BIOPESTICIDE REGISTRATION ACTION DOCUMENT

2-Methyl-1-butanol

PC Code: 431602

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

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

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I. EXECUTIVE SUMMARY

The biochemical active ingredient, 2-Methyl-1-butanol, is a colorless alcohol, which occurs naturally in fruit, wine and beer, and has an odor reminiscent of whiskey. It is commonly used as a flavor agent intended for human consumption. As a biopesticide, it is intended for use in traps to attract hornets and wasps, particularly yellowjackets. EPA has determined that 2-Methyl-1-butanol presents no issues of toxicological, ecological, or environmental concern. Accordingly, EPA is considering approval for a registration for 2-Methyl-1-butanol under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Adequate mammalian toxicology data and other information were submitted to support the registration of 2-Methyl-1-butanol. Acute toxicity data from the Hazardous Substances Data Bank provided sufficient information to satisfy acute oral toxicity, acute dermal toxicity, primary eye irritation and primary dermal data requirements. The Agency received acceptable rationales to support data waivers for acute inhalation toxicity and dermal sensitization.

Nontarget organism and environmental fate data requirements were waived based on rationales and information on file with the Agency. Notably, 2-Methyl-1-butanol is known to occur naturally in the terrestrial environment without known detrimental effects; and all information available to the Agency validates a non-toxic mode of action. In addition, the public literature confirms a lack of risk in the case of secondary aquatic exposures.

The toxicological data demonstrate that 2-Methyl-1-butanol is not toxic or pathogenic to mammals. Neither acute, sub-chronic, chronic, immune, or endocrine data, nor any non-dietary exposure issues indicate that the use of the active ingredient could be expected to cause no harm to infants, children, and the general U.S. population. Because of the low toxicity profile and the directed (and contained) use of the active ingredient, the risks associated with the proposed uses of this active ingredient are expected to be negligible.

Dietary exposures (including exposures via drinking water) are not expected for the active ingredient 2-Methyl-1-butanol. The active ingredient is intended only for non-food uses. Even in the event of incidental dietary exposures, the dietary risks would be negligible given the limited potential for any significant exposure associated with the use of this attractant. The risks associated with any incidental dietary exposures would be negligible considering the low acute toxicity profile of the active ingredient and the history of human ingestion of 2-Methyl-1-butanol without any known adverse effects.

The potential for aggregate, non-occupational exposure should be insignificant as 2-Methyl-1-butanol is not expected to be present in quantities greater than 2.466×10^9 g/liter air/week, and limited only to those times when yellowjackets and other wasps are active. Moreover, given a lack of acute toxicological endpoints and the fact that 2-Methyl-1-butanol is not known to share any structural similarity to any chemicals with a common mechanism of toxicity, the likelihood of risks resulting from such de minimus exposures is negligible.

Data waiver rationales were submitted in response to data requirements for avian, freshwater fish and invertebrate, insect, and honeybee non-target organism testing requirements. The information provided is sufficient to satisfy the Tier I non-target organism data requirements for the proposed end-use products containing 2-Methyl-1-butanol as an active ingredient, and further testing of non-target organisms at higher tier levels is not required. Based on the rationales submitted, adverse effects to terrestrial animals and plants or freshwater and marine/estuarine fish, invertebrates, and plants are not expected as a result of exposure to the attractant 2-Methyl-1-butanol. Based on the information submitted, EPA has made "No Effect" (NE) determinations for direct and indirect effects to listed threatened and endangered species and their habitat with regard to the proposed uses of 2-Methyl-1-butanol.

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients, first food use, first outdoor use, and first residential use.

Consistent with the new policy of making registration actions more transparent, 2-Methyl-1-butanol is subject to a 30 day comment period as a "new active ingredient" whose registration would result in a "first outdoor use" and a "first residential use." During this process, no comments were received. Accordingly, the preliminary decision to register 2-Methyl-1-butanol is affirmed. The basis for the preliminary decision can be found in the risk assessment for 2-Methyl-1-butanol, which is characterized in this BRAD. As discussed above, acute toxicity data for 2-Methyl-1-butanol demonstrate that it is toxicity category IV. 2-Methyl-1-butanol does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to 2-Methyl-1-butanol in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor or there concerns for any threatened and endangered species. Thus, given that 2-Methyl-1-butanol has very low toxicity and presents little if any risk to non-target organisms, and efficacy data confirm its effectiveness against target pests, EPA concludes that it is in the best interests of the public and the environment to issue the registration for 2-Methyl-1-butanol.

EPA reviewed data requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It was determined that the data/information submitted fulfilled current guideline requirements (refer to 40 CFR Subpart U § 158.2000).

II. ACTIVE INGREDIENT OVERVIEW

Common Name: 2-Methyl-1-butanol

Chemical Names: 2-Methyl-1-butanol

Trade & Other Names: Active Amyl Alcohol

CAS Registry Number: 137-32-6

OPP Chemical Code: 431602

Type of Pesticide: Attractant for hornets and certain wasps, particularly yellowjackets. (Yellowjackets are a subset of predatory wasps, and are often referred to distinctly in the literature.)

III. REGULATORY BACKGROUND

EPA published in the Federal Register (FR) on March 16, 2009 (Volume 74, Number 49) a notice announcing that Bull Run Scientific, VBT, Beaufont Springs Drive, Suite 300, Richmond, VA 23225, submitted an application to register a pesticide product (EPA File Symbol 84565-T) containing a new active ingredient (2-Methyl-1-butanol) not included in any currently registered products. No comments were received following the publication of this notice. In addition, on December 15, 2009, EPA provided the opportunity for a 30-day comment period on the Agency's draft risk assessment and intention to register this pesticide product. EPA has not received any comment on this proposed action.

A. CLASSIFICATION

2-Methyl-1-butanol is well recognized as a naturally occurring alcohol. With regard to its active properties, it is considered to be an attractant, and is not associated with direct toxicity to its target pests. Notably, pests are not harmed by the attractant; rather they are killed by physical means in the trap. Accordingly, 2-Methyl-1-butanol is considered to be a biochemical pesticide due to its nontoxic mode of action to target pest, natural occurrence in the environment, and its history of exposure to humans and the environment demonstrating minimal toxicity.

B. FOOD CLEARANCES/TOLERANCES

Currently, this active ingredient is not registered for use on food or feed commodities, and the applicant has not filed a petition for a tolerance (nor a tolerance exemption) for 2-Methyl-1-butanol. As a result, a tolerance or exemption from the requirement of a tolerance is not relevant.

IV. RISK ASSESSMENT

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

The classifications that are found for each data submission are assigned by EPA science reviewers and are an indication of the usefulness of the information contained in the documents for risk assessment. A rating of "ACCEPTABLE" indicates the study is scientifically sound and is useful for risk assessment. A "SUPPLEMENTAL" rating indicates the data provide some information that can be useful for risk assessment. The studies may have certain aspects determined not to be scientifically acceptable ("SUPPLEMENTAL: UPGRADABLE"). If a study is rated as "SUPPLEMENTAL: UPGRADABLE," the Environmental Protection Agency always provides an indication of what is lacking or what can be provided to change the rating to "ACCEPTABLE." If there is simply a "SUPPLEMENTAL" rating, the reviewer will often state that the study is not required by the current 40 CFR Part 158. Both "ACCEPTABLE" and "SUPPLEMENTAL" studies may be used in the risk assessment process as appropriate. An "UNACCEPTABLE" rating indicates that new data need to be submitted.

For the acute toxicity data requirements, toxicity categories are assigned for providing the appropriate precautionary labeling statement, based on the hazard(s) identified from studies and/or other information submitted to the Agency in support of a pesticide registration. The active ingredient or particular product is classified into Toxicity Category I, II, III, or IV, where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.

A. PRODUCT ANALYSIS ASESSMENT

1. Product Chemistry and Composition

2-Methyl-1-butanol is a naturally occurring alcohol that can be found in fruits, beer and wine. It has an odor that is described variously as whiskey-like, wine-like or onion-like. 2-Methyl-1-butanol is commonly used to formulate fragrances and flavors in processed foods. The attractant quality of the active ingredient 2-Methyl-1-butanol is attributed to its redolence.

All product chemistry data requirements for 2-Methyl-1-butanol have been satisfied. As an active ingredient, 2-Methyl-1-butanol is produced industrially with synthetic starting materials, but purified through later manufacturing processes. The nominal purity of the active ingredient is very high, and there are no impurities of toxicological significance. All data requirements for physical and chemical characteristics have been adequately addressed.

2. Analysis and Certification of Limits

The submitted data satisfied the requirement for Analysis and Certification of Limits. Five batch analyses and the analytical method used to determine the purity of 2-Methyl-1-butanol were examined and determined to be acceptable by the Agency. The certified limits for the active and inert ingredients fall within the ranges specified by OPPTS Guideline 830-1750**.**

3. Physical and Chemical Characteristics

The Agency has determined that the submitted data adequately describe the physical and chemical characteristics of 2-Methyl-1-butanol. Refer to Table 1 in Appendix A for The Series 830 physical and chemical properties.

B. HUMAN HEALTH ASSESSMENT

1. Toxicological Hazard Assessment

Adequate mammalian toxicology data/information were provided in support of the registration of 2-Methyl-1-butanol. Acute toxicology information for 2-Methyl-1-butanol, submitted in lieu of guideline studies, indicates that the active ingredient is virtually non-toxic to mammals, and that there are no toxicological endpoints relative to the use of 2-Methyl-1-butanol as an attractant. Public literature from Chemical Carcinogenesis Research Information System (CCRIS) indicates that 2-Methyl-1-butanol is non-mutagenic. Altogether, the information submitted demonstrates that the proposed uses of 2-Methyl-1-butanol pose no significant risks to human health.

Refer to Table 2 in Appendix A for a summary of the Toxicity Data Requirements for this non-food use active ingredient.

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

Acute Oral Toxicity – Rat [OPPTS Guideline 870.1100; Master Record Identification (MRID) Number (No.) 472465-07]: Information from the Hazardous Substances Data Bank (HSDB), submitted in lieu of a guideline study, shows that the active ingredient 2-Methyl-1-butanol has an LD_{50} of 4.92 mL/kg in rats, which is considered to be virtually non-toxic. However, additional information was submitted demonstrating that there are no significant oral exposures to the active ingredient when it is used as an attractant, obviating any oral toxicity risks. This information was found "ACCEPTABLE" and 2-Methyl-1-butanol was classified as TOXICITY CATEGORY IV for this route of exposure when used as an attractant.

Acute Dermal Toxicity– Rabbits (OPPTS Guideline 870.1200; MRID No. 472465-07): Information from the HSDB, submitted in lieu of a guideline study, shows that the active ingredient 2-Methyl-1-butanol has an LD_{50} of 2.58 g/kg in rabbits. Additional information was

submitted demonstrating that there are no significant dermal exposures to the active ingredient when it is used as an attractant, obviating any acute dermal toxicity risks. This information was found "ACCEPTABLE" and 2-Methyl-1-butanol was classified as TOXICITY CATEGORY IV for this route of exposure when used as an attractant.

Acute Inhalation Toxicity (OPPTS Guideline 870.1300; MRID No. 472465-07): A waiver was granted based on the rationale that there is effectively no inhalation exposure. Calculations were provided demonstrating that the maximum amount of active ingredient present in the air is less than 2.466×10^{9} g/liter air/week – an infinitesimal amount, especially when compared to the amounts of 2-Methyl-1-butanol inhaled as a result of our regular exposures to fruits and fragrances. A waiver was granted and 2-Methyl-1-butanol was classified as TOXICITY CATEGORY III for this route of exposure when used as an attractant.

Primary Eye Irritation (OPPTS Guideline 870.2400; MRID No. 472465-07): A waiver was granted based on the rationale that there is effectively no ocular exposure. The active ingredient is contained in a trap, and as referenced above when it is volatilized the amount of active ingredient present is so negligible that it may be considered comparable to naturally occurring exposure, which are not known to pose risks. This waiver was granted and 2-Methyl-1-butanol was classified as TOXICITY CATEGORY III based on a lack of exposure when used as an attractant.

Primary Dermal Irritation (OPPTS Guideline 870.2500; MRID No. 472465-07): Information from the HSDB submitted in lieu of a guideline study, shows that the active ingredient 2-Methyl-1-butanol is only minimally irritating to skin. Coupled with the established lack of significant dermal exposure, this information was found "ACCEPTABLE" and 2-Methyl-1-butanol was classified as TOXICITY CATEGORY IV for this route of exposure when used as an attractant.

Skin Sensitization (OPPTS Guideline 870.2600; MRID No. 472465-07): A waiver was granted based on the lack of dermal exposure and the low dermal toxicity profile established in the HSDB literature. While the waiver was granted, any reported incidents may cause this position to be reconsidered.

Subchronic Testing (OPPTS Guidelines 870.3100, 870.3250, 870.3465; MRID No. 472465-07): Subchronic testing data requirements do not apply in this case. Footnotes six, seven and eight for the respective subchronic testing requirements found in the Biochemical Pesticides Human Health Assessment Data Requirements table in 40 CFR § 158.2050 are relevant. 90-day oral testing is not required because there are no repeat oral exposures. 90-day dermal testing is not required because there would be neither a purposeful application to the skin nor prolonged dermal exposure to the active ingredient. The 90-day inhalation testing is, likewise, not required for there is no repeated exposure by inhalation.

Developmental Toxicity (OPPTS Guideline 870.3700; MRID No. 472465-07): In accordance with footnote nine in the Biochemical Pesticides Human Health Assessment Data Requirements

table in 40 CFR § 158.2050, the developmental toxicity data requirement are not required because there is no significant exposure to female humans.

Mutagenicity Testing (OPPTS Guidelines 870.5100, 870.5300, 870.5375; MRID No. 472465-07): In accordance with footnote ten in the Biochemical Pesticides Human Health Assessment Data Requirements table in 40 CFR § 158.2050, the data are not required due to lack of exposure and the absence of any structural similarity to a known mutagen. The registrant, however, submitted information from the public literature (CCRIS) for an *In vitro* Mammalian Cell Assay. The information submitted supports the conclusion that 2-Methyl-1-butanol is not mutagenic.

b. Acute Toxicology and Subchronic Toxicity/Pathogenicity – Tier II; Reproductive Fertility Effects, Carcinogenicity, Immunotoxicity, and Infectivity/Pathogenicity Analysis – Tier III (40 CFR § 158.2050)

Tier II and Tier III studies were not required for 2-Methyl-1-butanol based on the lack of exposure and the lack of acute toxicity indicated in the Tier I information.

c. Effects on the Endocrine System

EPA is in the process of issuing test orders for endocrine effects. The schedule for issuance of test orders, and details regarding status is available at http://www.epa.gov/endo/. EPA has also established a docket for the test orders in www.regulations.gov under docket number EPA-HQ-OPP-2009-0634.

Data required under the test orders will provide information to help EPA identify whether chemicals have the potential to interact with the estrogen, androgen, and/or thyroid hormone systems, which regulate growth, metabolism, development, and reproduction. The data generated from the screens will provide robust and systematic scientific information that will help EPA identify whether additional testing is necessary.

2-Methyl-1-butanol is a naturally occurring alcohol in fruits, beer and wine. To date, there is no evidence to suggest that our natural exposure to 2-Methyl-1-butanol affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Moreover, the use of 2-Methyl-1-butanol in the subject pesticide product is not expected to result in any significant exposures, effectively obviating any opportunity for negative effects on humans or the environment. Therefore, it is unlikely that 2-Methyl-1-butanol will have estrogenic or endocrine effects.

2. Dose Response Assessment

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

3. Dietary Exposure and Risk Characterization

The active ingredient 2-Methyl-1-butanol is intended for non-food uses. Accordingly, it is not expected to pose any direct dietary risk to humans. With regard to any incidental exposure, all routes of exposure associated with the active ingredient's use as an attractant are negligible. Additionally, the active ingredient occurs naturally in fruit and is a well-recognized flavor agent in processed foods. Its regular consumption in a human diet is not associated with any hazards. Finally, the acute toxicity information on file indicates that the risks associated with even incidental exposures would be negligible.

4. Drinking Water Exposure Risk Characterization

Incidental dietary exposure via drinking water is expected to be unlikely. The product volatilizes into the air and its exposure potential is localized. Additionally, the active ingredient volatilizes in measured doses and its proposed concentrations are so small that any potential exposures are expected to resemble those that occur naturally. Accordingly, 2-Methyl-1-butanol is not expected to pose any dietary risk when used as an attractant. Further, even if humans were exposed to 2-Methyl-1-butanol in drinking water, the information regarding acute oral toxicity suggests no adverse effect via drinking water.

5. Acute and Chronic Dietary Exposure and Risks for Sensitive Subpopulations, Particularly Infants and Children

Based on the non-food use pattern, the limited potential for even incidental exposure, and the dietary toxicity information discussed above, EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from aggregate exposure to any incidental residues of 2-Methyl-1-butanol.

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

Given the miniscule exposure potential associated with 2-Methyl-1-butanol and the low toxicity profile indicated in the acute toxicology information, no risks are expected for any of these exposure scenarios.

a. Occupational Exposure and Risk Characterization

This pesticide is intended for residential use patterns. Nonetheless, there would be no risks associated with professional handlers. Potential occupational exposures to 2-Methyl-1-butanol are not a concern based on the seasonal nature of pest pressure, the negligible potential for exposure, the low toxicity profile of the active ingredient, and the active ingredient's nontoxic mode of action.

b. Residential, School, and Daycare Exposure and Risk Characterization

The Agency does not expect any risks to children (or adults) in any of these environments. Due to the low rate of volatilization of the attractant, the potential for significant exposure is negligible. The active ingredient has a low toxicity profile and a history of consumption without incident. The exposure is limited by the seasonality of the use of traps. And because 2-Methyl-1-butanol is contained in traps, it is not readily accessible in any direct exposure scenario. Due to limited exposure scenarios and negligible toxicity hazards, no risks are expected relative to these exposure scenarios.

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

The potential for aggregate exposure is expected to be insignificant. 2-Methyl-1-butanol is not expected to be present in quantities greater than 2.466×10^{9} g/liter air/week, and limited only to those times when yellowjackets, hornets and wasps are active. Given a lack of acute toxicological endpoints for 2-Methyl-1-butanol, the aggregate exposure scenario presents no significant concerns for risk.

8. Cumulative Effects

2-Methyl-1-butanol is intended for non-food uses as an attractant in a trap. No dietary exposures are expected. To the degree that there might be any incidental dietary exposure, 2-Methyl-1-butanol does not share any known common mechanism of toxicity with other substances.

9. Risk Characterization

The Agency considered human exposure to 2-Methyl-1-butanol in light of the relevant safety factors in 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 2-Methyl-1-butanol when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards (Relative to the Biochemical Pesticides Nontarget Organisms and Environmental Fate Data Requirements - 40 CFR § 158.2060)

Nontarget organism and environmental fate data requirements were waived due to a lack of exposure and the active ingredient's non-toxic mode of action. 2-Methyl-1-butanol occurs naturally in fruit. No known adverse effects have been associated with its exposure to insects, birds, aquatic life or vegetation. Moreover, the active ingredient is contained in traps and has no direct or significant contact with birds, mammals, fish, or surrounding vegetation. With regard to 2-Methyl-1-butanol's attractive qualities for yellowjackets, wasps and hornets, the efficacy

trials demonstrate that its attraction is specifically targeted at these pests. Honeybees or other beneficial insects were shown to not be attracted to the traps. And to the extent that there may be any exposure to nontarget organisms, the active ingredient has no demonstrable toxicity. In sum, all nontarget toxicology data requirements for 2-Methyl-1-butanol have been satisfied.

Avian Testing (OPPTS Guidelines 850.2100, 850.2200; MRID Nos. 47457006 and 47457007): A waiver was granted based on a lack of exposure. The active ingredient is contained in traps and is inaccessible to birds. Any atmospheric exposure to birds would be miniscule. In any event, there are no incidences of toxicity to birds with regard to avian exposure relative to 2-Methyl-1-butanol's natural presence in fruits.

Aquatic Organism Testing (OPPTS Guidelines 850.1075, 850.1010; MRID Nos. 47457006 and 47457007): A waiver was granted based on a lack of exposure. The active ingredient is contained in traps and is inaccessible to aquatic organisms. Any incidental residues that might drift into water would be negligible. And even in the event of any accidental and direct exposure, data were submitted that confirm the lack of toxicity to fish. Information presented in MRID 47457001 shows the 2-methyl-1-butanol LC_{50} for fish is >100 mg/L, and the 96-hr acute static LC_{50} for fathead minnows is 580 mg/L.

Non-Target Plant Testing (OPPTS Guidelines 850.4100, 850.4150; MRID No. 472465-10; MRID Nos. 47457006 and 47457007): A waiver was granted based on a lack of exposure. The active ingredient is contained in traps and would have no direct contact with plants. Any incidental residues that might drift onto plants would be negligible, and virtually indiscernible from the naturally occurring volatilized 2-Methyl-1-butanol from fruits.

Non-Target Insect Testing (OPPTS Guideline 880.4350); MRID Nos. 47457006 and 47457007, 47457301): A waiver was granted based on the fact that nontarget exposure to the active ingredient is negligible and that information indicates that the volatilized active ingredient is targeted at yellowjackets, wasps, and hornets, with no demonstrable effects on nontarget insects.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because results of the acute toxicity assessment did not trigger any additional Tier I studies.

3. Ecological Exposure and Risk Characterization

The active ingredient is intended for formulation of end use products which would be placed in insect traps for residential or agricultural use. When used according to the proposed label directions, no direct exposures are expected for nontarget organisms. Moreover, the active ingredient is used at a low concentration as an attractant, and is not expected to accumulate in the environment. Given these characteristics of 2-Methyl-1-butanol, nontarget exposure and ecological effects studies were waived.

4. Threatened and Endangered Species Assessment

Based on the available data, a No Effects (NE) determination was made for 2-methyl-1-butanol on threatened and endangered species when the product is used according to label use directions. Specifically, in MRID 47457301, efficacy testing showed no honeybees or other non-target insect species were attracted or caught by the 2-methyl-1-butanol product. Since the active ingredient in contained in a trap, there is no exposure to birds, fish, aquatic invertebrates, or other non-target organisms.

V. 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 seeks information on any 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 2-Methyl-1-butanol, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

VI. RISK MANAGEMENT AND REGISTRATION DECISIONS

A. Determination of Eligibility

Section 3(c)(5) of FIFRA provides for the registration of a new active ingredient 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.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing 2-Methyl-1-butanol. Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, EPA concludes that 2-Methyl-1-butanol is eligible for registration for the labeled uses.

B. Regulatory Decision

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food use; first outdoor use; and first residential use. Accordingly, this pesticide was subject to a 30-day comment period as a new active ingredient with both outdoor uses and residential uses. No comments were received during that comment period.

At this time, EPA believes, the data submitted fulfill the requirements of registration for products containing 2-Methyl-1-butanol for use to attract yellowjackets, wasps and hornets. Acute toxicity information for 2-Methyl-1-butanol demonstrate that it is effectively Toxicity Category IV for all routes of exposure, except for Primary Eye Irritation, which is effectively Toxicity Category III. 2-Methyl-1-butanol does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to 2-Methyl-1-butanol in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor are there concerns for any threatened and endangered species. Given, the non-toxic character of 2-Methyl-1-butanol, EPA supports its registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Refer to Appendix B for product-specific information.

1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that an unconditional registration for Methyl-1-butanol is warranted under Section 3(c)(5) of FIFRA.

C. Labeling

Before releasing pesticide products containing Methyl-1-butanol for shipment, the applicant is required to provide appropriate labels.

VII. ACTIONS REQUIRED BY THE REGISTRANT

The Agency evaluated the data submitted in connection with the initial registration of 2-Methyl-1-butanol and determined that these data fulfill current registration guideline requirements. No additional data are required to be submitted to the Agency at this time. Additional data may be required for new uses and/or changes to existing uses.

Notwithstanding 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 and Hypersensitivity Incidents

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).

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2140 OPPTS Guideline reference number 885.3400.

VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticide Registration Action Document
CFR	Code of Federal Regulations
cm^3	cubic centimeter
CSF	Confidential Statement of Formula
°C	degrees Celsius
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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	gram
kg	kilogram
L	liter
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, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
MRID No.	Master Record Identification Number
mg	milligram
mL	milliliter
MP	manufacturing-use product
MPCA	microbial pest control agent
NE	"No Effect"
NIOSH	National Institute for Occupational Safety and Health
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PCR	polymerase chain reaction
PPE	personal protective equipment

TGAI technical grade of the active ingredient

IX. BIBLIOGRAPHY STUDIES SUBMITTED IN SUPPORT OF THIS REGISTRATION

A. Studies Submitted in Support of this Registration.

MRID	Citation	Receipt Date
47451400	Bull Run Scientific, VBT (2008) Submission of Product Chemistry, Environmental Fate, and Toxicity Data in Support of the Application for Registration of Disposable Bull Run Yellowjacket Trap E. Transmittal of 5 Studies.	17-Jun-2008
47451401	Smith, C. (2008) (Inert Ingredient): Product Identity, Composition and Analysis. Unpublished study prepared by Bull Run Scientific, VBT. 19 p.	17-Jun-2008
47451402	Smith, C. (2008) (Inert Ingredient): Color, Physical State, Odor, Stability, UV/Visible Light Absorption, Melting Point, Density, Dissociation Constant, Partition Coefficient, Water Solubility, and Vapor Pressure. Unpublished study prepared by Bull Run Scientific, VBT. 14 p.	17-Jun-2008
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APPENDIX A – BIOCHEMICAL PESTICIDE DATA REQUIREMENTS

TABLE 1. Physical/Chemical Properties for 2-methyl-1-butanol

Guideline Reference No./Property		Description of Result
830.6302	Color	Colorless
830.6303	Physical State	Liquid
830.6304	Odor	Wine, onion (at 100%)
830.6313	Stability	Thermally stable at typical use temperatures. Exposure to elevated temperatures can cause decomposition.
830.6314	Oxidation/Reduction: Chemical Incompatibility	Avoid contact with strong acids and oxidizers.
830.6315	Flammability	Flash point = 50°C (open cup) Flash point = 43° (closed cup)
830.6316	Explodability	Not required for TGAI
830.6317	Storage Stability	Not required for TGAI
830.6319	Miscibility	Not required for TGAI
830.6320	Corrosion Characteristics	Not required for TGAI
830.6321	Dielectric Breakdown Voltage	Not required for TGAI
830.7000	pH	5.8 ± 0.3 at 21°C[b] (1.0% w/v aqueous solution)
830.7100	Viscosity	Not required for TGAI
830.7200	Melting Range	Not applicable, ingredient is a liquid
830.7220	Boiling Range	128.7°C at 760 mm Hg
830.7300	Density/Relative Density/Bulk Density	0.815 g/cm^3
830.7370	Dissociation Constant in Water	Based on its structure, 2-methyl-1-butanol does not contain any readily ionizable protons, and no significant dissociation of protons in water is expected.
830.7550	Partition Coefficient	Log Kow = 1.29
830.7840	Water Solubility	3.22×10^4 mg/L at 25°C
830.7950	Vapor Pressure	3 mm Hg at 20°C; 4.54 mm Hg at 25°C

TABLE 2. Toxicity Data Requirements Summary

Study Type/OPPTS Guideline	LD_{50}/LC_{50}/Results	Reference	MRID
Acute Oral Toxicity/OPPTS 870.1100	4.92 mL/kg in rats	HSDB	47457007
Acute Dermal Toxicity/OPPTS 870.1200	2.58 g/kg in rabbits	HSDB	47457007
Acute Inhalation Toxicity/OPPTS 870.1300	Waiver Requested		47457007
Acute Eye Irritation/OPPTS 870.2400	Severely Irritating	HSDB	47457007
Acute Dermal Irritation/OPPTS 870.2500	Minimally Irritating	HSDB	47457007
Skin Sensitization/OPPTS 870.2600	Waiver Requested		47457007
Prenatal Developmental Toxicity/OPPTS 870.3700	Waiver Requested		47457007
Bacterial Reverse Mutation Test/OPPTS 870.5100	Waiver Requested		47457007
In vitro Mammalian Cell Assay	4.6 mM dose was negative in Chinese hamster V-79 Assay	CCRIS[2]	