Registration Decision for the New Active Ingredient PDHP 25279

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1. Summary

This document announces that the U.S. Environmental Protection Agency (EPA) completed its evaluation of the new biochemical pesticide PDHP 25279 and concluded that it meets the standard for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). On February 3, 2022, EPA proposed to register a pesticide product containing the new active ingredient, PDHP 25279, and released that proposed decision for a 15-day public comment period. EPA received no comments on the proposed decision.

Peptide Derived from Harpin Protein (PDHP) 25279 is a microbially produced peptide which is formulated into the end-use product PHC 25279 as wettable, spray-dried granules at a concentration of 1%. PHC 25279 is intended to be used in the field or greenhouse and is to be applied as a dip to leaves or roots pre-transplant, as a seed treatment, or by foliage spray to vegetable crops, ornamentals, tobacco, small fruit crops, landscape plants, and turf. PDHP 25279 does not directly interact with the target pest. Instead, it induces natural defense mechanisms in the plant by eliciting the hypersensitive response, which is characterized as rapid, localized cell death in plant tissue after infiltration of the peptide into the intercellular spaces of plant leaves.

Currently, there are three registered harpin protein active ingredients: harpin, harpin αβ, and Ea peptide 91398. Harpin (PC code 006477) is a 404 amino acid (AA) protein first registered in 2000. Harpin αβ (PC code 006506) is a 412 AA protein that is composed of harpin protein fragments derived from various bacterial plant pathogens and was registered in 2004. Ea peptide 91398 (the active ingredient in PHC 91398, PC code 005200) is a synthetically produced 27 AA peptide derived from the hrpW protein found in the bacterium *Erwinia amylovora*, a plant pathogen that causes fire blight in plants, and was first registered in 2020. The product characterization, human health, and nontarget organism data supporting the registration of PDHP 25279 and the product, PHC 25279, are in part based on molecular and toxicological similarities to these previously registered harpin active ingredients, particularly Ea peptide 91398 and its corresponding end-use product PHC 91398 (EPA Reg. No. 71771-12).

Dietary exposure to residues of the active ingredient in food and drinking water is expected to be negligible. PDHP 25279 was found to have low toxicity via the oral route of exposure, did not show any homology to known or putative allergens, and is rapidly degraded in simulated gastric fluids. Because PDHP 25279 is a protein, it generally is expected to be biodegradable through microbial activity in the soil. Supporting this assumption is the observation that PDHP 25279 is degraded within 5 minutes by subtilisin A, an environmental protease. It is expected that biological processes will reduce run-off and potential exposure of drinking water to negligible levels. The presence of PDHP 25279 on treated crops is likely to be further reduced through normal washing and handling processes. Together, any potential dietary risk from the use of PDHP 25279 to human health is therefore considered negligible.

There is a potential for occupational dermal, eye, and inhalation exposure from mixing the powder with solvent for application and from surface spraying. PDHP 25279 was found to be non-toxic via the oral route of exposure, and via inhalation. In studies conducted on Ea peptide 91398, it was not found to be a dermal sensitizer and was non-toxic in dermal application to rats in quantities of 5,000 mg per kg of body weight. As mentioned above, Ea peptide 91398 and PDHP 25279 share a high degree of similarity. The results from the acute oral and inhalation studies conducted on PDHP 25279, coupled with findings that Ea peptide 91398 is non-toxic when exposed dermally, support the conclusion that there are no occupational risks associated with manufacture of PHC 25279 containing PDHP 25279, or its application according to the use instructions on the product label. Respiratory personal protective equipment is required since repeated exposures to high concentrations of microbial proteins may cause allergic sensitization and PDHP 25279 is a microbially derived peptide.

Nontarget organism exposure and toxicity data were cited from previously registered products containing Harpin, Harpinαβ, and Ea Peptide 91398, which are similar to PDHP 25279. These studies did not result in any adverse effects on any non-target organisms tested. Additionally, the degradation study submitted to support the uses of PDHP 25279 demonstrated rapid degradation times, consistent with previous generations of products containing harpin protein. The lack of toxicity, coupled with minimal environmental exposure and the history of safe use of similar active ingredients indicate that the product containing PDHP 25279 will not result in adverse effects to non-target organisms. PDHP 25279 is not expected to result in discernible effects to non-target organisms. Due to a reasonable expectation of no discernible effects to occur to any non-target species, including listed species, a "No Effect" determination has been made for direct and indirect effects to listed species and their designated critical habitats resulting from the uses of PDHP 25279, as labeled.

After reviewing the submitted and publicly available data and information for PDHP 25279, EPA concluded that there is a reasonable certainty of no harm from residues of this new active ingredient, and its use will not cause unreasonable adverse effects to human health or the environment. Under FIFRA section 3(c)(5), EPA is registering one end use product:

PHC 25279 (EPA File Symbol: 717117-14)

Active Ingredient:	PDHP 25279
Activity:	The active ingredient is a plant response-elicitor peptide based on a naturally occurring harpin protein, PDHP 25279. The peptide works to reduce the incidence and severity of plant disease by eliciting the plant's own natural defense system, referred to as systemic acquired resistance, thereby enhancing overall plant health.
Uses:	Pre-plant foliar or root dip, foliar application, sprinkler or drip chemigation, and seed treatment.
Crops:	Artichoke, Asparagus, potato, corn, sweet corn, cotton, soybean, canola, sunflower, sugar beets, wheat, grass, hay, sugarcane, tobacco, berries, avocado, citrus, almond, walnuts, apple, pear, stone fruit, grapes, hops, kiwifruit, aloe, banana, coffee, figs, herbs, mango, mint, papaya, pineapple, trees, turf, and ornamentals.

Furthermore, EPA has established a tolerance exemption for residues of PDHP 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices (40 CFR 180.1398).

2. Background

On January 11, 2021, EPA received an application from Plant Health Care, Inc. that proposed to register a new pesticide product, PHC 25279, containing the new active ingredient, PDHP 25279. Plant Health Care provided data and other information (e.g., scientific rationales and published literature) to support the registration. In addition, Plant Health Care, Inc. submitted a petition to establish a tolerance exemption for residues of PDHP 25279 in or on all food commodities.

In the Federal Register of August 13, 2021 (86 FR 44706), EPA published a Notice of Receipt (NoR) that announced receipt of an application for registration of type of PDHP 25279. In the Federal Register of June 17, 2022 (87 FR 36438), EPA published a Notice of Filing (NoF) for the petition requesting the

exemption from the requirement of a tolerance for residues of PDHP 25279. During the public comment periods, no comments were received in response to the NoR; one comment was received in response to the NoF (see section 4 below). On February 8, 2023, EPA revised 40 CFR Part 180 to establish a tolerance exemption for residues of PDHP 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices (88 FR 8233).

3. Evaluation

In evaluating a pesticide registration application, EPA assesses a variety of studies to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the use of the product. Risk assessments are developed to evaluate how the active ingredient might affect a range of nontarget organisms, including humans and terrestrial and aquatic wildlife (plants and animals).

Based on these assessments, EPA evaluates and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk. In this way, the pesticide label communicates essential limitations and mitigations that are necessary for public and environmental safety. In fact, FIFRA section 12(a)(2)(G) states that it is unlawful for any person to use a registered pesticide in a way that conflicts with the label.

3.1 Assessment of Human Health Exposure and Risk

To assess risks to human health from use of biochemical pesticides, EPA evaluates the potential toxicity of a product and the likelihood, amount, and types of exposure users and bystanders are likely to experience. In conducting a risk assessment, EPA must consider: (1) the hazards of a substance and (2) the exposure to that substance that a person will be exposed to as a consequence of use either directly or indirectly. EPA uses this combined information to assess and characterize the risk(s) and predict the probability, nature, and magnitude of the adverse health effects that may occur from use of the substance in the manner described.

To evaluate hazard for biochemical pesticides, EPA typically requires a range of Tier I data: acute toxicity data (acute oral toxicity, acute inhalation toxicity, acute dermal toxicity); irritation tests (primary eye irritation, primary dermal irritation and dermal sensitization); subchronic testing (90-day oral); mutagenicity testing (bacterial reverse mutation test and in vitro mammalian cell assay) and developmental toxicity testing (prenatal development). Tier II and III testing is triggered only when there is indication, usually through lower tier testing, that a biochemical pesticide has unusual characteristics, such as subchronic toxicity, or is suspected or known to be a carcinogen.

3.1.1 Product Characterization

The data and information submitted to address the product analysis data requirements for the pesticide product containing PDHP 25279 have been classified as acceptable. PDHP 25279 is a microbially produced peptide which is formulated into the end-use product PHC 25279 as wettable, spray-dried granules at a concentration of 1%. PHC 25279 is intended to be used in the field or greenhouse and is to be applied as a dip to leaves or roots pre-transplant, as a seed treatment, or by foliage spray to vegetable crops, ornamentals, tobacco, small fruit crops, landscape plants, and turf. PDHP 25279 does not directly interact with the target pest. Instead, it induces natural defense mechanisms in the plant by eliciting the hypersensitive response, which is characterized as rapid, localized cell death in plant tissue after infiltration of the peptide into the intercellular spaces of plant leaves.

As a term of registration, the applicant will be required to submit the results of confirmatory storage stability and corrosion characteristic studies (ongoing at the time of registration).

3.1.2 Toxicological and Allergenicity Data and Information

In support of the application, Plant Health Care, Inc. submitted an acute oral study in rats, an acute inhalation study in rats, digestibility studies of PDHP 25279 in simulated gastric fluids and subtilisin A, a bioinformatics study on the allergenic potential of PDHP 25279, and requests to waive additional mammalian toxicity requirements as specified in 40 CFR § 158.2050 based on the similarities of PDHP 25279 to Ea peptide 91398.

The waiver rationales are based on the results of the previous human health evaluation for Ea peptide 91398 (end use product PHC 91398) and information on the equivalence of these substances to PDHP 25279 (end use product PHC 25279). There are two notable differences between these two active ingredients. First, Ea peptide 91398 is produced synthetically, whereas PDHP 25279 is produced through microbial fermentation, which results in the presence of microbial fermentation byproducts (biosolids) in the PHC 25279 end use product. Secondly, PDHP 25279 contains three amino acid substitutions that allow for post-fermentation processing of the peptide. To address the toxicological equivalence of the new active ingredient and end-use product, the applicant conducted two acute toxicity studies. Studies were conducted on the end-use product (EP), PHC 25279 containing 1% PDHP 25279 peptide active ingredient due to the instability of the peptide in the technical grade of the active ingredient (TGAI) form at room temperature. Both PHC 25279 and the previously registered PHC 91398 were shown to have low oral and inhalation toxicity profiles, resulting in both being classified as EPA Toxicity Category IV. The acute oral LD_{50} was determined to be >5,000 mg/kg for both end use products and the acute inhalation LC_{50} was found to be >5.23 mg/L for PHC 91398 and the LC_{50} > 2.11 mg/L for PHC 25279. Notably, in these studies the active ingredient content of the two products was virtually identical (1.039% and 1%, respectively), further supporting the comparability of the test results. Both acute toxicity studies were conducted with the maximum allowable level of biosolids per the manufacturing process and thus represent a worst-case scenario that still resulted in low toxicity through these routes of exposure.

Toxicological equivalence of the two active ingredients was also examined with regard to their potential to be cross-reactive with known or putative allergens. The peptide sequence of PDHP 25279 was compared to a database of known and putative allergenic proteins. The comparisons of the PDHP 25279 protein sequence to the allergen sequences showed no homology with any of the sequences in the allergen database. Subsequent re-analysis showed the same results, i.e., there were no contiguous 8-residue matches or >35% matches within a contiguous stretch of 80 AA between the PDHP 25279 protein sequence and known and putative allergen sequences. Similar results were observed in the bioinformatics analysis conducted for Ea peptide 91398. Thus, the likelihood for the PDHP 25279 peptide to be cross-reactive with any of these allergens is low.

Both harpin peptides also behaved similarly in the presence of the proteases pepsin and subtilisin A, showing rapid degradation in the presence of both enzymes. The results of an in vitro digestibility study using PDHP 25279 indicated that the digestion of PDHP 25279 was complete at the five-minute mark for pepsin and the one-minute mark for subtilisin A. A similar finding was made for Ea peptide 91398, in which complete digestion with pepsin and subtilisin A took place within one minute and twenty minutes, respectively. The more rapid degradation of PDHP 25279 in the presence of subtilisin A demonstrates that the PDHP 25279 peptide is likely rapidly degraded in soil, which may reduce dietary exposure for use of the product in soil. This information is relevant because the end use product, PHC 25279, is meant for application as a seed treatment and root dip (among other application methods to

include pre-transplant foliar dip and foliar application). Additionally, the subtilisin A susceptibility by this environmental protease further supports the biological equivalency finding of the two proteins.

EPA reviewed waiver rationales for the following data requirements: acute dermal toxicity study, primary dermal irritation study, primary eye irritation study, dermal sensitization study, 90-day oral toxicity in rodents, 90-day dermal toxicity, 90-day inhalation toxicity, prenatal developmental toxicity study, bacterial reverse mutation test, and in vitro mammalian cell assay. Included in these rationales were citations to studies which were conducted on PHC 91398, containing Ea peptide 91398. Given the high degree of similarity in the amino acid sequences between PDHP 25279 and Ea peptide 91398 and their similar findings in acute oral and acute inhalation studies, EPA found the waiver rationales to be adequate for evaluating human health risk for PHC 25279. Thus, considering the lack of effects observed in laboratory testing in both acute oral and inhalation studies for PHC 25279, acute toxicity to humans and animals is not expected via the dermal or ocular route.

To date, there have been no reported hypersensitivity incidents during the production of PHC 25279. *Erwinia amylovora*, the source organism from which PDHP 25279 is derived, is a plant pathogen responsible for causing fire blight in plants such as apple, pear, and raspberry. *E. amylovora* is a Gram-negative bacterium belonging to the family *Enterobacteriaceae*. Human infections by *Erwinia*-like microorganisms have rarely been identified. Although two cases of human infection with *Erwinia spp.* have been reported, neither case has been attributed to *E. amylovora*. Furthermore, while the DNA sequence information for the PDHP 25279 peptide from *E. amylovora* provided the genetic template for production of PDHP 25279, the bacterium itself is not used at any point during the production process. Therefore, there is no indication that the source organism would raise any toxicological concerns.

3.1.3 Aggregate Exposure and Risk Characterization

In examining aggregate exposure, EPA considers 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).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for PDHP 25279 residues, and exposure from non-occupational sources.

As described previously, no adverse effects of concern were observed in toxicological tests with PDHP 25279 and the highly similar Ea peptide 91398; therefore, the EPA did not conduct a quantitative exposure assessment.

Dietary Exposure and Risk Characterization:

EPA did not conduct a quantitative dietary exposure and risk assessment because dietary exposure to residues of the active ingredient, PDHP 25279, in food and drinking water is expected to be negligible. Supporting this conclusion is the observation that PDHP 25279 is degraded within 5 min by subtilisin A, an environmental protease. PDHP 25279 is a protein and as such is generally expected to be biodegradable through microbial activity in the soil. It is therefore expected that biological processes will reduce run-off and potential exposure of drinking water to negligible levels. Furthermore, the presence of PDHP 25279 on treated crops is likely to be further reduced through normal washing and handling processes.

EPA's risk assessment concluded that, similar to Ea peptide 91398, PDHP 25279 has low toxicity via the oral route of exposure, did not show any homology to known or putative allergens, and is rapidly degraded in simulated gastric fluids. Together, any potential dietary risk from the use of PDHP 25279 to human health is therefore considered negligible.

Non-occupational, Residential Exposure and Risk Characterization:

Because PDHP 25279 is not for residential use, EPA did not conduct a residential exposure assessment. For non-occupational exposure, there is a potential for dermal exposure by handling of plants treated with PDHP 25279. However, PDHP 25279 is expected to be of low toxicity through the dermal route of exposure, given the low toxicity through the oral and inhalation routes and its similarity to Ea peptide 91398, which was found to be of low toxicity and not a skin sensitizer.

Cumulative Effects:

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA consider "available information concerning the cumulative effects of [a particular pesticide's] … residues and other substances that have a common mechanism of toxicity." No risk of cumulative toxicity/effects from PDHP 25279 or the similar Ea peptide 91398 has been identified as no toxicity has been shown for PDHP 25279 in the submitted studies. Therefore, EPA has not assumed that PDHP 25279 has a common mechanism of toxicity with other substances.

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

U.S. Population:

For all the reasons discussed above, EPA concluded that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of PDHP 25279. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

Infants and Children:

FFDCA section 408(b)(2)(C) provides that, in establishing or modifying a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess risk considering 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 and ensure there is a reasonable certainty of no harm to infants and children from aggregate exposure to the pesticide chemical residue. In addition, FFDCA section 408(b)(2)(C) requires that, in the case of threshold effects, EPA apply an additional tenfold (10X) margin of safety for infants and children to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different safety factor when reliable data available to EPA support the choice of a different factor.

An FQPA safety factor is not required for PDHP 25279 at this time as no dietary endpoints have been identified based on the lack of human-relevant adverse effects, including toxicity and allergenicity of PDHP 25279.

3.1.5 Occupational Exposure and Risk Characterization

There is a potential for occupational dermal, eye, and inhalation exposure from mixing the powder with solvent for application and from surface spraying. PDHP 25279 was found to be non-toxic via the oral route of exposure, and via inhalation. In studies conducted on Ea peptide 91398, it was not found to be a dermal sensitizer and was non-toxic in dermal application to rats in quantities of 5,000 mg per kg of body weight. As mentioned above, Ea peptide 91398 and PDHP 25279 share a high degree of similarity. The results from the acute oral and inhalation studies conducted on PDHP 25279, coupled with findings that Ea peptide 91398 is non-toxic when exposed dermally, support the conclusion that there are no occupational risks associated with manufacture of PHC 25279 containing PDHP 25279, or its application according to the use instructions on the product label. Respiratory personal protective equipment is required since repeated exposures to high concentrations of microbial proteins may cause allergic sensitization and PDHP 25279 is a microbially derived peptide.

3.1.6 Human Health Conclusions

EPA previously conducted a thorough human health risk assessment for the registration request of PHC 91398 containing the active ingredient Ea peptide 91398 and found it to not pose a human health risk (US EPA 2020a; EPA File Symbol No. 71771-12). PDHP 25279 is highly similar to Ea peptide 91398 based on its molecular composition (i.e., only 3 AA are different) and toxicological profile. Similar to Ea peptide 91398, PDHP 25279 was found to have low toxicity via the oral and inhalation routes of exposure, did not show any homology to known or putative allergens, and is rapidly degraded in simulated gastric fluids. Therefore, EPA concludes that there will be no unreasonable adverse effects for humans as a result of the registration of PHC 25279 or its application if used according to the label and good agricultural practices.

The database of studies required to support the assessment of the risk posed by PDHP 25279 to human health is complete. For more information on the human health risk assessment of PDHP 25279 (U.S. EPA 2023), please see the supporting documentation provided in the associated regulatory docket (search for “EPA-HQ-OPP-2021-0394” at www.regulations.gov).

3.2 Assessment of Ecological Exposure and Risk

To assess ecological risks from use of biochemical pesticides, EPA evaluates the likely environmental impacts as a result of exposure of the chemical to plants and animals in the environment and to whether that exposure will cause harm or ecological effects. EPA uses this combined information and considers the overall toxicity to characterize the risk(s) in order to identify what levels may cause harmful effects on the plants and animals of concern that may occur from use of the substance in the manner described.

To evaluate toxicity, EPA initially requires that a wide range of studies including Tier I testing be done on the following nontarget organisms: mammalian (acute, subchronic, prenatal developmental, and mutagenicity), birds (acute oral and dietary), fish (acute freshwater fish and aquatic invertebrates), plants, and insects. Testing is organized in a tiered structure, where Tier I studies test worst-case exposure scenarios and higher tiers (Tiers II and III) generally encompass definitive risk determinations and longer-term greenhouse or field testing. Higher tier testing is implemented only when unacceptable

effects are seen at the Tier I screening level. All data requirements may be addressed with guideline studies or scientific rationales.

The database of studies and information required to support the assessment of risk to the environment is adequate for making a determination for the registration of PDHP 25279 (U.S. EPA 2022). To address the data requirements, Plant Health Care, Inc., submitted guideline studies, cited previously submitted studies for similar harpin active ingredients, and provided scientific rationales supported by the open literature. Based on these acceptable data and scientific rationales, adverse effects to nontarget organisms are not expected from use of the PDHP 25279 pesticide product when applied to use sites. A summary of the data and information reviewed for PDHP 25279 follows.

3.2.1 Terrestrial Animals and Plants

The application methods for PDHP 25279 include root dip and seed treatments as well as use as a foliar spray. Root dip and seed treatments result in negligible exposure to non-target organisms. The primary route of exposure for non-target organisms to PDHP 25279 is from the foliar spray use. The foliar spray use has the potential to leave residue that non-target organisms have access to via consumption, dermal contact, pollination, or run-off. The highest application rate for the product (PHC 25279) is 3 oz per acre. As the product contains 1% of the new active ingredient, this equates to a maximum of 0.03 oz of the active ingredient per acre at the highest application rate.

Birds and Mammals:

While foliar spray applications of PHC 25279 are likely to result in the highest level of potential exposure of PDHP 25279 for terrestrial animals, contact through foliar spray is expected to be limited from the low application rate and the low persistence of PDHP 25279 in the environment. Birds and mammals may be exposed through contact with the treated plant or consumption of treated plant material. The short degradation time of PDHP 25279 would likely not allow it to persist very long in an area impacted by drift. Previous studies on early generations of harpin active ingredients suggest that they rapidly degrade on plant surfaces with degradation times on the order of minutes to 3 to 4 days. A recent degradation study conducted with PDHP 25279 found that the peptide was almost entirely degraded within a minute of exposure to the environmental protease, Subtilisin A. Therefore, PDHP 25279 was determined to be readily biodegradable and is unlikely to persist in the environment, limiting exposure potential to non-target organisms. EPA concluded that, due to the combination of the quick degradation time demonstrated for PDHP 25279 and the low application rate, in conjunction with the high similarity between this peptide and previous generations of harpin proteins, PDHP 25279 exposure to terrestrial non-target organisms is expected to be minimal.

Nontarget Insects and Honeybees:

Exposure of PDHP 25279 to non-target insects and honeybees is not likely due to the low application rates of PHC 25279, quick degradation potential, and its non-toxic mode of action. A rationale and bridging argument were submitted to demonstrate the similarity between the previously registered synthetic Ea Peptide 91398 (PHC 91398) and PDHP 25279. This bridging argument and rationale were found acceptable to support PDHP 25279. A rationale based on the two honeybee toxicity studies, conducted for Ea Peptide 91398 (see US EPA 2020b), to satisfy the nontarget insect data requirement was also submitted and found acceptable. The rationale also noted that impacts to non-target insects are not likely due to the low application rates, quick degradation potential, history of safe use and its non-toxic mode of action. EPA concluded that, given that the mode of action is not likely to be toxic to

insects, the low exposure, and lack of toxicity to honeybees, risk to non-target insects and honeybees is not anticipated.

Nontarget Plants:

An acceptable scientific rationale was submitted by the applicant in lieu of data on the effect of PDHP 25279 on nontarget plants. No recent plant studies were submitted for this application. Exposure to off-field plants is expected to be minimal due to the combination of the quick degradation time demonstrated for PDHP 25279 and the low application rate of PHC 25279. The mode of action of this product is non-toxic in nature to plants. The product promotes gene expression through the jasmonic/ethylene and salicylic acid-dependent signaling, and it activates the plant's defense system which initially causes localized cell death in tissues infiltrated by the peptide. This triggers a cascade of metabolic effects, which promotes an immune response within the plant to increase resistance to bacterial and fungal infections, suppression of nematode egg production as well as increased yield and growth. The effect in the plant is direct but does not cause lethality to the plant. EPA found that, due to the lack of hazard to non-target plants and low expected environmental exposures, no discernible effects to non-target plants are anticipated from PDHP 25279.

3.2.2 Aquatic Animals and Plants

The only application method of PHC 25279 that could potentially result in exposure of PDHP 25279 to aquatic flora and fauna is the foliar spray method via drift. Exposure through runoff events is expected to be negligible due to the rapid degradation times in the field and previous studies with similar harpin proteins. As part of its human health and product characterization risk assessment, EPA reviewed a degradation study that demonstrates PDHP 25279 is readily degraded by two common proteases. Therefore, PDHP 25279 is unlikely to persist in the environment, and exposure to non-target aquatic animal and plants is expected to be limited. Furthermore, the transitory nature of PDHP 25279 is similar to Harpin and harpin αβ proteins, which in previous studies were found to degrade between 15 seconds and 15 minutes on plant surfaces. Another study found that the harpin protein degrades on plant surfaces from 3 to 4 days after application, which was thought to suggest photodegradation. Data from the same study also found that harpin proteins completely degrade in the presence of chlorinated water and other oxidative compounds, thereby limiting the potential of irrigation runoff of harpin proteins from impacting aquatic systems. The weight of evidence that oxidative agents and chlorinated water degrading harpin proteins supports the finding that potential exposure to aquatic systems is expected to be negligible.

The applicant submitted an acceptable rationale and bridging argument for freshwater fish and aquatic invertebrate (daphnia) data requirements. EPA concluded that, given the lack of toxicity of previous generations of harpin proteins and low exposure in aquatic environments, effects from PDHP 25279 on freshwater and estuarine/marine fish and aquatic invertebrates are not anticipated.

3.2.3 Endangered Species Conclusion

Since EPA has determined that no effects are anticipated for any nontarget species exposed to PDHP 25279 as a result of the uses, EPA also does not expect discernible effects to federally listed threatened and endangered ('listed') species. Therefore, EPA made a "No Effect" determination for direct and indirect effects to federally listed threatened or endangered species and their designated critical habitats resulting from the labeled uses of PDHP 25279.

4. Benefits and Public Comments

By definition, biochemicals are favorable when compared to currently registered conventional alternatives because biochemicals are naturally occurring substances (or substances structurally similar and functionally identical to naturally-occurring substances) with a history of exposure to humans and the environment demonstrating minimal toxicity and a nontoxic mode of action to the target pest(s). Benefits of biochemical pesticides as compared to conventional pesticides typically include lower toxicity profiles for humans and nontarget organisms, and faster degradation in the environment.

Like other biochemicals, PDHP 25279 aligns with some of the potential benefits above and could fill particular needs in unique markets. For example, PDHP 25279 does not directly interact with the target pest. Instead, it induces natural defense mechanisms in the plant by eliciting the hypersensitive response, which is characterized as rapid, localized cell death in plant tissue after infiltration of the peptide into the intercellular spaces of plant leaves. Hence, the mode of action of PDHP 25279 is non-toxic, and PDHP 25279 is not expected to have toxic effects on nontarget organisms, applicators in the field, or food or drinking water consumed by the U.S. population.

EPA has provided the public two opportunities to comment on the proposed registration of PDHP 25279 and its associated tolerance exemption petition through information presented in the Federal Register and/or on www.regulations.gov. On August 13, 2021, EPA announced receipt of an application in the Federal Register to register PHC 25279 (71771-RU), containing the new biochemical active ingredient PDHP 25279. No comments were received during the open comment period for the Notice of Receipt. On June 17, 2022 (86 FR 44706), EPA published a Notice of Filing (NoF) that announced requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of PDHP 25279 in or on all food commodities when used in accordance with label directions and good agricultural practices. On July 4, 2022, EPA received one comment on the NoF in support of the tolerance exemption:

"I am writing in support of this petition to modify regulations for residues of the fungicide chemical PDHP 25279 applied to growing crops or seeds. PDHP 25279 is classified as a toxicology category IV substance for exposure via the oral, dermal, and inhalation routes. This means that the LD_{50} for this drug via the oral route is >5000 mg/kg and the LD_{50} for this drug via the inhalation route is >2 mg/L (Office of Pesticide Programs, 2018; Pesticide Tolerance; Exemptions, Petitions, Revocations, etc.: Residues of a Pesticide Chemical in or on Various Commodities, 2022). The mechanism of action of this agent is by the Natural Defense Mechanism causing "rapid, localized cell death in plant tissue after infiltration … into the intracellular spaces of plant leaves or roots" (Pesticide Tolerance; Exemptions, Petitions, Revocations, etc.: Residues of a Pesticide Chemical in or on Various Commodities, 2022, p. 2). It degrades quickly when exposed to environmental conditions via hydrolysis and oxidation. Because of this, in addition to the low dose of application of PDHP 25279, it is unlikely that humans will be exposed to consuming it in their diet or in drinking water from pesticide run-off. Additionally, the product has been shown to be non-toxic and would not cause harm even if it was consumed dietarily or in drinking water unless consumed in extremely high doses. The use of pesticides can be beneficial in that they protect from crop loss and promote agricultural productivity (Aktar et al., 2009). Additionally, the benefits of increased availability of produce outweigh the risks of exposure to a toxicology class IV substance."

Because Plant Health Care's pesticide product contains a new active ingredient and involves the first agricultural use of this active ingredient, EPA opened a 15-day public comment period on this registration decision on February 3, 2023. EPA took this action in accordance with a policy, first implemented in October 2009, designed to provide a more meaningful opportunity for the public to

participate in major registration actions. The public comment period closed on February 18, 2023, and no comments were received.

5. Registration Decision

The PDHP 25279 database is comprised of studies and information that meet the data requirements and support the labeled uses. In considering the assessed risk to human health and the environment, EPA concludes that PDHP 25279 meets the regulatory standard under FIFRA. Therefore, EPA is granting the registration of PDHP 25279 as new active ingredient under FIFRA section 3(c)(5).

EPA is registering under FIFRA Section 3(c)(5) one end use product, PHC 25279, for use as a seed treatment, foliar spray, and pre-plant foliar/root dip on a range of agricultural crops. The end use product consists of wettable, spray-dried granules at a concentration of 1% active ingredient and is intended to manage plant diseases.

The risk assessments and label supporting this decision can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0394" at www.regulations.gov).

6. References

United States Environmental Protection Agency (U.S. EPA), 2020a. Human Health Risk Assessment for 3rd Generation Harpin Peptide PHC-91398. Memorandum from N. Baranova through J. Kough and M. Mendelsohn to K. Welch, dated February 4, 2020.

Unites States Environmental Protection Agency (U.S. EPA), 2020b. Environmental Risk Assessment for a FIFRA Section 3 Registration PHC-91398 End Use Product Containing the New Active Ingredient Ea Peptide 91398. Memorandum from S. Kelly through G. Sinclair and M. Mendelsohn to K. Welch, dated February 4, 2020.

United States Environmental Protection Agency (U.S. EPA), 2022. Environmental Risk Assessment for a FIFRA Section 3 Registration of PHC 25279 End Use Product. Containing the New Active Ingredient PDHP 25279; EPA File Symbols 71771-RU; PC Code 155667; Action Case No. 00149130; Submission Nos. 1062907; DP Barcodes: 1F8901; MRIDs 51113203 and 513860702. Memorandum from S. Kelly through A. Pierce and M. Mendelsohn to M. Glikes, dated November 9, 2022.

United States Environmental Protection Agency (U.S. EPA), 2023. Human Health Risk Assessment, Review of Product Characterization and Manufacturing Processes of the New End-Use Product PHC 25279 Containing the New Active Ingredient Peptide Derived from Harpin Protein (PDHP) 25279. Data was Provided in Support of a FIFRA Section 3 Registration and Establishment of a Permanent Tolerance Exemption. Memorandum from N. Ortiz through W. Striegel and M. Mendelsohn to M. Glikes, dated January 6, 2023.

GROUP **BM 02** FUNGICIDE

FUNGICIDE

OBRONA™

A Biochemical Pesticide • Wettable Dry Granule

Enhances plant's resistance to fungal and bacterial diseases

ACTIVE INGREDIENT:

PDHP 25279	1.0%
OTHER INGREDIENTS:	99.0%
Total:	100.0%

EPA Reg. No. 71771-14-2935

EPA Est. No. 88746-GA-1

KEEP OUT OF REACH OF CHILDREN

CAUTION / PRECAUCIÓN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Read the entire label before using this product. Read Conditions of Sale and Limitation of Warranty and Liability before buying or using. If terms are not acceptable, return at once unopened.

See inside booklet for complete Precautionary Statements and Directions for Use.

WILBUR-ELLIS.

Manufactured for:
WILBUR-ELLIS COMPANY LLC
2903 S. Cedar Ave., Fresno, CA 93725 • (559) 442-1220
2024-0227

0 71070 02557 6

NET WEIGHT: 5 lb

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust or spray mist. Remove and wash contaminated clothing before reuse.

FIRST AID	
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time, seven days a week. During other times, call the poison control center at 1-800-222-1222.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. (Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.)

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), restricted-entry interval and notification to workers. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Waterproof gloves, and
- Shoes plus socks.

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

PRODUCT INFORMATION

OBRONA is a plant response-elicitor peptide based on a naturally occurring harpin protein. This product reduces the incidence and severity of plant disease by eliciting the plant's own natural defense system, referred to as systemic acquired resistance (SAR). OBRONA has no direct effect on plant disease pathogens. Early applications prior to disease infection can delay or reduce disease severity resulting in improved fungicide activity. This product is most effective when combined with fungicide programs having alternative modes of action. The plants' enhanced defense system due to the application of OBRONA adds to fungicide programs, leading to improved overall disease control.

Sites: Use OBRONA for greenhouse, shadehouse, nursery, and field production of all plants listed on this label.

Coverage: Use spray volume adequate to obtain coverage without runoff. Uniform or full leaf coverage is helpful but is not required.

Days to Harvest: This product can be applied up to the day of harvest.

RESISTANCE MANAGEMENT RECOMMENDATIONS

For resistance management, this product contains a Group BM 02 fungicide/bactericide. Any fungal/bacterial population may contain individuals naturally resistant to OBRONA and other Group BM 02 fungicides/bactericides. A gradual or total loss of pest control may occur over time if these fungicides/bactericides are used repeatedly in the same fields. Appropriate resistance-management strategies should be followed.

To delay fungicide resistance, take one or more of the following steps:

- Rotate the use of this product or other Group BM 02 fungicides/bactericides within a growing season sequence with different groups that control the same pathogens.
- Use tank mixtures with fungicides/bactericides from a different group that are equally effective on the target pest when such use is permitted. Use at least the minimum application rate as labeled by the manufacturer.
- Adopt an integrated disease management program for fungicide/bactericide use that includes scouting, uses historical information related to pesticide use, and crop rotation, and which considers host plant resistance, impact of environmental conditions on disease development, disease thresholds, as well as cultural, biological and other chemical control practices.
- Where possible, make use of predictive disease models to effectively time fungicide/bactericide applications. Note that using predictive models alone is not sufficient to manage resistance.
- Monitor treated fungal/bacterial populations for resistance development.
- Contact your local extension specialist or certified crop advisor for any additional pesticide resistance-management and/or IPM recommendations for specific crops and pathogens.
- For further information or to report suspected resistance contact Wilbur-Ellis Company LLC at (720) 306-6340. You can also contact your pesticide distributor or university extension specialist to report resistance.

USE PRECAUTIONS

Use Promptly: Use product on the same day it is mixed with water and use opened packages within 3 weeks. Carefully reseal opened packages to minimize exposure to air and moisture.

TANK MIXING

Use in Mixtures: OBRONA is believed to be compatible with most other labeled pesticides, such as post-emergence herbicides, insecticides, acaricides, and fungicides, as well as most foliar nutritional products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry flowables first, then flowables, and then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding products to the spray tank. If OBRONA cannot be put in the tank first, before adding it to the tank, slurry the product in a small amount of clean water and add the slurry to the tank. Do not mix this product with any other product containing a label prohibition against such mixing. When tank mixing this product with any other approved pesticide, always read and follow all use directions, restrictions, and precautions of both OBRONA and the tank mix partner(s). The resulting tank mix must be used in accordance with the most restrictive label limitations and precautions. Do not exceed label dosage rates.

Glyphosate Herbicides: When tank mixing OBRONA with glyphosate for application on crops designated Roundup Ready®, only use formulations of glyphosate herbicide that are fully labeled for use on Roundup Ready® crops. Never spray this mixture on crops that are not designated Roundup Ready® as severe injury or death of the crop can occur. Some glyphosate formulations allow for the addition of surfactants. Please refer to the surfactant recommendations from the manufacturer.

Precautions: Do not use this product in tank mixes or water below pH 5 or above pH 10. Do not mix this product with pyrophosphates, phosphoric acid, or other strong oxidizers.

Surfactants: Use only non-ionic adjuvants approved for use on growing crops.

DILUTION WATER QUALITY: If dilution water is high in total mineral content, salinity, suspended solids and/or exhibits any other factors that reduce the solubility of this product, then first dissolve OBRONA in an appropriate volume of "clean water" such as municipal tap water. Pour the dissolved OBRONA solution into the dilution water for the spray (see step 1 of "Mixing Instructions").

DILUTION WATER QUANTITY: If 1 ounce of OBRONA is diluted in more than 35 gallons of chlorinated water (e.g., municipal water), add a labeled water treatment product such as sodium sulfite, sodium bisulfite, or sodium metabisulfite to remove excess chlorine before adding this product. Consult your Wilbur-Ellis Company representative if you need further directions on water treatment.

RAIN: Do not apply during rain. Reapplication is not necessary if the spray has dried before rain begins.

STRESSED PLANTS: Plants must be actively growing at the time of foliar applications. Applications made to plants that are stressed by extreme heat, cold, moisture, or nutrient deficiency can be less effective.

SPRAY DRIFT: Avoiding spray drift at the application site is the responsibility of the applicator. The interactions of many equipment- and weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering these factors when making decisions.

MIXING INSTRUCTIONS

Step 1. Fill at least one-half of the mix tank with clean water. Provide gentle agitation.

Step 2. If 1 ounce of OBRONA is diluted in more than 35 gallons of chlorinated water, add a labeled dechlorination water treatment product (such as sodium sulfite, sodium bisulfite, or sodium metabisulfite) and continue gentle agitation (see Use Precautions on "Dilution Water Quantity").

Step 3. If dilution water quality is suspect, dissolve OBRONA in clean water before adding to the mix tank (see Use Precautions on "Dilution Water Quality"). Add the required amount of this product. Agitate until dissolved and avoid excessive foaming.

Step 4. If tank mixing, add other materials to the mix tank. Add remaining water to mix tank.

Step 5. Continue gentle agitation and apply promptly.

APPLICATION INSTRUCTIONS

Apply OBRONA as a pre-transplant foliar dip, root dip, or as a foliar application.

Pre-Plant Dip: Apply this product as a pre-plant foliar dip or root dip to vegetable crops (e.g., cucurbit and cole vegetables), ornamentals, tobacco, and small fruit crops at the rate of 1-3 oz per 100 gallons of water immediately prior to transplanting. Wash transplants to remove excess soil prior to dipping. Completely immerse planting stock in solution. Dip, soak, or expose plants for a minimum of 2 to 5 minutes. DO NOT reuse dip solution. Dispose of dip solution according to local restrictions. Plant treated plants as quickly as possible. For continued crop management, follow with foliar applications of this product as specified in the tables that follow.

Foliar Application: Apply this product as a greenhouse or field application using conventional ground or aerial equipment. Use this product as part of an integrated pest management (IPM) program to assist disease management.

Application via Sprinkler or Drip (Trickle) Chemigation Systems: Apply this product only through sprinkler (including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move) and drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system. Crop injury and lack of effectiveness can result from non-uniform distribution of treated water. If you have questions about your system's calibration, you should contact State Extension Service

Specialists, equipment manufacturers or other experts. Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Sprinkler Chemigation System Requirements: The system must contain a functional check valve, vacuum relief valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back-flow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. Do not apply when wind speed favors drift beyond the area intended for treatment. Apply product continuously for the duration of the water application.

Drip (Trickle) Chemigation System Requirements: The system must contain a functional check valve, vacuum relief valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back-flow. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops. The irrigation line or water pump must include a functional pressure switch that will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock. Apply product continuously for the duration of the water application.

CROPS AND APPLICATION RATES

Use the following tables to make decisions on application rates and timing. Follow applicable specifications for your crop.

BERRIES AND SMALL FRUIT			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
BERRIES AND SMALL FRUIT All Types	1-3	10-200 by ground 2-50 by air	Begin applications when plants are established or 14 days after full leaf emergence. Repeat at 21- to 28-day intervals as needed. For fall-transplanted strawberries, resume applications in spring.

FIELD CROPS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
CEREAL GRAINS All crops	0.5-3	5-200 by ground 2-50 by air	Winter Wheat: Apply beginning at new growth and at flag leaf. Spring Wheat: Apply at 3-5 leaf and flag leaf.
CORN (Grain, Silage, Seed or Pop)			Apply at V-3 to V-6 stage and / or V-T stage.
COTTON			Apply at first true leaf, first bloom, and 21 days after first bloom to boost overall growth and production. For suppression of pests, begin applications prior to infestation and repeat at 21-day intervals.
FORAGE CROPS (Grass, Hay, Nongrass)			Apply at 21- to 28-day intervals, beginning after new growth commences and at cutting. For newly seeded crops, begin at first true leaf.
OILSEED CROPS All crops (i.e. Canola, Sunflower)			For canola, apply at bolting and 20% flower. For sunflower, apply the first application between stage V-6 to V-8 and repeat when the terminal bud forms (R1 stage).
SOYBEAN			Begin applications at first bloom followed by a second application 21 to 28 days after the first application.
SUGAR BEETS			Apply the first application prior to disease infection, then repeat applications in combination with the normal fungicide program.
SUGARCANE			Apply after new growth commences. Repeat at 28- to 35-day intervals as needed.

GRASSES GROWN FOR SEED			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
FORAGE GRASSES **TURF GRASSES**	0.5-3	10-200 by ground 2-50 by air	Apply at 21-day intervals, beginning 14 days after full emergence.

SPECIALTY CROPS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
ALOE **BANANA** **COFFEE** **FIGS** **HERBS** (All Types) **MANGO** **MINT** Peppermint Spearmint **PAPAYA** **PINEAPPLE**	1-3	10-200 by ground 2-50 by air	Apply at 21- to 28-day intervals, beginning 7 days after new growth/new spring growth is initiated.

TREES AND VINES			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
AVOCADO	1-3	10-200 by ground 2-50 by air	Apply at 21- to 35-day intervals, beginning before bloom initiation.
CITRUS			For tree establishment: Apply on 21-day schedule during active growth. For fruit set and sizing: Apply at First Flush, Petal Fall and 30 days later or with 1st Summer Oil application. For retention and color: Apply at 30 and 15 days before harvest.
POME FRUIT Apple Pear			Apply at pink bud, petal fall, 30 and 7 days prior to harvest.
STONE FRUIT			Apply 2 pre-bloom sprays, once at new growth and again 7-10 days later. Follow with post-bloom sprays at 21-day intervals.
TREE NUTS Almonds Walnuts			Almonds: Apply at pink bud, early leaf out, after pit hardening, hull split and post-harvest. Walnuts: Apply at leaf out, after flowering, at shell and kernel development (approx. 30-45 days after flowering), 21-28 days after kernel development and post-harvest.
TREES Broadleaf Conifer			Apply after complete emergence.
VINE CROPS Grapes (Juice, Raisin, Table, Wine) Hops Kiwifruit			Grapes: Apply at pre-bloom, post bloom, berry touch and veraison. Under moderate to heavy disease pressure, optimal results can be obtained by alternating or tank mixing with other products. Hops: Apply at 21- to 28-day intervals, beginning when new shoot growth is present.

TOBACCO			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
TOBACCO All Types	0.5-3	10-200 by ground 2-50 by air	Apply at 14-day intervals, beginning 7 days after transplanting through harvest.

VEGETABLE AND OTHER CROPS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
PERENNIAL VEGETABLES Asparagus Globe Artichoke	1-3	10-200 by ground 2-50 by air	Apply as a foliar spray at 21- to 28-day intervals, beginning at new growth.
POTATO			Apply at tuber initiation. Repeat applications as needed every 21-28 days.
POTATO Seed production			Apply at first hook and repeat applications as needed every 21-28 days.
OTHER ROOT AND TUBER VEGETABLES All crops			Apply at 21- to 28-day intervals, beginning at new growth.
OTHER VEGETABLES (Bulb, Cole, Cucurbit, Fruiting, Leafy, Legume) All crops			Begin applications at first new growth and repeat at 21- to 28-day intervals.
SWEET CORN (Fresh or Seed)	0.5-3		Apply at V-3 to V-6 stage and / or V-T stage.

TURF AND ORNAMENTALS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
ORNAMENTALS	1-3	10-200 by ground 2-50 by air	Apply at 14- to 21-day intervals, beginning 7 days after transplant and/or potting/repotting or once plants have initiated bud/leaf or fully leafed out. For roses, begin applications 7 days after grafted cuttings are planted and continuing at 14- to 21-day intervals.
TURF GRASSES All Types Golf Courses Sod Farms	0.5-3		Begin applications when plants are established or 14 days after full emergence. Repeat at 28- to 35-day intervals.

GREENHOUSE AND TRANSPLANT APPLICATIONS		
USE SITE & CROP	**RATE**	**TIMING**
Greenhouse Any Crop Listed Elsewhere on This Label	1-3 oz per 100 gal water	Apply overhead applications after seedling emergence. Repeat every 14-21 days.
Transplant Any Crop Listed Elsewhere on This Label		Apply 5-7 days before transplanting. Can also be applied as a plant drench at transplanting.

PRE-HARVEST APPLICATIONS FOR POST-HARVEST BENEFITS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
Any Crop Listed Elsewhere on This Label	1-3	20-200 by ground 2-50 by air	Apply 1-14 days before harvest. If no previous applications of OBRONA have been made, use higher rates.

FOLIAR NUTRIENT APPLICATIONS			
CROP	**RATE** (Oz/Acre)	**DILUTION** (Gal/Acre)	**TIMING**
Any Crop Listed Elsewhere on This Label	1-3	5-200 by ground 2-50 by air	Apply with foliar fertilizer applications at a rate of 1 oz OBRONA per 5 lb foliar fertilizer.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Keep product away from exposure to air, sunlight, moisture, or heat. Do not store in temperatures over 110°F for more than 7 days. Use product within 3 weeks of opening and the same day as mixing.

Pesticide Disposal: Wastes resulting from use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Conditions of Sale and Limitation of Warranty and Liability:

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using the product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

ALL STATEMENTS MADE HEREIN ARE SUBJECT TO APPLICABLE LAW, AND TO THE EXTENT THERE IS ANY INCONSISTENCY OR CONTENTION, APPLICABLE LAW SHALL GOVERN.

The Directions for Use of the product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of many different factors including, without limitation, manner of use or application, weather, combination with other products, or crop conditions. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Manufacturer and Seller harmless from any claims relating to such factors.

Seller warrants that this product conforms to the chemical description on the label. EXCEPT FOR THIS WARRANTY, THE PRODUCT IS FURNISHED "AS-IS", AND NEITHER SELLER NOR MANUFACTURER MAKES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE SELECTION, PURCHASE OR USE OF THIS PRODUCT; SELLER AND MANUFACTURER SPECIFICALLY DISCLAIM ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE BEYOND WHAT IS STATED ON THE LABEL. Buyer and User accept all risks arising from any use of this product, including without limitation, uses contrary to label instructions, or under conditions not reasonably foreseeable to (or beyond the control of) Seller or Manufacturer.

Neither Manufacturer nor Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE BUYER OR USER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER, FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THIS PRODUCT, OR, AT THE ELECTION OF MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

These Conditions of Sale and Limitation of Warranty and Liability shall be interpreted, unless otherwise required by the law of the state of purchase, in accordance with the laws of the State of California, excluding its conflicts of laws rules, and may not be amended by any oral or written agreement.

PHC: 20230406
2024-0227

WILBUR-ELLIS.

Manufactured for:
WILBUR-ELLIS COMPANY LLC
2903 S. Cedar Ave., Fresno, CA 93725 • (559) 442-1220

GROUP **BM 02** FUNGICIDE

FUNGICIDE

OBRONA™

ACTIVE INGREDIENT:

PDHP 25279	1.0%
OTHER INGREDIENTS:	99.0%
Total:	100.0%

EPA Reg. No. 71771-14-2935

EPA Est. No. 88746-GA-1

KEEP OUT OF REACH OF CHILDREN

CAUTION / PRECAUCIÓN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Read the entire label before using this product. Read Conditions of Sale and Limitation of Warranty and Liability before buying or using. If terms are not acceptable, return at once unopened.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Avoid breathing dust or spray mist. Remove and wash contaminated clothing before reuse.

FIRST AID

If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment information, call the National Pesticide Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time, seven days a week. During other times, call the poison control center at 1-800-222-1222.

ENVIRONMENTAL HAZARDS

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Keep product away from exposure to air, sunlight, moisture, or heat. Do not store in temperatures over 110°F for more than 7 days. Use product within 3 weeks of opening and the same day as mixing.

Pesticide Disposal: Wastes resulting from use of this product must be disposed of on site or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

See attached booklet for Directions for Use.

WILBUR-ELLIS.

Manufactured for:
WILBUR-ELLIS COMPANY LLC
2903 S. Cedar Ave., Fresno, CA 93725 • (559) 442-1220
2024-0227

NET WEIGHT: 5 lb