

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Product Chemistry Review 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), and 00330083 (EP)

E Submission Number: 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: See Bibliography of Studies Section

PRIA Code: B590

FROM: Yongqi Li, Biologist YONGQI LI Digitally signed by YONGQI LI Date: 2022.11.29 08.46.43 -05'00'

Risk Assessment Branch

Biopesticides & Pollution Prevention Division (7511M)

THRU: Angela Gonzales, Senior Scientist ANGELA Digitally signed by ANGELA GONZALES

Shannon Borges, Chief GONZALES Date: 2022.11.29

Risk Assessment Branch

Biopesticides & Pollution Prevention Division (7511M)

Digitally signed by SHANNON BORGES Date: 2022.11.29 12:10:49 -05'00'

TO: Alex Horansky, Risk Manager

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511M)

***Contains Confidential Business Information (CBI) ***

ACTION REQUESTED

Pyxis Regulatory Consulting 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 02-14-2022, basic Confidential Statements of Formula (CSFs) dated 08-26-2021, a data matrix dated 10-08-2021, and product chemistry, human health and ecological assessment data and information.

The two proposed EPs are intended to be used as insecticides/miticides. In support of the application for registration for these two EPs, the applicant submitted proposed product labels dated 10-11-2021, CSFs dated 06-21-2021 and 07-09-2021, data matrices dated 10-08-2021, and product chemistry and human health assessment data and information. This memo contains a review of the product chemistry data only, and human health and ecological assessments are in separate memos.

EXECUTIVE SUMMARY

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the product chemistry data submitted for the registration of Raw Linseed Oil Technical (EPA File Symbol: 94473-R), a 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. All product chemistry data requirements have been satisfied. The EPs are formulated using the proposed MP. The EPs are proposed insecticides/miticides for the treatment of agricultural crops, turf, and ornamental plants. Linseed oil has a non-toxic 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.

Product chemistry data deficiencies for the MP were previously identified by the Risk Assessment Branch (RAB) (US EPA, 2022). These deficiencies have been satisfactorily addressed with updated data and information. The updated data and information can be found in the newly submitted MRID numbers (51797001 – 51797003).

1.0 <u>Introduction</u>

1.1 Biopesticide Use Pattern

The MP is only for use in manufacturing end-use products.

CROPCOAT and CROPCOAT CX1098 are to be applied to agricultural crops, turf, and ornamental plants as insecticides/miticides. The EPs can be applied using non-agitating or agitating sprayer tanks. Sufficient water volume must be used to obtain thorough uniform coverage of all plant surfaces, and all leaf and fruit surfaces must be thoroughly treated to the point of runoff. All mixers, loaders, applicators and other handlers must wear personal protective equipment (PPE: long-sleeved shirt and long pants, chemical-resistant gloves and shoes plus socks). Based on the PPE requirement, the Risk Assessment Branch (RAB) has assumed that the product is for commercial use only. The maximum application rate is 17.3 lb. active ingredient/A.

2.0 **Product Chemistry**

A. Active Ingredient Identity and 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

Linseed oil has a non-toxic 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. Linseed oil has a long history of use in consumer products, including dietary supplements and cosmetic products. Linseed oil is also often blended with combinations of other oils, resins or solvents as an impregnator, drying oil finish or varnish in wood finishing, as a pigment binder in oil paints, as a plasticizer and hardener in putty, and in the manufacture of linoleum. Linseed oil is on the Agency's minimum risk pesticides list (40 CFR 152.25(f)) and is approved for use in pesticide products as an inert ingredient (food, non-food, and fragrance uses).

B. Active Ingredient/Manufacturing-Use Product

Raw Linseed Oil Technical contains 99.7% linseed oil. All product chemistry data requirements have been satisfied for the active ingredient/MP. Both guideline and non-guideline studies were submitted to satisfy the data requirements. The technical grade of the active ingredient (TGAI) is equivalent to the MP. Product chemistry and physical/chemical property data are provided in Tables 1 and 2, respectively. Refer to the data evaluation record (DER) for additional information.

Table 1: Product Chemistry Data for Raw Linseed Oil Technical (99.7% Linseed Oil) (40 CFR § 158.2030)			
OSCPP Guideline	Data Requirement	Results	MRID
880.1100 830.1550	Product Identity and Composition	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475201
880.1200 830.1650	Description of Starting Materials and Formulation Process	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475201, 51797001
880.1400 830.1670	Discussion of Formation of Impurities	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475201, 51797001
830.1700	Preliminary Analysis	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475202
830.1750	Certified Limits	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475201
830.1800	Enforcement Analytical Method	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475203

Table 2. Physical/Chemical Properties of Raw Linseed Oil Technical (99.7% Linseed Oil) (40 CFR § 158.2030) OCSPP Reference/MRID Property **Description of Result** Guideline Color 830.6302 51475204 Physical state 830.6303 51475204 Odor 830.6304 51475204 Stability to normal and elevated 51475208, 830.6313 temperatures, metals, 51475210 and metal ions Flammability 830.6315 51475204 830.6317 Storage stability 51475208 830.6319 Miscibility 51475210 Corrosion 830.6320 51475208 characteristics 830.7000, pН 51475204 UV/visible light 830.7050 51475204 absorption 830.7100 Viscosity 51475204 830.7200 Melting point / 51475210 melting range Boiling point / 830.7220 51475204 boiling range 830.7300 Relative density 51475204 Particle size, fiber 830.7520 length, & diameter 51475210 distribution

Table 2. Physical/Chemical Properties of Raw Linseed Oil Technical (99.7% Linseed Oil) (40 CFR § 158.2030)			
OCSPP Guideline	Property	Description of Result	Reference/MRID
830.7550, 830.7560, 830.7570	Partition coefficient		51475205
830.7840	Solubility in water		51475206
830.7950	Vapor pressure		51475209

C. End-Use Product, CROPCOAT (70.0% Linseed Oil)

All product chemistry data requirements have been satisfied for the EP. To satisfy these requirements, both guideline and non-guideline studies were submitted. All inert ingredients are approved for the proposed use pattern. Product chemistry and physical/chemical property data are provided in Tables 3 and 4, respectively. Refer to the DER for additional information.

Table 3: Product Chemistry Data for CROPCOAT (70.0% Linseed Oil) (40 CFR § 158.2030)			
OSCPP Guideline	Data Requirement	Results	MRID
880.1100	Product Identity and	Submitted data satisfy the requirement.	
830.1550	Composition	CBI ACCEPTABLE/GUIDELINE	51475401
880.1200	Description of Starting	Submitted data satisfy the requirement.	
830.1650	Materials and Formulation Process	CBI ACCEPTABLE/GUIDELINE	51475401
880.1400	Discussion of Formation of	Submitted data satisfy the requirement.	
830.1670	Impurities	CBI ACCEPTABLE/GUIDELINE	51475401
830.1700	Preliminary Analysis	Not required: Data submitted for MP pending registration.	
830.1750	Certified Limits	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475401
830.1800	Enforcement Analytical Method	Not required: Data submitted for MP pending registration.	

Table 4. Physical/Chemical Properties of CROPCOAT (70.0% Linseed Oil) (40 CFR § 158.2030)			
OCSPP Guideline	Property	Description of Result	Reference/MRID
830.6302	Color		51475403
830.6303	Physical state		51475403
830.6304	Odor		51475403
830.6315	Flammability		51475403

Table 4. Physical/Chemical Properties of CROPCOAT (70.0% Linseed Oil) (40 CFR § 158.2030)			
OCSPP Guideline	Property	Description of Result	Reference/MRID
830.6317	Storage stability		51475404
830.6319	Miscibility		51475405
830.6320	Corrosion characteristics		51475404
830.7000	pH		51475403
830.7100	Viscosity		51475403
830.7300	Density		51475403

D. End-Use Product, CROPCOAT CX1098 (54.0% Linseed Oil)

All product chemistry data requirements have been satisfied for the EP. To satisfy these requirements, both guideline and non-guideline studies were submitted. All inert ingredients are approved for the proposed use pattern. Product chemistry and physical/chemical property data are provided in Tables 5 and 6, respectively. Refer to the DER for additional information.

Table 5: Product Chemistry Data for CROPCOAT CX1098 (54.0% Linseed Oil) (40 CFR § 158.2030)			
OSCPP Guideline	Data Requirement	Results	MRID
880.1100 830.1550	Product Identity and Composition	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475301
880.1200 830.1650	Description of Starting Materials and Formulation Process	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475301
880.1400 830.1670	Discussion of Formation of Impurities	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475301
830.1700	Preliminary Analysis	Not required: Data submitted for MP pending registration.	
830.1750	Certified Limits	Submitted data satisfy the requirement. CBI ACCEPTABLE/GUIDELINE	51475301
830.1800	Enforcement Analytical Method	Not required: Data submitted for MP pending registration.	

Table 6. Physical/Chemical Properties of CROPCOAT CX1098 (54.0% Linseed Oil) (40 CFR § 158.2030)			
OCSPP Guideline	Property	Description of Result	Reference/MRID
830.6302	Color		51475303
830.6303	Physical state		51475303
830.6304	Odor		51475303
830.6315	Flammability		51475303
830.6317	Storage stability		51475304
830.6319	Miscibility		51475305
830.6320	Corrosion characteristics		51475304
830.7000	pH		51475303
830.7100	Viscosity		51475303
830.7300	Density		51475303

RECOMMENDATIONS AND CONCLUSIONS

Note to Risk Manager:

Linseed oil is combustible, so heat, sparks, and other ignition sources should be avoided. Linseed oil can also self-combust without outside heat or ignition sources. When linseed oil is exposed to air, it reacts with the oxygen molecules and creates heat. Rags and other flammable materials containing linseed oil may spontaneously ignite if enough heat accumulates. Appropriate precautionary language should be added to the label.

MP (94473-R):

- 1. The basic CSF dated 08-26-2021 and the label dated 02-14-2022 are ACCEPTABLE.
- 2. All product chemistry data requirements have been satisfied at this time.

EP (94473-E, CROPCOAT):

1. The basic CSF dated 06-21-2021 and the label 10-11-2021 are ACCEPTABLE.

2. All product chemistry data requirements have been satisfied at this time.

EP (94473-G, CROPCOAT CX1098):

- 1. The basic CSF dated 07-09-2021 and the label 10-11-2021 are ACCEPTABLE.
- 2. All product chemistry data requirements have been satisfied at this time.

BIBLIOGRAPHY OF STUDIES

MP (94473-R):

MRID 51475201: ACCEPTABLE	MRID 51475202: ACCEPTABLE
MRID 51475203: ACCEPTABLE	MRID 51475204: ACCEPTABLE
MRID 51475205: ACCEPTABLE	MRID 51475206: ACCEPTABLE
MRID 51475208: ACCEPTABLE	MRID 51475209: ACCEPTABLE
MRID 51475210: ACCEPTABLE	MRID 51797001: ACCEPTABLE

EP (94473-E, CROPCOAT):

MRID 51475401: ACCEPTABLE	MRID 51475403: ACCEPTABLE
MRID 51475404: ACCEPTABLE	MRID 51475405: ACCEPTABLE

EP (94473-G, CROPCOAT CX1098):

MRID 51475301: ACCEPTABLE	MRID 51475303: ACCEPTABLE
MRID 51475304: ACCEPTABLE	MRID 51475305: ACCEPTABLE

REFERENCES

US EPA (2022). Biochemical pesticide tech screen-chemistry report for 94473-R. Y. Li thru A. Gonzales and S. Borges to A. Horansky. January 19, 2022.