

US EPA ARCHIVE DOCUMENT

DP Barcode: 192521
 Shaughnessy No.: 079034
 Case No.: 4005
 Date Out of EFGWB: 11/13/92

TO: Bruce Sidwell, Chemical Review Manager
 Accelerated Re-registration Branch
 Special Review and Registration Division (H7508W)

FROM: Emil Regelman
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THROUGH: Henry Jacoby, Chief
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Attached, please find the EFGWB review of:

Reg./File #(s) : 057582-1

Common Name : Fatty Acid Methyl Esters

Chemical Name : Fatty Acid Methyl Esters

Product Type : Plant Regulator

Product Name : Off-Shoot-0

Company Name : Cochran Corporation

Purpose : Phase 4 Review, review of literature search

Action Code : 602

EFGWB #(s) : 92- 1363

EFGWB Guideline/MRID/Status Summary Table:
 The review in this package contains...

161-1	94029999	Y	162-4		164-4		166-1
161-2			163-1	42198001	S	164-5	166-2
161-3			163-2			165-1	166-3
161-4			163-3			165-2	167-1
162-1	42198001	Y	164-1			165-3	167-2
162-2			164-2			165-4	201-1
162-3			164-3			165-5	202-1

Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
 S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

1. CHEMICAL:

Common name:

Fatty Acid Methyl Esters

Chemical name:

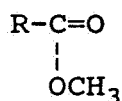
Fatty Acid Methyl Esters

C₆ Methyl ester = methyl caproate (or hexanoate)
C₈ Methyl ester = methyl caprylate (or octanoate)
C₁₀ Methyl ester = methyl capriate (or decanoate)
C₁₂ Methyl ester = methyl laureate (or dodecanoate)

Trade name(s):

Off-Shoot-0

Structure:



Formulations:

Emulsifiable Concentrate

Physical/Chemical properties:

Molecular formula: C_nH_{2n+1}CO₂CH₃ (n=5-11)
Physical state: Liquid at 20°C with a penetrating
fruity (slightly lemony) odor
Melting Point: Approximately -20°C,
Individual melting points of the chains
range from -70°C to -5°C
Boiling Point: Approximately 195°C at 760 torr
Solubility (20°C): 0 g/L in water;
100 g/L ethanol, eter

2. TEST MATERIAL:

N/A

3. STUDY/ACTION TYPE:

Review of Phase 4 package, review of search for literature to cover the Aerobic Soil Metabolism (162-1) and the Mobility in Soil (163-1) data requirements.

4. STUDY/DOCUMENT IDENTIFICATION:

Christensen, K. P. 1992. A Literature Review of Biodegradability and Adsorption/Leachability of Fatty Acids and Fatty Acids Esters. Unpublished report prepared by Springborn Laboratories, Inc. for Cochran Corporation, Tennessee, MRID# 42198001

Phase 3 Chemical Response Worksheet, MRID# 94029000

Registrant Correspondence and labels, MRID# 94029999

Luis Report dated July 14, 1992

Phase 2 Science Review and other related information

5. REVIEWED BY:

José Luis Meléndez
Chemist
EFGWB/EFED/OPP
Review Section #2

Signature: José Luis Meléndez

Date: 11/13/92

6. APPROVED BY:

Emil Regelman
Chief
EFGWB/EFED/OPP
Review Section #2

Signature: Emil Regelman

Date: 11/13/92

7. CONCLUSION:

• **Hydrolysis**

The submission is acceptable and can be used to fulfill the Hydrolysis (161-1) data requirement.

The methyl esters of fatty acids are stable in water at a neutral pH. They undergo hydrolysis reaction at acid or alkaline pH's. In the presence of a strong base such as sodium hydroxide, the reaction goes to completion. The degradation products are the acid (or salt) and methanol.

• **Aerobic Soil Metabolism**

This submission is acceptable and can be used to fulfill the Aerobic Soil Metabolism (162-1) data requirement.

The methyl esters of fatty acids are degradable under aerobic soil conditions with various reported half lives (depending on the particular conditions of the analysis). The main mechanism of

degradation is biological, both in aqueous and soil environments. It appears that there is some kind of induction, caused by the presence of the esters, for which there is a lag of time in the initial degradation. The ultimate degradate is carbon dioxide.

- **Soil Adsorption/Leaching**

This submission provided supplemental information to fulfill the data requirement. The report consists of a series of conjectures about the behavior of the methyl esters of fatty acids in soil media. However, the ultimate goal of the data requirement was not completely achieved. This goal is to provide information about the mobility of the pesticide. EFGWB will not request additional information at this time based on the information provided and the low volume use of the product.

The methyl esters of fatty acids are completely insoluble. This makes them likely to partition in soil or sediment and resist leaching. According to the registrant, the fatty acids are actually available to the microbes which use them as a carbon source at the lipid-water interface.

- **Other Data Requirements**

Based on the information provided and the low volume use for the product, EFGWB concurs with a waiver for all data requirements for the Methyl Esters of Fatty Acids. No additional data is required at this time.

The absorption of the Methyl Esters of Fatty Acids is expected to occur in the far UV, since the structure contains one double bond of the ester. Therefore, the aqueous photolysis will not be a significant route of degradation for the Methyl Esters of Fatty Acids.

The Methyl Esters of Fatty Acids are insoluble in water and soluble in octanol; therefore, the bioaccumulation in fish is likely to occur. The bioconcentration of these compounds in fish is not expected to be a serious environmental problem.

8. RECOMMENDATIONS:

EFGWB recommends that the registrant be notified of the following:

- The report submitted to satisfy the Hydrolysis (161-1) data requirement is acceptable. No additional data is required.
- The report submitted to satisfy the Aerobic Soil Metabolism (162-1) data requirement is acceptable. No additional data is required.

- o The report submitted to satisfy the Mobility and Adsorption/Leaching (163-1) data requirement provides supplemental information about the mobility of the Methyl Esters of Fatty Acids. No additional data is required.
- o The registrant did not attempt to satisfy any other data requirements besides the ones previously mentioned. EFGWB concurs with a waiver for the Photolysis in Water (161-2), the Volatility from Soil (163-2), the Terrestrial Field Dissipation (164-1), and the Bioaccumulation in Fish (165-4) data requirements. The waiver is based on the low volume use and the low environmental risk of the product. No additional data is required.

9. BACKGROUND:

Off-Shoot-O is a plant regulator manufactured by Cochran Corporation. It is a chemical pinching agent for woody ornamentals such as Azalea, Cotoneaster, Juniper, Ligustrum, Rhamnus, and Taxus. The active ingredients are the Methyl Esters of Fatty Acids. The concentrated product is a dilution with water to form a stable emulsion applied as a foliar spray. The following are the registered use patterns for the methyl esters of fatty acids: Terrestrial Non-Food, Greenhouse Non-Food, Outdoor residential. The use sites for these compounds include ornamental and/or shade trees, and ornamental woody shrubs and vines.

As per E. Regelman's memorandum to Sue Rathman dated 6/21/91, EFGWB suggested that "the registrant submit a comprehensive literature review, in Monograph form, to include a thorough analysis of the environmental fate of the Methyl Esters of Fatty Acids." The literature review may be evaluated by EFGWB to consider waiver request of their respective data requirements. The registrant submitted a literature review accordingly, to cover the Aerobic Soil Metabolism (162-1), and the Mobility in Soil (163-1) data requirement.

EFGWB received one data package containing the following: Registrant Correspondence and Labels, EFED/EFGWB Phase 2 Science Review, the Phase 3 Chemical Response Worksheet, Copy of Label, and a Literature Search to cover data requirements 162-1 and 163-1.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

• **Hydrolysis (MRID# 94029999)**

The registrant submitted a brief review of the available and widely accepted information about the hydrolysis of the methyl esters of fatty acids. These esters are stable in water at a neutral pH. They undergo hydrolysis at acidic pH. The reaction is faster in the presence of a strong acid than in the presence of a weak acid. The methyl esters of fatty acids also undergo hydrolysis at alkaline

pH's. In the presence of a strong base such as sodium hydroxide solution, the reaction goes to completion with the formation of soaps (saponification).

• **Aerobic Soil Metabolism (MRID# 42198001)**

The registrant submitted a literature review for the methyl esters of fatty acids to satisfy the Aerobic Soil Metabolism (162-1) data requirement. Some important aspects derived from the report are as follows:

The methyl esters of fatty acids in Off-Shoot-0 are derived from natural sources (coconut oil). These compounds are approved as adjuvant and flavoring agents. The organism produces and metabolizes these long chain fatty acids. The primary degradation mechanism in living organisms is by beta oxidation from the carboxyl end. This mechanism of degradation is common to all aerobic organisms.

The degradability of fatty acids and detergents has been discussed in the literature; however, the mechanisms of biodegradation are discussed more thoroughly than the rate of degradation. In a report, the extent and rate of biodegradation of fatty acids and related compounds was measured by oxygen consumption or by dissolved organic carbon (DOC). The biodegradation in soil has also been studied for three purposes:

1. Define the genesis of soil humic substances from plant litter.
2. Explore the exploitation of microbes that could metabolize fatty acids.
3. Concern about the degradation of oily wastes on soil.

Some of these studies support the fact that the fatty acids degrade in soil surfaces. However, they do not provide the rate of degradation of these substances. In one study, linear and branched C₁₂-C₂₅ oils and fatty acids were applied to soils. The apparent half-life was 9.5 days in acclimated soils. Higher application rates increased the half-life to 28 days. The application to de-acclimated soils shows a half-life of 60 days. This study was conducted using oils with chains longer than those found in Off-Shoot-0.

• **Soil Adsorption/Leaching (MRID# 42198001)**

The registrant submitted a brief literature review for the methyl esters of fatty acids to satisfy the Soil Mobility (163-1) data requirement. Some aspects are discussed in the following paragraphs.

In a study, using linear and branched C₁₂-C₂₅ oils, GC-resolvable organics were detected in the upper 48 cm for up to 104 days. According to one report, in a secondary sewage treatment system, up to 30% of the fatty acids are adsorbed onto the sludge particulates.

The methyl esters of fatty acids are completely insoluble. This makes them likely to partition in soil or sediment and resist leaching. According to the registrant, the fatty acids are actually available to the microbes which use them as a carbon source at the lipid-water interface. It is argued that in clay soils two phenomena are possible: that the oil would become tightly bound to the fine particles in the drier clays, making it unavailable for utilization; or, otherwise, that the bound water film in moist soils would occlude the oil and prevent adsorption.

The main purposes of the Adsorption/Desorption study are to assess the leaching potential of the pesticide and degradates, and predict the dispersion of the pesticide in aquatic sites. These goals of the data requirement were not fully achieved. Despite this, EFGWB does not require additional information at this time based on the information provided and the low volume use of the product. No additional information is required.

• **Other data requirements:**

The registrant did not attempt to provide information to satisfy any other data requirements in their submission. However, the following information was derived from the submission or from EFGWB files:

The methyl esters of fatty acids are approved as adjuvants and flavoring agents in human food under 21 CFR 172. The CFR lists the following compounds generally recognized as safe for human consumption: Methyl Hexanoate (C₆), Methyl Octanoate (C₈), and Methyl Laureate (C₁₂). According to the registrant, these compounds are also used as a source of fats in animal feeds. The 21 CFR 573 lists methyl esters of high fatty acids (≥ 14 carbons) that may be used safely in animal feeds with certain restrictions.

The methyl esters of fatty acids are exempt from the requirements of a tolerance under 40 CFR 180, when used according to good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. An exemption from a tolerance is granted when it appears that the total quantity of the chemical under conditions of use involves no hazard to the public health.

The product Off-Shoot-O is intended for use in ornamental and or shade trees, and ornamental shrubs and vines. The registrant estimated a production of the pesticide close to 12,000 pounds until 1999.

The absorption of the Methyl Esters of Fatty Acids is expected to occur in the far UV, since the structure contains one double bond of the ester. Therefore, the aqueous photolysis will not be a

significant route of degradation for the Methyl Esters of Fatty Acids.

The Methyl Esters of Fatty Acids are insoluble in water and soluble in octanol; therefore, the bioaccumulation in fish is likely to occur. The information available to EEB shows that these compounds are only slightly toxic to fish. The LC₅₀ for bluegill 24 hours is 27.5 ppm; the LC₅₀ for rainbow trout 96 hours is 21 ppm. However, aerobic organism biodegrade the fatty acids derived from these compounds, via beta-oxidation from the carboxyl end. The bioconcentration of these compounds in fish is not expected to be a serious environmental problem.

Based on the information provided and the low volume use for the product, EFGWB concurs with a waiver for all data requirements for the Methyl Esters of Fatty Acids. No additional data is required at this time.

11. COMPLETION OF ONE-LINER:

EFGWB updated the One-Liner database file for the methyl esters of fatty acids with this review.

12. CBI APPENDIX:

The registrant does not consider the data reviewed here as "company confidential."

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jlm

PRELIMINARY ENVIRONMENTAL FATE ASSESSMENT:

The Methyl Esters of Fatty Acids are derived from coconut oil. The oil is refined by the same process used for edible oils to remove any free fatty acids. Then the oil is dried and submitted to alcoholysis. The fatty acids derived from these compounds have an even number of carbons (from 6 to 12).

The methyl esters of fatty acids are approved as adjuvants and flavoring agents in human food under 21 CFR 172. The CFR lists the following compounds generally recognized as safe for human consumption: Methyl Hexanoate (C₆), Methyl Octanoate (C₈), and Methyl Laureate (C₁₂). According to the registrant, these compounds are also used as a source of fats in animal feeds. The 21 CFR 573 lists methyl esters of high fatty acids (≥ 14 carbons) that may be used safely in animal feeds with certain restrictions.

The methyl esters of fatty acids are exempt from the requirements of a tolerance under 40 CFR 180, when used according to good agricultural practice as inert (or occasionally active) ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. An exemption from a tolerance is granted when it appears that the total quantity of the chemical under conditions of use involves no hazard to the public health.

The methyl esters of fatty acids are stable in water at a neutral pH. They undergo hydrolysis at acid or alkaline pH's. In the presence of a strong base such as sodium hydroxide, the reaction goes to completion. The degradation products are the acid (or salt) and methanol.

The absorption of the Methyl Esters of Fatty Acids is expected to occur in the far UV, since the structure contains one double bond of the ester. This absorption band would be outside the range of natural sunlight. Therefore, the aqueous photolysis will not be a significant route of degradation for the Methyl Esters of Fatty Acids.

The methyl esters of fatty acids are degradable under aerobic soil conditions with various reported half lives (depending on the particular conditions of the analysis). The main mechanism of degradation is biological, both in aqueous and soil environments. It appears that there is some kind of induction, caused by the presence of the esters, for which there is a lag of time in the initial degradation. The ultimate degradate is carbon dioxide.

The methyl esters of fatty acids are completely insoluble in water. This fact makes them likely to partition in soil or sediment. According to the registrant, the fatty acids are actually available to the microbes which use them as a carbon source at the lipid-water interface. It is argued that in clay soils two phenomena are

possible: that the oil would become tightly bound to the fine particles in the drier clays, making it unavailable for utilization; or, otherwise, that the bound water film in moist soils would occlude the oil and prevent adsorption.

The Methyl Esters of Fatty Acids are insoluble in water and soluble in octanol; therefore, the bioaccumulation in fish is expected to occur. The information available to EEB shows that these compounds are only slightly toxic to fish. The LC_{50} for bluegill 24 hours is 27.5 ppm. The LC_{50} for rainbow trout 96 hours is 21 ppm. However, all aerobic organisms biodegrade the fatty acids derived from these compounds, via beta-oxidation from the carboxyl end. The bioconcentration of these compounds in fish is not expected to be a serious environmental problem.

Based on the information provided, EFGWB will not request any additional data requirements for the reregistration of this product at this time.