United States Environmental Protection Agency

April 26, 2007

BIOPESTICIDES REGISTRATION ACTION DOCUMEN
BALSAM FIR OIL **129035**

U.S. Environmental Protection Agency

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

BALSAM FIR OIL

(PC Code **129035**)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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I. Executive Summary:

Balsam fir oil is used as the active ingredient in a non-food use biochemical pesticide that repels rodents in non-living spaces indoors and in enclosed spaces outdoors. Balsam fir oil repels rodents by emitting an odor that is offensive to rodents but not offensive to humans.

The product chemistry data submitted for the balsam fir oil technical grade active ingredient (TGAI), manufacturing product (MP), and the end product (EP) satisfy the requirements for product identity, product analysis and manufacturing process, and physical/chemical properties.

Sufficient mammalian toxicology data are available to support registration of balsam fir oil. Acceptable acute toxicity guideline studies were submitted for balsam fir oil. Based on the results of those studies, the required acute toxicity studies for the EP were waived by the Agency. Waivers were also granted for immunotoxicity, 90-day dermal toxicity, and inhalation toxicity. No additional toxicological data are needed.

Data waivers were granted for ecological effects data requirements by the Agency based on the low toxicity of the active ingredient and the minimal risk of exposure expected from the EP. When the products are used according to label directions, there is no expectation of exposure, and therefore no expectation of risk, to non-target organisms.

There are no significant risk issues identified for dietary risk, residential risk, or ground and surface water contamination resulting from use of the products. Any occupational exposure to balsam fir oil is mitigated as long as the MP is used according to label directions. There are no occupational uses for the EP, and EP residential exposures are not of concern if used in accordance with label directions.

The Agency has evaluated balsam fir oil under the requirements of the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has not identified any dietary or non-dietary exposure issues that may affect the U.S. population in general, including infants and children. The Agency has thereby determined that there is reasonable certainty that no harm will result from aggregate exposure to balsam fir oil residues, including dietary exposures and all other exposures for which there is reliable information.

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Balsam fir oil or Fir needle oil

Chemical Names: None

Trade & Other Names: Canadian Wilderness Oil, Fresh Cab®

CAS Registry Number: 8021-28-1

OPP Chemical Code: 129035

Basic Manufacturer: Earth Kind, Inc.
Crane Creek Gardens
17 3rd Avenue, SE
Stanley, ND 58784

B. USE PROFILE

Pesticide uses and application methods include the following:

Type of Pesticide: Biochemical pesticide, rodent repellent.

Use Sites: MP: for manufacturing use only. EP: indoors in non-living areas (attics, basements, storage areas, garages, sheds, pantries, and barns) and in other enclosed spaces (automobiles, recreational vehicles, airplanes, boats, tractors, trucks, electric junction boxes, etc.).

Target Pests: Rodents.

Formulation Type: MP: liquid; EP: granular solid.

Method and Rates of Application: MP: For manufacturing use only. EP: For indoor uses, place one pouch per eight square feet of area to be protected. For enclosed spaces, place four pouches per storage unit per season.

Timing: EP: Replace when scent has diminished, about 30 days indoors and up to three months in cold storage areas. Length of effectiveness depends on air exchange rates and temperatures.

Use Practice Limitations: None.

C. ESTIMATED USAGE

None used yet because this is the first registered product.

D. DATA REQUIREMENTS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting this registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The product analysis and manufacturing process data requirements are adequately satisfied by the data submitted by the registrant (Table 1). Physical and Chemical Properties are adequately satisfied by the data listed in Table 2. The mammalian toxicology requirements were satisfied by data submitted for acute toxicity and primary irritation (Table 3). Ecological effects data requirements were fulfilled by waivers due to the low toxicity and use pattern. The Agency reviewed all the data/information submitted and determined that they adequately satisfy current guideline requirements. The Agency issued a product registration for Canadian Wilderness Oil, EPA Registration Number 82016-2, and for Fresh Cab®, EPA Registration Number 82016-1, on April 26, 2007. In granting this product registration, the Agency does not foresee any unreasonable adverse effects to humans and the environment from the use of balsam fir oil when used as directed by the product labeling.

E. REGULATORY HISTORY

Earth Kind, Inc. (Crane Creek Gardens) submitted an application for the registration of Canadian Wilderness Oil, EPA Registration Number 82016-2, active ingredient balsam fir oil, on March 9, 2005, and Fresh Cab®, EPA Registration Number 82016-1, active ingredient balsam fir oil, on February 22, 2005**.** A notice of receipt of an application for registration of Canadian Wilderness Oil and Fresh Cab®, containing balsam fir oil as an active ingredient, was published in the Federal Register on June 14, 2006 (71 FR 34340) with a 30-day comment period. No comments were received following this publication.

The Canadian Wilderness Oil registration is for manufacturing use only. The Fresh Cab® EP is intended to be used as a rodent repellent. An unconditional registration for these products was issued on April 26, 2007**.**

F. CLASSIFICATION

On February 28, 2005, the Biochemical Classification Committee determined that balsam fir oil can be classified as a biochemical pesticide due to its non-toxic mode of action.

G. FOOD CLEARANCES/TOLERANCES

Because this is a non-food use, no food clearances or tolerances are needed.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for registration of the technical grade active ingredient balsam fir oil have been satisfied.

1. Product Identity and Mode of Action

a. Product Identity

The balsam fir oil is a pale yellow to amber liquid with a fresh woodsy scent; the EP is a tan granular solid with a fresh woodsy scent. The descriptions of the product formulation and production processes as well as the formation of impurities were examined by the Agency and found to be acceptable in meeting current guideline standards. A preliminary analysis was conducted to determine the balsam fir oil content in five batches of MP, and the results were determined to be acceptable by the Agency. The analytical method was based on the specific gravity and refractive index of the product.

b. Mode of Action

Balsam fir oil repels rodents by emitting an odor that is offensive to rodents but not offensive to humans.

2. Physical and Chemical Properties Assessment

The physical and chemical characteristics for balsam fir oil were submitted to support their registration. The product chemistry requirements are summarized in Table 1. The physical and chemical properties are summarized in Table 2.

TABLE 1. Product chemistry data requirements

OPPTS Guideline No.	Study	Results		
		Balsam fir oil TGAI	Canadian Wilderness Oil MP (MRID 46784401)	Fresh Cab® EP (MRID 46784414)
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Not applicable	Submitted data satisfy the data requirements for product identity, manufacturing process, and discussion of formation of impurities.	
830.1700	Analysis of samples	Not applicable	Submitted data satisfy the data requirements for analysis of samples.	
830.1750	Certification of limits	Not applicable	Limits listed in the CSF are adequate / acceptable.	
830.1800	Analytical Method	Not applicable	Acceptable for Canadian Wilderness Oil. The analytical method requirement was waived for Fresh Cab.	

TABLE 2. Physical and Chemical Properties				
OPPTS Guideline Reference No./Property		**Description of Results**		
		Balsam fir oil TGAI	**Canadian Wilderness Oil MP**	**Fresh Cab® EP**
830.6302	Color	Pale yellow	Pale yellow to amber	Tan
830.6303	Physical State	Liquid	Liquid	Granular solid
830.6304	Odor	Pine scent	Fresh woodsy scent	Fresh woodsy scent
830.6313	Stability	Thermally stable	Not required for MP	Not required for EP
830.6314	Oxidation/Reduction: Chemical incompatibility	Not applicable; the product is not known to contain any ingredients that are strong oxidizing or reducing agents	Not applicable; the product is not known to contain any ingredients that are strong oxidizing or reducing agents	Not applicable; the product is not known to contain any ingredients that are strong oxidizing or reducing agents
830.6315	Flammability	Flash point = 43.3ºC	Flash point = 73ºC	Not applicable, the product is a solid
830.6316	Explodability	Not applicable, the product does not contain any explosive ingredients	Not applicable, the product does not contain any explosive ingredients	Not applicable, the product does not contain any explosive ingredients
830.6317	Storage Stability	Not required for TGAI	A storage stability study will be conducted in conjunction with the one-year corrosion characteristics study and submitted when available.	Waived
830.6319	Miscibility	Not required for TGAI	Not applicable; the product is not intended for dilution with petroleum solvents.	Not applicable, the product is not intended for dilution with petroleum solvents.
830.6320	Corrosion Characteristics	Not required for TGAI	A corrosion characteristics study will be conducted in conjunction with the one-year storage stability study and submitted when available.	Waived. The product is composed of non-corrosive formulation and ingredients. The packaging materials and cardboard boxes are not corrosive.
830.6321	Dielectric Breakdown Voltage	Not required for TGAI	Not required for MP	Not applicable, the product is not a liquid and is not intended for use around electrical equipment.
830.7000	pH	pH = 5	pH = 5	Not applicable, the product is not intended for dilution with water.
830.7050	UV/Visible	229.2 nm	Not required for MP	Not required for EP
830.7100	Viscosity	2.016 ± 0.004 cS @ 20ºC	46.943 ± 0.307 cS @ 20ºC 16.940 ± 0.029 cS @ 40ºC	Not applicable, the product is a solid.
830.7200	Melting Range	Not applicable, the product is a liquid	Not required for MP	Not required for EP
830.7220	Boiling Range	219 to 360ºF @ 100 torr absolute pressure	238 to 410ºF @ 10 torr absolute pressure	Not required for EP
830.7300	Bulk Density	0.867 to 0.882 @ 25ºC	0.981 to 0.998 g/mL @ 25ºC	43 lb/ft^3
830.7370	Dissociation Constant in Water	Not applicable, the product is insoluble in water	Not required for MP	Not required for EP
830.7520	Particle Size/Distribution	Not applicable, the product is a liquid	Not applicable, the product is a liquid.	Not required for EP

TABLE 2. Physical and Chemical Properties				
OPPTS Guideline Reference No./Property		**Description of Results**		
		Balsam fir oil TGAI	**Canadian Wilderness Oil MP**	**Fresh Cab® EP**
830.7550	Partition Coefficient	Not applicable	Not required for MP	Not required for EP
830.7840	Water Solubility	Not applicable	Not required for MP	Not required for EP
830.7950	Vapor Pressure	12.0 mm Hg @ 20ºC 14.6 mm Hg @ 25ºC	Not required for MP	Not required for EP

B. HUMAN HEALTH ASSESSMENT

The mammalian toxicity studies submitted to support the registration applications for the balsam fir oil TGAI satisfy the requirements to register a new biochemical pesticide intended for non-food uses.

1. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of products containing balsam fir oil as the active ingredient. Acceptable guideline studies were submitted for the balsam fir oil. No additional toxicological data are needed.

a. Acute Toxicity

Acute toxicity studies are summarized in Table 3. Balsam fir oil and the MP are in Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity, and in Toxicity Category III for primary eye irritation. Balsam fir oil is in Toxicity Category II and the MP is in Toxicity Category IV for acute dermal irritation. Balsam fir oil is a dermal sensitizer, whereas the MP and EP are not dermal sensitizers. Based on the results for balsam fir oil and the MP, the acute mammalian toxicity data requirements were waived for the EP. No additional toxicity data are required to support this non-food use of balsam fir oil in products.

TABLE 3. Mammalian toxicity requirements for Balsam fir oil TGAI, Canadian Wilderness Oil MP and Fresh Cab® EP

Study/OPPTS Guideline No.	Results	Toxicity category	MRID No.
Acute oral toxicity (rat) (870.1100)	LD_{50} = >5000 mg/kg (Balsam fir oil)	IV	46784402
	LD_{50} = >5000 mg/kg (Canadian Wilderness Oil, contains 10% Balsam fir oil)	IV	46784408
	Waived for Fresh Cab®	IV	46784415
Acute dermal toxicity (rat) (870.1200)	LD_{50} = >5000 mg/kg (Balsam fir oil)	IV	46784403
	LD_{50} = >5000 mg/kg (Canadian Wilderness Oil, contains 10% Balsam fir oil)	IV	46784409
	Waived for Fresh Cab®	IV	46784415
Acute inhalation toxicity (rat) (870.1300)	LC_{50} = >2.09 mg/L (Balsam fir oil)	IV	46784404
	LC_{50} = >2.07 mg/L (Canadian Wilderness Oil, contains 10% Balsam fir oil)	IV	46784410
	Waived for Fresh Cab®	IV	46784415
Primary eye irritation (rabbit) (870.2400)	The maximum average score was 17.7 at one hour after test material instillation. Balsam fir oil was mildly irritating	III	46784405
	The maximum average score was 15.7 at one hour after test material instillation. Canadian Wilderness Oil was mildly irritating	III	46784411
	Waived for Fresh Cab®	IV	46784415
Primary dermal irritation (rabbit) (870.2500)	The primary irritation index was 5.1. Balsam fir oil was severely irritating.	II	46784406
	The primary irritation index was 1.4. Canadian Wilderness Oil was slightly irritating.	IV	46784412
	Waived for Fresh Cab®	IV	46784415
Dermal sensitization (guinea pig) (870.2600)	Several test animals showed positive signs of reactivity at 24 and 48 hours, respectively, after challenge. Balsam fir oil was a dermal sensitizer.	A dermal sensitizer	46784407
	After three consecutive weekly inductions, no test animals showed any positive signs of reactivity at 24 or 48 hours after challenge. Canadian Wilderness Oil was not a dermal sensitizer.	**Not** a dermal sensitizer	46784413
	Waived for Fresh Cab®	**Not** a dermal	46784415

TABLE 3. Mammalian toxicity requirements for Balsam fir oil TGAI, Canadian Wilderness Oil MP and Fresh Cab® EP			
Study/OPPTS Guideline No.	**Results**	**Toxicity category**	**MRID No.**
		sensitizer	
Hypersensitivity incidents (885.3400)	Must be reported	--	--
Genotoxicity (870.5100-5395)	Waived	Waived	Waived
90-Day oral toxicity (870.3100)	Waiver granted for Canadian Wilderness Oil and Fresh Cab®	Waived	Waived
90-Day dermal toxicity (870.3250)	Waiver granted for Canadian Wilderness Oil and Fresh Cab®	Waived	Waived
90-Day inhalation (870.3465)	Waiver granted for Canadian Wilderness Oil and Fresh Cab®	Waived	Waived
Teratogenicity (870.3700)	Waiver granted	Waived	Waived
Immunotoxicity (870.3550)	Waiver granted for Canadian Wilderness Oil and Fresh Cab®	Waived	Waived

b. Mutagenicity and Developmental Toxicity

Balsam fir oil has not been determined to be a mutagen, nor is it related to any known classes of mutagens. Teratogenicity testing (OPPTS 870.3700) is not required.

c. Subchronic Toxicity and Immunotoxicity

Waivers were granted for subchronic toxicity [90-day oral toxicity (OPPTS 870.3100), 90-day dermal toxicity (OPPTS 870.3250), and 90-day inhalation toxicity (OPPTS 870.3465)] and immunotoxicity (OPPTS 870.3550) studies for the EP. The rationale for waivers included the low acute oral, dermal, and inhalation toxicity of the MP, and the lack of toxicity of the corn cob inert ingredient in the product, which is on inert list 4A.

The EP is individually packaged in ready-to-use packets, and the potential for dermal exposure is limited. There will be no repeated inhalation exposure under the label-directed conditions of use of the product as a rodent repellent. The EP is already being marketed as an indoor air freshener to which there is regular human exposure, and no immunotoxicity has been reported. No additional data are required.

d. Chronic Exposure and Oncogenicity Assessment

Repeated dose studies are conditionally required if the potential for adverse chronic effects are indicated based on: 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required only if the active ingredient or any of its metabolites, degradation products, or impurities produced in Tier I studies any morphologic effects in any organ that potentially could lead to neoplastic

changes. None of the results of the submitted studies triggered the need for chronic exposure or oncogenicity testing.

e. Effects on the Endocrine System

EPA is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of the active ingredient balsam fir oil at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect on humans similar to an effect produced by naturally-occurring estrogen or other endocrine effects. There is no known metabolite that acts as an endocrine disrupter produced by this active ingredient. Based on the low potential exposure level associated with the proposed use, the Agency expects no incremental adverse effects to the endocrine or immune systems.

2. Dose Response Assessment

No toxicological endpoints were identified; therefore, a dose response assessment was not required.

3. Dietary Exposure and Risk Characterization

The TGAI and MP are both in Toxicity Category IV for acute oral toxicity, and acute oral toxicity testing; the EP data were waived as a result. The MP is for manufacturing use only, and the EP is for non-food use only. Due to the low toxicity and the expected low exposure to humans, no risk to human health is expected.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

The potential for dermal, eye, and inhalation exposure to balsam fir oil exists for handlers and applicators. Due to the low toxicity of balsam fir oil in animal testing, the low level of

anticipated exposure to human skin, and low likelihood of repeated inhalation exposure to balsam fir oil at toxic levels, worker exposure data for the MP and EP are not required. Occupational exposure to balsam fir oil is mitigated as long as the manufacturing use product and the end-use product are used according to label directions. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure via these routes.

b. Residential, School and Day Care Exposure and Risk Characterization

Significant human exposure to balsam fir oil from the registered products is unlikely in residential, school, or day care areas. The MP is for manufacturing use only; the EP is to be used in non-living areas indoors or in enclosed spaces outdoors. Should accidental exposure occur, the health risk is expected to be minimal based on the lack of oral, dermal, and inhalation toxicity, and the minimal potential for eye and dermal irritation.

5. Drinking Water Exposure and Risk Characterization

The registrations for balsam fir oil as the TGAI is not intended for aquatic use. It is unlikely that any residues of balsam fir oil would migrate into drinking water when the product is used in accordance with label directions.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that the Agency shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless the Agency determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency has concluded that there is reasonable certainty that no harm to infants and children or adults will result from the use of balsam fir oil in these product registrations.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm to the US population will result from aggregate exposure to residues of balsam fir oil. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity of balsam fir oil and the expected low exposure to humans. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Therefore, the Agency has not used a margin of exposure (safety) approach to assess the safety of balsam fir oil.

8. Cumulative Effects

When used as proposed, residues of balsam fir oil will not reach levels that are of toxicological concern. Because of its low toxicity and the use patterns of the products, no cumulative effect with other toxins is anticipated.

9. Risk Characterization

The Agency considered human exposure to balsam fir oil under the requirements of FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of balsam fir oil products when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The registrant was granted waivers for avian acute oral toxicity, avian dietary toxicity, fish toxicity, aquatic invertebrate toxicity, non-target plant toxicity, and non-target insect toxicity data requirements. The use pattern results in the lack of exposure of non-target organisms when the product is used according to label directions (Table 4).

TABLE 4. Non-target organism toxicity requirements for Canadian Wilderness Oil MP and Fresh Cab® EP

Study/OPPTS Guideline No.	Results	MRID No.
Avian acute oral toxicity (850.2100)	Waived	N/A
Avian dietary toxicity (850.4100)	Waived	N/A
Freshwater fish LC_{50} (850.1075)	Waived	N/A
Freshwater invertebrate LC_{50} (850.1010)	Waived	N/A
Non-target plant studies (850.4000-4800, as applicable)	Waived	N/A
Non-target insect testing (880.4350)	Waived	N/A

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because the acute toxicity studies did not trigger any additional Tier I studies. Risk is minimal due to the low toxicity, use pattern, and exposure rate.

3. Ecological Exposure and Risk Characterization

The potential for exposure to non-target wildlife is minimal. Due to the low toxicity of the TGAI and the low exposure rate, the environmental risk may be characterized as minimal when the products are used according to label directions.

D. EFFICACY DATA

The Agency only requires efficacy data to be submitted for review in connection with the registration of products directly pertaining to the mitigation of disease bearing human health organisms and certain designated quarantine pests, e.g., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, and Japanese beetles. Efficacy data submitted for the EP (MRID 46784416) indicated the product provides approximately 68% repellency to mice over a 31-day period. While the study design contained certain flaws, the submitted study was judged to be acceptable. No additional efficacy data are needed.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, the MP and EP are not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current labels and the data presented in this document. It is believed that these products will not cause any unreasonable adverse effects and do provide protection as claimed, satisfying Criteria "C." Criteria "D" was satisfied by the data submitted and the low exposure to the products when used according to label directions. Therefore, these products containing balsam fir oil as the TGAI are eligible for registration.

B. REGULATORY POSITION

1. Unconditional Registration

The data requirements are fulfilled sufficiently for BPPD to grant an unconditional registration for the Canadian Wilderness Oil MP and the Fresh Cab® EP. As a term and condition of registration, the registrant must submit a storage stability and corrosion characteristic study for the MP within 1 year of this registration.

Tolerance Establishment

The uses of the products containing balsam fir oil have been determined to be non-food uses and therefore do not require the establishment of a food tolerance or an exemption from the requirement of a tolerance.

2. CODEX Harmonization

Not applicable, because this is a non-food use.

3. Nonfood Registrations

There are no non-food issues at this time.

4. Risk Mitigation

There are no significant risk issues identified for dietary risk, residential risk, or ground and surface water contamination. There is not significant risk to non-target organisms; in addition, the use pattern specified on the label precludes exposure to exposure to non-target organisms.

5. Endangered Species Statement

Based on the information discussed above, the Agency has determined that use of these products containing balsam fir oil will have No Adverse Effects (NAE) on threatened and/or endangered species when the products are used according to label directions. Due to the use pattern (non-living spaces indoors or in enclosed areas outdoors), exposure threatened or endangered species is unlikely. Therefore, there will be NAE on threatened or endangered species.

C. LABELING RATIONALE

The Agency's position is that the labeling for the products containing balsam fir oil as the active ingredient complies with current pesticide labeling requirements imposed under FIFRA and 40 CFR 156.10.

1. Human Health Hazard

a. Worker Protection Standard

These products do not come under the provisions of the Worker Protection Standards.

b. Non-Worker Protection Standard

There are no non-worker (non-mixer/loader/applicator) human health hazard issues.

c. Precautionary Labeling

The precautionary statements on the pesticide label are designed to provide the pesticide user with information regarding the toxicity, irritation and sensitization hazards associated with the use of a pesticide, as well as treatment instructions and information to reduce exposure potential. The Agency has examined the toxicological data base for balsam fir oil and has concluded that the precautionary labeling (i.e., signal word, first aid statement, and other label statements) listed on the respective labels (section D, below) adequately mitigates the risks associated with the proposed uses.

d. Spray Drift Advisory

No spray drift advisory statement is necessary for the proposed use.

2. Environmental Hazards Labeling

The following language is to appear in this section of the MP labels:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit, and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

3. Application Rate

For MP: not applicable, the product is for manufacturing use only.

For EP: Indoors in non-living spaces: One scent pouch per eight square feet in areas to be protected. In enclosed spaces: Four scent pouches per storage unit per season. Replace when scent has diminished.

D. LABELING

Product name: **Canadian Wilderness Oil (MP)**

Active Ingredient:

Balsam fir oil…….....10.0%

Other Ingredients.....90.0%

Total……..……100.0%

Signal word is "CAUTION".

The product label shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (CAUTION)
- Product name: **Fresh Cab® (EP)**

Active Ingredient:

Balsam fir oil…….....2.0%

Other Ingredients.....98.0%

Total……..…….100.0%

Signal word: None required

The product label shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number

Additional Label Language Requirements

FIRST AID

Required for the TGAI:

If in eyes:
Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice.

If on skin or clothing:
Take off contaminated clothing
Rinse skin immediately with plenty of water for 15-20 minutes.
Call a poison control center or doctor for treatment advice.

Required for the MP:

If in eyes:
Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice.

Required for the EP: None

The following statement must accompany the First Aid text block: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment." The Agency guidance also suggests including a contact telephone number for additional emergency medical treatment information.

V. Actions Required by Registrants

The Agency evaluated all of the data submitted in connection with the initial registration of products containing balsam fir oil and has determined that these data are sufficient to satisfy current registration guideline requirements. Therefore, these balsam fir oil products are eligible for registration. As a term and condition of registration, the registrant must submit a storage stability and corrosion characteristic study for the Canadian Wilderness Oil MP within 1 year of this registration. These products will be subject to registration review in 2022, unless new information regarding this product warrants earlier review.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. REPORTING OF ADVERSE EFFECTS

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. REPORTING OF HYPERSENSITIVITY INCIDENTS

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.690(c), guideline reference number 152-16.

VI. Appendix A.

Tables 5 and 6 list the use sites for the products.

TABLE 5. Use Sites for Canadian Wilderness Oil MP	
Canadian Wilderness Oil For manufacturing use only.	**Official date registered:**

TABLE 6. Use Sites for Fresh Cab® EP	
Fresh Cab® Indoors: Use in non-living areas (attics, basements cellars, storage areas, garages, sheds, pantries, and barns). Enclosed Spaces: Use in autos, recreational vehicles, airplanes, boats, tractors, trucks, electric junction boxes, etc.	**Official date registered:**

VII. Appendix B.

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