OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Environmental Risk Assessment and Biological Evaluation in Support of the Section 3 Registration of the Products, Linseed Oil Technical, containing 99.7% Linseed Oil, CropCoat, containing 70.0% Linseed Oil and CropCoat CX1098, containing 54.0% Linseed Oil

Case Number:	00330078 (MP), 00330080 (EP), and 00330083 (EP)
e-Submission Package ID:	68639 (MP), 68642 (EP), and 68644 (EP)
EPA File Symbol:	94473-R (MP), 94473-E (EP), 94473-G (EP)
PC Code:	031603
CAS Number:	8001-26-1
AI Tolerance/Exemption:	40 CFR 180.950(c)
MRID Numbers:	5147211, 5147212, 51475307
PRIA Code:	B590

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ACTION REQUESTED

Crop Enhancement requests registration of Raw Linseed Oil Technical (EPA File Symbol: 94473-R), a manufacturing-use product (MP) containing the new active ingredient, linseed oil (99.7%), and two end-use products (EPs), CropCoat (EPA File Symbol: 94473-E) and CropCoat CX1098 (EPA File Symbol: 94473-G), containing 70.0% and 54.0% linseed oil, respectively. In support of the application for registration for the MP and EPs, the applicant submitted proposed product labels, and non-target organism toxicity data and information.

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EXECUTIVE SUMMARY

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the ecological effects data submitted for the registration of products containing a new active ingredient, Raw Linseed Oil Technical (EPA File Symbol: 94473-R). These products include an MP containing the new active ingredient, linseed oil (99.7%), and two EPs, CropCoat (EPA File Symbol: 94473-E) and CropCoat CX1098 (EPA File Symbol: 94473-G), containing 70.0% and 54.0% linseed oil, respectively. Linseed oil has a non-toxic, physical mode of action that smothers the target pest. The EPs are proposed as insecticides and miticides for use on a wide variety of fruit, vegetable, vine, tree, herb, spice, coffee, and other miscellaneous crops, as well as on turf and ornamentals. CropCoat products are liquid biopesticides and are applied as a foliar spray using a variety of ground application methods. The application rate is 17.3 lb a.i./A.

The CropCoat formulations are designed for terrestrial uses. Once dry (12 to 24 hours after application depending on environmental conditions), the formulations are rainfast, and there is very low likelihood for transport due to wash off or runoff. Linseed oil is also not expected to be mobile in soil. Terrestrial taxa may be exposed by contact with spray droplets and/or through consumption of treated material. Aquatic taxa may be exposed through spray drift and/or runoff/erosion. CropCoat formulations are expected to be relatively immobile in soil and the fraction that may be transported to aquatic environments will be immiscible in water and likely entrained with the soil that ran off the treated field.

Based on the submitted toxicity data, linseed oil is practically non-toxic to mammals, birds, insects, fish, aquatic invertebrates, and plants. Based on lack of toxicity, direct effects are not expected for mammals, birds, amphibians, reptiles, plants, and aquatic taxa on or off the treated field. Although the active ingredient (a.i.) has a non-toxic mode of action, it is proposed as an insecticide and miticide because it may smother target pests that are residents on foliage of treated crops. Linseed oil has to completely cover the target pest to be effective. Therefore, invertebrates 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.

Although linseed oil is non-toxic, federally listed threatened or endangered ("listed") terrestrial invertebrate species, if present in the area coated with linseed oil, may be susceptible to the formulation's physical mode of action. For this reason and to meet the ESA section 7(a)(2) obligation, the EPA conducted a more extensive assessment to make effect determinations for listed species based on direct effects to invertebrate species and effects to other listed taxa's prey, pollination, habitat, and/or dispersal (PPHD) if the species depends upon terrestrial invertebrates (*e.g.,* for diet or pollination). In addition to toxicity and exposure considerations, the refined assessment considered overlap of listed species' ranges and designated critical habitats within the action area that encompasses all the proposed label uses. Details of the overlap analysis are described in Section V. The EPA made "no effect" (NE) determinations for 600 listed, proposed, or candidate species and 325 proposed or designated critical habitats (CH) because either the species or CH is outside of the action area (based on lack of overlap according to the spatial analysis) or direct effects and effects to the species' PPHD are not

expected (including effects to physical or biological features of CHs). For linseed oil, lack of direct effects and lack of effects to the species' PPHD is applicable for all fully aquatic species and for listed terrestrial/semi-aquatic plants that do not depend on terrestrial invertebrate pollinators, as well as for the CHs of these species.

EPA made "may affect" (MA) determinations for 1242 listed, proposed, or candidate species and 574 CHs. These MA determinations were made because the range or CH of these species has greater than 1%[1] overlap with associated use data layers (UDL) and a maximum 30 m drift distance[2], indicating that there is a potential for linseed oil exposure based on the proposed use sites. Due to the low probability of adverse effects given the limited spatial and temporal window for exposure and the lack of direct toxicity, the EPA made "not likely to adversely affect" (NLAA) determinations for these 1242 species and 574 CHs of listed terrestrial vertebrates (including amphibians, birds, mammals, and reptiles), plants, and terrestrial invertebrates. The EPA made these NLAA determinations because effects to the PPHD of listed amphibian, bird, mammal, reptile, and plant species that may be reliant on non-target invertebrates are considered unlikely despite spatial overlap. Effects to a species' PPHD are anticipated to be unlikely because direct effects to invertebrates are primarily limited to the treated field or in close proximity to it. Linseed oil is unlikely to deplete invertebrate populations to the point where effects to the PPHD of invertebrate-reliant species would occur. Alternative, unaffected sources of invertebrate prey items and/or pollinators would also still be available. Therefore, effects to terrestrial vertebrates and plants' PPHD are unlikely and thus are considered to be discountable. Risk to non-target invertebrate populations is also reduced through the incorporation of multiple mitigation measures that the applicant has agreed to include on the label, including prohibition of aerial applications, spray height restrictions, shutting off the outward facing nozzles while spraying the end or outer rows, and bloom restrictions. These mitigation measures are detailed in Section VII.

For terrestrial invertebrates specifically, a NE determination was made for 2 species and 1 CH due to the lack of overlap between the proposed use sites and habitats in which the species are present. The EPA made NLAA determinations for 161 listed, proposed, or candidate terrestrial invertebrate species and 63 CHs of terrestrial invertebrates where overlap was identified (*i.e.,* ≥1%), and exposure could not be ruled out based on the proposed use sites of linseed oil. The NLAA determinations for terrestrial invertebrates were made for the following reasons.

1) Linseed oil works via a physical mode of action, which requires saturation of the invertebrate for smothering.

[1] The overlap percentage is rounded to whole numbers due to the precision of the remotely sensed data; therefore <1% overlap represents ≤0.44% overlap, with any overlap between 0.45 and 0.99% (inclusive) rounding up to 1% overlap.

[2] The 30 m distance was selected to expand the footprint of the action area analyzed to conservatively account for potential off-field spray drift exposure. Droplet sizes, and thus efficacy of linseed oil, are expected to decrease with distance off the treated field and less than 1% of the a.i. is expected to drift to this distance of 30 m. The EPA does not expect this low amount of applied that drifts to 30 m off-field to have an effect on non-target invertebrates.

2) Exposure to linseed oil is only expected at the time of the application for it to work and is unlikely to impact species that are not residents of the treated field at the time of the application. The oil dries within hours so its temporal impact is highly restricted and is primarily expected to affect invertebrates on the field at the time of the application.
3) The body sizes of many listed terrestrial invertebrates are larger than the target pests; complete coverage of an invertebrate's respiratory organs (and thereby efficacy of the EPs) is most likely for smaller invertebrates.
4) Most listed terrestrial invertebrates are not expected to be on the treated use site during the time of application.
    a. This is particularly true for listed species that obligately rely on native host plants and for listed species with highly specific habitats that are not proposed use sites (*e.g.,* caves, prairies or grasslands, mountaintops, etc.).
    b. Additionally, the proposed bloom restriction (as explained in Section VII) is expected to minimize potential exposure for listed pollinators that otherwise may forage on blooming plants on the treated field.

Based on the limited spatial and temporal scope of the exposure and after the proposed mitigation measures (*e.g.,* bloom restriction) were incorporated into the assessment, direct effects to terrestrial invertebrates in proximity to treated areas are anticipated to be discountable. Similarly given the narrow temporal and spatial window in which linseed oil can cause effects and because linseed oil is practically non-toxic, effects to CHs of terrestrial invertebrates are also predicted to be unlikely. **Table 1** summarizes the effects determinations by taxon for listed, proposed, and candidate species, and **Table 2** summarizes the effects determinations for proposed and designated CHs.

Table 1. Summary of Listed Species Effects Determinations and Predictions of Likelihood of Jeopardy by Taxon.

Taxon	Number of Species	NE	MA		
			NLAA[1]	LAA, No J	LAA, J
Amphibians	42	11	31	0	0
Aquatic Invertebrates	228	228	0	0	0
Birds	111	7	104	0	0
Fish	201	201	0	0	0
Mammals	102	24	78	0	0
Plants	946	115	831	0	0
Reptiles	49	12	37	0	0
Terrestrial Invertebrates	163	2	161	0	0
Total	1842	600	1242	0	0

NE = No Effect; MA = May Affect; NLAA = Not Likely to Adversely Affect; LAA = Likely to Adversely Affect; No J = Not a Likelihood of Jeopardy; J = Likelihood of Jeopardy.

[1]All NLAA determinations for taxa other than terrestrial invertebrates are based on effects to the species' prey/pollination/habitat/dispersal only.

Table 2. Summary of Listed Species Effects Determinations and Predictions of Likelihood of Adverse Modification of Designated Critical Habitats.

Taxon	Number of Designated CHs	NE	MA		
			NLAA[1]	LAA, No AM	LAA, AM
Amphibians	31	7	24	0	0
Aquatic Invertebrates	102	102	0	0	0
Birds	33	5	28	0	0
Fish	122	122	0	0	0
Mammals	46	12	34	0	0
Plants	482	71	411	0	0
Reptiles	19	5	14	0	0
Terrestrial Invertebrates	64	1	63	0	0
Total	899	325	574	0	0

CH = designated critical habitat; NE = No Effect; MA = May Affect; NLAA = No Likely to Adversely Affect; LAA = Likely to Adversely Affect; No AM = Not a Likelihood of Adverse Modification; AM = Likelihood of Adverse Modification.

[1]All NLAA determinations for CHs of taxa other than terrestrial invertebrates are based on effects to the species' prey/pollination/habitat/dispersal.

The conclusions conveyed in this assessment were developed in full compliance with the *EPA Scientific Integrity Policy for Transparent and Objective Science*, and the EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions.* The full text of the *EPA Scientific Integrity Policy for Transparent and Objective Science*, as updated and approved by the Scientific Integrity Committee and the EPA Science Advisor can be found here: https://www.epa.gov/sites/default/files/2014-02/documents/scientific_integrity_policy_2012.pdf.
The full text of the EPA Scientific Integrity Program's *Approaches for Expressing and Resolving Differing Scientific Opinions* can be found here: https://www.epa.gov/scientific-integrity/approaches-expressing-and-resolving-differing-scientific-opinions.

I. BACKGROUND

A. Active Ingredient Characterization

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*). Raw Linseed Oil Technical containing 99.7% linseed oil is [redacted]. Linseed oil has a long history of use in consumer products, including dietary supplements and cosmetic products. 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).

B. Mode of Action

Linseed oil has a non-toxic, physical mode of action and can effectively 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. The product is most effective during and immediately after application when sprayed to completely cover any infested leaf and fruit surfaces. Typically, when oils like linseed oil are applied as pesticides, they work best on small, soft-bodied invertebrates that are immobile or slow-moving (such as aphids, leafhopper nymphs, and whiteflies)[3], presumably because it is more likely that the application will cover the entire body of such invertebrates and block their spiracles[4], preventing respiration and causing suffocation. Per the proposed labels, the target pests of linseed oil include aphids, ambrosia beetles, black twig borer, codling moth, coffee berry borer, coffee leafminer, fruit flies, leafhoppers, leafminers, leafrollers, mites, mullein leaf bug, navel orangeworm, oriental fruit moth, peach twig borer, plant bugs, planthoppers, plum curculio, psyllids, sawfly, tomato leafminer, tufted apple budmoth, and whiteflies. These are generally small species ranging from about 1 to 25 mm in size (with the exception of larvae of some sawfly species and adult codling moths).

C. Biopesticide Use Pattern

The EPs CropCoat and CropCoat CX1098 are liquid biopesticides that are proposed to be applied to agricultural crops, turf, and ornamental plants as an insecticide and miticide. The EPs can be applied using properly calibrated non-agitating or agitating sprayer tanks including conventional ground sprays and ground booms, as well as using handheld and backpack sprayers. Aerial applications are not permitted. 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 label states that a small amount of runoff is acceptable, but if substantial runoff is observed, most of the EP will end up in the soil, not on the plant surfaces, and the level of protection will be reduced. To minimize off-site runoff, the label states that the EPs should not be applied if rain is expected within four hours of application and overhead irrigation to crops treated with the EPs should not be applied within four hours of application. The application rate is 17.3 lb a.i./A. There is a 4-hour restricted-entry interval (REI) on both EP labels. The labels state that the EPs should not be applied more than 4 times a year.

[3] Texas Agricultural Extension Service: https://kendall.agrilife.org/files/2011/08/acfad41_5.pdf; University of Florida: https://gardeningsolutions.ifas.ufl.edu/care/pests-and-diseases/pests/management/natural-pest-control-with-oils.html; University of Nebraska, Nebraska Extension in Lancaster County: https://lancaster.unl.edu/hort/articles/2004/oils.shtml

[4] Spiracles are the external openings of invertebrates' tracheal respiratory system. The number, role, and sophistication of spiracles varies widely in insects depending on the species and life stage; spiracle number ranges from 0 to 20 in insects (Harrison, 2009). Changes in the respiratory system (including changes in spiracle number) can occur at each molt and during the pupal period for insects (Harrison, 2009).

II. ENVIRONMENTAL EXPOSURE

Linseed oil has non-toxic, physical mode of action and is most effective during and immediately after a spray application. It must completely cover invertebrates on the infested leaf and fruit surfaces in order to smother the target pests. The physical mode of action is limited to direct contact with non-target terrestrial invertebrates on the treated field. Non-target organisms off the treated field could be exposed to linseed oil from runoff and drift, but the potential of these exposure pathways causing an effect is low due to the rainfast nature of linseed oil once the application water has evaporated (limiting potential runoff) and also due to the lack of complete coverage of the non-target organisms off of the treated field via drifting droplets. Once dry, the residues of the linseed oil remain on the plant surface, which may lead to exposure when non-target taxa ingest treated leaf or fruit surfaces after application.

This assessment assumes that non-target invertebrates including bees and other pollinators present on the field during application may be directly exposed. Terrestrial animals may also be exposed through consumption of linseed oil residue on food items following foliar spray applications or by consumption of target pests exposed to linseed oil. Because saturation is required to suffocate insects, it is uncertain how far off the field effects would occur. Drift distances were calculated using AgDRIFT v 2.1.1 to estimate the fraction of the product that drifts off the treated field. Using the highest application rates of 17.3 lb a.i./A from a high boom ground application with a very fine to fine droplet size, off-field drift concentrations could range from 45% of the maximum application rate at 5 ft off the treated field to 1% of the maximum application rate at 237 ft off the treated field. For ground application of fine to medium/coarse droplets, off-field concentrations could range from 9% of the maximum application rate at a distance of 5 ft off the treated field to 1% of the maximum application rate at a distance of 66 ft off the treated field. Any droplets that may drift off-field are expected to be small in diameter because small droplets can be carried farther than larger droplets by wind. Overall, reductions in concentration and droplet size are expected to limit the efficacy of the a.i. off-field, because such reductions decrease the likelihood of completely covering the organism. Small droplets that drift off-field at low concentrations of <1% are not expected to constitute reasonable exposure for potential lethal effects to non-target insects.

At this time, there are no required geographical restrictions on the proposed labels; therefore, potential use sites of linseed oil may occur throughout the United States (U.S.) and its territories where labeled commodities or use sites may occur.

Within this assessment, estimated environmental concentrations (EECs) were not calculated due to the lack of toxicity, and suffocation is not expected unless the target organism is completely covered at the time of application, limiting the utility of EECs to represent an actual expected effect. The CropCoat formulations are designed for terrestrial uses. Once dry (12 to 24 hours after application depending on environmental conditions), they are rainfast, and there is very low likelihood for transport due to wash off or runoff scenarios. Additionally, linseed oil is not expected to be mobile in soil. Therefore, aquatic EECs due to runoff/erosion exposure were not calculated in this assessment. Aquatic environments may be exposed through spray drift

from use of conventional ground spray equipment. Concentrations in water bodies in close proximity to treated sites are expected to be well below concentrations that would elicit an effect. Using AgDRIFT v 2.1.1 and the highest application rate of 17.3 lb a.i./A applied with high boom ground equipment, linseed oil concentrations are estimated to be 44 µg/L (very fine to fine droplets) or 10 µg/L (fine to medium/coarse droplets) in water bodies 5 ft from the treatment site. Any linseed oil that may be transported to aquatic environments is not likely to result in persistent exposure due to the immiscible nature of linseed oil. Therefore, aquatic taxa are highly unlikely to be exposed to the a.i. at levels that would render any effects.

III. ECOLOGICAL EFFECTS

Data and scientific rationale have been submitted to satisfy the non-target organism and environmental fate data requirements for the proposed uses of linseed oil. The studies used to satisfy the data requirements are listed in **Table 3** and summaries follow.

No deficiencies were identified regarding fulfilling the data requirements for linseed oil. The toxicity studies and waiver rationales are classified as acceptable.

TABLE 3. Non-Target Organism and Environmental Fate Information for CropCoat Products.

OCSPP Guideline	Data Requirement	Description of Result	MRID and Classification
870.1100	Mammalian Acute Oral Toxicity, Rat	LD_{50} > 5000 mg a.i./kg-bw	51475214; Practically non-toxic; ACCEPTABLE
850.2100 850.2200	Avian Acute Oral and Dietary Toxicity	Data requirement addressed with acceptable scientific rationale. Literature suggests that consumption of linseed oil provides nutritional benefits. A study cited in this waiver request tested the active ingredients at 50,000 mg/kg-diet without any adverse effects noted.	50962101, ACCEPTABLE
850.1075 850.1010	Freshwater Fish and Aquatic Invertebrate Acute Toxicity	Data requirement addressed with acceptable scientific rationale. Freshwater acute toxicity is not anticipated based on linseed oil being immiscible in water. Once linseed oil dries, it is rainfast and has very low likelihood for transport due to wash off or runoff scenarios.	50962102, ACCEPTABLE

OCSPP Guideline	Data Requirement	Description of Result	MRID and Classification
850.4150	Terrestrial Plant Toxicity (Seedling Emergence and Vegetative Vigor)	NOAEC = 32 lb EP/acre or 17.9 lb a.i./acre for monocots (onion, oat, ryegrass, and corn) and dicots (cabbage, cucumber, soybean, sunflower, tomato and radish)	51475306, 51475307; Practically non-toxic; ACCEPTABLE
880.4350	Honey Bee Acute Oral Toxicity	48-hr oral LD_{50} > 100 µg a.i./bee	51474212; Practically non-toxic; ACCEPTABLE
850.3020	Honey Bee Acute Contact Toxicity	48-hr contact LD_{50} > 100 µg a.i./bee	51475211; Practically non-toxic; ACCEPTABLE

LD_{50} = median lethal dose; bw = body weight; NOAEC= no observed adverse effect concentration; EP = end-use product

A. Terrestrial Taxa

1. Avian and Mammalian Toxicity

A scientific rationale for avian acute oral and dietary toxicity was submitted for linseed oil (MRID 50962101). Raw linseed oil is comprised of fatty acids and is anticipated to be immobile in soil with a high estimated K_{OC} (estimated 1×10^{10}) and will not vaporize from soils based on the estimated vapor pressure [redacted]) from EPA's EpiSuite (HSDB, 2019). The data presented show that raw linseed oil will be available to foraging birds; 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 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. Therefore, the Agency granted the waiver request for the avian toxicity studies.

In an acute oral toxicity up-and-down procedure test (MRID 51475214), three fasted female Sprague-Dawley-derived albino rats were given single oral gavage doses of undiluted raw linseed oil (100% a.i.) at a dose level of 5000 mg a.i./kg-bw. Treatment was on Day 0 with observations conducted for up to 14 days. The animals were 9 to 11 weeks old (185-220 g) at the time of dosing. 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.

2. Terrestrial 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 (MRIDs 51475306 and 51475307). CropCoat CX1098 was applied at the maximum application rate of 32 lb CropCoat CX1098/A to the soil in case of seedling emergence study and to the leaves and aboveground portions of plants at the 2- to 4-true leaf stage in the vegetative study. 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). Both studies are classified as acceptable and were conducted in accordance with the guideline recommendations.

3. Non-Target Invertebrates

In a 48-hour acute contact toxicity study, honey bees (*Apis mellifera*) were exposed to a single nominal dose of 100 µg a.i./bee of raw linseed oil (MRID 51475211). Mortality and behavioral abnormalities were recorded at 0, 4, 24, and 48 hours. 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 honey bees on an acute contact basis. This study is classified as acceptable. This study was conducted in accordance with the guideline recommendations for contact toxicity studies for toxicity testing (OECD guideline 214) with the honey bee.

In a 48-hour acute oral toxicity study, honey bees (*Apis mellifera*) were exposed to a single nominal dose of 100 µg a.i./bee of raw linseed oil (MRID 51475212). Mortality and behavioral abnormalities were recorded at 0, 4, 24, and 48 hours. 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 honey bees on an acute oral basis. This study is classified as acceptable. This study was conducted in accordance with the guideline recommendations for acute oral toxicity studies for toxicity testing (OECD guideline 213) with the honey bee.

B. Aquatic Taxa

The scientific rationale (MRID 50962102) 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 physical and chemical property data in MRID 50962102 indicates 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.

IV. RISK CHARACTERIZATION

A. Terrestrial Taxa

Based on the submitted toxicity data and waiver rationales, linseed oil is practically non-toxic to birds, mammals, and terrestrial insects, and has no effects on plants at the highest labeled application rate. Because birds are a test species surrogate for terrestrial amphibians and reptiles, linseed oil is expected to be non-toxic to these taxa as well.[5] Linseed oil has a non-toxic, physical mode of action and is most effective during and immediately after application. When sprayed to completely cover any infested leaf and fruit surfaces, it smothers the target pests. Thus, its physical mode of action is limited to direct contact with terrestrial invertebrates. Because the honey bee toxicity data are the only data available for estimating risks to terrestrial invertebrates from use of linseed oil, the risk conclusions for all terrestrial invertebrates (insects and non-insects) are the same.

1. Terrestrial Vertebrates (Birds, Mammals, Reptiles, and Amphibians)

An extensive literature search yielded no available data indicating toxicity or other adverse effects in birds exposed to linseed oil. Linseed oil is widely used as a dietary supplement for human consumption and has been generally recognized as safe for use in food (MRID 50962101). The literature suggests that consumption of high dietary concentrations of linseed oil provides nutritional benefits, and it is used in the dietary supplements in poultry feed. However, the application rate of CropCoat and CropCoat CX1098 is not at a high enough concentration to provide beneficial effects to birds. Due to the lack of toxicity, direct effects to birds, mammals, reptiles, and terrestrial phase amphibians are not expected at the proposed application rates.

Effects to the PPHD of non-target birds, reptiles, amphibians, and mammals are possible if the vertebrate relies on terrestrial invertebrate prey. However, linseed oil is unlikely to deplete invertebrate prey populations to the point where effects to terrestrial vertebrates (including birds, mammals, amphibians, and reptiles) would occur as a result. Moreover, these terrestrial vertebrates are expected to be able to forage both on and off treated areas, and invertebrate prey items would still be available in unexposed off-field areas. Therefore, effects to terrestrial vertebrates (including listed species) are unlikely to occur when the products are used in

[5] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/technical-overview-ecological-risk-assessment-0

accordance with the proposed labeled use directions, and the effects are therefore considered discountable.

2. Terrestrial Invertebrates

Raw linseed oil is classified as practically non-toxic to honey bees with acute contact and oral LD_{50} values of > 100 µg a.i./bee (MRIDs 51475211 and 51475212). However, linseed oil is labeled as an insecticide and miticide and can smother non-target insects and invertebrates that are present on the field during the application. It acts with a physical mode of action through complete coverage of invertebrates, and therefore terrestrial invertebrates on the treated field at the time of application are expected to be affected. Foraging invertebrates could be exposed via contact if they are present on the field during the time of application. Considering the lack of complete coverage expected for foraging invertebrates off the treated field, smothering of non-target invertebrates off the treated field is not expected to be likely.

3. Terrestrial/Semi-Aquatic Plants

The submitted studies for vegetative vigor and seedling emergence were both conducted at the highest application rate of 32 lb CropCoat CX1098/A (equivalent to 17.9 lb a.i./A). No test species demonstrated sensitivity to CropCoat CX1098, nor demonstrated any inhibition compared to the control groups sufficient to calculate EC/IC_{25} values. As such, the 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). Based on these results, no effects to terrestrial/semi-aquatic plants are anticipated from linseed oil when applied according to the proposed label use directions.

B. Aquatic Taxa

Aquatic environments may be exposed to linseed oil through both spray drift and runoff. Although exposure may theoretically occur, concentrations of linseed oil in water bodies are expected to be low. Drift modeling with AgDRIFT v2.1.1 indicates that applications at the highest proposed application rate from a high boom sprayer result in water column concentrations as low as 44 µg/L (very fine to fine droplets) or 10 µg/L (fine to medium/coarse droplets) in water bodies within 5 ft of the treated field, indicating that drift exposure is expected to be minimal. Runoff is expected to be limited due to linseed oil's propensity to bind to particles. Linseed oil is rainfast once dry (12 to 24 hours after application depending on environmental conditions), further limiting potential transport to aquatic environments. Additionally, any linseed oil residues that drift or are entrained in sediment runoff (*i.e.,* erosion) are not likely to impact aquatic taxa due to the immiscible nature of the product in water. Lastly, a literature search yielded no data indicating toxicity or other adverse effects on aquatic species such as *Daphnia* sp. exposed to linseed oil on an acute or chronic basis. Therefore, even if exposure does occur, effects to aquatic taxa are not expected.

V. LISTED SPECIES EFFECTS DETERMINATIONS

This section presents the rationale supporting the linseed oil effects determinations made by the EPA for all 1842 currently listed, proposed, or candidate species. This assessment considers all listed, proposed, or candidate species as of February 16, 2022, and the overlap analysis in support of the effects determinations was conducted on April 2, 2024. The effects determination considers both direct effects and effects to listed species' PPHD from the proposed uses of linseed oil. Refinements to the taxa-based assessment (*e.g.,* assessment of potential for effects to a species' PPHD, spatial analysis) are then considered in the species-specific effects determination. Linseed oil is proposed to be used as an insecticide and miticide on a wide variety of crops, and the EPA has identified a potential for direct effects to terrestrial invertebrates only. Listed species in other taxa were determined to be potentially impacted via effects on terrestrial invertebrates that are the species' prey, pollinator, or disperser. A spatial overlap analysis was conducted to determine where listed invertebrate species and their CHs may be present in relation to proposed linseed oil use sites. This analysis was also performed to determine potential effects to the PPHD of listed species that depend on invertebrates for ecosystem services such as prey items or as pollinators.

A. Defining Spatial Overlap

The locations of species and their proposed or designated CHs in relation to the proposed linseed oil agricultural uses were identified using agricultural use data layers (UDLs) generated from the U.S. Department of Agriculture (USDA) cropland data layer (CDL). Use data layers spatially represent application sites for agricultural and non-agricultural label uses in the EPA's listed species biological evaluations (BEs). These data layers leverage several different landcover and land use datasets acquired from remote sensing technology to create a spatial footprint for a given label use. The EPA uses USDA's CDL for the agricultural use sites found in the conterminous United States (CONUS) and the 2016 U.S. Geological Survey National Land Cover Dataset (NLCD) for many non-agricultural uses (when available). Where NLCD was not available, the EPA uses the National Oceanic and Atmospheric Administration Coastal Change Analysis Program (C-CAP) dataset and corresponding landcover classes for non-agricultural uses. For Alaska and Puerto Rico, the EPA uses the NLCD, and for Hawaii, American Samoa, Guam, Commonwealth of the Marianas, and the U.S. Virgin Islands, the EPA uses the C-CAP data. Updated periodically, these publicly available datasets include a robust accuracy assessment which is used by the EPA to ensure the UDLs used in the BEs are of sufficient accuracy for decision making. The threatened and endangered species range and designated CH locations were provided by the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS). The overlap or co-occurrence analysis compares the exposure area for each UDL and the species/CH locations resulting in a percent overlap calculated as the acres of the exposure area for the UDL divided by the total acres for the species range/CH.

The action area is defined as the area represented by the spatial locations of linseed oil's proposed use sites and other areas where effects are reasonably expected to occur (due to the off-field transport from the use sites to non-target areas). A species or CH is within the action

area if it is found within one or more of the UDL exposure areas identified using the maximum overlap across UDLs. Given the known spatial relationship and correlation across the landscape and the accuracy[6] of the available UDLs, if the resulting maximum overlap is <1%[7] (including the off-field exposure area of the species), the species or CH is considered outside of the action area. Therefore, the Agency made NE determinations for species and CHs with <1% overlap with each UDL. For all species and CHs with ≥1% overlap with the action area, the EPA made MA determinations unless habitat characteristics and life histories of the species did not align with the proposed action (*i.e.,* aquatic animals, plants that do not depend on terrestrial invertebrates for pollination).

For all species with MA determinations, the EPA evaluated if linseed oil was "not likely to adversely affect" (NLAA) or "likely to adversely affect" (LAA) an individual listed organism.

The proposed uses of linseed oil were used to identify spatial data that represent potential application sites of linseed oil. **Table 4** provides a crosswalk of the UDLs associated with each proposed use site for linseed oil. The UDLs represent the potential locations of linseed oil applications in the CONUS and areas outside of CONUS (referred to as non-lower 48 or NL48). The non-lower 48 areas include Alaska, America Samoa, Commonwealth of the Marianas, Guam, Hawaii, Puerto Rico, and the U.S. Virgin Islands. At this time, there are no required geographical restrictions on the proposed labels.

Table 4. Crosswalk of the Use Data Layers (UDLs) associated with the Use Patterns Proposed for Linseed Oil.

Crop/Use	CONUS UDL	NL48 UDL
Agricultural Uses		
Pome Fruit; Stone Fruit; Tree Nuts; Tropical and Subtropical Fruit (edible and inedible peels); Coffee	Other Orchards	Ag
Citrus Fruit	Citrus	Ag
Grapes	Grapes	Ag
Cotton[1]; Cottonseed	Cotton	Ag
Soybean	Soybeans	Ag
Flaxseed; Rapeseed; Safflower	Other Grains	Ag

[6] The EPA used this 1% overlap criteria because a known source of error within spatial datasets is positional accuracy and precision. The National Standard for Spatial Data Accuracy outlines the accepted method for calculating the horizontal accuracy of a spatial dataset (FGDC, 1998). To prevent false precision when calculating area and the percent overlap, the EPA rounded the percentages to whole number to account for significant digits, where ≤0.44% overlap is represented as 0% overlap and overlaps between 0.45 and 0.99% (inclusive) are represented as 1% overlap.

[7] The overlap percentage is rounded to whole numbers due to the precision of the remotely sensed data; therefore <1% overlap represents ≤0.44% overlap, with any overlap between 0.45 and 0.99% (inclusive) rounding up to 1% overlap.

Crop/Use	CONUS UDL	NL48 UDL
Root and Tuber Vegetables; Leaves of Root and Tuber Vegetables; Bulb Vegetables; Leafy Vegetables; Brassica Leafy Vegetables; Legume Vegetables (except soybean); Fruiting Vegetables; Cucurbit Vegetables; Berry and Small Fruits (except grapes); Stalk, Stem, and Leaf Petiole Vegetables; Herbs and Spices; Spices; Artichoke (globe)	Vegetables and Ground Fruit	Ag
Hops; Peanut; Sunflower	Other Row Crops	Ag
Hemp; Oilseeds[2]	Other Crops	Ag
Non-Agricultural Uses		
Turf; Ornamentals (unspecified)	Developed, Open Space Developed, Other Crops[3]	Developed, Open Space Developed, Ag[3]
Foliage and Flowering Plants; Cut Flowers	Field Nurseries, Nurseries	Field Nurseries
Non-Bearing Fruit Trees	Other Orchards	Ag
Non-Bearing Grapevines	Grapes	Ag
Conifers	Forest Trees, Xmas Trees	Forest Trees, Managed Forest

UDL = use data layer; CONUS = conterminous United States; NL48 = non-lower 48 (*i.e.,* not CONUS)

[1] Cotton is included under "spices" in the CropCoat labels, which creates some uncertainty and ambiguity for the EPA. However, the EPA conservatively assumed that cotton is a proposed use site for linseed oil.

[2] All oilseeds proposed for use except cottonseed, flaxseed, rapeseed, safflower, and sunflower (which are included in other UDLs).

[3] The EPA conservatively assumed that uses on turf may include sod farms, which is represented by the Other Crops (CONUS) and Ag (NL48) UDLs.

In addition to assessing potential linseed oil exposure for invertebrate species on treated use sites, the Agency considered potential off-site exposure by extending the area of the UDLs. This off-site buffer area was used to account for any potential spray drift exposure. The selected off-field distance conservatively represents the farthest distance from the treated sites where potential drift exposure for listed species or CH is reasonably expected to occur. A 30 m buffer is the minimum buffer that can be implemented in the UDL Overlap Tool[8]; therefore, the EPA conducted the spatial overlap analysis with a conservative 30-m buffer added omnidirectionally to each UDL. Based on the drift deposition modeling performed in AgDRIFT, less than 5% of the applied rate (17.3 lb a.i./A) drifts and deposits at 66 ft (20 m) off-field.[9] Therefore, a 30-m

[8] UDL Overlap Tool is available at: https://www.epa.gov/endangered-species/provisional-models-and-tools-used-epas-pesticide-endangered-species-biological#overlap

[9] This is based on modeling in AgDRIFT (v.2.1.1) using the Tier I ground model with a high boom and the 90th percentile data. For very fine to fine droplets, approximately 3.8% of the applied rate deposits at 66 ft off-field, whereas for fine to medium/coarse droplets, approximately 1% of the applied rate deposits at 66 ft off-field.

buffer distance conservatively accounts for potential spray drift exposure with less than 5% of the applied rate drifting and depositing off-field at this distance.

The EPA does not expect spray drift exposure to lead to effects on non-target species beyond 30 m because: 1) the droplets that drift beyond 30 m are expected to be small in diameter, which greatly reduces the likelihood of the droplets completely covering and smothering terrestrial invertebrates, and 2) the concentration of linseed oil drifting to 30 m off-field is low (*e.g.,* 0.71% of applied, which equates to an application rate of 0.1221 lb a.i./A). Therefore, the EPA determined that species with <1% overlap at 30 m off-field are outside of the action area and made No Effect (NE) determinations for these species.

B. Effect Determinations

For all listed aquatic animals, EPA made an NE determination regardless of overlap because both exposure and effects to aquatic taxa are extremely unlikely. This includes open ocean species (*e.g.,* whales, sea otters, sea turtles) and fully aquatic amphibian species and is relevant for 201 fish, 228 aquatic invertebrate, 11 aquatic amphibian, 24 aquatic mammal, and 12 aquatic reptile species.

1. Terrestrial Invertebrates

Effect determinations for terrestrial invertebrates consider toxicity and exposure characterizations and the extent of spatial overlap between the species' range and UDLs. For the 163 listed, candidate, or proposed terrestrial invertebrates (including arachnids, insects, and snails), NE is determined for 2 species due to the lack of spatial overlap with the action area (**Appendix 1**; **Table 5**). Specifically, the NE determinations are based on less than 1% overlap between the species' range and the action area (defined as the UDL plus a 30-m drift distance), where overlap of less than 1% indicates that exposure will not occur because the invertebrate's habitat and range are not within areas where linseed oil is proposed to be used nor areas where linseed oil exposure via spray drift is expected.

The EPA made a "may affect" (MA) determination for 161 terrestrial invertebrates (**Appendix 1**; **Table 5**). These MA determinations are based on: 1) the potential for direct effects; 2) greater than 1% overlap between the species range and the action area (to 30 m off-field); and 3) the inability to rule out exposure based on habitat requirements and life history characteristics (**Appendix 1**).

Table 5. Summary of Effects Determinations for Listed Terrestrial Invertebrates.

ESA Determination		Number of Listed Terrestrial Invertebrates (n = 163)	Rationale
NE		2	<1% spatial overlap at 30 m off-field indicating that exposure will not occur because the invertebrate's habitat and range are not within the action area of the proposed uses of linseed oil
MA	NLAA	161	• Spatial overlap ≥1% • Potential for effects discountable based on: non-toxic, physical mode of action, relatively large body size of listed invertebrates (species-specific), and/or temporally and spatially limited exposure to linseed oil (*i.e.,* primarily expected at the time of the application on the treated field while listed species are generally expected to be off-field during applications)

NE = No Effect; MA = May Affect; NLAA = not likely to adversely affect

Raw linseed oil is classified as practically non-toxic to honey bees with acute contact and oral LD_{50} values of > 100 µg a.i./bee. Given that no treatment-related toxic effects were observed in the acute honey bee tests (which serve as a surrogate for other terrestrial invertebrates), lethal effects to listed terrestrial invertebrates via contact or oral exposure are not expected. The a.i. elicits its pesticidal mode of action by smothering the target pest species and is practically non-toxic via other routes of exposure. Its physical mode of action is limited to direct contact with terrestrial invertebrates that are completely covered by the linseed oil during the application.

The EPA made NLAA determinations for 161 listed, proposed, or candidate terrestrial invertebrate species where overlap ≥1% was identified and potential for exposure could not be precluded. The NLAA determinations for terrestrial invertebrates were made for the following reasons.

1) Linseed oil works via a physical mode of action, which requires saturation of the invertebrate for smothering.
2) Exposure to linseed oil is only expected at the time of the application for it to work and is unlikely to impact species that are not residents of the treated field at the time of the application. The oil dries within hours so its temporal impact is highly restricted and is primarily expected to affect invertebrates on the field at the time of the application.
3) The body sizes of many listed terrestrial invertebrates are larger than the target pests; complete coverage of an invertebrate's respiratory organs (and thereby efficacy of the EPs) is most likely for smaller invertebrates.

4) Most listed terrestrial invertebrates are not expected to be on the treated use site during the time of application.
    a) This is particularly true for listed species that obligately rely on native host plants and for listed species with highly specific habitats that are not proposed use sites (*e.g.,* caves, prairies or grasslands, mountaintops, etc.).
    b) Additionally, the proposed bloom restriction (as explained in Section VII) is expected to minimize potential exposure for listed pollinators that otherwise may forage on blooming plants on the treated field.

Based on the above reasons, direct effects to terrestrial invertebrates in proximity to treated areas are anticipated to be discountable.

2. Terrestrial Vertebrates (Birds, Mammals, Reptiles and Amphibians)

For the listed terrestrial vertebrate species representing 111 bird, 78 mammal, 37 reptile, and 31 amphibian species, NE determinations are being made for 7 birds (**Appendix 1**). These NE determinations are based on less than 1% overlap between the species' range and action area (to 30 m off-field) or because the species is a seabird that that forages in the open ocean where exposure is not expected (applicable for the 6 species). An MA determination based on potential effects to the species' PPHD is being made for 104 birds, 78 mammals, 37 reptiles, and 31 amphibians. These MA determinations are based on greater than 1% overlap between the species range and the action area.

For all birds, mammals, reptiles, and amphibians with MA determinations, the EPA made a NLAA determination. Linseed oil is practically non-toxic to birds, mammals, reptiles, and amphibians, indicating that direct effects are not likely. Effects to the PPHD of terrestrial vertebrates may occur through reductions in certain prey items based on previously described direct effects to terrestrial invertebrates. However, linseed oil is not likely to deplete invertebrate prey populations to the point where effects to the listed species' PPHD would likely occur. Prey items would still be available from other sources off the treated use sites. Therefore, linseed oil is not likely to adversely affect listed terrestrial vertebrates (including birds, mammals, reptiles, and amphibians) when the products are used in accordance with the proposed label use directions.

3. Terrestrial and Semi-Aquatic Plants

For the 946 listed or proposed terrestrial/semi-aquatic plant species, a NE determination is being made for 115 species (**Appendix 1**). For 16 of these species, the NE determinations are based on less than 1% overlap between the species range and action area (to 30 m off-field). For the remaining species, the NE determination is based on the mechanism of reproduction indicating that effects are not expected. All listed and proposed lichens, ferns, fern allies, conifers, and cycads (n = 46 species) depend solely on abiotic mechanisms of pollination and/or asexual reproduction (*e.g.,* vegetative propagation). There are also 41 listed monocots and 12 listed dicots that depend on abiotic pollination vectors. Thus, effects to terrestrial invertebrates from the proposed uses of linseed oil will not disrupt the reproduction of these plant species.

Therefore, given the lack of direct effects to plants and the lack of effects to these species' PPHD, the EPA has made NE determinations for these 99 listed or proposed plant species (**Appendix 1**).

A MA determination is being made for 831 species of listed or proposed terrestrial/semi-aquatic plants based on effects to these plants via reliance on the invertebrates for pollination. These MA determinations are based on greater than 1% overlap between the species range and action area. The MA determinations for terrestrial plants are considered to be NLAA. The weight of evidence suggests that direct effects to the species are not likely due to the lack of toxicity of linseed oil. The submitted studies for both vegetative vigor and seedling emergence were conducted at the highest application rate of 32 lb CropCoat CX1098/A (equivalent to 17.9 lb a.i./A). No test species demonstrated sensitivity to CropCoat CX1098, nor yielded any inhibition compared to the control groups sufficient to calculate EC/IC_{25} values. As such, the 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 were > 32 lb CropCoat CX1098/A (> 17.9 lb a.i./A). Based on these results, no direct effects to terrestrial/semi-aquatic plants are anticipated from the proposed uses of CropCoat CX1098.

The potential for effects to plant species' PPHD from linseed oil exists due to the loss of insect pollinators. However, listed plants are generally assumed to be off the treated field (with few exceptions such as the Spring Creek bladderpod (*Lesquerella perforate*)) and unaffected pollinators present off-field would also still be available for plant pollination. Additionally, the potential impacts to pollinators from the proposed uses of linseed oil are temporally and spatially restricted as explained above for terrestrial invertebrates. For these reasons, likelihood of use of linseed oil affecting an individual listed plant and threatening the continued existence of a plant species is very low based of available data and scientific rationale. Thus, effects to these plants are discountable.

VI. EFFECTS DETERMINATIONS FOR CRITICAL HABITAT (CH)

The CH effects determination process for linseed oil begins by identifying the taxa described in risk characterization (Section IV) which have potential for direct effects or effects to the species' PPHD. For CH analyses, these identified taxa were translated to the following physical or biological features (PBFs) that may be affected by linseed oil.

1. Terrestrial habitat quality (for listed terrestrial invertebrate CHs)
2. Terrestrial insect prey (for terrestrial vertebrates)
3. Insect pollinators (for plants)

The discussion below summarizes the CH conclusions by determination and whether adverse modification is predicted for the MA determinations. This assessment considers all 899 CHs that were proposed or designated as of February 16, 2022.

A. No Effect Determinations

Effects determinations for CHs were based on the potential for effects to the species, the species' PPHD, or the PBFs of the CH as a result of effects on terrestrial invertebrates. The NE determinations for proposed or designated CHs are based on areas where exposure is not reasonably expected to occur at levels that could cause effects. Out of 899 CHs analyzed, the EPA made NE determinations for 1 listed terrestrial invertebrate CH, 71 listed terrestrial/semi-aquatic plant CHs, and 6 listed terrestrial vertebrate CHs (**Appendix 2**; **Table 6**). These NE determinations are based on less than <1% overlap between the species' CH and the action area (to 30 m off-field) or lack of direct effects and effects to PBFs based on the reproduction mechanism for some plants or an incomplete exposure pathway for seabirds that feed in the open ocean. As is consistent with the species analysis, the EPA also made NE determinations for designated CHs of aquatic animals (n = 247 CHs; **Appendix 2**; **Table 6**). Overall, the EPA made NE determinations for 325 CHs (**Appendix 2**; **Table 6**).

B. Not Likely to Adversely Affect Determinations

For designated CHs, an MA determination was made if there was a potential for effects due to the loss of invertebrates and for those species where FWS identified insect pollinators/prey as a PBF. The EPA made MA determinations for the 63 designated or proposed CHs of terrestrial invertebrate where direct effects to the species may occur and overlap was ≥1%. Additionally, the EPA made MA determinations for the proposed or designated CHs of 100 terrestrial vertebrate species and 411 terrestrial/semi-aquatic plants where effects to invertebrate PBFs may occur.

Effects to the PBFs of CHs for listed terrestrial animals (including birds, mammals, amphibians, reptiles, insects, and arachnids) can occur through reductions in certain prey items based on previously described direct effects on terrestrial invertebrates. Effects are also possible for plants due to loss of invertebrate pollinators. However, these effects to a listed species' PPHD are not likely to adversely affect species in these taxa or their designated CHs for several reasons. As stated above, linseed oil has non-toxic, physical mode of action and is most effective during and immediately after application when sprayed to completely cover any infested leaf and fruit surfaces, thus smothering the target pests. Its physical mode of action is limited to direct contact with terrestrial invertebrates. For these reasons, linseed oil is unlikely to deplete invertebrate prey populations to the point where effects to the listed species' PPHD would occur. Unaffected prey items would still be available from several other sources off-field. Likewise, pollinators present off-field would also still be available to plants for pollination. For these reasons, an NLAA determination is being made for the CHs of taxa that depend upon terrestrial invertebrates for diet or pollination, including the CHs of birds, mammals, amphibians, reptiles, insects, arachnids, and plants (**Appendix 2**; **Table 6**).

Similar to the species analysis, the EPA made NLAA determinations for 63 proposed or designated CHs of listed terrestrial invertebrates based on: 1) the non-toxic, physical mode of action; 2) the restricted spatial and temporal window within which effects are expected; 3) the

larger body size of most listed terrestrial invertebrates (limiting the potential for smothering to occur); and 4) the off-field expectation for most listed terrestrial invertebrates and their CHs (limiting the potential for direct effects to occur) (**Appendix 2**; **Table 6**).

Table 6. Summary of Effects Determinations for Designated Critical Habitats of Listed Species.

ESA Determination		Number of Designated CHs (n = 899)	Rationale
NE		247	No direct effects nor effects to the PPHD of aquatic animals expected. Effects to the PBFs of the designated CHs for aquatic animals are not expected.
		51	No direct effects nor effects to the PPHD expected because these listed plant species rely on abiotic pollination vectors/asexual reproduction. Effects to the PBFs of the designated CHs for these plants are not expected.
		1	No direct effects nor effects to the PPHD expected because this listed bird is a seabird, and the exposure pathway is incomplete. Effects to the PBFs of the designated CHs for this bird are not expected.
		26	<1% spatial overlap at 30 m off-field indicating that exposure will not occur because the CH is not within the action area of the proposed uses of linseed oil
MA	NLAA	574	• Spatial overlap ≥1% • Potential for effects discountable based on: non-toxic, physical mode of action, relatively large body size of listed invertebrates (species-specific), and/or temporally and spatially limited exposure to linseed oil (*i.e.,* primarily expected at the time of the application on the treated field while listed species are generally expected to be off-field during applications)

CH = critical habitat; NE = No Effect; PPHD = prey, pollination, habitat, and/or dispersal; PBF = physical or biological feature; MA = May Affect; NLAA = not likely to adversely affect

VII. MINIMIZATION OF OFF FIELD EXPOSURE THROUGH MITIGATION

The Agency made NLAA determinations for all the listed terrestrial invertebrate species within the action areas for uses of linseed oil. This is partly due to the incorporation of mitigation measures to minimize potential exposure for on-field species and minimize drift from use sites.

The applicant has made following changes to the proposed label as mitigation measures to minimize off-field exposure.

1. Do not apply by air (*i.e.,* applications limited to ground and airblast equipment only).
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. Linseed oil cannot be applied when plants within the application site are blooming.

In the final malathion Biological Opinion, the USFWS stated that avoiding pesticide applications during blooming periods is a common practice to protect beehives by reducing exposure and resultant mortality (USFWS, 2022). Such bloom restrictions also should be protective of listed insect pollinator species, insect pollinators of listed plants, invertebrate seed dispersers that are attracted to blooming crops or found in/around these crops, and, to a lesser extent, the broader terrestrial invertebrate community that enters these use areas during blooming periods (USFWS, 2022).

Based on either lack of effects (considering direct effects, effects to the species' PPHD, and effects to the PBFs of the CH) or less than 1% overlap between the species' range/CH and action area (including a 30 m drift distance), the Agency is making NE determinations for 600 listed species and 325 CHs. Based on the limited exposure potential, especially when considering the mitigation measures, and the non-toxic mode of action, the Agency expects that on- or off-field effects to listed terrestrial taxa and their CHs are extremely unlikely to occur, and therefore, the EPA is making a may affect, not likely to adversely affect determination based on discountable effects for all terrestrial taxa within the action area for which effects are possible (considering direct effects, effects to the species' PPHD, and effects to the PBFs of the CH; n = 1242 species and 574 CHs).

VIII. CONCLUSIONS

The ecological risk assessment for linseed oil concluded that while effects to non-target species could occur, these effects are extremely unlikely and are not likely to adversely affect terrestrial taxa. As stated above, linseed oil has non-toxic, physical mode of action and is most effective during and immediately after application when sprayed to completely cover any infested leaf and fruit surfaces, thus smothering the target pests. Adverse effects from linseed oil are limited both spatially and temporally due to its specific, physical mode of action and effects from this

mode of action are limited to direct contact with terrestrial invertebrates during and immediately after spraying.

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