BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Prohydrojasmon

(Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate)

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

(*last updated September 6, 2013*)

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I. EXECUTIVE SUMMARY:

Prohydrojasmon (PDJ) is a synthetically made plant growth regulator that is structurally and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator present in all vascular (higher) plants. As a pesticidal active ingredient, PDJ stimulates fruit ripening by enhancing the red color on apple varieties that have difficulty developing color and red grapes that have difficulty developing color.

The manufacturing-use pesticide product, Prohydrojasmin Technical (EPA File Symbol No. 62097-EI), is proposed to be registered. This product contains prohydrojasmin propyl-3-oxo-2-pentylcyclo-pentylacetate at 98%. Prohydrojasmin Technical is intended for formulating the end-use product, Blush, (EPA File Symbol No. 62097-EO) that will be applied pre-harvest, as a foliar spray to apples and grapes.

Data derived from appropriate tests give no indication that PDJ is toxic to humans. No unreasonable adverse effects to humans are expected from its use as a fruit ripening agent. Furthermore, pesticide products containing PDJ are not likely to pose a risk to the environment, including non-target organisms when used according to label instructions.

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 policy, EPA provides a public comment period prior to making a registration decision for the following types of applications: new active ingredients, first food use, first outdoor use, first residential use; and any registration decisions for which the Agency believes there may be substantial public interest.

Consistent with the policy of making registration actions more transparent, PDJ is subject to a 15-day comment period as a “new active ingredient.” EPA has established a comment period of 15 days on the basis of PDJ’s lack of toxicity and the determination that PDJ presents low risk of any adverse effects to human health and the environment. The notice for this comment period includes the draft Biopesticides Registration Action Document (BRAD) and draft product labels for the MP, polyhydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate Technical, and EP, propyl-3-oxo-2-pentylcyclo-pentylacetate, which contain this new active ingredient. The docket identification (ID) number is EPA-HQ-OPP-2012-0831. The Agency believes that based on the risk assessment and information submitted in support of the registration of the MP and EP containing prohydrojasmon pentylcyclo-pentylacetate, it is in the best interests of the public to issue the registration for Prohydrojasmon pentylcyclo-pentylacetate Technical and Prohydrojasmon pentylcyclo-pentylacetate EP. The basis for this decision can be found in the risk assessment for Prohydrojasmon pentylcyclo-pentylacetate, which is characterized in this BRAD.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: Prohydrojasmon

Chemical Names: Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate

Trade & Other Names: Prohydrojasmon

CAS Registry Number: 158474-72-7

OPP Chemical Code: 028000

Type of Pesticide: Plant growth regulator

III. REGULATORY BACKGROUND

On June 18, 2012, EPA received an application filed by SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192 on behalf of Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester WR5 2RQ, United Kingdom, to register the products, Prohydrojasmon Technical (EPA File Symbol No. 62097-EI), and Blush EP (EPA File Symbol No. 62097-EO), containing the new biochemical active ingredient, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate. A notice of receipt (NOR) of this application, allowing for a 30-day comment period, was published in the *Federal Register* on Wednesday December 16, 2012 (75 FR 11175). No comments were received following this publication.

A. Classification

On September 22, 2008, the Biochemical Classification Committee determined that Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate was "biochemical like" and was eligible for a reduced data set. Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate can be classified as "biochemical like" due to its non-toxic mode of action and the compound is structurally and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator.

B. Food Clearances/Tolerances

In the **Federal Register** of January 9, 2013, (Vol. 78 FR 1798) (FRL-9374-2), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F8056) by Fine Agrochemicals Ltd. (the Petitioner), on behalf of SciReg, Inc., 12733 Director's Loop, Woodbridge, VA, 22192. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate, in or on red apples and grapes. The notice referenced a summary of the petition prepared by the Petitioner, which is available in the docket, *http://www.regulations.gov*. No substantive comments were received in response to the notice of filing.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

Prohydrojasmon (PDJ) is a synthetically made plant growth regulator that is structurally and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator present in all vascular (higher) plants. As a pesticidal active ingredient, PDJ stimulates fruit ripening by enhancing the red color on apple varieties that have difficulty developing color and red grapes that have difficulty developing color. (EPA, 2013).

All product chemistry data requirements for registration of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate have been satisfied.

B. Human Health Assessment

1. Toxicology

For acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient 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.

Adequate mammalian toxicology data/information are available to support registration of propyl-3-oxo-2-pentylcyclo-pentylacetate. All toxicology data requirements for propyl-3-oxo-2-pentylcyclo-pentylacetate have been satisfied.

a. Acute Toxicity

For acute dermal toxicity, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate Technical has been classified in the Toxicological Category of Toxicity III. For acute oral and acute inhalation, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate Technical has been classified in the Toxicological Category of Toxicity IV. Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is a slight eye irritant (Toxicity Category IV) and is not a skin sensitizer or a primary skin irritant (Toxicology Category IV). Assays for mutagenicity, chromosomal aberration, developmental toxicity, and subchronic oral did not present any clinical or toxicologically significant effects. The toxicology profile for the EP (Blush 5.25% ai) shows that this compound is practically non-toxic to mammals with a Toxicity Category IV as noted for acute oral and acute inhalation toxicity studies. The acute dermal toxicity study produced an LD_{50} > 2,000 mg/kg bw (Toxicity Category III) and the primary eye irritation study produced acute symptoms after the test material was administered; however, they were resolved by day 7 (Toxicity Category III). The EP is not a skin sensitizer or a primary skin irritant.

b. Subchronic Toxicity

Subchronic data is required to determine a no-observed-effect-level (NOEL) and toxic effects (if any) associated with repeated or continuous exposure to a test substance for a period of 90 days No clinically or toxicologically significant effects were found in any treatment-group. Therefore, EPA establishes the NOAEL as the highest dose, 1,000 ppm (566 mg/kg bw/day for males and 587 mg/kg bw/day for females). A LOAEL was not established suggesting that the test animals could have tolerated a higher dose (protocol calls for a high test level of at least 1,000 mg/kg).

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c. Developmental Toxicity

No treatment-related effects were found at necropsy in maternal animals nor were there effects on *copra lutei*, number of implantations, sex ratio, fetal body weight, or pre-implantation embryonic mortality. EPA does not consider the transient decrease in body weight or food intake as adverse and establishes the NOAEL for the study as 500 mg/kg bw/day. A LOAEL was not identified. No treatment-related effects were found on external examination of the fetuses. Visceral examination showed a slight increase in the incidence of thymic remnants; however, the increase was within the historical background of the performing laboratory. Therefore, EPA does not consider this a treatment-related effect. There was also a slight increase in the incidence of a 14^{th} rib but this was not accompanied by an increased incidence of abnormal embryos either on external, skeletal, or visceral examination. Additionally, no increase in the incidence of litters with this effect was found. This effect is a common variation in this strain of rat and is therefore not considered an adverse effect. Based on the study results, the NOAEL for the study is the high-dose 500 mg/kg bw/day. A LOAEL was not identified. EPA has calculated the possibility of dietary exposure and concludes that in a worst case scenario (no degradation) the PDJ residues consumed by a 70 kg man are four orders of magnitude below NOAEL that was calculated for this compound in the Developmental Toxicity Test (OCSPP 870.3700) (EPA, 2013).

d. Mutagenicity

No data, except to confirm that prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is not a mutagen were required due to the nature of the active ingredient (structural and functional identity of the naturally occurring JA) and its intended use in the new EP product (ripening agent).

e. Effects on the Endocrine System

As required under Federal Food, Drug, and Cosmetic Act (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 dose-response 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 nine 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.

Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Under FFDCA section 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients.

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/.

2. Dose Response Assessment

Because no toxicological endpoints were identified for this active ingredient, a dose-response assessment was not required.

3. Food Quality Protection Act (FQPA) Considerations

a. Dietary Exposure and Risk Characterization

The most likely dietary route of exposure of humans to prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is via exposure to treated fruit or foliage (e.g. apples and grapes). Table 7.0 shows possible prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate residues on various matrices after one maximum application of 0.009 lbs ai/A (200 ppm ai/A). The dietary-based estimated environmental concentrations range from 0.77 to 0.06 ppm on the day of application and decline to 0.0 by Day 2. This compound is relatively unstable in the environment with an aerobic soil half-life of 1.6 – 2.3 hours, and upon consumption breaks down in the stomach within 0.8 days.

EPA has calculated the possibility of risk to humans through dietary exposure by using a worst case scenario of maximum application and no degradation. These calculations show that the prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate residues consumed by a 70 kg person are about seven orders of magnitude below Developmental Toxicity values (NOAEL > 500 mg/kg) and about eight orders of magnitude below the Acute Oral toxicity value (LD_{50} > 5,000 mg/kg), suggesting no dietary or sublethal risk.

b. Drinking Water Exposure and Risk Characterization

No significant exposure via drinking water is expected when prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is used in accordance with EPA-approved product labeling. The end product is not to be applied directly to water or to areas where surface water is present. In the unlikely event that exposure via drinking water did occur, the health risk would be expected to be minimal, based on low acute oral toxicity of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate.

EPA estimated environmental concentrations (EECs) to an aquatic site from prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate runoff (spray to apple trees) using the GENeric Estimated Environmental Concentration model (GENEEC; EPA, 2001). The model assumed 2 maximum applications of end product at 0.009 lbs ai/A (4g ai/A) at 7 day intervals, a 10.7 day aquatic half-life, a 57.8 hours photodegradation half-life in water, and a 1.6 – 2.3 hour half-life in

aerobic soil. The peak aquatic EEC was calculated at about 0.00048 ppm with a decline to 0.000024 ppm after 21 days. No acute or subacute endpoints were identified through mammalian testing and the expected concentrations in surface water are well below (6 to 7 orders of magnitude) the maximum doses used in laboratory testing (e.g. Acute Oral Toxicity LD_{50} > 5,000 mg/kg; Developmental Toxicity NOAEL > 500 mg/kg).

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

FFDCA section 408 provides that the Agency shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless the Agency determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency has concluded that there is reasonable certainty that no harm to infants and children or adults will result from the use of Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate when label instructions are followed.

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

a. Occupational Exposure and Risk Characterization

Occupational exposure to prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is mitigated as long as the end-use product is used in accordance with EPA-approved labeling. Occupational exposures are not included under the Federal Food, Drug, and Cosmetic Act (FFDCA) in the assessment of aggregated exposures for the purpose of establishing tolerances and exemptions from tolerance.

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

Significant exposure of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate to humans is highly unlikely to occur in residential, school and day care areas when the end use product is used in accordance with EPA-approved labeling. The product is only intended for commercial use as a plant growth regulator on apples and grapes.

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

There is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to residues of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate. This included all exposures for which there is reliable information. The Agency arrived at this conclusion based on lack of toxicity and rapid break-down of the compound upon consumption and into soil. The risk from aggregate exposure via oral, dermal, and inhalation are a compilation of three low-risk exposure scenarios (oral, dermal, and inhalation) and are negligible. Since there are no threshold effects of concern for this compound, and no known toxic endpoints, the provision requiring an additional margin of safety does not apply.

6. Cumulative Effects

Residues of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate will not reach levels that are of toxicological concern if the compound is used as proposed. Because of its lack of toxicity and low level of exposure, cumulative effects with other substances that share a common mechanism of toxicity are not expected.

7. Risk Characterization

The Agency considered human exposure to prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate in light of 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 prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate when used in accordance with EPA-approved labeling.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

Adequate non-target toxicology data/information are available to support registration of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate. All non-target toxicology data requirements for prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate have been satisfied.

2. Environmental Fate and Ground Water Data

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

3. Ecological Exposure and Risk Characterization

Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is not naturally-occurring but is structurally and functionally identical to jasmonic acid (JA) which is an intermediate in the pathway to plant abscisic acid synthesis and can influence growth inhibition, senescence, leaf abscission, as well as, a role in wound response and systemic resistance. When plants are attacked by insects there is a release of JA, which inhibits the insect's ability to digest protein.

In order to evaluate the risk of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate exposure to terrestrial species, the Agency has estimated RQ values using the Terrestrial Residue Exposure Model (T-REX) Version 1.4.1. A terrestrial risk assessment includes calculated expected residues, as well as, numerous calculations of dietary exposure for multiple weight class animals (Appendix B). Expected residues were calculated for avian and mammalian food items along with dissipation rate of a chemical applied to foliar surfaces (single or multiple applications) in order to estimate worst case acute RQs relative to weight class for various sized birds and mammals. These calculations showed upper bound Kenega values and that exposure to prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate (0.009 lbs ai/A) has a low potential for toxic impact to birds (RQ = 0.00) and mammals (RQ= 0.00) that may be feeding in the area of application as noted in Appendix B. The unique characteristics of this product, prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate, and the non-toxic mode of action, biodegradability and low potential for exposure will result in no risk to all non-target terrestrial

organisms.

Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate exposure to aquatic species should result in no toxicity effects. Estimated environmental concentrations (EECs) in aquatic sites from prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate runoff after application to terrestrial crops were estimated using the GENeric Estimated Environmental Concentration model (GENEEC; EPA, 2001). The model assumed 2 maximum applications of end product at 0.009 lbs ai/A (4g ai/A) at 7 day intervals, a 10.7 day aquatic half-life, a 57.8 hours photodegradation half-life in water, and a 1.6 – 2.3 hour half-life in aerobic soil. The peak aquatic EEC was calculated at a peak of about 0.00048 ppm which declined to 0.000024 ppm after 21 days (Table 8.0). Since the LC_{50} values for fish and aquatic invertebrates is 3.3 mg/L and 9.54 mg/L this would result in Risk Quotients (RQs) of 0.0001 and 0.00005, respectively, which are about three and four orders of magnitude below the Agency's levels of concern (LOCs = 0.05 - 1), suggesting no risk concerns for aquatic species.

4. Endangered Species Assessment

The Agency's Individual Effects Chance Model Version 1.1 was used to estimate to the chance of risk to endangered/threatened avian and aquatic species from exposure to prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate. These values (avian risk at 1 in 294,000 and aquatic risk at 1 in 418,000,000) suggest that prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate should not cause toxic risk to endangered/threatened species. In evaluating risk to aquatic endangered species the calculated RQs are about two and three orders of magnitude below the aquatic endangered species LOC = 0.05 resulting in no effect (NE) to aquatic endangered species. The calculated RQ values for terrestrial species are 0.00 resulting in a no effect (NE) to endangered/threatened terrestrial organisms.

D. PRODUCT PERFORMANCE DATA (EFFICACY)

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. Customarily, the Agency requires efficacy data to be submitted for review only in connection with the registration of products directly pertaining to the mitigation of disease bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles, etc. For a list of organisms considered by the Agency as "public health pests", please refer to Pesticide Registration Notice 2002-1 (http://www.epa.gov/PR_Notices/pr2002-1.pdf).

V. Risk Management Decision

A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the

environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing *active ingredient*. 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, prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is eligible for registration for the labeled uses.

B. Regulatory Decision

The data submitted fulfill the registration requirements of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate for use as a ripening agent. Refer to Appendix B for product-specific information.

1. Conditional/Unconditional Registration

All data requirements are fulfilled, and EPA determined that an unconditional registration of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is appropriate.

Consistent with the policy of making registration actions more transparent, prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate is subject to a 15-day comment period as a "new active ingredient." EPA has established a comment period of 15 days on the basis of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate minimal toxicity, the determination that prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate presents low risk of any adverse effects to human health and the environment, and critical need for this active ingredient. The notice for this comment period includes the draft Biopesticides Registration Action Document (BRAD) and draft product labels for the MP, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate Technical, and EP, Blush, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate, which contain this new active ingredient, prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate. The docket identification (ID) number is EPA-HQ-OPP-2012-0831. The Agency believes that based on the risk assessment and information submitted in support of the registration of the MP and EP containing prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate, it is in the best interests of the public to issue the registration for Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate Technical and Blush, Prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate EP. The basis for this decision can be found in the risk assessment for prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate, which is characterized in this BRAD.

C. 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—with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time, EPA does not believe that use of prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate pesticide products will cause harm 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*.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the initial registration of *active ingredient* and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

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

A. Reporting of Adverse Effects

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

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. Appendix A. Data Requirements (40 CFR Part 158-Subpart U)

*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements forBLUSH (EP) and Prohydrojasmon Tech. (40 CFR § 158.2030)

OPPTS Guideline No.	Study	Results *(below are example results)*
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	The product identity and composition were adequately addressed. Confidential Business Information (CBI).
830.1700	Analysis of samples	The analysis of samples data were adequately addressed. Confidential Business Information (CBI).
830.1750	Certification of limits	The certified limits have been adequately addressed. Confidential Business Information (CBI).
830.1800	Analytical method	The Analytical method is acceptable. Confidential Business Information (CBI).

TABLE 3.0. Physical and Chemical Properties for BLUSH (EP) and Prohydrojasmon Tech[a]

Guideline Reference No./Property		Description of Result	Methods
830.6302	Color	EP: Clear with very slight yellow coloring. TGAI: Light yellow and clear.	Visual observation at room temperature
830.6303	Physical State	EP: Clear, homogeneous mobile liquid. TGAI: Oily liquid.	Visual observation at room temperature
830.6304	Odor	EP: Sweet, fruity, solvent-like. TGAI: No odor.	
830.6313	Stability	Not required for EP. TGAI: Stable at room temperature and at 54°C for 14 days. Stable in contact with iron, zinc, aluminum, and their acetates at room temperature and at 54°C for 14 days. Degrades at 342°C and above.	OCSPP 830.6313 OECD No. 113, 1981
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not applicable, the product does not contain an oxidizing or reducing agent.	
830.6315	Flammability	EP: flashpoint = 33.0°C. EP: flashpoint = 33.5°C. Not required for TGAI.	Tag closed cup Setaflash closed cup
830.6316	Explodability	Not applicable, the product is not potentially explosive and has no explosive characteristics.	
830.6317	Storage Stability	EP: stable at room temperature for 36 months. Not required for TGAI.	Stored in polyethylene containers in the dark at room temperature, and analyzed for active ingredient content after 22 and 36 months.
830.6319	Miscibility	Not applicable, the product is not an emulsifiable liquid and is not to be diluted with petroleum solvents.	
830.6320	Corrosion Characteristics	EP: no change in appearance of containers after 36 months of storage at room temperature in the dark. Not required for TGAI.	Stored in polyethylene containers in the dark at room temperature, and appearance of the container was examined after 22 and 36 months.
830.6321	Dielectric Breakdown Voltage	Not applicable, the product is not for use around electrical equipment.	
830.7000	pH	EP: 6.1 TGAI: Not applicable, the product is not dispersible in water.	Method based on Notification No. 71 of the Ministry of Agriculture, Forestry, and Fisheries (February 3, 1960)
830.7100	Viscosity	EP: at 20°C, mean viscosity ranges from 23.9 mPa at a spindle speed of 3.0 rpm to 23.5 mPa at a spindle speed of 25.0 rpm. At 40°C, mean viscosity ranges from 8.9 mPa at a spindle speed of 8.0 rpm to 9.1 mPa at a spindle speed of 60.0 rpm. Not required for TGAI.	Brookfield DVII+Pro Viscometer using a ULA adapter and spindle
830.7200	Melting Range	Not applicable, the EP and TGAI	

TABLE 3.0. Physical and Chemical Properties for BLUSH (EP) and Prohydrojasmon Tech[a]			
Guideline Reference No./Property		**Description of Result**	**Methods**
		are liquids.	
830.7220	Boiling Range	Not required for EP. TGAI: 318°C.	Differential thermal analysis (OECD No. 103, 1995)
830.7300	Density/Relative Density/Bulk Density	EP: specific gravity = 0.955 at 20°C. TGAI: 0.974 g/cm^3 at 25°C.	Hydrometer method (JIS K0061) Pycnometer (OECD No. 109, 1995)
830.7370	Dissociation Constant in Water	Not required for EP. TGAI: indeterminate.	Conductometric method (OECD No. 112, 1981)
830.7550	Partition Coefficient	Not required for EP. TGAI: Not applicable, the product is partially/completely soluble in water.	
830.7840	Water Solubility	Not required for EP. TGAI: 60.2 mg/L at 25°C.	Flask method (OECD No. 105)
830.7950	Vapor Pressure	Not required for EP. TGAI: 0.0167±0.00017 Pa at 25°C. 0.324±0.0221 Pa at 50°C[b].	Gas saturation method (OECD No. 104, 1995)

[a]Data from MRIDs 47927804-10, 47927812-17, 47927843

Table 4.0. Toxicological Data for FAL 1800 5.25%ai

Data Requirement	LD_{50}	MRIDs	Study Conclusion
Acute Oral Toxicity OCSPP 870.1100	LD_{50} >5000 mg/kg IV	47927818, 47927819	Acceptable
Acute Dermal Toxicity OCSPP 870.1200	LD_{50} >2000 mg/kg III	47927818, 47927820	Acceptable
Acute Inhalation Toxicity OCSPP 870.1300	LC_{50} > 5.0 mg/L IV	47927818, 47927821	Acceptable
Primary Eye Irritation OCSPP 870.2400	Acute symptoms were observed after test material was administered, but resolved by day 7. BLUSH produces reversible intense eye irritation III	47927818, 47927822	Acceptable
Primary Dermal Irritation OCSPP 870.2500	No skin irritation. IV	47927818, 47927823	Acceptable
Dermal Sensitization OCSPP 870.2600	Not a dermal sensitizer	47927818, 47927824	Acceptable

Table 5.0. Toxicological Data for Prohydrojasmon Technical (PDJ)

Guideline # Test	Results/Toxicity Category	MRIDs	Study Conclusion
Acute Oral Toxicity OCSPP 870.1100	LD_{50} > 5000 mg/kg IV	47927818, 47927825	Acceptable
Acute Dermal Toxicity OCSPP 870.1200	LD_{50} > 2000 mg/kg III	47927818, 47927826	Acceptable
Acute Inhalation Toxicity OCSPP 870.1300	LC_{50} > 5.0 mg/L IV	47927818, 47927827	Acceptable
Primary Eye Irritation OCSPP 870.2400	slight eye irritation IV	47927818, 47927828	Acceptable
Primary Dermal Irritation OCSPP 870.2500	No skin irritation. IV	47927818, 47927829	Acceptable
Dermal Sensitization OCSPP 870.2600	Not a dermal sensitizer	47927818, 47927830	Acceptable
90-day Oral Toxicity-Rat OCSPP 870.3100	NOEL= 1,000 ppm (56.6-58.7 mg/kg/day)	47927831	Acceptable
90-day Inhalation Toxicity OCSPP 870.3465	Waiver Request	48869007	Acceptable
90-day dermal toxicity OCSPP 870.3250	Waiver Request	48869006	Acceptable
Prenatal Developmental Toxicity Study - Rat OCSPP 870.3700	Maternal NOEL $\geq$ 500 mg/kg/day Developmental NOEL > 500 mg/kg/day	47927832	Acceptable
Bacterial Reverse Mutation Test OCSPP 870.5100	There was no evidence of induced mutant colonies over background	47927833	Acceptable
In Vitro Mammalian Chromosome Aberration Tests OCSPP 870.5375	There was no evidence of cells with chromosomal abnormalities	47927834	Acceptable

Classification: Acceptable; no additional data are required.

TABLE 4. Non-Target Organism Toxicity Requirements for prohydrojasmon propyl-3-oxo-2-pentylcyclo-pentylacetate (40 CFR § 158.2060)

Guideline # Test	Results/Toxicology Category	MRID	Study Conclusion
850.1010 Acute Toxicity Test, Daphnids	EC_{50} = 9.54 mg/L. Moderately toxic	47927838	Acceptable
850.1075 Acute Toxicity Freshwater Fish *Cyprinus carpio*	96 hr LC_{50} = 3.3 mg/L. Moderately toxic	47927837	Acceptable
850.2100 Avian Acute Oral Toxicity Bobwhite (*Colinus virginianus*)	LD_{50} >2000 mg/kg Practically non-toxic	47927835	Acceptable
850.2200 Avian Dietary Toxicity Japanese quail (*Colinus virginianus*)	LC_{50} >5000 ppm Practically non-toxic	47927836	Acceptable
Honey bee Acute Oral Toxicity	LC_{50} > 100 ug ai/bee	47927838	Acceptable
850.4100 Seedling Emergence and Seedling	ER_{50} > 1,140 g ai/ha (> 456 g ai/A)	48869004	Acceptable

Guideline # Test	Results/Toxicology Category	MRID	Study Conclusion
Growth			
850.3020 Acute Contact Honeybees	LD_{50} = 0.129 ug ai/bee (0.116 – 0.148 ug ai/bee)	48869002	Acceptable
Ecotoxicity Data for FAL 1800 4.25 % ai (PDJ)			
850.4150 Terrestrial Plant Vegetative Vigor	ER_{50} > 1,140 g ai/ha (> 456 g ai/A)	48869005	Acceptable

VIII. Appendix B.

For product specific information, please refer to http://www.epa.gov/pesticides/pestlabels.

IX. Appendix C.

REFERENCES

1. Parker, R.D., R.D. Jones and H.P. Nelson., 1995. GENEEC: A Screening Model for Pesticide Environmental Exposure Assessment, in Proceedings of the International Exposure Symposium on Water Quality Modeling; American Society of Agricultural Engineers, pp. 485-490; Orlando, Florida.

2. U.S. EPA. 1998. Guidance for Ecological Risk Assessment. Risk Assessment Forum. EPA/630/R-95/002F, April 1998.

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4. U.S.EPA 2004. Individual Effects Chance Model Version 1.1. EFED/OPP/USEPA.

5. U.S. EPA. 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs. Office of Prevention, Pesticides, and Toxic Substances. Office of Pesticide Programs. Washington, D.C. January 23, 2004.