UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Human Health Risk Assessment for FIFRA Section 3 Registrations of Raw Linseed Oil Technical, Containing 99.7% Linseed Oil, CropCoat, Containing 70.0% Linseed Oil and CropCoat CX1098, Containing 54.0% Linseed Oil.

Action Code Case Number:	00330078 (MP); 00330080 (EP); 00330083 (EP); 00330077 (petition)
OPPIN Submission Number:	1076623 (MP); 1076625 (EP); 1076626 (EP); 1076624 (petition)
EPA File Symbol:	94473-R (MP); 94473-E (EP); 94473-G (EP); 1F8959
PC Code:	031603
CAS Number:	8001-26-1
AI Tolerance/Exemption:	40 CFR 180.950(c)
MRID Numbers:	94473-R: 54175214-28; 94473-E: 51475407-12; 94473-G: 51475308-13; 52174901
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. The MP is proposed to be used for formulating EPs only. In support of the application for registration for the MP, the applicant submitted a proposed product label dated 02/22/2022, basic Confidential Statements of Formula (CSF) dated 08/26/2022, a data matrix dated 05/12/2023, and human health data and information.

The two proposed EPs are intended to be used as insecticides and miticides. In support of the application for registration for these two EPs, the applicant submitted proposed product labels, CSFs dated 06/21/21 and 02/25/2022 and data matrices dated 02/18/2022 and 02/25/2022 for CropCoat and CropCoat CX1098 respectively, and human health assessment data and information.

EXECUTIVE SUMMARY

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the human health data submitted for the registration of Raw Linseed Oil Technical (EPA File Symbol: 94473-R), 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. The EPs are formulated using the proposed MP. The EPs are proposed as insecticides and miticides. Linseed oil has a non-toxic mode of action and has been proposed to control insects and mites on agricultural crops, turf and ornamentals.

The active ingredient (AI) is proposed for food uses; therefore, dietary exposure may occur. Based on the available data, no toxicological endpoints have been identified thus dietary risk is anticipated to be negligible. A petition for the exemption from a tolerance was submitted to the Agency, however, the Risk Assessment Branch (RAB) has determined that this AI is considered an edible oil and thus is covered under the exemption at 40 CFR 180.950(c); a tolerance exemption petition is not required.

Based on the proposed use pattern, short- and intermediate-term occupational handler and post-application dermal and inhalation exposures are anticipated; however, no risks of concern have been identified at this time. Current Personal Protective Equipment (PPE) requirements on the proposed EP labels will further mitigate exposure and risk. There are no proposed residential uses; therefore, a residential risk assessment has not been conducted. Non-occupational exposure resulting from spray drift from agricultural applications onto residential areas may also occur.

If the formulation of the end-use products should change in the future, or if new products are proposed containing linseed oil additional data may be required, and a new risk assessment may need to be performed.

1.0 Introduction

1.1 Biopesticide Use Pattern

The product, Raw Linseed Oil Technical, is a manufacturing-use only product.

CropCoat and CropCoat CX1098 are EPs that are to be applied to agricultural crops, turf, and ornamental plants as an insecticide and miticide. Both EPs must be applied using properly calibrated, conventional ground spray using handheld and backpack sprayers or agitating sprayer tanks. All mixers, loaders, applicators and other handlers must wear personal protective equipment (PPE: long-sleeved shirt and long pants, nitrile or Viton gloves, and shoes plus socks). Based on the PPE requirement, the Risk Assessment Branch (RAB) has assumed that

these products are for commercial use only. The maximum application rate is 17.3 lbs AI/A. There is a 4-hour restricted-entry interval (REI) on both labels.

2.0 Human Health Risk Assessment

2.1 Toxicology Studies Available for Analysis for Linseed Oil

To assess risks to human health from use of biochemical pesticides, BPPD typically requires a range of tiered toxicity data requirements. Tier I data requirements are:

- Acute toxicity (acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and skin sensitization
- Subchronic toxicity (90-day oral toxicity, 90-day dermal toxicity and 90-day inhalation toxicity
- Prenatal developmental toxicity
- Genotoxicity (in vitro bacterial reverse mutation assay and in vitro mammalian cell assays)

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.

The toxicology database is complete for biopesticide risk assessment for the use of linseed oil in the proposed EPs. To satisfy the human health assessment data requirements for the TGAI, the applicant submitted the following: 1) guideline studies to address acute oral, dermal, inhalation, primary eye irritation, primary skin irritation, and skin sensitization data requirements, 2) a 90-day oral gavage toxicity study (OCSPP 870.3100), 3) a prenatal developmental toxicity study (OCSPP 870.3700), 4) a 14-day oral gavage dose-range finding study, 5) an oral prenatal developmental dose-range finding study, and 6) genotoxicity studies that include the following: an Ames study (OCSPP 870.5100), and an *in vitro* mammalian cell assay (OCSPP 870.5300).

The rationales for the 90-day dermal and 90-day inhalation toxicity studies were accepted by OPP's Hazard and Science Policy Council (HASPOC) on October 14, 2022 (U.S. EPA, 2022) for linseed oil.

Summaries of the available toxicology data and information are provided in Table 1 and in the subsequent text. Refer to the Data Evaluation Records for additional information.

A. Toxicological Profile

1. Acute Toxicity

Linseed oil is categorized 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).

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 question by the scientific community of 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.

2. Subchronic Toxicity

A 14-day oral gavage dose-range finding study, a 90-day oral toxicity study, a prenatal dose-range finding study, and a prenatal developmental toxicity study were submitted for linseed oil.

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 considered to be 1000 mg/kg/day (highest dose tested).

90-day Oral Gavage 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 considered to be 1000 mg/kg/day (highest dose tested).

90-day Dermal Toxicity

An acceptable rationale was submitted in MRID 51475222. This MRID contains information from publicly available scientific literature.

There are no guideline repeat-dose dermal toxicity studies for linseed oil. Primary dermal irritation study results indicate that linseed oil is non-irritating (Toxicity Category IV), and the

dermal sensitization study results indicate that it is potentially a dermal sensitizer; however, data are inconclusive based on literature for free fatty acids in LLNA and GPMT studies. The LD_{50} in the acute dermal toxicity study is > 5000 mg/kg/day (Toxicity Category IV). A semisolid formulation of linseed oil has been shown to aid in wound healing when dermally applied to the skin of rats when compared to petroleum jelly. No adverse effects were noted in this study (De Souza Franco, E. et al. 2012). Also, the Brazilian national pharmacopoeia has approved the topical use of linseed oil in cases of pruritis and burn-patients (De Souza Franco, E. et al. 2012). In addition, data suggest that it is also anti-oxidative, prevents peristomal skin excoriation, and is used as a treatment for atopic dermatitis (Kildaci 2021).

The RAB used a weight of the evidence (WOE) approach to address the 90-day dermal requirement which considered the following: (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

An acceptable rationale was submitted in MRID 51475223. This MRID contains information from publicly available scientific literature.

There are no subchronic inhalation toxicity data available for linseed oil. The RAB used a WOE approach to address the 90-day inhalation requirement which considered the following: (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).

Dose Range-finding Prenatal Developmental Oral Toxicity Study (rat)

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 considered to be 1000 mg/kg/day.

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, 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 considered to be 1000 mg/kg/day

3. Genotoxicity

In vitro Bacterial Gene Mutation

In a guideline study, *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2*uvrA* 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 (MRID 51475226). 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 (MRID 51475227), 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.

Table 1: Human Health Assessment Data for Linseed Oil (40 CFR § 158.2050)

Data Requirement (OCSPP Guideline)	Results	Toxicity Category/ Description	MRID
Acute Oral Toxicity (870.1100)	LD_{50} > 5000 mg/kg bw	IV; **Acceptable/Guideline**	51475214
Acute Dermal Toxicity (870.1200)	LD_{50} > 5000 mg/kg bw	IV; **Acceptable/Guideline**	51475215
Acute Inhalation Toxicity (870.1300)	LC_{50} > 5.07 mg/L	IV; **Acceptable/Guideline**	51475216
Primary Eye Irritation (870.2400)	Non-irritating	IV; **Acceptable/Guideline**	51475217
Primary Dermal Irritation (870.2500)	Non-irritating	IV; **Acceptable/Guideline**	51475218
Dermal Sensitization (870.2600)	Sensitizer; however, data are inconclusive based on literature on free fatty acids in LLNA and GPMT studies	**Acceptable/Guideline**	51475219 51475228
Hypersensitivity Incidents (none)	None reported to date	**Acceptable**	52174901
LD50 = median lethal dose; LC50 = median lethal concentration; HDT = highest dose tested			

Table 1: Human Health Assessment Data for Linseed Oil (40 CFR § 158.2050)			
14-day Dose Range-finding Study	Doses: 0, 250, 500, 1,000 mg/kg/day NOAEL> 1,000 mg/kg/day (HDT) **Acceptable/Guideline**		51475220
90-Day Oral Toxicity (870.3100)	Doses: 0, 100, 300, 1,000 mg/kg/day NOAEL > 1,000 mg/kg/day (HDT) **Acceptable/Guideline**		51475221
90-Day Dermal Toxicity (870.3250)	Rationale based on a WOE approach that includes lack of acute dermal toxicity and dermal and eye irritation of the AI, lack of systemic toxicity in available subchronic toxicity studies, natural occurrence and history of exposure in dietary supplements without significant adverse reactions, therapeutic use of AI for wounds and other skin conditions, AI approved for inert ingredient use and exempt from the requirement of a tolerance and 25b minimum risk pesticide		51475222 TXR 0058427 (HASPOC Document)
90-Day inhalation toxicity (870.3465)	Rationale based on a WOE approach that includes low acute inhalation toxicity, non-irritating to eye and skin, lack of systemic toxicity in available subchronic toxicity studies, low vapor pressure, natural occurrence and history of exposure in dietary supplements without significant adverse reactions, AI approved for inert ingredient use and exempt from the requirement of a tolerance, and 25b minimum risk pesticide		51475223 TXR 0058427 (HASPOC Document)
Dose Range-Finding Prenatal Development Toxicity Study	Doses: 250, 500, 1,000 mg/kg/day NOAEL> 1,000 mg/kg/day **Acceptable/Non-Guideline**		51475224
Prenatal Developmental toxicity (870.3700)	Doses: 0, 250, 500, 1,000 mg/kg/day Maternal and Developmental NOAEL> 1,000 mg/kg/day **Acceptable/Guideline**		51475225
Bacterial reverse mutation test (870.5100)	Doses: 1.58, 5.0, 15.8, 50, 158, 500, 1580, and 5000 µg/plate Negative for reverse gene mutations in *Salmonella typhimurium* TA 1535, TA 1537, TA 98, and T100, and in *Ecoli QP2 uvrA* in presence or absence of metabolic activation. **Acceptable/Guideline**		51475226
In vitro mammalian cell assay (870.5300/870.5375)	No induction of gene mutations at the HPRT locus of CHO-K1 cell in presence or absence of metabolic activation. **Acceptable/Guideline**		51475227

B. Absorption, Distribution, Metabolism, & Elimination (ADME)

The absorption, distribution, metabolism, and elimination data collectively characterize the fate of a chemical once absorbed. No ADME data for linseed oil were submitted. These data are typically not required for biopesticide risk assessment and have not been triggered for the proposed use.

C. Dermal Absorption

A dermal-absorption factor (DAF) is derived from dermal toxicity studies to determine the amount of dermal penetration that may occur if a compound were to get onto the skin. This factor is then applied within occupational and residential exposure scenarios. A DAF has not been determined for linseed oil and is not needed at this time because a qualitative risk assessment has been conducted for the proposed use pattern of the active ingredient.

2.2 Safety Factor for Infants and Children (FQPA Safety Factor)[1]

An FQPA safety factor has not been selected at this time for linseed oil because a qualitative dietary assessment has been conducted that is based on the lack of toxicological endpoints for the active ingredient.

2.3 Toxicity Endpoint and Point of Departure Selections

No endpoints have been identified for linseed oil.

2.4 End-Use Product Toxicology Studies: CropCoat & CropCoat CX1098

Acute toxicity data (acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation, skin sensitization, hypersensitivity incidents) are required for biochemical EPs. To satisfy these data requirements, guideline studies, rationale for bridging data, and waiver requests were submitted. Refer to the DERs for additional information.

TABLE 2: Human Health Assessment Data for CropCoat (40 CFR § 158.2050)

Study/OCSPP Guideline No.	Results	Toxicity Category/Description	MRID
Acute oral toxicity (870.1100)	LD_{50} > 5000 mg/kg bw	IV; Acceptable/Guideline	51475407
Acute dermal toxicity (870.1200)	Waived based on EPA's Guidance for Waiving Acute Dermal Toxicity Document[2]	N/A	51475408
Acute inhalation toxicity (870.1300)	LC_{50} Males > 2.09 mg/L LC_{50} Females > 2.09 mg/L LC_{50} Combined > 2.09 mg/L	IV; Acceptable/Non-Guideline	51475409

[1] BPPD's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children).
[2] U.S. EPA, 2016.

TABLE 2: Human Health Assessment Data for CropCoat (40 CFR § 158.2050)			
Primary eye irritation (rabbit) (870.2400)	Minimally irritating	IV; Acceptable/Guideline	51475410
Primary dermal irritation (870.2500) (rabbit)	Slightly irritating	IV; Acceptable/Guideline	51475411
Dermal sensitization (870.2600) *(OECD 429 Local Lymph Node Assay)*	Not a sensitizer	Not a Sensitizer; Acceptable/Guideline	51475412

TABLE 3: Human Health Assessment Data for CropCoat CX1098 (40 CFR § 158.2050)			
Study/OCSPP Guideline No.	**Results**	**Toxicity Category/Description**	**MRID**
Acute oral toxicity (870.1100)	LD_{50} > 5000 mg/kg bw	IV; Acceptable/Guideline	51475308
Acute dermal toxicity (870.1200)	Waived based on EPA's Guidance for Waiving Acute Dermal Toxicity Document[3]	N/A	51475309
Acute inhalation toxicity (870.1300)	LC_{50} Males > 2.12 mg/L LC_{50} Females > 2.12 mg/L LC_{50} Combined > 2.12 mg/L	IV; Acceptable/Non-Guideline	51475310
Primary eye irritation (rabbit) (870.2400)	Mildly irritating	IV; Acceptable/Guideline	51475311
Primary dermal irritation (870.2500) (rabbit)	Slightly irritating (Data bridged from CropCoat primary dermal irritation study-MRID 51475411)	IV; Acceptable	51475312 51475411
Dermal sensitization (870.2600) *(OECD 429 Local Lymph Node Assay)*	Sensitizer (Data bridged from Raw Linseed Oil Technical)	Sensitizer; Acceptable	51475313

3.0 Dietary Exposure (Food and Drinking Water) and Risk Assessment

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. This dates back to the Bronze Age and possibly earlier.[4] 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. In addition, based on negligible toxicity, exposure to the active ingredient is not of concern. No dietary risks of concern have been identified.

4.0 Residential (Non-Occupational) Exposure/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

[3] U.S. EPA, 2016.
[4] Thomas, 2000.

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.

5.0 Non-Occupational Spray Drift Exposure and Risk Estimates

Spray drift is a potential source of exposure to those nearby pesticide applications. This is particularly the case with aerial application, but, to a lesser extent, spray drift can also be a potential source of exposure from the ground application methods (e.g., ground boom and airblast). Spray drift can be anticipated for linseed oil based on the ground application method. However, based on negligible toxicity, exposure to the active ingredient is not of concern.

6.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, OPP must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources that have the same toxicological endpoints are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, OPP considers both the route and duration of exposure.

As there are no anticipated toxicity concerns for linseed oil, a quantitative aggregate exposure and risk assessment is not required.

7.0 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to linseed oil and any other substances, and linseed oil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, EPA has not assumed that this active ingredient has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs released a guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* [https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA). During Registration Review, the Agency will utilize this framework to determine if the available toxicological data for powdered corn cobs suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

8.0 Tolerance Exemption Petition

Although the applicant submitted a tolerance exemption petition, a tolerance exemption is not necessary. The Risk Assessment Branch (RAB) has determined that this particular linseed oil is considered an edible oil as it is processed [redacted] and thus, is covered under the exemption at 40 CFR 180.950(c).

9.0 Occupational Exposure/Risk Characterization

Summary

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 negligible toxicity of the AI, no risks of concern have been identified.

Short- and Intermediate-Term Handler Exposure and Risk

No toxicological endpoints of concern have been identified for this AI, therefore risk estimates were not calculated.

Post-Application Exposure and Risk

No toxicological endpoints of concern have been identified for this AI, therefore risk estimates were not calculated.

Restricted-Entry Interval

The restricted-entry interval (REI) is 4 hours, according to the proposed EP labels and is considered acceptable and protective by the Agency.

RECOMMENDATIONS AND CONCLUSIONS

1. The toxicological database is complete for biopesticide risk assessment for the proposed use of linseed oil in end-use products. All mammalian toxicology data requirements have been satisfied at this time.

2. In consideration of the available hazard and exposure information, no dietary or occupational risks of concern have been identified at this time.

3. The RAB has determined that this particular linseed oil is considered an edible oil as it is [redacted] and thus it is covered under the tolerance exemption at40 CFR 180.950(c).

MP (94473-R):

1. All human health data requirements have been satisfied at this time.

EP (94473-E, CropCoat):

1. All human health data requirements have been satisfied at this time.

EP (94473-G, CropCoat CX1098):

1. [redacted]

2. All human health data requirements have been satisfied at this time.

BIBLIOGRAPHY OF STUDIES

MP (94473-R):

MRID 51475214: ACCEPTABLE
MRID 51475215: ACCEPTABLE
MRID 51475216: ACCEPTABLE
MRID 51475217: ACCEPTABLE
MRID 51475218: ACCEPTABLE
MRID 51475219: ACCEPTABLE
MRID 51475228: ACCEPTABLE
MRID 51475220: ACCEPTABLE
MRID 51475221: ACCEPTABLE
MRID 51475222: ACCEPTABLE
MRID 51475223: ACCEPTABLE
MRID 51475224: ACCEPTABLE
MRID 51475225: ACCEPTABLE
MRID 51475226: ACCEPTABLE
MRID 51475227: ACCEPTABLE
MRID 51475228: ACCEPTABLE
MRID 52174901: ACCEPTABLE

EP (94473-E, CropCoat):

MRID 51475407: ACCEPTABLE
MRID 51475408: ACCEPTABLE
MRID 51475409: ACCEPTABLE
MRID 51475410: ACCEPTABLE
MRID 51475411: ACCEPTABLE
MRID 51475412: ACCEPTABLE

EP (94473-G, CropCoat CX1098):

MRID 51475308: ACCEPTABLE
MRID 51475309: ACCEPTABLE
MRID 51475310: ACCEPTABLE
MRID 51475311: ACCEPTABLE
MRID 51475312: ACCEPTABLE
MRID 51475313: ACCEPTABLE

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