Docket Number EPA-HQ-OPP-2009-0258

Wood Oils and Gums
Proposed Registration Review Decision
Case 3150

Cedar Oil, PC 040505 (CAS# 8000-27-9)

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) *Proposed Registration Review Decision* for *Wood Oils and Gums* and is being issued in accordance with 40 CFR §§ 155.57 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For further information on *Wood Oils and Gums*, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2007-0258) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

In 2006, the Agency implemented the Registration Review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

In accordance with 40 CFR § 155.50, the Agency formally initiated registration review for *Wood Oils and Gums* (Case 3150). The following timeline highlights significant events that have occurred during the registration review of *Wood Oils and Gums*:

- September 30, 2009 – Publication of the *Wood Oils and Gums Summary Document* in the docket (EPA-HQ-OPP-2007-0258) for a 60-day public comment period. The *Summary Document* also included the preliminary work plan (PWP). One comment was received on December 4, 2009 from the Physicians Committee for Responsible Medicine.
- April 7, 2010 – Publication of the *Wood Oils and Gums Final Work Plan*, which stated that the most recent exposure and risk assessments still supported the registration of the currently registered pesticide products containing *Wood Oils and Gums* and that these products appeared to have met the requirement of registration review under 40 CFR § 155.50.

The information evaluated to support *Wood Oils and Gums*, as published in the *Summary Document* (September 30, 2009), continue to support the pesticide registration as summarized herein. The status of this and other registration review cases is available at: http://www.epa/gov/oppsrrd1/registration_review/. Additional information on *Wood Oils and Gums* (specifically Cedar Oil) is available on the Biopesticides and Pollution Prevention Division's website in the form of a succinct fact sheet and more comprehensively in a

Reregistration Eligibility Decision (RED)
(http://www.epa.gov/oppbppd1/biopesticides/ingredients/index.htm).

On October 26, 2007, the Agency issued a Final Rule in the Federal Register (FR) on the data requirements to support registration of biochemical and microbial pesticides and updated definitions for both biochemical and microbial pesticides (72 FR 61002). This rule became effective on December 26, 2007. The data and information summarized below were considered in light of these requirements.

A. Wood Oils and Gums General Background

The Wood Oils and Gums Registration Review Case case no longer contains any other wood oils or gums with active ingredients with registered products except for Cedar oil. Therefore, this registration review consists of the active ingredient: Cedar oil. Cedarwood oils are extracted from the *Cupressaceae* family, which includes true cedars, junipers, and cypresses. In the US, cedarwood oil is mainly extracted from *Juniperus virginiana* (Eastern red cedar or Virginia cedar), *Juniperus ashei* or *mexicana* (Texas cedar), and *Thuja plicata* (Western red cedar). As a biochemical active ingredient, products containing Cedar oil are registered as insect repellents. A non-toxic mode of action has been confirmed, and risk assessments have accounted for the potential hazards posed by each use. Information submitted in support of registered products containing Cedar oil uniformly confirms that no adverse human health or ecological risks are expected as a result of exposure to this compound, when used as labeled. Moreover, the assessment conducted in the course of this Registration Review and included in the docket, indicate that all data requirements have been adequately addressed in the course of Cedar oil registration and reregistration.

B. Cedar Oil Registered Pesticide Products

There are currently four Cedar oil products registered with EPA. Pesticidal uses include: a sunscreen and insect repellent lotion; two sprays to repel flies and gnats from horses; and a controlled release dispenser to repel moths from clothing. A complete list of the currently registered products is available for reference in Table 4 in the Appendix.

II. SCIENTIFIC ASSESSMENT

A. Product Analysis (40 CFR § 158.2030)

The data and information submitted to support applications for registration for the active ingredient Cedar oil were reassessed and found sufficient to fulfill current product chemistry data requirements (40 CFR § 158.2030) for all the use patterns described above. Adequate product analysis data for Cedar oil were found in the 1993 Reregistration Eligibility Decision (RED) and in the reassessment documents associated with this registration review. A list of supporting product chemistry studies (including Master Record Identification Numbers |(MRID's)) can be found within the 'List of Studies Submitted' for Cedar Oil in Table 5 in the Appendix. A summary of the specific physical and chemical characteristics of Cedar Oil is found in Table 1 of the Appendix.

B. Human Health

1. Acute Toxicity – Tier I (40 CFR § 158.2050)

The rationales provided to support waiver requests for acute toxicity data requirements for the active ingredient Cedar oil were reassessed and found sufficient to address current acute toxicity data requirements (40 CFR § 158.2050). In particular, the acute toxicity assessment in the 1993 Cedar oil RED was affirmed to be sufficient to address all current data requirements. In the RED, the generic acute toxicity data requirements were waived because the Agency was not aware of any adverse effects to human health or the environment, and there had been no reported incidents of toxicity for any of the registered products. The product-specific acute toxicity guideline studies (provided for the various end-use products (EP's)) demonstrate the active ingredient's lack of acute toxicity. Available acute toxicity data on the EP's indicate that all the EP products fall into the lowest two toxicity classes of pesticides (Toxicity Category III or IV) for all routes of exposure, except for the inhalation route. No specific data were found regarding acute inhalation, however the data requirement was addressed in a Health Effects Division memorandum from Charles Frick to Esther Salto and Penelope Fenner-Crisp dated June 1, 1993. It was determined from this memo that human health risk is not expected as a result from exposure to cedar oil by the inhalation route. Some acute toxicity results from the EP with the highest percentage of active ingredient are discussed below. A summary of Cedar oil's generic acute toxicity profile is available in the Appendix in Table 2. A complete list of the acute toxicity studies can be found in the Bibliography, also located in the Appendix. The locations of product specific acute toxicity assessments are available in EPA's product registration jackets.

- **Acute Oral Toxicity (Office of Prevention, Pesticides, and Toxic Substances (OPPTS) Guideline 870.1100)** – In a guideline acute oral toxicity study on rats using a test substance containing 40% Cedar oil (MRID 44412001), the substance was determined to be **Toxicity Category III.** There were no mortalities and necropsy results revealed no abnormalities. The Median Lethal Dose (LD_{50}) was between 500 and 5000 mg/kg and no toxic endpoints were established.

- **Acute Dermal Toxicity (OPPTS Guideline 870.1200)** – No acute dermal toxicity data was available for Cedar oil in the Agency's database. Based on results from a study in the publicly available peer-reviewed literature, a rabbit study resulted in a median lethal dose (LD_{50}) of the test substance to be greater than 5,000 mg/kg. The Agency has classified the test substance as **Toxicity Category IV** (Food and Cosmetics Toxicology. 1974. Vol. 12: 845.).

- **Acute Inhalation Toxicity (OPPTS Guideline 870.1300)** A group of 5 male and 5 female Sprague-Dawley rats were exposed to the test substance by the inhalation route for a period of 28 days. Each modified cage was 90% closed by a covering with a plastic pane. A single test substance blister pack with a dispenser volume of 9 ml was fastened to the cage. Under the conditions of this 28-day experiment, the test substance caused no mortality. No animal showed toxicological signs during the application period of 28 days. During the first five days of the experiment, all ten rats

tried to avoid the odor of the test substance. This was concluded from the different patterns of behavior of all the rats, including burrowing into the bedding and staying in one area of the cage far from the test substance. The body weight of all animals remained normal.

The test substance main ingredients, (-)-α-cedrene and (+)-cedrol, were analyzed by gas chromatography after air sampling and adsorption on charcoal. On the last day of the observation period, the air concentration of (-)-α-cedrene was between 7 and 10 mg/l00L air and (+)-cedrol was at 4.1 mg/100L (0.041mg/L).

The acute inhalation toxicity data requirement was also addressed in a Health Effects Division memo from Charles Frick to Esther Salto and Penelope Fenner-Crisp dated June 1, 1993. It was determined that there is no expected risk to human health from inhaling Cedar oil.

- **Primary Eye Irritation (OPPTS Guideline 870.2400)** – The undiluted test substance was applied in a single dose of 0.1 ml into the right eye of each of 3 albino rabbits. Upon evaluation of the eye of the three rabbits, all animals developed hyperemic blood vessels. This effect was estimated at grade 1 (maximum possible 3). Hyperemic blood vessels were not observed past day 1 for two of the rabbits and past day 2 for one of the rabbits. None of the animals showed swelling of lids.

  All symptoms observed were reversible. Ocular lesions of the cornea or iris were not noted during this study. Under the conditions of this experiment, the test substance did not cause acute toxicological symptoms or mortality. The left eye was not treated and was used as a control. Symptoms of eye irritation did not occur in this eye. Throughout the experiment, all three animals had an increase in weight.

  Upon the administration of 0.1 ml of test substance into the right eye of the animals, none of them died during the experiment. Additionally, no signs of toxicological symptoms were observed. The result shows that acute eye irritation should be at **Toxicity Category IV.**

- **Primary Dermal Irritation (OPPTS Guideline 870.2500)** – A peer-reviewed acute dermal irritation study using rabbits had a primary irritation index (PII) of 3.3 with 100% Port-Orford-cedar oil extract. The test was using the essential oil extracts of western juniper oil (*Juniperus occidentalis*) and Port-Orford-cedar oil (*Chamaecyparis lawsoniana*) for dermal toxic effects on mice and rabbits. At 0.5% concentration, western juniper oil extract was found to be a non-irritant. Although there is a registered product with an active ingredient concentration of 40%, it is embedded in a dispenser and dermal exposure to the active ingredient is highly unlikely. The remaining three registered products' active ingredient concentration is 0.5% or less. This dermal irritation can be used for the risk assessment of wood oil. (**Toxicity category III**) (Toxicology Letters. 2004. Vol. 154 (3): 217-224)

- **Skin Sensitization (OPPTS Guideline 870.2600)** – In a guideline skin sensitization study with guinea pigs using a test substance containing 40% Cedar oil (MRID 44412004), the substance was determined to be **a non-sensitizer.**

2. Subchronic Toxicity, Developmental Toxicity, Mutagenicity, and Immunotoxicity (Tier II); Chronic Testing (Tier III)

Tier II and Tier III studies were not required for *Cedar oil* based on the lack of acute toxicity in the Tier I studies for the EP's.

3. FQPA Assessment: Dietary Exposure and Risk Characterization

Section 408(c)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... " Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information, and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

On the basis of acute toxicity data discussed above, the data requirements required for FQPA risk assessments for *Cedar oil* have been satisfied.

a. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

i. Dietary Exposure and Risk Characterization

Dietary exposure to *Cedar oil* is not expected. None of the cedar oil products have food-use applications, and cedar oil is not known to persist or bioaccumulate in the environment. Currently registered products include a lotion repellent, two horse insect repellent sprays and a "moth ball" type product that repels moths from clothing. Additionally, the acute toxicity data on file with the Agency confirm its lack of acute toxicity.

ii. Drinking Water Risk Characterization

Cedar oil residues are not expected to be able to reach drinking water. There are no agricultural applications for cedar oil products. In addition, cedar oil is not known to persist or bioaccumulate in the environment. Data on file with the Agency confirm Cedar oil's lack of toxicity.

iii. Non-Occupational, Residential Risk Characterization

The use sites for products containing Cedar oil include non-residential and residential sites. Non-residential sites include horse barns/stalls for the horse insect repellent sprays. Non-occupational exposures are expected to be minimal. The residential uses of Cedar oil are limited to skin lotion repellents, mainly used during the summer months, and dispensers used to repel moths in clothing which remain effective for 3 months. Both of these products are used infrequently, and when they are used, use is at relatively low rates. Applications of Cedar oil are very dilute, and residues are rapidly biodegraded. In the event of exposure, no non-occupational risks are anticipated. The acute toxicity data on file with the Agency shows a lack of acute toxicity for all routes of exposure.

b. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effects of exposure to Cedar oil and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. No mechanism of toxicity in mammals has been identified for Cedar oil; therefore, no cumulative effect with other related compounds is anticipated. Because the data available demonstrate a low toxicity potential for Cedar oil, the likelihood of adverse dietary effects is expected to be minimal.

c. Determination of Safety for U.S. Population, Infants, and Children

FFDCA section 408(b)(2)(C) provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety), which are often referred to as uncertainty factors, are incorporated into EPA risk assessment either directly or through the use of a margin of exposure analysis, or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk.

Based on the available acute toxicity data for Cedar oil, EPA believes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to the residues of Cedar oil. This includes all routes of exposure for which there is reliable information. The Agency has arrived at this conclusion because the submitted data available on Cedar oil do not appear to demonstrate toxic effect on mammals, nor is there any anticipated dietary exposure. Thus, there are no threshold effects of concern and, as a result, the provision requiring an additional margin of safety does not apply. Further, the considerations of consumption patterns, special susceptibility, and cumulative effects do not apply to pesticides without a demonstrated significant adverse effect.

d. Food Tolerance Exemptions

Cedar oil does not have any food-use applications; therefore, a tolerance or tolerance exemption is not required.

4. Occupational Exposure and Risk Characterization

There are no agricultural applications for Cedar oil. Horse applications are by directed spray in a closed area such as a stable or barn. Lotion insect repellent product applications are by direct application to skin and clothing repellent applications are by placement of dispenser in clothing. Any exposure to the active ingredient is expected to be incidental and minimal. Repellent sprays for horses are not expected to be used regularly because they are employed on an as-needed basis. In all cases, exposures to users of these products are expected to be indirect and minimal. Even if there were exposure, the acute toxicity studies for Cedar oil do not show any toxic effects *via* the oral, dermal, or inhalation routes of exposure. Accordingly, occupational exposure to Cedar oil is not expected to pose any undue risk. Regardless, appropriate precautionary statements are required on the product labels to mitigate any potential risks to pesticide handlers due to prolonged exposure.

5. Endocrine Disruptors

As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a quantitative relationship between the dose and the E, A, or T effect.

Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.

Cedar oil is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA § 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP orders/data call-ins for all Registration Review cases, including those for which EPA has already opened a Registration Review docket for a pesticide active ingredient.

For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

6. Human Health Risk Characterization

The human hazard and exposure assessments for Cedar oil indicate that the risks to human health are negligible to non-existent when products containing Cedar oil are used in accordance with their respective labels. These assessments are considered complete and current, and satisfy the standards of registration review. All biochemical pesticide toxicology data requirements to determine human health effects for Cedar oil were considered and are fulfilled.

Human health hazard and exposure scientific reviews for Cedar oil are located and or cited in the Wood Oils and Gums registration review docket (EPA-HQ-OPP-2009-0258).

C. Environmental Assessment

1. Effects on Non-Target Organisms – Tier I (40 CFR § 158.2060)

All Tier I ecotoxicity data requirements for Cedar oil have been waived. The existing data waiver rationales on file with the Agency, and presented in the 1993 RED, have been reassessed in the course of registration review and are considered sufficient to fulfill current ecotoxocity data requirements. The unique characteristics of Cedar oil products, their non-toxic mode of action, biodegradability (low to no persistence), and use patterns (indoor uses and sprays to be applied to horses) should minimize the potential for risk to all non-target organisms, including threatened and endangered species. Mammalian toxicology data affirm its lack of acute toxicity to mammals through the acute inhalation, dermal, and dietary routes of exposure, and strongly indicate that Cedar oil should be nontoxic to terrestrial wildlife. Table 3 in the Appendix provides reference to the rationales that support the non-target data requirements.

2. Environmental Fate, Ecological Exposure, and Environmental Expression – Tiers II, III, and IV (40 CFR § 158.2150)

Environmental fate data requirements (i.e., Tiers II and III) were not triggered for Cedar oil because the information submitted to explain the Tier I non-target toxicity waiver rationales did not indicate significant adverse hazards to the environment.

3. Endangered Species Assessment

The non-target information reviewed by the Agency in support of the data waiver requests, in conjunction with information from the public literature, indicates that Cedar oil is not harmful to endangered species at the current label use rates. The Agency's acute levels of concern (0.05 – 0.1) were not exceeded for terrestrial, aquatic, or plant endangered species. The unique characteristics of Cedar oil - its non-toxic mode of action, its low use volumes, and its biodegradability - minimize the potential for any risks to threatened and endangered species. Calculated RQ values were approximately two orders of magnitude below the Agency's Endangered Species levels of concern. As a result of these analyses, the Agency has determined that the registered uses of Cedar oil will have "No Effect" on endangered and threatened terrestrial or aquatic species, or any designated critical habitat, as listed by the United States Fish and Wildlife Service and the National Marine Fisheries Service. The 'Wood Oils and Gums Endangered Species Assessment' can be found in the Registration Review docket EPA-HQ-2009-0258.

4. Environmental Risk Characterization

Based on the complete reviews of the aforementioned non-target organism and environmental fate studies, and the endangered species assessment, the Agency does not anticipate any unreasonable adverse effects to non-target organisms or the environment when products containing *Cedar oil* are used in accordance with their respective labels. These assessments are considered complete and current, and they satisfy the standards of registration review.

All biochemical pesticide non-target organism and environmental fate data requirements used to determine environmental effects for Cedar oil were considered and are fulfilled.

Environmental scientific reviews (to include the endangered species assessment) for Cedar oil are located in the Wood Oils and Gums registration review docket (EPA-HQ-OPP-2009-0258).

D. Product Performance (Efficacy) (40 CFR § 158.2070)

Product performance data must be developed for all biochemical pesticides to ensure efficacy when used in accordance with labeling directions and commonly accepted pest control practices. The Agency has waived all requirements to submit such efficacy data unless the pesticide product bears a claim to control public health pests, although the Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration. Because Cedar oil pesticide products do not have labeled uses for public health pests, the Agency has not required submission of efficacy data to support those claims.

E. Incidents

The National Pesticides Information Center (NPIC) database included three reports of incidents involving products containing Cedar Oil. There were no ecological incidents reported. The reporting period was covered from 6/1/1992 to 4/14/2009. The first incident resulted when a woman touched a cedarwood block, and sap or oil remained on her hand and later caused eye irritation. There no longer are any cedarwood block products registered with the Agency. The next two incidents involved domestic animals: cats and dogs. There were 37 reports of domestic animal incidents from Illinois Animal Poison Control. Symptoms included depression, dehydration, and muscle tremors. One cat died within a week of the incident. The two products cited in these incidents (Cedar Chips and Solid Gold Insect Shoo) are both no longer registered with the Agency. None of the incidents involved occupational exposure; and none reflected hazard or risk unknown to the Agency regarding the nature of Cedar oil. Label language on presently registered Cedar oil products is appropriate and sufficient to protect users/handlers of these products. These incidents do not have a bearing on the hazard or risk assessed pertaining to the use of registered Cedar oil pesticide products in accordance with their product labels.

F. Public Comments

In accordance with 40 CFR § 155.50, the Agency formally initiated registration review for *Cedar oil* in September 2009 with the opening of a docket and the issuance of a *Summary Document* for a 60-day public comment period. The Agency received one comment in response to the *Wood Oils and Gums Summary Document* and the initial opening of the docket. This comment was sent by the Physicians Committee for Responsible Medicine (PCRM). The comment included several useful links to scientific data regarding Cedar Oil's acute toxicity. References from HSDB, ChemIDPlus, Registry of Toxic Effects of Chemical Substances (RTECS) Database, and New Zealand Environmental Risk Management Authority were cited in

the comment. In addition, PCRM encouraged the Agency to consult other national, regional, and state authorities for relevant data. Non-animal methods for evaluating acute toxicity were also described. Two of the listed scientific references were utilized in addressing two of the three acute toxicity data gaps, namely acute dermal toxicity and acute dermal irritation.

G. Water Quality

Cedar oil is not identified as a cause of impairment for any water bodies listed as impaired under Section 303(d) of the Clean Water Act, based on information provided at: http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885. In addition, no Total Maximum Daily Loads (TMDLs) have been developed for Cedar oil, based on information provided at: http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/. The Agency solicited comments when the *Summary Document* was published in September 2009; however, no comments, data, or information regarding the existence of any water quality issues associated with Cedar oil were received.

H. Trade Irritants

Trade irritants are not expected for *Cedar oil*. Through the registration review process, the Agency is soliciting information on trade irritants and, to the extent feasible, will take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Levels (MRLs) or disparities between U.S. tolerances or exemptions from tolerance and MRLs or exemptions from MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Trade irritants are not expected for Cedar oil because there are no U.S. tolerances for Cedar oil, nor are there Codex MRL's. The Agency did not receive any comments regarding the existence of any trade irritant issues associated with *Cedar oil* following issuance of the *Summary Document*.

I. Environmental Justice

EPA seeks to achieve environmental justice—the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income—in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency sought information, as explained in the *Summary Document*, on groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to registered pesticide products containing *Cedar oil* compared to the general population. The Agency did not receive any comments. At this time, EPA does not believe that use of the registered pesticide products containing *Cedar oil* will cause harm to or a disproportionate impact on at-risk communities.

For additional information regarding environmental justice issues, please visit EPA's website at: http://www.epa.gov/compliance/environmentaljustice/index.html.

III. PROPOSED REGISTRATION REVIEW DECISION

The Agency has determined that no additional data are required at this time to support registrations containing Cedar oil. The Agency has considered *Cedar oil* in light of the standard for registration and safety factors in FIFRA and FFDCA, as amended by FQPA. EPA does not anticipate any unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, or to non-target organisms or the environment from the use of registered pesticide products containing *Cedar oil* when currently required label instructions are followed. In addition, EPA has made a "No Effect" determination for endangered and threatened species, and their designated critical habitat, for *Cedar oil*. The Agency has found that it is not necessary to conduct a new risk assessment for this case and is therefore issuing a proposed decision in accordance with 40 CFR Section 155.53(c)(2) and 40 CFR Section 155.58.

Therefore, in accordance with 40 CFR §§ 155.57 and 155.58, the Agency's proposed registration review decision is that the standards for Registration Review have been met and that the registrations of the four products containing *Cedar oil* may be maintained.

IV. NEXT STEPS AND TIMELINE

In accordance with 40 CFR § 155.58, the Agency is issuing this proposed decision document and placing it in the *Cedar oil* registration review docket (EPA-HQ-OPP-2009-0258). A Federal Register Notice will announce its availability and allow a 60-day public comment period. If there are no significant comments or additional information submitted to the docket during that comment period that lead the Agency to change its decision, EPA will issue a final decision for *Wood Oils and Gums* (case 3150). The Agency anticipates the final decision will be issued in September 2010.

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VI. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

APHIS	Animal and Plant Health Inspection Service
BPPD	Biopesticides and Pollution Prevention Division
BRADs	Biopesticides Registration Action Documents
°C	degrees Celsius
CFR	Code of Federal Regulations
cfu	colony-forming unit
cm	centimeter
EC_{50}	half maximal effective concentration
EDSP	Endocrine Disruptor Screening Program
EEC	estimated environmental concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA	Environmental Protection Agency (the Agency)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g	grams
g/kg	grams per kilogram
kg	kilograms
L	liter
LC_{50}	median lethal concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air, or feed (e.g., mg/L, mg/kg, or ppm).
LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
LOC	level of concern
LOEC	lowest observable effect concentration
mg	milligrams

mg/kg	milligrams per kilogram
mg/L	milligrams per liter
mL	milliliter
mL/kg	milliliters per kilogram
MRID Nos.	Master Record Identification Numbers
NOAEC	no observable adverse effect concentration
NOEC	no observable effect concentration
OECD	Organization for Economic Cooperation and Development
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PC Code	Pesticide Chemical Code
ppm	parts per million
PWP	preliminary work plan
SAR	systemic acquired resistance
TGAI	technical grade of the active ingredient
TMDLs	Total Maximum Daily Loads
TSA	trypticase soy agar
USDA	United States Department of Agriculture

VII. APPENDIX

Table 1. Cedar Oil Physical and Chemical Properties: EP-Nexa Cedarwood Oil Moth Protection (40 CFR § 158.2030)

Guideline Reference No.	Property	Description of Result
830.6302	Color	Light brown
830.6303	Physical State	Liquid
830.6304	Odor	Cedarwood odor
830.6313	Stability	
830.6314	Oxidation/Reduction: Chemical Incompatibility	N/A components are non-interacting
830.6315	Flammability (Flashpoint)	86°C
830.6316	Explodability	Components do not have explosive characteristics
830.6317	Storage Stability	30 days storage
830.6319	Miscibility	N/A not an emulsifiable liquid and is not intended for dilution with petroleum products.
830.6320	Corrosion Characteristics	Product is not corrosive and does not interact with packaging
830.6321	Dielectric Breakdown Voltage	Product is not intended for use around electrical equipment
830.7000	pH	Material does not dissolve in water
830.7050	UV/Visible	
830.7100	Viscosity	20-30 centipoise at 20°C
830.7200	Melting Range	Material is a liquid at room temperature.
830.7220	Boiling Range	264-280°C @ 750 mmHg
830.7300	Bulk Density	0.99 g/mL
830.7370	Dissociation Constant in Water	Material does not dissociate
830.7520	Particle Size	
830.7550	Partition Coefficient	-log P = 4.8 (needs clarification)
830.7840	Water Solubility	Insoluble in water
830.7950	Vapor Pressure	N/A

Table 2. Human Health Assessment: Acute Toxicity Results- EP-Nexa Cedarwood Oil Moth Protection (40 CFR § 158.2050)

Data Requirement	LD50	Toxicity Category	MRID's
Acute Oral Toxicity OPPTS 870.1100	>2000 mg/kg	III	44412001
Acute Dermal Toxicity OPPTS 870.1200	>5000 mg/kg	IV	Food and Cosmetics Toxicology. 1974. Fragrance raw materials monographs: Cedarwood oil Virginia. *Food and Cosmetics Toxicology* 12: 845.
Acute Inhalation Toxicity OPPTS 870.1300	Low exposure based on anticipated low rate of product release. (Any sprayable at concentrations greater than 2.5% would need to be specifically examined.)		US EPA HED Memorandum
Primary Eye Irritation OPPTS 870.2400	No corneal opacity, iritis, or positive conjunctival irritation.	IV	44412003
Primary Dermal Irritation OPPTS 870.2500	Primary irritation index was 3.3 – moderately irritating	III	Craig, A.M., Karchesy, J.J., Blythe, L. L., Gonzales-Hernandez, M., Swan, L. R. 2004. Toxicity studies on western juniper oil (*Juniperus occidentalis*) and Port-Orford-cedar oil (*Chamaecyparis lawsoniana*) extracts utilizing local lymph node and acute dermal irritation assays. *Toxicology Letters* 154 (3): 217-224.
Dermal Sensitization OPPTS 870.2600	Not a dermal sensitizer	-	44412004

Table 3. Waiver Request for Ecotoxicity Studies for EP-Nexa Cedarwood Oil Moth Protection (40 CFR § 158.2060)

Study Type/OPPTS Guideline	LD_{50}/LC_{50}/Results	Classification	MRID
Avian Acute Oral/OPPTS 850.2100	Waiver	Acceptable	RED (1993)
Avian Dietary/OPPTS 850.2200	Waiver	Acceptable	RED (1993)
Freshwater Fish LC50/OPPTS 850.1075	Waiver	Acceptable	RED (1993)
Freshwater Invertebrate/OPPTS 850.1010	Waiver	Acceptable	RED (1993)
Non-target Plants/OPPTS 850.4000	Waiver	Acceptable	RED (1993)
Non-target Insects	Waiver	Acceptable	RED (1993)

Table 4. Currently Registered Products Containing Cedar Oil

EPA Reg. #	Registration Name	Company Name	Current Status	% of AI
1543-14	Bug Block Sunscreen & Insect Repellent	W.F. Young, Inc.	Active - Conditionally Registered (17-May-2000)	.46
66963-8	Aloe Herbal Horse Spray	Espree Animal Products, Inc	Active - Conditionally Registered (14-Jun-2007)	.5
66963-9	Aloe Herbal Horse Spray Ready-To-Use	Espree Animal Products, Inc	Active - Registered (10-Dec-2007)	.1
69129-1	Nexa Cedarwood Oil Moth Protection	Celaflor Gmbh	Active - Registered (13-Apr-1998)	40

Table 5. List of Studies Submitted for Cedar Oil (PC 040505, CAS# 8000-27-9)

MRID	Citation	Receipt Date
24592	Vlahakis, G.; Sabine, J.R.; Horton, B.J.; et al. (1979) Cedar Shavings. (Unpublished study received Jun 24, 1980 under un- known admin. no.; prepared in cooperation with National Cancer Institute and Great Britain, Royal Veterinary College, Dept. of Pathology, submitted by Natural Research People, Inc., Lavina, Mont.; CDL:241704-A)	24-Jun-1980
24593	Vlahakis, G. (1977) Possible carcinogenic effects of cedar shavings in bedding of C3H-A^vyIfB mice. Journal of the National Cancer Institute 58(1):149-150. (Also~In~unpublished submission received Jun 24, 1980 under unknown admin. no.; submitted by Natural Research People, Inc., Lavina, Mont.; CDL:241704-B)	24-Jun-1980
24594	Heston, W.E. (1975) Testing for possible effects of cedar wood shavings and diet on occurrence of mammary gland tumors and hepatomas in C3H-A^vyI and C3H-A^vyIfB mice. Journal of the National Cancer Institute 54(4):1011-	24-Jun-1980

	1014. (Also~In~unpublished submission received Jun 24, 1980 under unknown admin. no.; submitted by Natural Research People, Inc., Lavina, Mont.; CDL:241704-C)	
46115	Michaelson, J.B. (1971) Report: Laboratory No. 8539. (Unpublished study received on unknown date under 10487-1; prepared by Applied Biological Sciences Laboratory, Inc., submitted by Donnelly Co., Tarzana, Calif.; CDL:103621-A)	02-Apr-1971
67331	Mace, E.F. (1956) Bioassay Report: W.A.R.F. No. 511057-59. (Unpublished study received Jan 26, 1956 under 5269-1; prepared by Wisconsin Alumni Research Foundation, submitted by M & S Chemi cal Co., Vincennes, Ind.; CDL:231097-A)	26-Jan-1956
93884	Ecosafe Laboratories, Incorporated (1982) Data in Support of Insect Shooo, Skeeter Shooo Spray & Skeeter Shooo Balm. (Unpublished study received Jan 19, 1982 under 45220-3; CDL:246625-A)	19-Jan-1982
118746	Michaelson, J. (1971) Report: ?Skin Irritation and Acute Eye Irri- tation Tests for Medicated Ointment and Oil|: Laboratory No. 8539. (Unpublished study received Mar 12, 1971 under 10487-2; prepared by Applied Biological Sciences Laboratory, Inc., submitted by Donnelly Co., Tarzana, CA; CDL:008603-A)	12-Mar-1971
119783	Michaelson, J. (1971) Report: ?Evaluation of Medicated Ointment and Medicated Oil for Primary Irritation Test|. (Unpublished study received May 10, 1974 under 19215-2; prepared by Applied Bio- logical Sciences Laboratory, submitted by Dunham Co., Temple City, CA; CDL:028202-A)	10-May-1974
119784	Dunham Co. (1974) ?Case Histories of Dogs Treated with Pidge's Medicated Veterinary Oil and Ointment|. (Unpublished study received May 10, 1974 under 19215-2; submitted by Dunham Co., Temple City, CA; CDL:028202-C)	10-May-1974
130230	Baltezore, M.; Shu, H. (1981) Acute Dermal Toxicity Test/Eye Irritation Test: ?Insect Shooo|: ES Unilab #14078. (Unpublished study received Jan 19, 1982 under 45220-3; prepared by ES Unilab Research, Inc., submitted by Ecosafe Laboratories, Oakland, CA; CDL:246626-A)	19-Jan-1982
131242	Rosenfeld, G.; Robbins, G. (1983) Acute Oral Toxicity Study in Rats: ?Nature's Own Herbal Flea Repellent Collar|: Study #0646A. (Unpublished study received Oct 3, 1983 under 270-174; prepared by Cosmopolitan Safety Evaluation, Inc., submitted by Farnam Cos., Inc., Phoenix, AZ; CDL:251420-A)	03-Oct-1983
131243	Rosenfeld, G.; Robbins, G. (1983) Acute Dermal Toxicity and Irritancy Study--Rabbit LD50: ?Nature's Own Herbal Flea Repellent Collar|: Study #0646B. (Unpublished study received Oct 3, 1983 under 270-174; prepared by Cosmopolitan Safety Evaluation, Inc., submitted by Farnam Cos., Inc., Phoenix, AZ; CDL:251420-B)	03-Oct-1983
131244	Rosenfeld, G.; Robbins, G. (1983) Primary Eye Irritation Study in Rabbits: ?Nature's Own Herbal Flea Repellent Collar|: Study #0646D. (Unpublished study received Oct 3, 1983 under 270-174; prepared by Cosmopolitan Safety Evaluation, Inc., submitted by Farnam Cos., Inc., Phoenix, AZ; CDL:251420-C)	03-Oct-1983
131245	Boyd, J. (1982) Effectiveness Evaluations on the Herbal Collar, a Repelling Device, against Fleas on Dogs: Project Report 151. (Unpublished study received Oct 3, 1983 under 270-174; prepared by P.A.C.E. International, submitted by Farnam Cos., Inc., Phoenix, AZ; CDL:251420-D)	03-Oct-1983
134320	Natural Research People, Inc. (1979) ?Chemistry of Natural Herbal Flea Collar|. (Compilation; unpublished study received Oct 4, 1979 under 42443-1; CDL:241133-A)	04-Oct-1979
134321	Natural Research People, Inc. (1979) ?Efficacy of Natural Herbal Flea Collar|. (Compilation; unpublished study received Oct 4, 1979 under 42443-1; CDL:241133-B)	04-Oct-1979
134322	Unilab Research (1979) Rat Acute Oral Toxicity Study: Natural Herb- al Flea Collar Ingredients: Laboratory No. 11226. (Unpublished study received Oct 4, 1979 under 42443-1; submitted by Natural Research People, Inc., Lavina, MT; CDL:241133-C)	04-Oct-1979
153949	Pet Guard, Inc. (1985) [Product Manufacturing Chemistry of PetGuard Herbal Flea Repellent Collar for Dogs and Cats]. Unpublished study. 41 p.	14-Nov-1985
164042	PetGuard, Inc. (1986) Amendment to Application for Registration of Pesticide: PetGuard Herbal Flea Repellent Collar for Dogs and Cats: (Product Chemistry Data). Unpublished compilation. 75 p.	29-Jul-1986
41549500	Boswell R&D (1990) Submission of Chemistry, Toxicity and Efficacy Summary Data in Support of Product Green Earth Natural Flea Spray Application for Registration. Transmittal of 10 studies.	09-Jul-1990
41549503	Gunther (19??) Oil of Cedarwood. pp. 356-363 in unknown source.	09-Jul-1990

41549505	Food & Drug Administration. (1989) Code of Federal Register CFR 21(1):46-51.	09-Jul-1990
41549506	Singh, D. (1985) Toxicity of Cedarwood oil against pulse beetle. Chemical Abstracts.104: 4 p.	09-Jul-1990
41549507	Singh, D. (1984) Cedarwood oil as a potential insecticidal agent against mosquitoes. P. 231 in 5-Agrochemicals Vol. 101, 1984.	09-Jul-1990
41549508	Nicholas, C. (1980) Flea treatment composition for animal. Chemical Abstracts 93:228-228.	09-Jul-1990
41549509	Huddle, H. (1952) Toxicity of cedar oil vapor to clothes moths. Chemical Abstracts 46:6789-6790.	09-Jul-1990
41549510	Kartseva, V. (1982) Repellents instead of insecticides. Chemical Abstracts 97:209-209.	09-Jul-1990
42101200	Arbor American Corp. (1991) Submission of product chemistry data in support of registration of pesticide products containing cedar wood oil. Transmittal of 2 studies.	14-Nov-1991
42101201	Arbor American Corp. (1991) Chemical Identity: Cedar Wood Oil. Un- published study. 6 p.	14-Nov-1991
42101202	North Carolina State University (1991) Analysis of Red Cedar Samples. Unpublished study. 7 p.	14-Nov-1991
42319000	Corr-Pak International (1992) Submission of Product Chemistry Data in Support of registration for Cedar Wood Oil. Transmittal of 2 studies.	13-May-1992
42319001	Anon. (1992) Product Identification and Disclosure of Ingredients; Description of Beginning Materials and Manufacturing process; Discussion of formation of impurities ?Contains Published Material|. Unpublished study prepared by Cork-Pak International. 15 p.	13-May-1992
42319002	Maltese, L. (1992) Analysis of Redwood Cedars: Lab Project Number: 92-1076: 92-1117: 92-1216. Unpublished study prepared by Stillwell & Gladding. 13 p.	13-May-1992
42362600	P & M Consumer Products, Inc. (1992) Submission of Product Chemistry data in support of registration for Aromatic Cedar. Transmittal of 2 studies.	16-Jun-1992
42362601	Anon. (1992) Description of Materials Used to Produce Product and Description of Production Process: Aromatic Cedar. Unpublished study prepared by P & M Consumer Products, Inc. 7 p.	16-Jun-1992
42362602	Zavarin, E. (1992) Analysis of Red Cedar Wood Juniperus Virginiana: Unpublished study prepared by Forest Products Laboratory (University of California at Berkley). 8 p.	16-Jun-1992
42696700	Boswell R&D Inc. (1993) Submission of efficacy and product chemistry data in support of the "me too" registration for Greg's Green Earth Carpet and Kennel Flea Powder. Transmittal of 2 studies.	11-Mar-1993
42696701	Boswell, G. (1993) G G E Carpet Flea Test: Test of Efficacy. Unpublished study prepared by Boswell R&D Inc. 5 p.	11-Mar-1993
42696702	Boswell, G. (1993) G G E Carpet Product Chemistry Data. Unpublished study prepared by Boswell R&D Inc. 4 p.	11-Mar-1993
43603500	US EPA (1995) Submission of Administrative Record for Cedarwood Oil (Case 3150). Transmittal of 1 Study.	05-Apr-1995
43603501	US EPA (1995) Administrative Record for the RED of Cedarwood Oil (Case 3150). Unpublished Compilation (with Confidential Attachment). 228 p.	05-Apr-1995
44414800	Bug Block (R.H. Industries) (1997) Submission of Toxicity and Product Chemistry Data in Support of the Application for Registration of Bug Block Sunscreen and Insect Repellent. Transmittal of 7 Studies.	24-Oct-1997
44414801	Wnorowski, G. (1997) Acute Dermal Toxicity Limit Test (in Rats): Bug Block w/SPF 15: Lab Project Number: 5206: P322. Unpublished study prepared by Product Safety Labs. 15 p.	24-Oct-1997
44414802	Wnorowski, G. (1997) Primary Eye Irritation (in Rabbits): Bug Block w/SPF 15: Lab Project Number: 5207: P324.	24-Oct-

	Unpublished study prepared by Product Safety Labs. 21 p.	1997
44414803	Wnorowski, G. (1997) Dermal Sensitization Test--Buehler Method (in Guinea Pigs): Bug Block w/SPF 15: Lab Project Number: 5017: P328. Unpublished study prepared by Product Safety Labs. 23 p.	24-Oct-1997
44414804	Quinn, E. (1997) Product Identity and Physical and Chemical Properties of Bug Block: Lab Project Number: 17. Unpublished study prepared by Insect Control and Research, Inc. 9 p.	24-Oct-1997
44414805	Willis, C. (1997) Bugblock: Precision and Accuracy of Analytical Method: Final Report: Lab Project Number: 1580-01. Unpublished study prepared by Case Consulting Labs., Inc. 31 p. {OPPTS 830.1800}	24-Oct-1997
44414806	Spero, N. (1997) Laboratory Evaluation of Topical Repellents Containing Citronella Oil Against Aedes aegypti Mosquitoes on Six Subjects: Lab Project Number: G17896001A117: 1296-178-0036. Unpublished study prepared by Insect Control and Research, Inc. 87 p.	24-Oct-1997
44414807	Quinn, E. (1997) Published Monographs: Toxicology of Technical Grade Active Ingredients of Bug Block Citronella Oil and Cedarwood Oil from the Research Institute of Fragrance Manufacturers: Lab Project Number: TIER 1. Unpublished study prepared by Insect Control and Research, Inc. 38 p.	24-Oct-1997
44471000	Bug Block (R.H. Industries) (1997) Submission of Product Chemistry Data in Support of the Application for Registration of Bug Block Sunscreen and Insect Repellent. Transmittal of 1 Study.	24-Oct-1997
44471001	Quinn, E. (1997) Manufacturing Process for Bug Block, a Sunscreen/Repellent Formulation: Discussion of Formation of Unintentional Ingredients (Certification): Lab Project Number: 11-12. Unpublished study prepared by Insect Control and Research, Inc. 40 p.	24-Oct-1997
44487100	R.H. Industries (1998) Submission of Toxicity Data in Support of the Application for Registration of Bug Block. Transmittal of 2 Studies.	11-Feb-1998
44487101	Wnorowski, G. (1998) Acute Oral Toxicity Limit Test (in Rats): Bug Block w/SPF 15: Lab Project Number: 5796: P320. Unpublished study prepared by Product Safety Labs. 15 p.	11-Feb-1998
44487102	Wnorowski, G. (1998) Primary Skin Irritation (in Rabbits): Bug Block w/SPF 15: Lab Project Number: 5797: P326. Unpublished study prepared by Product Safety Labs. 16 p.	11-Feb-1998
44752500	Celaflor GmbH (1999) Submission of Product Chemistry Data in Support of the Registration of NEXA Cedarwood Oil Moth Protection. Transmittal of 1 Study.	05-Feb-1999
44752501	Werle, H. (1997) Certificate of Analysis--Content of Active Ingredient: 5 Lots of CEL 590 16 I VP: Lab Project Number: 97 50 40 057. Unpublished study prepared by BioChem GmbH. 25 p.	05-Feb-1999
46684701	Dickens, T. (2005) Herbal Armor Lotion: Product Chemistry. Project Number: SCI/HA/L/090905. Unpublished study prepared by Scientific Coordination, Inc. and Intertek Caleb Brett. 73 p.	01-Nov-2005
46684702	Dickens, T. (1998) Laboratory Evaluation of the Efficacy of All Terrain, An Essential Oil-Based Product, to Repel Aedes aegypti Mosquitoes: (Final Report). Project Number: SCI/HA/L/110698. Unpublished study prepared by University of Guelph. 6 p.	01-Nov-2005
46684703	Smedley, J. (2005) A Primary Eye Irritation Study in Rabbits with Herbal Armor Lotion: Final Report. Project Number: ZMP00001. Unpublished study prepared by Charles River Laboratories, Inc. 28 p.	01-Nov-2005
46684704	Smedley, J. (2005) A Primary Skin Irritation Study in Rabbits with Herbal Armor Lotion: Final Report. Project Number: ZMP00004. Unpublished study prepared by Charles River Laboratories, Inc. 27 p.	01-Nov-2005
46684705	Smedley, J. (2005) An Acute Oral Toxicity Study in Rats with Herbal Armor Lotion (Up/Down Study Design): Final Report. Project Number: ZMP00002. Unpublished study prepared by Charles River Laboratories, Inc. 27 p.	01-Nov-2005
46684706	Smedley, J. (2005) An Acute Dermal Toxicity Study in Rats with Herbal Armor Lotion: Final Report. Project Number: ZMP00003. Unpublished study prepared by Charles River Laboratories, Inc. 35 p.	01-Nov-2005
46684707	Smedley, J. (2005) A Dermal Sensitization Study in Guinea Pigs with Herbal Armor Lotion - Modified Buehler Design - : Final Report. Project Number: ZMP00005. Unpublished study prepared by Charles River Laboratories, Inc. 63 p.	01-Nov-2005
47029300	Espree Animal Products, Inc. (2007) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Aloe Herbal Horse Spray. Transmittal of 10 Studies.	11-Jan-2007
47029301	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition Source Active Ingredients. Unpublished study prepared for Espree Animal Products, Inc. 31 p.	11-Jan-2007

47029302	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study prepared for Espree Animal Products, Inc. 50 p.	11-Jan-2007
47029303	Lewis & Harrison, LLC (2007) Aloe Herbal Horse Spray: Wavier (sic) Request for Enforcement Analytical Method and Storage Stability. Unpublished study prepared for Espree Animal Products, Inc. 9 p.	11-Jan-2007
47029304	Sinning, D. (2006) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	11-Jan-2007
47029305	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Oral Toxicity Up and Down Procedure in Rats. Project Number: 21101, P320/UDP. Unpublished study prepared by Product Safety Laboratories. 14 p.	11-Jan-2007
47029306	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Dermal Toxicity Study in Rats - Limit Test. Project Number: 21102, P322/RAT. Unpublished study prepared by Product Safety Laboratories. 14 p.	11-Jan-2007
47029307	Durando, J. (2006) Aloe Herbal Horse Spray: Acute Inhalation Toxicity Study in Rats - Limit Test. Project Number: 21103, P330. Unpublished study prepared by Product Safety Laboratories. 22 p.	11-Jan-2007
47029308	Durando, J. (2006) Aloe Herbal Horse Spray: Primary Eye Irritation Study in Rabbits. Project Number: 21104, P324. Unpublished study prepared by Product Safety Laboratories. 17 p.	11-Jan-2007
47029309	Durando, J. (2006) Aloe Herbal Horse Spray: Primary Skin Irritation Study in Rabbits. Project Number: 21105, P326. Unpublished study prepared by Product Safety Laboratories. 15 p.	11-Jan-2007
47029310	Durando, J. (2006) Aloe Herbal Horse Spray: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Project Number: 21106, P328. Unpublished study prepared by Product Safety Laboratories. 23 p.	11-Jan-2007
47220600	Espree Animal Products, Inc. (2007) Submission of Product Chemistry Data in Support of the Application for Registration of Aloe Herbal Horse Spray Ready-to-Use. Transmittal of 2 Studies.	31-Aug-2007
47220601	Lewis and Harrison (2007) Aloe Herbal Horse Spray Ready-To-Use: Product Identity and Composition, Beginning Materials, Formulating Process, Formation of Impurities, Preliminary Analysis, and Certified Limits. Unpublished study. 50 p.	31-Aug-2007
47220602	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray Ready to Use: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/02. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	31-Aug-2007
47229600	Espree Animal Products, Inc. (2007) Submission of Toxicity Data is Support of the Application for Registration of Aloe Herbal Horse Spray Ready-to-Use. Transmittal of 1 Study.	13-Sep-2007
47229601	Lewis & Harrison, LLC (2007) Acute Toxicity Studies Supporting Aloe Herbal Horse Spray Ready-to-Use. Unpublished study. 6 p.	13-Sep-2007
47280900	Espree Animal Products, Inc. (2007) Submission of Efficacy Data in Support of the Application for Registration of Aloe Herbal Horse Spray Ready-to-Use. Transmittal of 1 Study.	14-Nov-2007
47280901	Snell, E.; Smith, T.; Weiner, D. (2007) Evaluation of the Repellent Effect of Espree Aloe Herbal Horse Spray on Flies when Applied to Horses Under Field Conditions. Project Number: ESPREEEQUINEFLYREPEL07. Unpublished study prepared by Snell Scientifics, LLC. 14 p.	14-Nov-2007
47316800	Espree Animal Products, Inc. (2008) Submission of Product Chemistry Data in Support of the Registration of Aloe Herbal Horse Spray. Transmittal of 1 Study.	08-Jan-2008
47316801	Sinning, D. (2007) Physical and Chemical Characteristics of Aloe Herbal Horse Spray: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density: Final Report. Project Number: 3660/01. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	08-Jan-2008
47536900	Espree Animal Products, Inc. (2008) Submission of Product Chemistry Data in Support of the Registration of Aloe Herbal Horse Spray Ready-to-Use. Transmittal of 1 Study.	10-Sep-2008
47536901	Sinning, D. (2008) Physical and Chemical Characteristics of Aloe Herbal Horse Spray Ready to Use: Physical State, Oxidation/Reduction, Corrosion Characteristics, pH, Viscosity and Relative Density. Project Number: 3660/02. Unpublished study prepared by Case Consulting Laboratories, Inc. 7 p.	10-Sep-2008
93221000	Farnam Companies Inc (1990) Reregistration Phase 3 Response: Cedarwood oil.	01-Aug-

		1990
93221999	Farnam Companies Inc (1990) Reregistration Phase 3 Response: Cedarwood oil. Correspondence and Supporting Material.	01-Aug-1990
93277000	Woodland Sales, Inc. (1992) Reregistration Phase 3 Response: Cedarwood Oil.	02-Apr-1993
93279000	Natural Research People, Inc. (1993) Reregistration Phase 3 Response: Cedarwood Oil.	21-Apr-1993
93279999	Natural Research People, Inc. (1993) Reregistration Phase 3 Response: Cedarwood Oil. Correspondence and Supporting Material.	
44931900	R.H. Industries (1999) Submission of Product Chemistry Data in Support of the Registration of Bug Block Sunscreen and Insect Repellent. Transmittal of 1 Study.	17-Sep-1999
44931901	Herd, R. (1999) Manufacturing Process for Bug Block a Sunscreen/Repellent Formulation, Discussion of Formation of Unintentional Ingredients (Certification): Lab Project Number: 11-12. Unpublished study prepared by R.H. Industries. 40 p.	17-Sep-1999
44230500	Celaflor GmbH (1997) Submission of Product Chemistry Data in Support of the Application for Registration of Nexa Cedarwood Oil Moth Protection. Transmittal of 1 Study.	26-Feb-1997
44230501	Miller, L. (1997) CELAFLOR GmbH Nexa Cedarwood Oil Moth Protection: Product Chemistry: Lab Project Number: CEL-151-MOTH. Unpublished study prepared by BioLogic, Inc. 16 p.	26-Feb-1997
44412000	Celaflor GmbH (1997) Submission of Toxicity Data in Support of the Registration for Nexa Cedarwood Oil Moth Protection. Transmittal of 4 Studies.	29-Oct-1997
44412001	Grunert, B. (1995) Acute Oral Toxicity (in Rats): CEL 590 16I VP (Nexa Cedarwood Oil Moth Protection): (Final Report): Lab Project Number: 95 10 42 258 F: 95 10 42 258. Unpublished study prepared by BioChem GmbH. 25 p.	29-Oct-1997
44412002	Grunert, B. (1995) Pilot Study Inhalation Toxicity (in Rats): CEL 590 16I VP (Nexa Cedarwood Oil Moth Protection): (Final Report): Lab Project Number: 95 10 42 258 H: 95 10 42 258. Unpublished study prepared by BioChem GmbH. 30 p.	29-Oct-1997
44412003	Grunert, B. (1995) Acute Eye Irritation/Corrosion (in Rabbits): CEL 590 16I VP (Nexa Cedarwood Oil Moth Protection): (Final Report): Lab Project Number: 95 10 42 258: 95 10 42 258 E. Unpublished study prepared by BioChem GmbH. 31 p.	29-Oct-1997
44412004	Grunert, B. (1995) Skin Sensitization Study According to Magnusson & Kligman (in Guinea Pigs): CEL 590 16I VP (Nexa Cedarwood Oil Moth Protection): (Final Report): Lab Project Number: 95 10 42 258: 95 10 42 258 G. Unpublished study prepared by BioChem GmbH. 38 p.	29-Oct-1997