guideline and showed moderate toxicity at the highest concentration, which gave a percent relative cloning efficiency (% RCE) of 59.85% and 52.77% without and with activation, respectively. No biologically significant increase in mutant frequency over that of the solvent controls was observed for any test article concentration without or with activation. The positive controls did induce the appropriate responses. The mutant frequencies in the solvent and positive controls were within the range of the laboratory's historical database. There was no evidence of induced mutant colonies over background.

3.1.2 Dietary and Occupational Exposure and Risks

Dietary and Drinking Water Exposure and Risk Characterization:

A quantitative dietary exposure and risk assessment has not been conducted because dietary exposure to residues of the active ingredient in food and drinking water are not expected to be of toxicological concern when linseed oil is formulated into end-use products. This finding is

based on the lack of toxicological endpoints in the linseed oil database. Linseed oil has a long history of exposure through the cultivation of flax and crushing of its seed. Other dietary exposures from commercially available food-grade flaxseed oil are also possible. No significant adverse health effects have been reported from the use of food-grade flax seed oil. Further, based on low toxicity, exposure to the active ingredient is not of concern. No dietary risks of concern have been identified.

Residential (Non-occupational) Exposure and Risk Characterization:

There are no proposed residential (non-occupational) uses associated with linseed oil, however, there does exist the potential for residential post-application and handler exposure. Due to the low toxicity profile of linseed oil, 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:

Based on the proposed use pattern for linseed oil, short- and intermediate-term occupational handler and occupational post-application exposures are anticipated. However, due to the low toxicity of linseed oil, no risks of concern have been identified.

3.1.3 Cumulative Risk

EPA has not made a common mechanism of toxicity finding for linseed oil 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 linseed oil has a common mechanism of toxicity with other substances.

3.1.4 Human Health Conclusions

The toxicological database is complete for biopesticide risk assessment for the proposed use of linseed oil as an insecticide and miticide. Data demonstrates that linseed oil is of low toxicity for all routes of exposure. Furthermore, EPA does not expect dietary (food and drinking water) or other non-occupational risks of concern from use of linseed oil. Occupational exposures for individuals handling linseed oil or entering treated areas are not expected to result in risks of concern. EPA concludes that the use of linseed oil 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 linseed oil.

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 linseed oil, see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0504" at http://www.regulations.gov).

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

For all the reasons discussed above, EPA concluded 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 linseed oil. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

Infants and Children:

With particular regard to infants and children, FFDCA section 408(b)(2)(C) provides that, in establishing or modifying a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess risk considering the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity and ensure there is a reasonable certainty of no harm to infants and children from aggregate exposure to the pesticide chemical residue. In addition, FFDCA section 408(b)(2)(C) requires that, in the case of threshold effects, EPA apply an additional tenfold (10X) margin of safety for infants and children 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. In applying this provision, EPA either retains the default value of 10X or uses a different safety factor when reliable data available to EPA support the choice of a different factor.

As discussed previously, EPA concluded that linseed oil is not toxic to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when linseed oil is used in accordance with label directions and good agricultural practices, EPA determined that the additional margin of safety is not necessary to protect infants and children.

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 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, birds (acute oral and dietary), aquatic animals (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 linseed oil. All data requirements for avian, mammalian, aquatic taxa, terrestrial plants, and non-target insects were satisfied with acceptable studies or waiver rationales. All submitted information for linseed oil demonstrates that linseed oil is practically non-toxic to mammals, birds, insects, fish, aquatic invertebrates, and plants. Linseed oil has a non-toxic mode of action wherein it smothers target pests on foliage of treated crops. Based on lack of toxicity, direct effects are not expected for mammals, birds, plants, and aquatic taxa on or off the treated field. Invertebrates (including insects and non-insects) on the treated field at the time of the application are anticipated to be impacted due to the physical mode of action of linseed oil. However, effects to listed terrestrial invertebrates are considered to be discountable because listed terrestrial invertebrates often are larger than the target pests and are expected to be primarily off the treated use sites during and shortly after application, limiting the potential effects of linseed oil. Additionally, because the potential effects are expected to be limited to treated areas, alternative sources of invertebrate prey items and/or pollinators would still be available. Therefore, effects to terrestrial animals and plants are unlikely and thus are considered to be discountable.

For more information on the environmental hazard assessment of linseed oil, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0504" at http://www.regulations.gov).

3.2.1 Terrestrial Animals and Plants

Birds and Mammals

A scientific rationale for avian acute oral and dietary toxicity was submitted for linseed oil. Raw linseed oil is comprised of fatty acids and is anticipated to be immobile in soil with an estimated high K_{OC} (estimated 1×10^{10}) and will not vaporize from soils based on the estimated vapor pressure from EPA's EpiSuite (HSDB, 2019). The data presented show that the raw linseed oil will be available to foraging birds from the soil; however, it is not expected to persist in the environment. Finally, the rationale demonstrated that linseed oil is generally recognized as safe for use in food, provides nutritional benefits, and is widely used as a dietary supplement in poultry production at concentrations that are substantially higher than exposures that would be anticipated from any CROPCOAT and CROPCOAT CX1098 crop application scenario. An extensive literature search conducted by the applicant yielded no available data indicating toxicity or other adverse effects in birds exposed to linseed oil. The study cited in this waiver request tested the active ingredient at 5% of the diet (50,000 mg/kg-diet) in birds without any adverse effects noted. Endpoints exceeding 5000 mg a.i./kg-diet are classified as practically non-toxic by EPA. Therefore, the Agency granted the waiver request for the avian toxicity studies.

In an acute oral toxicity test with the rat, single oral gavage doses of undiluted raw linseed oil

(100% a.i.) were given at a dose level of 5000 mg a.i./kg-bw. Treatment was on Day 0 with observations conducted for up to 14 days. There were no mortalities, abnormal clinical signs, nor abnormal gross necropsy findings, and all three animals gained weight during both weeks of the study. The acute oral LD_{50} is > 5000 mg a.i./kg-bw, and linseed oil is classified as practically non-toxic to mammals on an acute oral basis.

Nontarget Insects

In a 48-hour acute contact toxicity study, honeybees (*Apis mellifera*) were exposed to a single nominal dose of 100 µg a.i./bee of raw linseed oil. No test material-related toxic effects were observed. The 48-hour contact LD_{50} value was >100 µg a.i./bee, classifying linseed oil as practically non-toxic to honeybees on an acute contact basis.

In a 48-hour acute oral toxicity study, honeybees (*Apis mellifera*) were exposed to a single nominal dose of 100 µg a.i./bee of raw linseed oil. No test material-related toxic effects were observed. The 48-hour oral LD_{50} value was >100 µg a.i./bee, classifying linseed oil as practically non-toxic to honeybees on an acute oral basis.

Nontarget Plants

Terrestrial plant toxicity studies were conducted to evaluate the effects of CROPCOAT CX1098 on vegetative vigor and seedling emergence of terrestrial plants following aboveground exposure. The effects of CROPCOAT CX1098 on seedling emergence, survival, shoot length, and shoot dry weight of 4 monocot species and 6 dicot species was assessed over a period of 21 days. At the limit application rate tested, no species demonstrated sensitivity to CROPCOAT CX1098 nor exhibited any inhibition compared to the control groups sufficient to calculate EC/IC_{25} values. As such, the No Observed Adverse Effect Concentration (NOAEC) for each species tested was 32 lb CROPCOAT CX1098/A, equivalent to 17.9 lb a.i./A, and the EC/IC_{25} values are > 32 lb CROPCOAT CX1098/A (> 17.9 lb a.i./A).

3.2.2 Aquatic Organisms

Freshwater Fish, Aquatic Invertebrates, and Aquatic Plants

The scientific rationale submitted for acute freshwater fish and invertebrate toxicity was based on an expected lack of exposure. The CROPCOAT formulations are designed for terrestrial uses and do not have direct application to water proposed. Once linseed oil dries after application, it is rainfast, and there is very low likelihood for transport due to wash off or runoff scenarios. Raw linseed oil is comprised of fatty acids and is anticipated to be immobile in soil with a high estimated K_{OC} from EPA's EpiSuite (HSDB, 2019). The submitted physical and chemical property data indicate that linseed oil is immiscible in water. As part of the rationale, the registrant conducted an extensive literature search which yielded no reports indicating toxicity or other adverse effects of linseed oil on an acute or chronic basis in aquatic plants and other aquatic animal species like *Daphnia magna*. Based on this rationale, the waiver request was granted by

the Agency.

3.2.3 Endangered Species Conclusion

Linseed oil has a non-toxic mode of action wherein it smothers target pests that are on foliage of treated crops. Based on lack of toxicity, direct effects are not expected for listed mammals, birds, amphibians, reptiles, plants, and aquatic taxa on or off the treated field. Terrestrial invertebrates (including insects and non-insects) on the treated field during or shortly after the application are anticipated to be impacted by the physical mode of action of linseed oil. Although effects are possible, linseed oil requires saturation of the invertebrate for smothering and exposure to linseed oil must occur during or within hours of the application before the droplet dries, after which linseed oil is not an effective pesticide. Because listed terrestrial invertebrates often are larger than the target pests and are expected to be primarily off the treated use sites during and shortly after application, effects to listed terrestrial invertebrates are considered to be discountable. This conclusion of discountable effects is further supported by the incorporation of mitigation measures to minimize drift from the treated use sites and potential exposure to pollinators via bloom restrictions. Additionally, the potential also exists for effects of linseed oil on listed species that are reliant on terrestrial invertebrates for ecosystem services such as a prey items or pollinators. Because the potential effects to terrestrial invertebrates are expected to be limited to treated areas, alternative sources of invertebrate prey items and/or pollinators would still be available. Therefore, effects on the prey, pollination, habitat, and dispersers of listed terrestrial animals and plants are unlikely and thus are also considered to be discountable.

Therefore, EPA's environmental risk assessment and effects determinations for linseed oil concluded that while the potential for impacts on non-target species exists, these effects are not likely to adversely affect these taxa. A "may affect, not likely to adversely affect" (NLAA) determination was made for effects to listed terrestrial invertebrates and to terrestrial taxa that depend upon terrestrial invertebrates (e.g., for diet or pollination), including listed birds, mammals, amphibians, reptiles, insects, arachnids, and plants. 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 July 8, 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 linseed oil, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0504" at www.regulations.gov).

4. Benefits

Linseed oil is an insecticide with a low toxicity profile that protects crops from insect damage. Beyond being a lower toxicity alternative to many conventional insecticides, end-use products containing this active ingredient can also be used in Integrated Pest Management (IPM) programs as a complement or replacement for multiple conventional insecticides. Of additional

note, linseed oil biodegrades more rapidly than most alternative conventional pesticides, potentially making it a more environmentally protective choice. Altogether, pesticides containing linseed oil 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 September 20, 2022 (87 FR 57494), EPA published a Notice of Receipt (NOR) that announced receipt of three new product applications containing the new active ingredient, linseed oil: Raw Linseed Oil Technical (EPA File Symbol: 94473-R), CROPCOAT (EPA File Symbol: 94473-E), CROPCOAT CX1098 (EPA File Symbol: 94473-G). No comments were received in response to the NOR.

In the Federal Register of September 23, 2022 (87 FR 58047), EPA published a Notice of Filing (NOF) that announced a request to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the insecticide/miticide linseed oil in or on all raw agricultural commodities. No comments were received in response to this NOF. Subsequently, as noted above, linseed oil is an "edible oil" per 40 CFR 180.950(c) and is therefore exempt from FFDCA and the tolerance petition submitted with this application was withdrawn by the applicant on April 2, 2024.

Because the pesticide products contain a new active ingredient, linseed oil, EPA is opening a 15-day public comment period per EPA's "Public Participation Process for Registration Actions" (https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions). EPA is taking this action in accordance with that policy, first implemented in October 2009, designed to provide a more meaningful opportunity for the public to participate in major registration actions. This public comment period is in addition to the public comment period provided per FIFRA section 3(c)(4).

6. Proposed Registration Decision

The linseed oil database is comprised of studies and information that meet the data requirements and support the labeled uses. In considering the assessed risk to human health and the environment, EPA concluded that linseed oil meets the regulatory standard under the FIFRA. Therefore, EPA is proposing to grant the registration of the linseed oil pesticide products under FIFRA section 3(c)(5).

EPA is proposing to register one MP and two EPs. The MP will be for manufacturing and formulating and contains linseed oil at 99.7%. The EPs also contain linseed oil at 70.0% and 54.0%, respectively. The EPs will be applied to a variety of crops, turf, and ornamental plants as insecticides/miticides. Linseed oil is an edible oil. For the biochemical new active ingredient, a tolerance exemption for edible oils is already established, if such use is in accordance with good agricultural or manufacturing practices.

In the endangered species assessment portion of its review of the proposal to register linseed oil 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 linseed oil, EPA initiated consultation with the FWS on July 8, 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 Crop Enhancement, Inc. 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, Crop Enhancement, Inc. 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-2022-0504" http://www.regulations.gov).

7. Registration Requirements

The EPA is proposing registering the following products:
Raw Linseed Oil Technical (94473-R)
- 99.7% Linseed oil
- This product may be used for formulation into end-use products for the following uses:
1. Terrestrial Food/Feed Crops
2. Terrestrial Nonfood Uses: Turf and Ornamentals
3. Use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).
4. Uses for experimental purposes that are in compliance with US EPA requirements.

CROPCOAT (EPA File Symbol: 94473-E)
- 70% Linseed oil
- For use on fruit-citrus, pome, stone, berry and small, tropical, subtropical, edible and inedible peel; herbs and spices; tree nuts; oilseeds; vegetables-fruiting, leafy, bulb, brassica, legume, root and tuber, stalk, stem and leaf petiole; artichoke, globe; coffee; hemp; hops; peanut; turf, and ornamentals. Applied by using properly calibrated non-agitating (conventional ground spray and ground boom as well as using handheld and backpack) or agitating sprayer tanks. Sufficient water volume must be used to obtain thorough uniform coverage of all plant surfaces, and all leaf and fruit surfaces must be thoroughly treated to the point of runoff.

CROPCOAT CX1098 (EPA File Symbol: 94473-G)
- 54% Linseed oil
- For use on fruit-citrus, pome, stone, berry and small, tropical, subtropical, edible and inedible peel; herbs and spices; tree nuts; oilseeds; vegetables-fruiting, leafy, bulb, brassica, legume, root and tuber, stalk, stem and leaf petiole; artichoke, globe; coffee; hemp; hops; peanut; turf, and ornamentals. Applied by using properly calibrated non-agitating (conventional ground spray and ground boom as well as using handheld and backpack) or agitating sprayer tanks. Sufficient water volume must be used to obtain thorough uniform coverage of all plant surfaces, and all leaf and fruit surfaces must be thoroughly treated to the point of runoff.

Labeling Mitigations

Label language must include the following mitigation measures to minimize off field exposure:

1. Applications are limited to ground and airblast equipment only and cannot be applied by air.
2. Spray cannot be released at a height greater than 2 feet above the ground or crop canopy.
3. Sprays must be directed into the canopy.
4. Applicators must turn off outward pointing nozzles at row ends and when spraying outer row.
5. The linseed cannot be applied when plants within the application site are blooming.

8. Supporting Documents

The risk assessments supporting this proposed decision and the draft product labels for products to be registered – Raw Linseed Oil Technical (EPA File Symbol: 94473-R), CROPCOAT (EPA File Symbol: 94473-E), and CROPCOAT CX1098 (EPA File Symbol: 94473-G) – can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2022-0504" http://www.regulations.gov).

9. Future Data Requirements

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