Registration Decision for the New Active Ingredient

Potassium Carbonate

A fungicide for use on food, turf, ornamentals, and in greenhouses

PC Code: 073504

Approved by:

LEO GUERIGUIAN

Digitally signed by LEO GUERIGUIAN
Date: 2024.08.22 19:44:22 -04'00'

for Ed Messina, Esq.
Director, Office of Pesticide Programs
Office of Chemical Safety & Pollution Prevention
U.S. Environmental Protection Agency

Table of Contents

1. Introduction

This document announces that the Environmental Protection Agency (EPA) has completed its initial evaluation of the new biochemical active ingredient (AI), potassium carbonate, for use as a fungicide and has concluded that it meets the regulatory and safety standards under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). EPA's assessment of potassium carbonate was also considered relative to a public participation process, which allowed for a 15-day comment period.

Potassium carbonate is a white, odorless solid that is classified as an inorganic salt. It is, used as a food additive for pastas and breads, a pH adjustor for chocolate production, a buffering agent for making wine, and a food additive for chicken feed. The Joint Food and Agriculture Organization of the United Nations (FAO)/ World Health Organization (WHO) Expert Committee on Food Additives has determined that potassium carbonate has no limited terms for daily intake when used as a food additive (JFAO/WHO, 1966). Additionally, potassium carbonate has been granted "Generally Recognized as Safe" (GRAS) status for use as a food additive by the United States Food and Drug Administration (FDA).

Humans have been regularly exposed to potassium carbonate in the environment without known incident. This naturally occurring inorganic salt is a primary constituent of potash, which has been used as a primary ingredient in ceramics, soaps, and fertilizers since the Bronze Age. Currently, humans are also regularly exposed to potassium carbonate in cosmetics and foods without known toxic effects. With regard to exposure, sustained exposures are unlikely in the environment, as this inorganic salt is extremely soluble, readily dissociating into innocuous substances in the environment. Given humans' regular exposures to potassium carbonate without incident, its high solubility, and its overall low toxicological profile, no significant risks are expected relative to any potential pesticidal uses.

As a pesticidal active ingredient, the active ingredient potassium carbonate, is intended for use as a broad-spectrum fungicide. With specific regard to the mode of action, it is posited that potassium carbonate causes a pH shift and disrupts osmosis in fungi, effectively inhibiting its growth. The end-use product (EP), NSTKI-014 (EPA File Symbol# 94218-E), is intended for use on food, turf and ornamentals in both agricultural and residential settings. The EP is a wettable powder that is diluted in water and applied as a foliar spray every 5-10 days, effective control depending. The EP is mixed at a rate of 2-7 pounds (lbs.) product in 100 gallons (gal.) of water to obtain a solution with a pH of 7-10. Based on the label, application rates should be between 50-75 pounds of active ingredient per acre. The restricted-entry interval (REI) is 4 hours from the time of application. All occupational applicators and handlers are required to wear the following baseline attire: long-sleeved shirts, long pants, shoes and socks, as well as personal protective equipment (PPE) including chemical-resistant gloves and protective eyewear.

After reviewing the submitted and publicly available data and information for potassium carbonate, EPA has concluded that there is a reasonable certainty of no harm from residues of this new active ingredient and that its use will not cause unreasonable adverse effects to human health or the environment. Therefore, the Agency is granting the unconditional registration of

two products, one manufacturing-use product (MP), Potassium Carbonate (99.5% Fine Powder) (EPA File Symbol: 94218-G), and one EP, NSTKI-014 (EPA File Symbol# 94218-E), containing the new active ingredient, potassium carbonate, under FIFRA section 3(c)(5). Moreover, the Agency published a final rule under 40 CFR 180, establishing a tolerance exemption for residues of potassium carbonate in or on all food commodities when used as a fungicide in accordance with label directions and good agricultural practices.

2. Background

On June 9, 2020, EPA received applications from Biofungitek, S.L. for the registration of two pesticide products, one manufacturing product (MP) and one end-use products (EP), containing the new biochemical active ingredient potassium carbonate and a petition [0F8851] to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for residues of potassium carbonate when used on agricultural crops in accordance with label directions and good agricultural practices. To support the FIFRA section 3 registration applications, Biofungitek, S.L. provided a combination of guideline studies, data waiver requests, and scientific rationales supported by information from the open scientific literature to address product chemistry, human health, and ecological toxicity data requirements.

In the Federal Register of May 28, 2021, EPA published a Notice of Receipt (NOR) that announced receipt of two new product applications: one MP and one EP, containing the new active ingredient, potassium carbonate. In the Federal Register of June 1, 2021, EPA published a Notice of Filing (NOF) that announced a request to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of potassium carbonate in and on all agricultural food commodities when used in accordance with label directions and good agricultural practices.

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 pesticide product. Risk assessments are developed to evaluate how the active ingredient might affect a range of non-target 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's label helps to communicate essential limitations and/or mitigations that are necessary for public and environmental safety. In fact, it is a violation of FIFRA to use a registered pesticide in a manner inconsistent with the label.

3.1 Assessment of Risk to Human Health

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 direct or indirect human exposure to that substance as a consequence of

use. EPA uses this 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 the toxicity of 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, 90-day dermal, and 90-day inhalation); mutagenicity testing (bacterial reverse mutation test and in vitro mammalian cell assay); and developmental toxicity testing (prenatal development). Tiers II and III testing requirements are 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 Toxicological Data/Information

Adequate mammalian toxicology data/information are available to support a food-use registration of potassium carbonate on all food commodities. All toxicology data requirements for potassium carbonate have been satisfied and an updated dietary risk assessment is available in the regulatory docket (search for "EPA-HQ-OPP-2021-0232" at http://www.regulations.gov).

The toxicology database used for the biopesticide risk assessment for potassium carbonate includes: 1) acute toxicity guideline studies and rationales for acute primary dermal irritation and acute primary eye irritation, 2) rationales for the 90-day dermal toxicity and 90-day inhalation toxicity, 3) data from the open scientific literature was submitted for 90-day oral toxicity, prenatal developmental toxicity, *in vitro* mammalian cell assay, bacterial reverse mutation test toxicity, and *in vivo* cytogenetics data requirements, and 4) a non-guideline 21-day inhalation toxicity study. The rationales for the 90-day dermal and 90-day inhalation requirements were accepted by OPP's Hazard and Science Policy Council (HASPOC) on December 14, 2022 (U.S. EPA, 2022). After consideration of the database, the Agency conducted a qualitative risk assessment for potassium carbonate based on the facts that no toxicity data for this active ingredient were identified in a search of the scientific literature and that no endpoints were indicated in the available toxicological data. Based on the available information from the database, EPA has determined that exposure to potassium carbonate from use as a pesticide is expected to result in negligible risk to humans. The toxicology data requirements and the toxicological profile for potassium carbonate are discussed in the following sections.

Acute Toxicity

All acute toxicity data requirements for potassium carbonate were satisfied by either guideline studies or waiver rationales. The guideline studies submitted for potassium carbonate resulted in the active ingredient being classified as Toxicity Category IV for acute dermal and inhalation toxicity, and Toxicity Category III for acute oral toxicity. The data requirements for primary eye and dermal irritation were satisfied by rationale. The applicant observed that because potassium chloride as an inorganic salt has high pH, it is both is severely irritating and corrosive. In recognition of these physical-chemical characteristics, the applicant ascribed Toxicity Category I

for both primary eye and primary dermal irritation. Lastly, available data indicate that potassium carbonate is not a skin sensitizer. As a result of the pH, the signal word "Danger" will be used on the product (MP) label containing the active ingredient potassium carbonate.

Subchronic Toxicity (90-day oral toxicity, 90-day dermal toxicity and 90-day inhalation toxicity)

Waiver rationales were submitted for the 90-day dermal toxicity and 90-day inhalation toxicity. The rationales were reviewed by OPP's HASPOC using a weight of the evidence (WOE) approach that considered all of the available hazard and exposure information; both rationales were accepted by HASPOC on December 14, 2022 (U.S. EPA, 2022). The subchronic oral toxicity data requirement was satisfied by a non-guideline subchronic oral toxicity repeat-dose oral 90-day dietary study using a surrogate salt, potassium bicarbonate, in rats. Information submitted in the rationales demonstrated that potassium bicarbonate was an acceptable surrogate for potassium carbonate as both salts were shown to be functionally and structurally similar.

90-day oral toxicity

The Agency accepted a non-guideline 90-day oral toxicity on potassium bicarbonate, which was considered to be sufficiently similar to potasssium carbonate to satisfy this data requirement. In this study, rats were dosed at 1480 and 3130 mg/kg/day (males), and 1660 and 3530 mg/kg/day (females) in the diet. The feeding study resulted in a no observed adverse effect level (NOAEL) of 1480 mg/kg/day in males and 1660 mg/kg/day in female rats. The dose levels tested were well above the limit dose of 1000 mg/kg/day. There were no treatment-related adverse effects on mortality, clinical signs, functional observational battery (FOB), body weight, body weight gain, food consumption, ophthalmoscopy, macroscopic findings, testosterone, follicle stimulating hormone, luteinizing hormone levels, organ weights, or histopathology.

*90-day dermal toxicit*y

A waiver rationale to fulfill the 90-day dermal toxicity data requirement was accepted by the HASPOC using a WOE approach that considered all of the available hazard and exposure information. The rationale is based on the following considerations: (1) potassium carbonate has been assigned Toxicity Category III for acute dermal toxicity and is not a dermal sensitizer; (2) there were no adverse effects observed in the available repeat oral dose toxicity study with similar salts including potassium bicarbonate; (3) humans have a history of exposure to potassium carbonate and similar carbonate salts without adverse reactions seen in cosmetics and foods approved for use by the FDA; (4) the physical chemical properties of potassium carbonate such as high pH, high solubility in water, a low partition coefficient and low vapor pressure indicate a low probability for dermal penetration; (5) the carbonates and bicarbonates are recognized as GRAS by the FDA (21 CFR 184.1619) for use as flavoring agents; (6) potassium carbonate is approved for inert ingredient (buffering agent) use in pesticide products and has an exemption from the requirement of a tolerance (40 CFR 180.920) when applied to growing crops; (7) human health risk from occupational dermal exposure to the pesticide product is expected to be comparatively minimal, as the maximum concentration reported in cosmetics is 93.4% (in rinse-off products), which already exceeds the product formulation concentration (58.04%) of the

EP prior to being further diluted into a spray solution; and (8) using a conservative dermal absorption estimate of 10% and an oral point of departure (POD) of 180 mg/kg/day, any potential exposure would be far below the limit dose of 1000 mg/kg/day.

90-day inhalation toxicity

A waiver rationale to fulfill the 90-day inhalation toxicity data requirement was accepted by the HASPOC using a WOE approach that considered all of the available hazard and exposure information. The rationale is based on the following considerations: (1) the physical-chemical properties of potassium carbonate show negligible vapor pressure because it is a solid powder that dissociates into K^+ and CO_3^{2-} ions when mixed with water; (2) the toxic effects of potassium carbonate are low based on the acute inhalation toxicity study (Toxicity Category IV); (3) during a non-guideline 21-day inhalation study for a potassium carbonate-based scrubbing solution, male and female rats dosed at 0.1, 0.2, and 0.4 mg/L showed no adverse systemic or neurotoxic effects; (4) no adverse effects or evidence of irritation were identified in the publicly available repeat-dose oral toxicity or developmental toxicity studies; and (5) although a qualitative risk assessment approach was taken, relevant margins of exposure (MOEs) were calculated from an oral POD of 180 mg/kg/day to represent worst-case scenarios. The occupational and residential handler MOEs ranged from 13,000 to 90,000,000 which are above 10X the Agency's Level of Concern (LOC) of 100.

Developmental Toxicity

In four publicly available non-guideline prenatal developmental toxicity studies for potassium carbonate and other related carbonates, no adverse effects on maternal or developmental parameters up to the highest doses tested were reported in rats and mice. One developmental study administered potassium carbonate via oral gavage at 290 mg/kg/day to mice and at 180 mg/kg/day to rats. No discernible effects were observed on implantation, maternal or fetal survival; and no abnormalities were observed in soft or skeletal tissues. Another study using an accepted surrogate, potassium bicarbonate, was conducted on pregnant animals up to 330 mg/kg/day in rabbits, 340 mg/kg/day in rats, and 580 mg/kg/day in mice. No adverse effects were observed for any animals. In a third study, sodium carbonate, a carbonate which is significantly similar to potassium carbonate, was administered via oral gavage at dose levels up to 179 mg/kg/day in mice, 245 mg/kg/day in rats, and 340 mg/kg/day in rabbits with no adverse effects observed. In a fourth study, calcium carbonate, another carbonate which is significantly similar to potassium carbonate, was administered to rats up to 2188 mg/kg/day in the diet showed no evidence of maternal toxicity or embryotoxic/teratogenic effects.

Genotoxicity

Genotoxicity studies from the open scientific literature on potassium carbonate and similar carbonate/bicarbonate salts indicated that potassium carbonate and related carbonates were not genotoxic. In a non-guideline Ames test, potassium carbonate tested negative and did not induce mutations in the *Salmonella typhimurium* strains TA92, TA1535, TA1000, TA 1537, TA94, and TA98 in the presence or absence of metabolic activation. In the same non-guideline report,

potassium carbonate did not induce chromosome aberrations in a mammalian cell line (Chinese hamster fibroblasts) in the presence and absence of S9 metabolic activation. In another study, potassium bicarbonate and sodium bicarbonate, two carbonates considered similar to potassium carbonate, both tested negative and did not induce mutations in the *S. typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA100 in the presence or absence of metabolic activation. An *in vitro* gene mutation guideline study in bacteria, showed calcium carbonate, another carbonate considered to be similar to potassium carbonate, was determined to be non-mutagenic to the S. *typhimurium* strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* WP2 uvrA with and without metabolic activation. Calcium carbonate did not induce chromosome aberrations in a mammalian cell line (L5178Y) in the presence or absence of S9 metabolic activation.

Lastly, a guideline bacterial reverse mutation assay (OCSPP 870.5100) was submitted using potassium carbonate. In the guideline Ames test, potassium carbonate did not induce mutations in the *S. typhimurium* strains TA98, TA100, TA1535, TA 1537, and *Escherichia coli* WP2 uvrA in the presence or absence of metabolic activation.

3.1.2 Dietary and Occupational Exposure and Risks

Dietary and Drinking Water Exposure and Risk Characterization

Dietary risk assessment incorporates both exposure (food and drinking water) and toxicity of a given pesticide. In the case of potassium carbonate, the Agency has conducted a qualitative dietary risk assessment in lieu of a quantitative assessment. Dietary risk is expected to be negligible, as significant residues of the substance are not anticipated on treated commodities at the time of consumption based on its physical and chemical properties. Foremost, potassium carbonate, an inorganic salt, is highly water soluble and is expected to dissociate into potassium and carbonate ions soon after any pesticidal application. Notably, potassium and carbonate ions naturally occur and are already ubiquitous in the environment; and no significant increase in exposure to potassium and carbonate ions are expected relative to the use of the EP. Equally important, the human body has natural regulation mechanisms for potassium and carbonate ions that enter the body. The kidneys regulate the concentration of these ions; and excess ions are filtered out and excreted through urine. With regard to any potential oral toxicity, potassium carbonate showed low acute oral toxicity and no major adverse effects in the available subchronic oral toxicity database. Based on the physicochemical properties and toxicological profile of the active ingredient potassium carbonate, no dietary risks of concern are anticipated.

Residential (Non-occupational) Exposure and Risk Characterization

Potassium carbonate is intended for use in residential (non-occupational) settings. However, significant residential exposure is not expected because potassium carbonate is an inorganic ionic salt that does not easily volatilize and readily dissociates into potassium and carbonate ions in water. Both potassium and carbonate ions are ubiquitous in the environment, so there is no significant increase in exposure to potassium carbonate expected from use of the EP formulation. In addition, the ions K^+ and CO_3^{2-} resulting from the ionization (dissociation) of

K_2CO_3 will not influence the natural K^+ or CO_3^{2-} level in the body due to how the kidneys regulate the ion concentration found in the blood. Given the physicochemical properties and rapid dissociation of the ionic salt, residential handler, and post-application risk are not expected.

Occupational Exposure and Risk Characterization

Short and intermediate-term dermal and inhalation exposures to potassium carbonate are expected for occupational handlers from application of the EP. There is also potential for post-application exposure for agricultural workers re-entering treated areas. However, no significant exposures are anticipated as the EP contains labeling mitigation to make any occupational exposures unlikely such as: (1) occupational handlers are required to wear the following personal protective equipment (PPE): long-sleeved shirts, long pants, shoes, and socks, chemical resistant gloves, and protective eyewear; (2) the spray equipment designated in the EP - groundboom and shielded tank sprayers - will result in directed applications, which are expected to preclude many of the exposures that result from more undirected broadcast applications; (3) there is a 4-hour restricted entry interval (REI) for occupational workers; (4) potassium carbonate does not easily volatilize because of its physicochemical properties, so significant inhalation exposure is not expected; (5) due to the low partition coefficient value and low vapor pressure associated with potassium carbonate, significant dermal absorption is unlikely; and (6) due to the high solubility of potassium carbonate, this inorganic salt will readily dissociate after application. Therefore, based on the physicochemical properties of potassium carbonate and the labeling mitigation, no significant occupational exposures or risks of concern are expected for the pesticidal uses of potassium carbonate.

3.1.3 Cumulative Risk

EPA has not made a common mechanism of toxicity finding for potassium carbonate and any other substances, and this biopesticide does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that potassium carbonate has a common mechanism of toxicity with other substances.

3.1.4 Human Health Conclusions

EPA concludes that the use of potassium carbonate will not result in unreasonable adverse effects to human health and that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of potassium carbonate. EPA does not expect dietary (food and drinking water) or other non-occupational risks of concern from the use of potassium carbonate as an active ingredient in pesticide products for food use. Data demonstrate that potassium carbonate is of low toxicity for oral, dermal and inhalation routes of exposure, and that no significant exposures are anticipated when the product is used in accordance with label directions. Of additional note, no endpoints have been established for potassium carbonate; and it is readily metabolized by humans.

The database of studies required to support the hazard assessment to human health is complete. For more information on the human health hazard assessment of potassium carbonate, see the

supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0232" at http://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 non-target organisms: mammalian (acute, sub-chronic, 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.

The database of studies required to support the hazard assessment to the environment is complete for potassium carbonate. All data requirements for avian, mammalian, aquatic taxa, terrestrial plants, and nontarget insects were satisfied with acceptable studies or waiver rationales. Based on the submitted acute oral toxicity study with rats, the EP is practically non-toxic to wild mammals. Phytotoxicity was observed in the seedling emergence study conducted with the EP, whereas no effects were observed in any species tested in a vegetative vigor study conducted with the same EP. The waiver rationales for avian acute oral toxicity and avian oral toxicity, which relied on the same information, were determined to be acceptable. In short, the rationales noted that potassium carbonate is involved in many avian physiological processes; and as a result, potassium carbonate is a regular additive for bird feed. It is additionally noted that the amount of potassium carbonate added to bird feed is often significantly greater than the amount available in any residues of potassium carbonate. The aquatic invertebrate toxicity study and the nontarget insect toxicity (honeybees) studies indicate practical nontoxicity. The freshwater fish toxicity study indicated that potassium carbonate was only slightly toxic to fish.

For more information on the environmental hazard assessment of potassium carbonate, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0232" at http://www.regulations.gov).

3.2.1 Terrestrial Animals and Plants

Terrestrial Vertebrates

Terrestrial vertebrates (including birds, mammals, amphibians, and reptiles) may be exposed to

potassium carbonate as a result of the intended applications; however, the submitted data indicate that no significant effects are anticipated for nontarget birds or mammals.

With regard to birds, similar waiver rationales for acute avian oral toxicity and acute avian dietary toxicity were submitted for potassium carbonate. The rationales demonstrate that dietary potassium, which is often sourced from potassium carbonate for incorporation into avian dietary formulations, is involved in many physiological processes, including maintenance of water balance, maintenance of osmotic pressure, maintenance of acid base balances, activation of enzymes, metabolism of carbohydrate and proteins, regulation of neuromuscular activity, and regulation of heartbeat. Due to its beneficial properties, potassium carbonate is sometimes incorporated into avian feed to provide additional potassium in a form that can also be used to combat the effects of heat stress. The rationales further discussed several potassium carbonate nutritional dietary studies with broiler chickens, Japanese quails, and turkeys. The studies, which ranged in length from 42 to 84 days, demonstrated that potassium carbonate was well tolerated and did not cause mortality in birds at doses ranging from 2,119 mg/kg to 2,955 mg/kg body weight per day. Finally, the rationales demonstrated that increase in potassium carbonate levels presented by use of EP would not significantly increase avian exposure to potassium and carbonate compared to levels that exist naturally in the environment. Potassium levels in soils frequently exceed 2%, and carbonate soil levels typically range from 0.5% to 15.3%. Applications of the EP are estimated to contribute only 3.43×10^{-4} % potassium and 2.64×10^{-4} % carbonate, many magnitudes of order below what might be expected through natural occurrence.

With regard to the potential toxicity of potassium carbonate to mammals, studies conducted for acute oral toxicity and subchronic oral toxicity on rats indicate that potassium carbonate is practically nontoxic to mammals. One, an acute oral toxicity test conducted with rats determined the acute oral LD50 of the EP to be 3129 mg/kg of body weight, indicating that potassium carbonate is virtually nontoxic relative to the oral route of exposure for mammals (MRID 50898904). Two, the subchronic oral toxicity data using an accepted surrogate salt, potassium bicarbonate demonstrated a no observed adverse effect level (NOAEL) of 1480 mg/kg/day in males and 1660 mg/kg/day in female rats, indicating that potassium carbonate is practically nontoxic relative to subchronic oral exposures.

Nontarget Terrestrial Invertebrates

The nontarget insect data requirement was satisfied with an acceptable honeybee acute contact toxicity study for potassium carbonate. Potassium carbonate is considered practically nontoxic to insects, and no significant exposures for nontarget insects are expected. A guideline study on honeybee acute toxicity demonstrated that potassium carbonate was practically nontoxic to insects. A 48-hour contact toxicity study, honeybees (*Apis mellifera*) exposed to potassium carbonate an LD_{50} value for potassium carbonate was determined to be > 100 µg AI/bee. The no observed adverse concentration (NOAEC) value, based on mortality, was 100 µg a.i./bee.

Nontarget Plants

The nontarget plant data requirements were satisfied through the submission of acceptable

guideline seedling emergence and vegetative vigor studies that indicate that potassium carbonate is largely nontoxic to plants. For all plant species except for lettuce and tomatoes, measured endpoints were not significantly different from negative controls and no compound-related phytotoxic effects were reported after 21 days. Lettuce had NOAEC values of 0.44 lb EP/acre for shoot height and dry weight and 3.5 lb EP/acre for emergence and survival. The LOAEC (Lowest Observed Adverse Effect Concentration) values for lettuce were 0.88 lb EP/acre for height and weight and 7 lb EP/acre for emergence and survival. For effects on tomato height and dry weight, the NOAEC and LOAEC values were 3.5 and 7.0 lb EP/acre, respectively. The most sensitive dicot species was lettuce with an IC_{25} value of 0.62 lb EP/acre for shoot dry weight.

In the vegetative vigor study, the effects of the EP on survival, growth, and condition of terrestrial plants were measured. Plants were treated with the test substance approximately 2-3 weeks after planting, allowing them to reach the 2- to 4-leaf stage at the time of application. For all species, there were no significant effects on plant survival, shoot height, or shoot dry weight at 21 days after treatment. The NOAEC and EC/IC_{25} values were 7 and >7 lb EP/acre, respectively, for survival, shoot height, and shoot dry weight.

3.2.2 Aquatic Organisms

Freshwater Fish, Aquatic-Phase Amphibians, Aquatic Invertebrates and Aquatic Plants

A guideline study from the scientific literature was submitted to support the acute freshwater fish toxicity data requirement. The study was a 96-hour acute toxicity test on rainbow trout exposed to varying concentrations of potassium carbonate. Based on mean measured concentrations, the 96-hr LC_{50} was 68 mg/L. The NOAEC based on mortality was 33 mg/L. No exposure-related sublethal effects were reported. The study indicates that potassium carbonate is only slightly toxic to fish.

A guideline study from the scientific literature was submitted to support the aquatic invertebrate acute toxicity data requirement. The study was a 48-hour acute toxicity test on daphnids exposed to varying concentrations of potassium carbonate. Based on mean measured concentrations, the 48-hour EC_{50} for mortality/immobilization was 430 mg/L. The 48-hour NOAEC based on mortality/immobilization was 190 mg/L. The study indicates that the potassium carbonate is practically nontoxic to aquatic invertebrates.

With regard to aquatic plants, no significant exposure is anticipated given the low estimated environmental concentration of potassium carbonate and the rapid degradation of potassium carbonate the environment. As such, no significant risks are anticipated for any aquatic plants.

3.2.3 Listed Threatened and Endangered Species Conclusions

Potassium carbonate is a new active ingredient that has a fungicidal mode of action. Based on lack of adverse effects at the low estimated environmental concentrations of potassium carbonate, direct effects are not expected for all federally listed threatened and endangered

("listed") mammals, birds, amphibians, reptiles, terrestrial invertebrates, and aquatic taxa when the EP is used in accordance with the label use directions. Based on the phytotoxic effects on lettuce and tomato in the submitted seedling emergence study conducted with the EP, impacts are possible for listed terrestrial and semi-aquatic plants via spray drift exposure. For the EP, risk to off-field plants from runoff exposure is expected to be low due to the rapid degradation of potassium carbonate in the environment.

The EPA made "no effect" (NE) determinations for 1,377 listed species and 771 designated CHs. These NE determinations were made because either a species or critical is outside of the action area (based on an overlap analysis) or because no direct effects and no effects to the species' prey, pollination, habitat, and dispersal are expected (including effects to physical or biological features of any designated critical habitat). For the remaining 465 listed species and 128 designated critical habitats, EPA made a "may affect" (MA) determination.

Although effects to listed plants from spray drift exposure are possible, EPA does not anticipate any adverse effects to nontarget plants as a result of applications of the EP due to incorporation of multiple mitigations to minimize exposure for nontarget plants. The EPA expects that most listed plant species are not present on agricultural fields or highly managed, non-agricultural use sites (such as golf courses or managed residential lawns), because agronomic/management practices make these use sites highly unlikely habitats for listed plants. Additionally, the incorporation of mitigation measures on the label minimizes off-field exposure for listed plants in the vicinity of the use sites. These mitigation measures are outlined in 'Section 7' of this document and include spray height restrictions, droplet size restrictions, and a 7-foot buffer to minimize spray drift. Additionally, the EP label includes use restrictions for Wilson County, Tennessee, to avoid on-field exposure for the listed Spring Creek bladderpod (*Lesquerella perforata*) that may be present on agricultural lands.

Based on the label mitigations, the Agency does not expect any on field or off-field risk to listed plants and is making a "may affect, not likely to adversely affect" (NLAA) determination based on discountable effects for all listed plants and their designated critical habitats within the action area. Because exposure and effects to plants are not anticipated following mitigation, effects to listed animals that depend on such plants for food or habitat are anticipated to be discountable as well. Direct effects to animals are not expected, and the EPA expects that any effects to listed animals are discountable, even if the animal species relies on plants for its food or habitat. Therefore, the EPA made NLAA determinations for the remaining 465 listed species and 128 designated critical habitats.

Pursuant to the requirements of section 7(a)(2) of the Endangered Species Act (16 U.S.C. § 1536(a)(2)) and 50 C.F.R. § 402.13, EPA initiated consultation with the U.S. Fish and Wildlife Service (FWS) on June 28, 2024.

The database of studies required to support the assessment of risk to the environment is complete at this time. For more information on the environmental risk assessment of potassium carbonate, please see the supporting documentation provided in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0232" at www.regulations.gov).

4. Benefits

Potassium carbonate is a fungicide with a low toxicity profile. It is a lower toxicity alternative to conventional fungicides such as ferbam, ziram, zineb, maneb, mancozeb captafol, captan, folpet and chlorothalonil. End-use products containing potassium carbonate can also be used in Integrated Pest Management (IPM) programs as a complement or replacement for the aforementioned conventional fungicides. Of additional note, potassium carbonate biodegrades more rapidly than most alternative conventional pesticides, potentially making it a more environmentally protective choice. Altogether, pesticides containing potassium carbonate have both environmental and human health benefits relative to many conventional fungicides, making them a valuable addition to the pesticide tool kit and an attractive alternative to conventional fungicides.

5. Public Comments

In the Federal Register of May 28, 2021 (86 FR 28830), EPA published a NOR that announced receipt of two new product applications: one MP and one EP, containing the new active ingredient, potassium carbonate. No comments were received in response to the NOR.

In the Federal Register of June 1, 2021 (86 FR 29229), EPA published a NOF that announced a request to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of potassium carbonate in and on all agricultural food commodities when used in accordance with label directions and good agricultural practices (Pesticide Petition # 0F8851). No comments were received in response to this NOF.

Because this pesticide product contains a new active ingredient, potassium carbonate, EPA opened a 15-day public comment period on August 5, 2024. 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 15-day public comment period closed on August 20, 2024; and no comments were received as part of that process.

6. Registration Decision

The potassium carbonate 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 concluded that potassium carbonate meets the regulatory standard under the FIFRA. Therefore, EPA is granting the registration of the potassium carbonate pesticide products under FIFRA section 3(c)(5).

EPA is registering one MP and one EP. The MP will be for manufacturing and formulating and contains potassium carbonate at 99.5%. The EP contains potassium carbonate at 58.04%. The EP will be applied to a variety of crops, turf, and ornamental plants as a fungicide. As part of its registration, the Agency published a final rule under 40 CFR part 180.1413 on August 5, 2024.

establishing a tolerance exemption for residues of potassium carbonate in or on all food commodities when used as a fungicide in accordance with label directions and good agricultural practices.

In the endangered species assessment portion of its review to register potassium carbonate pesticide products, EPA made a "may affect, not likely to adversely affect" (NLAA) determination for discountable effects to listed terrestrial invertebrates and to taxa that depend upon terrestrial invertebrates (e.g., for diet or pollination), including listed birds, mammals, amphibians, reptiles, insects, arachnids, and plants. Therefore, as part of the registration of the MP and EP containing potassium carbonate, EPA initiated consultation with the FWS on June 28, 2024, and we are requiring the following term on both registrations:

"If, following consultation with the United States Fish and Wildlife Service, the Service identifies additional issues or needed modifications, EPA will determine whether any changes are needed to this registration or labeling and will notify Biofungitek, S.L. in writing if any changes are necessary and whether they are required to submit an amendment application incorporating any required data or modification, including an amended label. Alternatively, Biofungitek S.L. must submit a request for voluntary cancellation of the product. If this term of registration is not met, EPA may cancel the registration under an expedited process under FIFRA 6(e)."

The risk assessments and labels supporting this decision can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0232" http://www.regulations.gov).

7. Registration Requirements

The EPA is registering the following products:

An MP: Potassium Carbonate (99.5% Fine Powder) (EPA File Symbol: 94218-G)
- 99.5% Potassium Carbonate
- The following statements and directions for use must appear on the MP label:
"ONLY FOR FORMULATION INTO FUNGICIDE PRODUCTS INTENDED FOR:
(1) AGRICULTURAL APPLICATIONS (GREENHOUSE, ORCHARD, NURSERY, AND FIELD): For Berries, Bulb Vegetables, Citrus Fruits, Cole Crops (Brassicas), Corn, Cucurbits, Edible Gourds, Fruiting Vegetables, Leafy Vegetables, Pome Fruits, Stone Fruits, Strawberry. Tree Nuts, Tropical Fruits.
(2) FOR CONTROL OF CERTAIN DISEASES IN TURF AND ORNAMENTALS.
(3) For disease control in residential products.
(4) Uses for which US EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
(5) Uses for experimental purposes that are in compliance with US EPA requirements."

An EP: NSTKI-014 (EPA File Symbol# 94218-E)
- 58.04% Potassium Carbonate
- The following statements and directions for use must appear on the EP label:

"Applicators, mixers, loaders, and other handlers must wear: Long-sleeved shirt; Long pants; Chemical-resistant gloves made of any waterproof material; Protective eyewear; Socks plus shoes"
"RESTRICTIONS
Do not make more than 10 applications (70 lbs/A) in a year.
Do not apply NSTKI-014 through any type of irrigation system.
Do not apply when wind speeds exceed 10 miles per hour at the application site.
Do not apply during temperature inversions."
"In California: Do not apply via high-pressure hand wand to more than 2.8 acres per day per applicator."
"Do not apply NSTKI-014 within Wilson County, Tennessee from September 15 to May 15. The restricted-entry interval (REI) is 4 hours from the time of application."
"BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS."
"IMPORTANCE OF DROPLET SIZE
An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions."

Required Labeling Mitigations to Minimize Off-field Exposure:
1) The height of application is to be no more than 3 feet from the target vegetation in order to minimize drift.
2) The product must be applied with nozzles that dispense medium to coarse droplet sizes (Dv0.5 of 341 µm) to minimize drift distances.
3) Applicators must maintain a 7-foot buffer strip between the point of direct application and the closest downwind edge of off-field habitats in order to minimize drift.
4) For home and garden uses label and the turf and ornamental uses, the label has the following language: "apply directly to turf, ornamental plants, and fruit or vegetable plants via handheld sprayer only."

8. Supporting Documents

The risk assessments supporting this decision and the product labels for the MP, Potassium Carbonate (99.5% Fine Powder) (EPA File Symbol: 94218-G) and the EP, NSTKI-014 (EPA File Symbol# 94218-E), can be found in the associated regulatory docket (search for "EPA-HQ-OPP-2021-0232" at http://www.regulations.gov).

9. Future Data Requirements

Should the formulation of the end-use product or the application methods described in 'Section 7' of this document change in the future, or if new products are proposed containing potassium carbonate, additional data may be required, and new risk assessments may need to be performed.