Captan
Proposed Interim Registration Review Decision
Case Number 0120

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Approved by: _____

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Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for captan (PC Code 081301, case 0120). In a registration review decision under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on captan, see EPA's public docket (EPA-HQ-OPP-2013-0296) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing a PID for captan so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) to improve the consultation process for national threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[5] The Agency has not yet fully evaluated captan's risks to federally listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the captan registration review. Before completing registration review, EPA will also complete endocrine screening for captan under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6] For more information on the listed-species assessment and the endocrine screening for the captan registration review, see Appendices C and D.

Captan was first registered as a fungicide in 1951. The Reregistration Eligibility Decision for Captan was completed in 1999 and amended in 2004. There are currently six technical

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[6] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

registrants: ADAMA and UPL (jointly the Captan Task Force (CTF) and responsible for data development), Albaugh, Drexel Chemical, Loveland, and RedEagle. ADAMA is also the technical registrant for folpet, another fungicide that is a structural analogue to captan that shares a common degradate with captan.

Captan is a broad-spectrum fungicide registered for use on fruit and nut trees, grapes, berries, ginseng, and ornamentals. It suppresses fungal growth by direct contact with fungal spores on foliage or fruit. It is a "multi-site" fungicide, acting on multiple biochemical sites on a pathogen, in contrast to many other fungicides which act on a single biochemical site. In addition, captan is registered for use as a seed treatment for vegetables, corn, soybeans, cereal grains, and forage crops; as a seed piece treatment for ornamental tubers and bulbs; as a pre-plant root dip for peach trees and strawberry plants; and as a post-harvest fruit dip for apples, cherries, and pears. Captan is also registered for use as a home and garden fungicide. There are no antimicrobial or turf uses of captan.[7]

This document is organized into five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how and where captan is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Proposed Interim Registration Review Decision* (presenting EPA's proposed decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete this registration review).

A. Summary of Captan Registration Review

On June 26, 2013, the Agency formally initiated registration review for captan with the opening of the registration review docket for the case.[8] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of captan:

- June 2013 – EPA posted the *Captan Preliminary Work Plan* (PWP) (June 19, 2013), *Captan: Human Health Risk Seeping Document in Support of Registration Review* (May 1, 2013), and *Registration Review Problem Formulation for Captan* (May 2, 2013) to the public docket for a 60-day public comment period.

- December 2013 – EPA posted the *Captan Final Work Plan* (FWP) (December 19, 2013) and the antimicrobial problem formulation (*Captan - Anticipated Antimicrobial Risk Assessments and Data Needs for Registration Review*, December 9, 2013) to the public

[7] All antimicrobial uses of captan were voluntarily cancelled at the beginning of this registration review under the provisions of FIFRA § 6 (f). Use of captan on turf was also voluntarily canceled and removed from all captan product labels.
[8] 40 C.F.R. § 155.50

docket. The Agency received six comments on the PWP. None of these comments resulted in changes to the captan registration review schedule, risk assessment needs, or the anticipated data requirements in the FWP. Additional data were necessary to evaluate both the conventional and antimicrobial uses of captan.

- May 2014 – EPA issued two generic data call-ins (GDCIs) for captan to obtain data needed to conduct the registration review risk assessments (DCI GDCI-0810301-1381, to support antimicrobial uses, and GDCI-081301-1383, to support conventional uses). The requirements of GDCI-081301-1381 were waived after all captan technical registrants amended their registrations to delete all antimicrobial uses of captan. GDCI-081301-1383 included data requirements to address risk from conventional uses of captan and all required studies, with the exception of a turf transferable residue study were submitted.[9] The DCIs are posted together in the docket, EPA-HQ-OPP-2013-0296-0022. For more information, see Sections III.A.4 and III.B.3 of this document.

- November 2018 – EPA posted *Captan. Human Health Draft Risk Assessment in Support of Registration Review* (2018 HHRA) and *Captan: Preliminary Ecological Risk Assessment for Registration Review* (2018 ERA) for a 60-day public comment period. This comment period was extended for 45 days at the request of the Captan Task Force. The Agency received 210 comments. The Agency has summarized and responded to these comments in Section I.B., below, and in the supporting documents for this PID. The comments did result in changes to the risk assessments and registration review timeline for captan. Both the human health and ecological risk assessments were amended to incorporate new data and other information submitted during and after the public comment period.

- March 2019 to July 2021 – The Captan Task Force submitted numerous voluntary studies to EPA, including *in vitro* dermal penetration studies, in vivo dermal absorption studies for captan and folpet, and dislodgeable foliar residue dissipation studies for captan. The Task Force also submitted published literature articles on dermal toxicokinetics and five white papers[10] to inform various aspects of the human health risk assessment for captan. The Agency reviewed these submissions and incorporated the new data into the human health risk assessment as appropriate. EPA posted two addenda to the human health risk assessment and numerous supporting review documents to the public docket. These include the following:

    - *Captan. Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* (March 2, 2021);

[9] EPA expects to waive this study requirement when all turf-related uses are deleted from product labels.
[10] These white papers included submissions on (1) the dermal toxicokinetics to refine dermal absorption estimates for captan and (2) use of new DFR data to calculate re-entry risks of captan, both submitted with the public comments on the captan risk assessments, (3) the inhalation exposure potential of captan's dry flowable (DF) and water dispersible granular (WDG) formulations, (4) use of Multiple Path Particle Dosimetry (MPPD) modeling to inform inhalation exposure and risk estimates for captan, and (5) Captan and Folpet Dermal Penetration.

  - *Captan. Review and Fitting of Kinetic Dissipation Models for Dislodgeable Foliar Residues* (March 1, 2021); and
  - *Captan. Second Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment.* (November 3, 2021).
  - *USDA Response to EPA Inquiry on Captan Usage, Application Methods, and Benefits for Multiple Crops and Ornamentals*. (December 7, 2020).
  - *Farm and Field Size Data for Ginseng and Strawberry Use sites for Characterization in the Second Addendum to the Human Health Draft Risk Assessment for Captan* (October 29, 2021).

- November 2021 – EPA finalized the voluntary cancellation of one residential end-use product (EPA Reg. No. 4-459) and use termination for residential home and garden sublabels for several additional captan end-use products (EPA Reg. Nos. 19713-385, 19713-405, 19713-646, and 19713-652), all containing 49-80% of captan active ingredient. The Agency published a notice of receipt of these voluntary cancellation requests in the Federal Register on September 2, 2001 (86 FR 49,327). The final cancellation and use deletion order published on November 15, 2001 (86 FR 63,019).

- March 2022 – EPA completed a PID for captan and it will be available in the public docket for a 60-day public comment period. Along with the PID, EPA has posted the following documents to the public docket.
  - *Captan: Addendum to the Draft Ecological Risk Assessment for Registration Review Based on a New Honey bee Larval Acute Toxicity Study* (August 15, 2019)
  - *Captan: Second Addendum to the Draft Ecological Risk Assessment for Registration Review* (May 4, 2021)
  - *Captan. Health Effects Division Response to Public Comments* (November 3, 2021)
  - *Captan. Review of Risk Estimates from Proposed Mitigation Measures for Select Crops* (March 30, 2022)
  - *Captan: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision* (February 16, 2022).
  - *Captan SIAB Use and Usage Matrix.* (June 13, 2018, amended March 25, 2021)
  - *Captan Screening Level Usage Analysis (SLUA)* (July 8, 2020)
  - *Use, Usage, Benefits, Impacts of Potential Risk Mitigation and Summary of Public Comments for Captan Use in Strawberry* (March 8, 2022)
  - *Amended Captan Usage and Pest Management Benefits on Ginseng and Ornamentals.* (March 17, 2022)
  - *Assessment of Usage, Benefits and Impacts of Proposed Mitigation in Stone Fruit Production for the Fungicide Captan* (March 18, 2022)
  - *Benefits of Captan in Caneberries, Blueberry, and Grape, and Impacts of Potential Mitigation* (March 23, 2022)
  - *Captan Usage, Pest Management Benefits and Impacts of Possible Mitigation on Pome Fruits* (March 30, 2022).

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the public comment period[11] for the Captan Draft Risk Assessments (November 30, 2018 to March 15, 2019), the Agency received 210 public comments. Comments were submitted by the Captan Task Force, the Center for Biological Diversity, Drexel Chemical Company, the IR-4 Project, the Maryland State Horticultural Society, the National Agricultural Aviation Association, Northwest Horticultural Council, USDA's Office of Pest Management Policy, the Illinois Foundation Seeds Sweet Corn Division, the California Strawberry Plant Nursery Growers Association, the South Carolina Peach Council, numerous individual fruit growers, grower associations, crop advisors, cooperative extension, researchers, university faculty, and a number of anonymous commenters.

Comments of a technical nature concerning the draft captan risk assessments are summarized and addressed in the following documents:

- *Captan. Review and Fitting of Kinetic Dissipation Models for Dislodgeable Foliar Residues* (March 1, 2021),
- *Captan. Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* March 2, 2021), and
- *Captan. Health Effects Division Response to Public Comments* (November 3, 2021).

Comments related to the benefits of captan, such as its broad spectrum of activity, its cost effectiveness, its role in fungicide resistance management, and the importance of its use in orchard crops, berries, grapes, and other crops, are summarized and incorporated into the following memos:

- *Use, Usage, Benefits, Impacts of Potential Risk Mitigation and Summary of Public Comments for Captan Use in Strawberry* (March 8, 2022);
- *Amended Captan Usage and Pest Management Benefits on Ginseng and Ornamentals.* (March 15, 2022);
- *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for the Fungicide Captan* (March 18, 2022);
- *Benefits of Captan in Caneberries, Blueberry, and Grape, and Impacts of Potential Mitigation* (March 23, 2022); and
- *Captan Usage, Pest Management Benefits, and Impacts of Possible Mitigation on Pome Fruits* (March 30, 2022).

Additional substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized below.

[11] The public comment period was originally planned to be 60 days; however, because the Federal docket system was inaccessible during the 35-day December 2018 to January 2019 government shutdown, the comment period was extended.

Comments Submitted by the National Agricultural Aviation Association (NAAA) in EPA-HQ-OPP-2013-0296-0057

Comment: The NAAA provided comments regarding the spray drift analysis conducted in the draft risk assessment, particularly concerning the spray drift model, AgDRIFT, and the inputs used in the model (*e.g.*, aircraft type, swath width and displacement, number of passes, wind speed, height for wind speed measurement, boom length and boom drop, droplet size, atmospheric stability, and surface roughness). NAAA believes that the tier-1 component of the AgDRIFT model is inadequate because some of the assumptions it uses are unrealistic. NAAA recommended the use of the Multiple Application Assessment Method (MAAM) to model drift potential for products that can be applied multiple times annually on a crop. NAAA also recommended a refined assessment with a higher tiered model and reconsideration of several modeling parameters.

EPA Response: The Agency acknowledges and thanks NAAA for its comments. AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. EPA appreciates the additional suggestions provided by NAAA for revising the AgDRIFT modeling inputs and continues to work with industry to update and improve modeling methods to better reflect typical application practices. At the December 2020 Center of Excellence in Regulatory Science in Agriculture (CERSA) workshop, EPA, NAAA, and other stakeholders discussed these potential refinements for AgDRIFT modeling. The Agency is currently reviewing these suggestions and will consider them for future risk assessment. However, modeling for a national-level assessment is first conducted using maximum application rates, limitations, and instructions listed on the pesticide (captan) labels. In the absence of specific use directions and application restrictions implemented across all product labels, default assumptions (based on empirical data) are used.

Comment: NAAA expressed concern about EPA pursuing mitigation based on the aerial mixer/loader handler inhalation risks of concern identified for Dry Flowable and Wettable Powder formulations of captan. NAAA was concerned that EPA's risk assessment did not consider newer data developed for mixing and loading these formulations for aerial application. In its review of the newer data, NAAA determined that the mixing and loading scenarios for these formulations using engineering controls (i.e., enclosed systems) were not yet approved by the Agricultural Handler Exposure Task Force (AHETF). Therefore, NAAA assumed that older data, from the Pesticide Handler Exposure Database (PHED) was used for estimating worker exposer to captan. NAAA argued that the AHETF data is more reliable than PHED data, and therefore requested that EPA refrain from restrictions for aerial applications of captan based on the inhalation risks until AHETF exposure data for mixing and loading Dry Flowable and Wettable Powder formulations has been evaluated and approved. NAAA also expressed concerns about other aspects of EPA's algorithm for estimating worker exposure.

EPA Response: The Agency thanks the NAAA for its comment. The Agency evaluated the mixer/loader scenario for aerial applicators using the best available unit exposure data. EPA evaluated various scenarios using PF10 and PF50 respirators and engineering controls for mixer/loader scenarios. The Agency's proposed interim registration review decision is based on

these best available data. EPA utilizes AHETF data in its risk assessment process after the data undergoes appropriate peer review.

Comments Submitted by Center for Biological Diversity (CBD) (Docket ID: EPA-HQ-OPP-2013-0296-0231)

Comment: CBD's comments focus on the EPA's duty to consult with the Services on the registration review of captan in accordance with the Endangered Species Act (ESA). The CBD comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the agency's preliminary determinations regarding the effects of captan on listed species and their designated critical habitat for the captan registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

EPA Response: EPA has reviewed CBD's comments and is addressing many of the concerns about listed species by collaborating with the Services and USDA to improve the consultation process for listed species and pesticides. For more information on this ongoing collaboration, see Appendix C. EPA intends to address endocrine-disruption and listed-species concerns specific to captan when developing its final registration review decision. For more information on endocrine disruption, see Appendix D. EPA is currently developing a policy on how to consider synergy claims made by registrants in their patents and patent applications. For more information on this policy, see the interim process posted for public comment on September 9, 2019, to EPA's public docket (EPA-HQ-OPP-2017-0433).

Although EPA has not yet completed a nationwide listed species assessment for captan, the Agency is in the process of implementing the 2011 National Marine Fisheries Service Biological Opinion (BiOp) on the impacts of captan on listed Pacific salmonids. For more information, see Sections III and IV of this document.

Comments Submitted by the Captan Task Force (Docket ID: EPA-HQ-OPP-2013-0296-0244)

Comment: The CTF submitted two white papers to inform and refine the captan human health risk assessments: (1) *Registrant Rationale for Acceptability of New Dislodgeable Foliar Residue Studies and their Use in Post-Application Reentry Risk Assessment Calculation* and (2) *The Use of Human Toxicokinetic Studies to Define the Dermal Absorption Factor for Captan*. In the first white paper, the CTF presented a summary of unpublished foliar dislodgeable residue dissipation data on stone fruit from studies conducted in the European Union, as well as an analysis of these data for use in refining the captan reentry assessment. In the second white paper, on use of human toxicokinetic studies[12] to refine dermal absorption, the CTF presented a

[12] These studies used data from human volunteers.

summary of human toxicokinetic studies and pharmacokinetic modeling from two 2012 publications in the *Journal of Applied Toxicology*. The CTF asserted that this approach could reduce the dermal absorption factor used in the captan human health risk assessment from 10% to 1%. In the comment, the CTF committed to submitting the referenced data and published literature to EPA; these materials were submitted after the comment period closed.

EPA Response: The Agency reviewed the CTF rationale for reducing the dermal absorption factor from 10% to 1% described in the first white paper.[13] EPA conducted an independent analysis of the European DFR data and determined that it could be used to refine the 2018 captan worker re-entry assessment. See the March 1, 2021, memo, *Captan. Review and Fitting of Kinetic Dissipation Models for Dislodgeable Foliar Residues* for details of this analysis. However, when EPA reviewed the second white paper on dermal toxicokinetics, the Agency identified issues with the supporting evidence, including use of data from human subjects and the mathematical modeling presented. EPA has obligations under 26 CFR, Subpart M to ensure the ethical conduct of any human studies used for regulatory purposes. To comply with this regulation, EPA requires submission of information on the ethical conduct of human studies, including review by an Institutional Review Board and materials confirming informed consent of study participants, at the time of data submission. When EPA staff informed the CTF of its obligation to provide information to confirm the ethical conduct of the captan dermal toxicokinetic studies, the CTF was unable to provide the necessary materials. Therefore, EPA did not use the human toxicokinetic studies.

II. USE AND USAGE

Captan is a broad-spectrum fungicide registered for use on fruit and nut trees, grapes, berries, ginseng, and ornamentals. It is also registered for use as a seed treatment; a preplant dip for ornamental tubers and bulbs, peach trees, and strawberry plants; and as a post-harvest fruit dip for apples, cherries, and pears. In addition, captan is registered for residential use; the sole registered home and garden product[14] is a liquid concentrate containing 11.7% captan co-formulated with two other active ingredients. This product is sold in child-resistant packaging.

Captan is formulated as a dry flowable (DF)/water dispersible granule (WDG), liquid concentrate, flowable concentrate (FlC), and wettable powder (WP). It is formulated as a dust (D) for seed treatment use only. It may be applied by air, ground, or dip tank. Although ground application is typically conducted with an airblast rig or ground boom, captan may also be applied with a mechanically pressurized handgun, low-pressure handwand, backpack sprayer, or hose end sprayer. Post-harvest fruit treatment and seed treatment with captan use specialized application equipment.

Most captan product labels require pesticide handlers (mixers, loaders, applicators, and other handlers) to wear baseline protective clothing (i.e., long-sleeved shirt, long pants, shoes and socks) and personal protective equipment (PPE) including a double layer (i.e., coveralls,

[13] New European DFR studies were submitted in 2019 and information comparing the study conditions for these studies with US growing conditions was submitted in 2020.
[14] All other home and garden products or product sublabels were canceled effective November 15, 2021. See 86 FR 49327 and 86 FR 63019 for details.

chemical resistant apron), chemical-resistant gloves, protective eyewear, and/or a PF10 respirator. The restricted entry intervals (REIs) range from 12 to 96 hours, and the pre-harvest interval (PHI) ranges generally from 0 to 30 days.

The greatest usage of captan is on fruit, especially apples, stone fruits, and berries. Between 2009 and 2018, an annual average of 1,600,000 pounds (lbs.) of captan active ingredient was applied to apples, 400,000 lbs. were applied to strawberries, and 300,000 lbs. were applied to peaches. In terms of percent crop treated, 65% of strawberries, 50% of blueberries, and 40% of apples were treated with captan during this time period. Additional information on the usage of captan may be found in the July 8, 2020, memo, *Screening Level Usage Analysis* and in the benefits memos for different crops. These documents may be found in the captan registration review docket (EPA-HQ-OPP-2013-0296).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

EPA completed the preliminary human health risk assessment (HHRA) for captan in September 2018 and took comments on this document. This risk assessment identified potential risk concerns for pesticide handlers who mix, load, or apply captan as part of their work and for consumers who apply captan to home gardens. The 2018 assessment also identified potential risk concerns for agricultural workers who enter fruit orchards treated with captan up to 30 days after captan application and for adults and children who enter home gardens after they have been treated with captan. This assessment assumed a 10% dermal absorption factor based on the best scientific information available at the time.

Throughout the registration review risk assessment process, the Captan Task Force submitted additional voluntary data, including dermal penetration studies for captan's structural analogue folpet, *in vitro* dermal absorption studies for captan and folpet, and additional dislodgeable foliar residue dissipation (DFR) studies for captan in orchard crops. After a review of these data to determine the most appropriate DFR data for use in the captan re-entry assessment, the Agency conducted a kinetic modeling exercise to determine whether the data from multiple studies could be combined. EPA incorporated the new DFR data, as appropriate, and a 7% dermal absorption factor into an HHRA Addendum released to the docket in March 2021. The Agency reviewed *in vitro* dermal absorption data submitted in June 2021 and determined that these data could be used to derive a 3% dermal absorption factor, which was incorporated into the HHRA Addendum released in November 2021. The Agency used the most current science policies and risk assessment methodologies to prepare both the 2018 risk assessment and the two 2021 risk assessment addenda to support the captan registration review.

The 2021 HHRA addenda showed potential inhalation risk concerns for pesticide handlers who mix, load, or apply captan as part of their work and potential dermal risk concerns for workers who re-enter vineyards and ornamental nurseries to perform high contact activities up to 10 days after captan application. EPA also has identified potential dermal risk concerns associated with some seed treatment scenarios. In addition, the Agency identified potential risk concerns for consumer products; however, since publication of the 2021 assessment, these have been

addressed by the registrants through voluntary cancellations and use deletions. A summary of the Agency's current conclusions regarding human health risk from use of captan is presented below.

For additional details, see the following documents in the registration review docket for captan, EPA-HQ-OPP-2013-0296: *Captan. Human Health Draft Risk Assessment in Support of Registration Review* (September 2020)*, Captan. Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* (March 2, 2021), *Captan. Review and Fitting of Kinetic Dissipation Models for Dislodgeable Foliar Residues* (March 1, 2021), *Captan. Second Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* (November 3, 2021), and *Captan. Review of Risk Estimates from Proposed Mitigation Measures for Select Crops.* (March 30, 2022).

1. Risk Summary and Characterization

i. Hazard Evaluation

EPA reviewed its robust toxicological database for captan to determine the effects associated with captan exposure in toxicology studies conducted in animals. The Agency determined the studies and effects most appropriate for use in the captan HHRA. EPA also determined the appropriate safety factors to account for extrapolation from animal studies to humans (intraspecies variability), variability within a population (interspecies variability), and any special susceptibility of infants and children (FQPA safety factor). The Agency also reviewed captan's absorption and metabolism in the body and degradation in the environment. Captan and its structural analogue, folpet, share a common degradate, thiophosgene (THPI), which is one of the major captan metabolites and degradates.[15]

To estimate risks from acute and chronic dietary, incidental oral, and short and intermediate-term dermal exposure to captan, EPA used data from a multigeneration reproductive toxicity study in rats, showing skeletal malformations and decreased body weights in offspring, to derive a point of departure (POD). For dermal and oral exposure, the level of concern (LOC) is 100, based on safety factors of 10X for interspecies variability, 10X for intraspecies variability, and a 1X FQPA safety factor. The Agency also used a dermal absorption factor of 3%, based on human *in vitro* dermal absorption data submitted in 2021.

To estimate risks from inhalation exposure to captan, EPA used data from a 90-day subchronic inhalation study in rats, showing upper respiratory tract effects. For the inhalation route, the LOC is 30, based on safety factors of 3X for interspecies extrapolation, 10X for intraspecies sensitivity, and a 1X FQPA safety factor. Because animals and humans have differences in both respiratory tract structure and breathing rates, EPA also calculated the Human Equivalent Concentration for captan.

[15] PAI and PI are the other major captan metabolites and degradates.

Captan is considered to be a threshold carcinogen. Although tumors were observed in a mouse study, they were attributed to a non-genotoxic mode of action (i.e., the tumors were a response to local irritation and cytotoxicity). The current captan reference dose (RfD) is expected to be protective of the cytotoxicity and other effects that potentially result in tumors. Therefore, the non-cancer endpoint for captan is expected to be protective of potential carcinogenic effects and no separate cancer assessment is necessary.

ii. Dietary (Food + Water) Risks

The Agency conducted a highly refined acute and chronic dietary assessment for captan residues from food, using percent crop treated data, USDA Pesticide Data Program monitoring data[16], residue data from representative commodities, and anticipated residues for livestock commodities (based on field trial data). The drinking water component of the assessment was based on the most conservative modeled daily drinking water estimates. The captan dietary and drinking water assessments are unchanged from 2018.

EPA has not identified acute or chronic dietary risk concerns for residues of captan or its degradates in food or drinking water. The Agency's level of concern is exposure greater than the Population Adjusted Dose or PAD (>100% acute or chronic PAD).[17] At the 99.9th percentile, acute dietary exposure from food and drinking water comprises 29% of the acute population adjusted dose (aPAD) to the most sensitive population: women of childbearing age (females aged 13-49). Chronic dietary exposure to infants, the highest exposed subgroup, comprises 60% of the chronic population adjusted dose (cPAD). Chronic dietary exposure for the general U.S. population comprises <1.0% of the cPAD; for children, chronic exposure to children aged 1-2 comprises 2.0% of the cPAD.

iii. Residential Handler and Post-Application Risks

The only captan product registered for use in home gardens is a fruit tree spray (11.76% captan, co-formulated with two other active ingredients).[18] The captan technical registrants have chosen not to support turf uses. In residential settings, captan may be applied by backpack sprayer, hose-end sprayer, and manually pressurized handwand.

After completion of the 2018 HHRA, EPA refined the risk estimates for residential handlers using new dermal absorption data. The Agency also refined risk estimates for post-application exposure to adults and children using new DFR data. In addition, the registrants of captan consumer product registrations voluntarily canceled or deleted sublabels for products containing more than 12% captan active ingredient to address the residential risk concerns associated with these products. These actions were effective in November 2021. The results of EPA's revised

[16] US Department of Agriculture's Pesticide Data Program monitors residues of pesticides on numerous raw agricultural commodities. USDA takes samples of food and feed crops on the farm, before shipping to distributors, and analyzes the samples for pesticide residues. Therefore, the PDP data provide excellent information on measured pesticide residues in food and feed.

[17] Acute PAD is abbreviated as aPAD, and chronic PAD is abbreviated as cPAD.

[18] All other captan products registered for residential use have either been cancelled or amended to remove the home and garden sublabel. See 86 FR 49327 and 86 FR 63019.

residential assessment, following the product cancellations and use deletions, are summarized below.

EPA has not identified any potential risk concerns for the sole remaining captan residential use product (EPA Reg. No. 4-122). For residential pesticide applicators, the Margins of Exposure (MOEs) for inhalation range from 67 to 3,000, above the level of concern (LOC) of 30 for inhalation exposure. Dermal MOEs for applicators range from 5,600 to 12,000, above the LOC of 100. Post-application dermal MOEs for adults and children, who are re-entering treated gardens, are also above the level of concern, with MOEs for adults and children ranging from 4,700 to 75,000. Therefore, EPA has not identified any potential risk concerns for either residential handlers applying captan or for post-application exposure for adults and children re-entering treated areas.

iv. Bystander Risks

The Agency evaluated risk from inhalation and dermal exposure to adults and children living adjacent to agricultural fields treated with captan. In the second 2021 HHRA addendum, EPA refined the bystander assessment, using a 3% dermal absorption value, to re-evaluate spray drift exposure. To evaluate inhalation exposure, based on the potential for captan to volatilize, EPA used data developed by the California Air Resources Board in Tulare County, California following application of captan to agricultural fields. EPA estimated inhalation exposure and risk for people living next to a treated field with potential exposure to a peak concentration of captan and its THPI degradate volatilizing off a treated field for 24-hour period. Because the inhalation MOE for this conservative scenario is 86, which is greater than LOC of 30, the Agency has not identified an inhalation risk concern for bystanders. To estimate dermal exposure, EPA used the AgDRIFT model to estimate residues of captan that might be deposited on lawns adjacent to treated fields from spray drift. The Agency calculated dermal MOEs from 910 to 1,700 for adults and combined dermal and incidental oral MOEs from 270 to 520 for children, for groundboom and airblast application, respectively. Because these MOEs are greater than the LOC of 100 for dermal exposure, EPA has not identified any potential dermal risk concerns for bystanders.

v. Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. When aggregating exposures and risks from various sources, EPA considers both the route and duration of exposure. For captan, the Agency has determined that the oral (from food + drinking water) and dermal routes of exposure may be aggregated because they share a common toxicity endpoint. However, the inhalation route of exposure cannot be combined with dermal or oral routes of exposure because the observed toxic effects are different. Short-term aggregate risk assessments are necessary for both adults and children, because there is the potential for both short-term handler exposure and short-term post-application exposure from the residential uses of captan. Intermediate-term and chronic residential exposures are not anticipated. Because short- and intermediate-term PODs are the same, the results of the short-term risk assessment are protective of any intermediate-term exposure. EPA has not identified short-term aggregate risk concerns for combined residential exposure and dietary exposure from food and drinking water. The short-

term aggregate MOEs for combined food, water, and residential exposure to adults (3,900) and children (4,000) are above the level of concern of 100.

vi. Cumulative Risks

Captan has not been identified as a member of a cumulative group of pesticides sharing a common mechanism of toxicity. Captan and folpet share a common degradate thiophosgene. This degradate is short-lived, degrading almost instantaneously in water. Therefore, EPA has premised this PID and the underlying risk assessments on the understanding that captan does not have a common mechanism of toxicity with other substances.

vii. Occupational Handler Risks

EPA has identified potential risk concerns for occupational handlers who mix, load, and apply captan to orchard crops, berries and grapes, and ornamentals. The Agency has also identified risk concerns for use of captan as a seed treatment and as a post-harvest fruit dip. For orchard crops, grapes, and berries, EPA has identified potential inhalation risk concerns for handlers using dry flowable (DF)/water-dispersible granule (WDG) and wettable powder (WP) formulations for three scenarios: (1) mixers and loaders for supporting airblast application, (2) mixers and loaders supporting aerial application, and (3) airblast applicators. In general, the highest risks are associated with inhalation exposure to dry flowable (DF)/water-dispersible granule (WDG) and wettable powder (WP) formulations, for mixers and loaders who are supporting aerial application. The Agency's risk estimates are summarized below and in Appendix F of this document. Additional details may be found in the November 2021 and March 2022 HHRA addenda, in EPA's public docket (EPA-HQ-OPP-2013-0296).

Current captan product labels require all handlers to wear single-layer baseline attire (i.e., long-sleeved shirt, long pants, shoes and socks) as well as personal protective equipment (PPE) consisting of chemical resistant gloves, protective eyewear, and a PF10 respirator. Some captan product labels also require use of coveralls or a chemical- resistant apron and a chemical-resistant hat for high contact activities.

Orchard Crops. For orchard crops (fruit and nut trees), risk estimates vary by application method, application rate, formulation, and amount of PPE. Captan is applied to orchard crops primarily by airblast, with use of mechanically pressurized handguns to treat areas that are missed by airblast application. Captan may also be applied by air. EPA has identified potential inhalation risk concerns for mixers and loaders handling DF/WDG and WP formulations, especially those supporting aerial application, even with the use of current label PPE.

Inhalation MOEs for mixers and loaders who are wearing a PF10 respirator range from <1 (for mixer/loaders supporting aerial application of DF/WDG applied to almonds at 4.5 lbs. ai/A) to 580 (for mixer/loaders supporting airblast and groundboom applications of liquid formulations at 2.5 lbs. ai/A); the inhalation LOC is 30. However, with the addition of a PF50 respirator, the same scenarios result in inhalation MOEs for mixers and loaders ranging from 4.5 (for mixers and loaders supporting aerial application of 4.5 lb ai/A DF/WDG and WP captan to almonds) to 2,900 (for mixers and loaders supporting airblast application of 2.5 lb ai/A of liquid captan to

highbush blueberries). For applicators, EPA has identified potential inhalation risk concerns for airblast application, even when a PF10 respirator is worn, with MOEs ranging from 15 to 27, less than the inhalation LOC of 30. When airblast applicators use enclosed cabs, all inhalation MOEs are above the LOC, and not of concern to the Agency.

The Agency has not identified any potential dermal risk concerns for airblast mixers/loaders or applicators who are wearing current label PPE of eye protection, single-layer clothing, and chemical-resistant gloves.

EPA has identified potential inhalation risk concerns for mixing, loading, and applying captan using a mechanically pressurized handgun for DF/WDG and WP formulations; MOEs range from 6.6 to 12 when a PF10 respirator is worn. These MOE values improve when less captan is applied. Dermal MOEs (for all captan formulations) for mixer/loader/applicators using a mechanically pressurized handgun are above the dermal LOC of 100 for application rates below 0.158 lbs ai/gal. For rates greater than 0.158 lbs. ai/gal., the MOE is 72 or below and of concern.

Last, the Agency has identified inhalation risk concerns for both mixers and loaders and fruit packing house workers when captan is used as a post-harvest fruit dip for apples, cherries, and pears. When EPA assumes that fruit is dipped in 25,000 gallons of captan at a rate of 0.0128 lbs ai/gal, inhalation MOEs are as follows. For mixers/loaders using the DF/WDG formulation and wearing a PF10 respirator, the inhalation MOE is 4.5 (LOC is 30); the MOE is 22 with use of a PF50 respirator. For mixers/loaders using the WP formulation and wearing a PF10 respirator, the MOE is 15; the MOE is 73 with use of a PF50 respirator. For fruit packing workers who are sorting or packing treated fruit, the inhalation MOE is 1.3 with no respirator, 13 with a PF10 respirator, and 63 with a PF50 respirator. For fruit packing workers involved in other activities, the inhalation MOE is 28 with no respirator and 280 with a PF10 respirator. There are no dermal risk concerns associated with the use of captan as a post-harvest fruit dip.

Berries and Grapes. The Agency has risk concerns for mixer/loaders handling the DF/WDG formulations to support airblast or groundboom applicators, but no risk concerns for mixer/loaders handling liquid or WP formulations, provided a PF10 respirator is worn. The inhalation MOE for mixers/loaders handling the DF/WDG formulations to support airblast or groundboom applicators is 14 with a PF10 respirator and 74 with a PF50 respirator. The MOE for an airblast applicator wearing a PF10 respirator is 27. EPA does not have risk concerns for mixers/loaders or applicators who are applying any formulation of captan to blueberries, caneberries, and grapes using groundboom equipment. For additional details, see Appendix F to the March 2021 HHRA addendum.[19]

For mixer/loader/applicators applying any formulation of captan using mechanically pressurized handguns, inhalation risk estimates range from 12 to 37; the LOC is 30. EPA has identified inhalation risk concerns for mixer/loader/applicators using a mechanically pressurized handgun to treat blueberries, assuming use of a PF10 respirator and application of 1000 gal[20] of solution containing 0.125 lb ai/gal captan (all formulations). This can be addressed by limiting the

[19] *Captan. Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment.* March 2, 2021.
[20] This is EPA's default estimate of the volume that could be applied in a day.

amount of solution handled, as described in Sections IV.A.4. and IV.B.1. of this document.

For strawberries, EPA identified potential inhalation risk concerns for mixer/loaders who are supporting aerial application of DF/WDG and WP formulations, assuming 350 acres are treated daily. For DF/WDG formulations, the inhalation MOE is 1.4 with a PF 10 respirator and 6.8 with a PF 50 respirator. For WP formulations, the inhalation MOE is 4.4 with a PF10 respirator and 22 with a PF50 respirator. However, there is no inhalation risk concern for mixer/loaders supporting aerial application of liquid formulations. For mixers/loaders who are supporting groundboom application to strawberries (with 80 acres treated per day), EPA has identified potential risk concerns for DF/WDG and WP formulations but not for liquid formulations. Specifically, the MOE for mixers/loaders of DF/WDG is 8 when a PF10 respirator is worn and 40 when a PF50 respirator is worn. For the WP formulation, the MOE is 19 with a PF10 respirator and 97 with a PF50 respirator.

The Agency was able to refine the risk estimates for strawberries using farm size data from USDA's National Agricultural Statistics Service and Farm Service Agency. Because the vast majority of strawberry farms are 15 acres or less, and the 90th percentile farm size is 48 acres, EPA calculated MOEs assuming either 15 or 48 acres are treated each day by groundboom.[21] No exposure scenarios are of concern when 15 acres are treated per day. However, when 48 acres are treated daily, the MOE for mixers/loaders of DF/WDG formulations supporting groundboom is 14 with a PF 10 respirator and 72 with a PF50 respirator.

Ginseng. EPA's 2018 HHRA and 2021 HHRA addenda assumed that ginseng is a typical field crop, grown on large fields of 80 acres or more, and that captan was applied to the crop by groundboom, with a typical grower treating 80 acres/day. However, information from USDA[22,23] and other stakeholders indicates that the vast majority of ginseng is grown on small farms of 10 acres or less and that growers typically apply captan and other chemicals using custom-made boom sprayers which hold approximately 100 gallons of spray solution and travel low to the ground. Assuming an area treated of 10 or fewer acres, inhalation MOEs for mixers, loaders, and applicators who are wearing the required PF10 respirator range from 48 to 1,900, all greater than the LOC of 30. Dermal MOEs for workers who are wearing the required single layer of clothing and chemical-resistant gloves range from 540 (for handlers using mechanically pressurized handgun and assuming 1,000 gallons solution handled) to nearly 70,000 (for aerial applicators), all greater than the LOC of 100. Therefore, if captan application to ginseng is limited to 10 acres or less, there are no occupational risk concerns.

Ornamentals. Because little information is available on the use of captan on ornamentals, EPA's

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[21] See Appendix D of the November 21, 2021, HHRA addendum, *Captan. Second Addendum to the Human Health Draft Risk Assessment in Suppo1t of Registration Review with Updated Occupational and Residential Exposure Assessment,* item OPP-HQ-2013-0296-0270 in the public docket.

[22] *USDA Response to EPA Inquiry on Captan Usage, Application Methods, and Benefits for Multiple Crops and Ornamentals.* December 7, 2020. See EPA-HQ-OPP-2013-0296-0276 in the public docket.

[23] USDA-FSA. 2010-2014. *Crop Acreage Data. Data from the USDA FSA on Field Size*, obtained through a Freedom of Information Act request. https://www.fsa.usda.gov/news-room/efoia/electronic-reading-room/frequently-requested-information/crop-acreage-data/index.

HHRA and HHRA addenda used the best available information[24] to estimate worker risk using a variety of application methods. The Agency identified potential risk concerns for pesticide handlers.

For pesticide handlers applying captan to ornamentals, inhalation MOEs range from 3.6 to 1,200 for workers wearing PF10 respirators, depending on the formulation and specific worker activities (LOC is 30). In general, EPA has identified potential inhalation risk concern for the DF/WDG and WP formulations and for mixers/loaders supporting groundboom application. For mixers/loaders handling DF/WDG formulations, the inhalation MOE is 5.5 for workers wearing a PF10 respirator and 27 for workers wearing a PF50 respirator. For mixers and loaders handling WP formulations, the inhalation MOE is 18 for workers wearing a PF10 respirator and 89 for workers wearing a PF50 respirator. Dermal MOEs are ≥ 810 for workers wearing single layer PPE and chemical-resistant gloves (LOC is 100); therefore, EPA has no potential risk concern.

Seed Treatment. EPA has identified potential risk concerns for commercial seed treatment workers who are performing multiple activities. Inhalation MOEs for workers who are wearing the PF10 respirators required on current product labels while conducting multiple activities range from 12 to 29 (the LOC is 30), which are of concern.[25] However, those MOEs are above the LOC when workers are wearing PF50 respirators. For commercial seed treatment, dermal MOEs are all greater than the LOC of 100 and are not of concern when workers are wearing single layer clothing and chemical-resistant gloves. There are no other potential risk concerns for commercial seed treatment.

The Agency has also identified potential risk concerns for on-farm seed treatment, specifically for planter box loaders and applicators. Dermal MOEs for the on-farm planter box scenarios range from 74 to 740 for workers wearing the single layer of clothing and chemical resistant gloves required on current captan product labels. The lowest MOE (74) is for treating soybeans with a hopper box. However, dermal MOEs are above the LOC of 100 when double layer clothing is worn (in addition to chemical resistant gloves). There are no risk concerns if workers wear a PF10 respirator and the label prescribed PPE (double layer clothing); the mitigation completely addresses the worker risks.

viii. Occupational Post-Application Risks

EPA has identified potential dermal risk concerns for agricultural workers who enter orchards, vineyards, and ornamental nurseries after captan application. The 2018 HHRA showed potential dermal risk concerns (i.e., MOEs below the LOC of 100) for numerous crops 30 days or more following captan application. The Agency estimated post-application risks using dislodgeable foliar residue dissipation (DFR) data, the application rate, the dermal POD, and the dermal absorption factor. After the HHRA was published in 2018, the Captan Task Force submitted additional DFR data for captan use on orchard crops. EPA used these data and the previously

[24] For example, EPA assumed that nurseries treat 40 acres per day.
[25] Scenarios for alfalfa; clover; trefoil; barley and rye; sweet corn; cotton; cowpeas; sorghum; soybean; and strawberry.

submitted DFR data for captan to determine the best-fit residue decline curve.[26] The Agency also used new *in vitro* dermal absorption data for captan to derive a dermal absorption factor of 3%. This enabled the Agency to refine the post-application risk estimates for captan. The March and November 2021 HHRA addenda show lower potential risk concerns and identify fewer crops with risk concerns, as described below.

For most crops, there are no potential post-application risks at the current REI. However, EPA has identified risks of concern for workers involved in hand thinning of orchard fruit, girdling and turning table grapes (a cultural practice unique to this crop), and adjusting, maintaining, or repairing handset irrigation equipment in ornamental nurseries. The November 2021 HHRA addendum shows that there are potential risk concerns (i.e., MOEs above the LOC) associated with hand thinning apples, peaches, and nectarines for 6 days after treatment. In addition, there are potential risk concern for hand thinning cherries for 1 day after treatment; for tying, training, hand harvesting, and leaf pulling wine and juice grapes for 3 days after treatment; for turning and girdling table grapes for 8 days after treatment; and for working with handset irrigation equipment in ornamentals for 10 days after treatment. However, growers are changing horticultural practices to use a new Y-Trellis system that makes turning and girdling unnecessary for table grapes.[27] In addition, ornamental growers seldom use handset irrigation. For most crops, there is no risk concern at the current REI. Furthermore, the risk concern for hand-thinning orchard fruit can be addressed by slight application rate reductions, as described in Section IV.A.4 of this document. The Agency's revised post-application risk estimates for current registered uses of captan on orchard and vineyard crops may be found in Appendix F of this document.

2. Human Incidents and Epidemiology

EPA reviewed the captan incidents reported to OPP Incident Data System (IDS) and the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR). The purpose of this database search was to identify potential patterns in the frequency and severity of the health effects attributed to captan exposure. Two reviews of the incident data were conducted - the first in January 2018 and the second in January 2022. An IDS analysis from January 1, 2013, to January 16, 2018, reported two cases involving a single active ingredient and one case involving multiple active ingredients in the Main IDS and seven cases to the Aggregate IDS. A search of SENSOR-Pesticides data from 2010 to 2014 identified 12 cases involving captan. Three of the 12 cases involved a single active ingredient and nine cases involved multiple active ingredients. One case was high in severity, one case was moderate in severity, and ten cases were low in severity. Six cases were associated with occupational use of captan and six cases with residential use. Five of the residential cases involved illness without a violation of the pesticide labeling; these five cases were low in severity. The most frequently reported symptoms were dizziness, nausea, and burning/prickling sensation. A second search of the SENSOR-Pesticides database from 2015 to 2017 identified a total of seven case reports involving exposure

[26] For more information on how EPA modeled the best fit residue decline curve, see the March 1, 2021, memo, *Captan. Review and Fitting of Kinetic Dissipation Models for Dislodgeable Foliar Residues* (March 1, 2021).
[27] See the August 23. 2021 memo, *Grapevine Cane Turning and Girdling in Modern Production of Table Grapes – Prevalence and Potential Worker Exposure to Pesticides*, available in the captan docket, EPA-HQ-OPP-0296-02xx.

to multiple pesticide active ingredients including captan. Most cases (6 of 7) involved homeowner exposure to the pesticide, some to existing stocks of canceled products. One case involved deliberate ingestion of a pesticide product containing captan. Five cases were low in severity and two cases were moderate in severity, with symptoms similar to the incidents reported previously.

Captan was included in the Agricultural Health Study (AHS), a multi-year, federally funded study that evaluates associations between pesticide exposures and cancer and other health outcomes. The Agency conducted Tier I reviews of published epidemiological studies in both 2018 and 2022. In the 2022 updated Tier I review, EPA identified 36 epidemiologic publications on the AHS and on the broader epidemiology literature that considered captan exposure and adverse health effects. Although some of these studies reported a positive association between captan exposure and various health effects, at this time, there is insufficient evidence to suggest a clear associative or causal relationship between exposure to captan and the adverse health effects in the studies reviewed by EPA.

The Agency intends to monitor human incidents for captan and will conduct additional analyses if necessary. EPA also intends to continue to monitor the results of the AHS study, publications using AHS study data, and other studies in the published literature for positive associations between captan exposure and adverse health outcomes. See EPA's August 13, 2018, incident memo, *Captan: Tier I Update Review of Human Incidents and Epidemiology* (EPA-HQ-OPP-2013-0296-0045) and the February 16, 2022, memo, *Captan: Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision* for additional details.

3. Tolerances

Captan is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover the residues, or the affected food is considered adulterated.[28] EPA believes that all of the necessary tolerances are in place to cover residues resulting from legal uses of captan. EPA has established tolerances in 40 CFR §180.103 (a)(1) for direct residues of captan resulting from application to growing crops and in 40 CFR §180.103 (a)(2) for indirect residues of captan in livestock commodities resulting from application to feed crops. During the captan registration review, the Agency has identified changes to the tolerance expression, to specific tolerance values, and to definitions of commodity groups (crop groups). As part of the captan registration review, EPA also looked for opportunities to harmonize the U.S. tolerances for captan with Codex and/or Canadian MRLs. These changes are described in detail in both the 2018 HHRA and in Section IV of this document.

4. Human Health Data Needs

The human health database for captan is considered complete, with the exception of a turf transferable residue study. The captan technical registrants have chosen to amend their registrations to delete the turf use from their labels rather than develop these data. The requirement for the turf transferable residue study will be waived when all captan product labels

[28] 21 U.S.C. §§ 342, 346(a).

are amended to delete turf and turf related uses, including lawn seed beds, ornamental grasses, and dichondra. There are no other human health data gaps.

B. Ecological Risks

EPA used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of captan. The Agency amended the Ecological Risk Assessment (ERA) in 2019 to incorporate a captan honey-bee-larvae acute toxicity study and again in 2021 to address errors in both the maximum application rate for an agricultural crop and the mammalian chronic effects endpoint used for risk assessment. For additional details on the 2018 ERA, see *Captan: Preliminary Ecological Risk Assessment for Registration* (September 26, 2018). For additional details on the 2019 ERA addendum, see *Captan: Addendum to the Draft Ecological Risk Assessment for Registration Review Based on a New Honey Bee Larval Acute Toxicity Study* (August 15, 2019) and for details on the 2021 ERA addendum, see *Captan: Second Addendum to the Draft Ecological Risk Assessment for Registration Review* (May 4, 2021)[29]. These documents may be found in EPA's public docket (EPA-HQ-OPP-2013-0296).

Although EPA has not yet conducted a nationwide endangered species assessment for captan as part of this registration review, in 2003 the Agency conducted a focused biological evaluation (BE) for Pacific salmonids and initiated a formal consultation with the National Marine Fisheries Service (NMFS) in response to litigation. NMFS completed a Biological Opinion (BiOp) on the effects of captan on Pacific salmonids in 2011. EPA has summarized the captan 2018 ERA, the 2019 and 2021 ERA addenda, and the Pacific salmonids BiOp below. The salmonid BiOp, *National Marine Fisheries Service Endangered Species Act Section 7 Consultation. Biological Opinion. Environmental Protection Agency Registration of Pesticides 2,4-D, Triclopyr BEE, Linuron, Captan, and Chlorothalonil*[30] may be found on the NMFS website.

1. Risk Summary and Characterization

EPA has identified potential chronic risks for non-listed mammals and acute risks to honey bee larvae for all captan uses. The Agency has also identified acute risks to freshwater fish associated with captan runoff from treated orchards. The risk estimates are based on the current registered uses of captan, the available ecotoxicity data, and the environmental fate properties. EPA compares the risk estimates (Risk Quotients, or RQs) with EPA's Level of Concern (LOC) for non-listed species; EPA has a risk concern when RQs are greater than the LOC. For scenarios in which RQs could not be calculated, EPA compared the estimated environmental concentrations (EECs) of captan with the appropriate toxicological endpoint. No potential risk concerns were identified for aquatic invertebrates (water-column and benthic), freshwater and estuarine/marine fish, aquatic plants, terrestrial plants, birds, and the taxa they represent.

i. Terrestrial Risks

[29] These are described as the 2019 EERA addendum and the 2021 EERA addendum.
[30] The captan salmonid BiOp may be found at https://media.fisheries.noaa.gov/dam-migration/63806559pesticide_opinion4.pdf

EPA estimated the potential risk associated with captan use for birds, mammals, honey bees, plants, and the taxa they represent. For birds and mammals, the acute and chronic LOCs are 0.5 and 1.0 respectively; for plants the LOC is 1.0. For bees, the acute and chronic LOCs are 0.4 and 1.0, respectively.

Mammals. The 2018 ERA did not identify potential acute risk concerns for mammals for any registered uses of captan. However, chronic LOC exceedances were reported for mammals in the 2018 ERA and in the 2019 ERA addendum. The 2021 addendum revised mammalian risk estimates for captan to incorporate changes to the chronic mammalian effects endpoint[31] and to the application rates[32] modeled. As summarized in the 2021 ERA addendum, chronic dose-based RQs (upper bound Kenaga) range from 0.1 to 38 for a single application and from 0.41 to 134 for multiple applications. Chronic dietary-based RQs for a single application range from 0.11 to 4.3 (upper bound Kenaga) or from <1 to 1.5 (mean Kenaga). The chronic mammalian RQs exceed the LOC for both single and multiple captan applications at the minimum and maximum agricultural application rates of 1.88 and 4.5 lbs. a.i./A, respectively. RQs continued to exceed the LOC at the Lowest-Observed-Adverse-Effect-Level (LOAEL), providing additional support for chronic risk concerns to mammals.

Chronic mammalian dose-based RQs for small mammals consuming short grass (most conservative estimate) exceeded the NOAEL from 140 days (single application to caneberries at 1.88 lbs. a.i./A) to 269 days (4.5 lbs. a.i./A to almonds, multiple applications) after the initial captan application.[33] In addition, EPA identified potential chronic risk concerns for mammals ingesting seeds treated with captan (RQs ranged from 3.6 to 39). The number of ingested seeds required to reach the chronic LOC for captan range from 1 seed (for small mammals ingesting large seeds such as cowpeas, sweet corn, and peanuts) to 3000 seeds (for larger mammals ingesting smaller seeds for crops including rye, lettuce, and kale).

EPA also conducted spray drift modeling to evaluate off-field chronic risks for mammals. For captan ground applications, drift distances range from 6.6 feet (assuming one application at 1.88 lbs. a.i./A with low boom, fine to medium droplets) to 322 feet (assuming multiple applications at 4.5 lbs. a.i./A with high boom, very fine to fine droplets). For captan aerial applications, drift distances range from 151 feet (assuming one application at 1.88 lbs. a.i./A) to >1000 feet off the field (for multiple applications at 4.5 lbs. a.i./A for fine to medium droplets).

Birds, Reptiles, and Terrestrial-Phase Amphibians. The 2018 ERA did not identify any potential acute risk concerns for nontarget exposure to birds and the taxa they represent (*i.e.,* reptiles and terrestrial-phase amphibians). In avian acute toxicity studies, no effects were seen at the highest dose tested (10,000 mg a.i./kg-diet, a non-definitive endpoints). Captan EECs did not exceed non-definitive acute avian toxicity endpoints for both foliar applications and seed treatments.

[31] The correct NOAEL of 12.5 mg a.i./kg body weight is from a multi-generation rat study that showed decreases in pup litter weight in the first and second generations (MRIDs 00120315 and 00125293). These endpoints are 20 times higher than the previous values.
[32] The previous assessment erroneously modeled a maximum application rate of 6 lb ai/A for apples, rather than the maximum orchard crop rate of 4.5 lbs ai/A for almonds.
[33] These estimates assume that captan has a 35-day foliar dissipation half-life.

Chronic avian reproductive testing showed no adverse effects at doses up to 1,000 mg a.i./kg-diet (non-definitive endpoints).

EECs for some foliar and seed treatment uses exceed the highest tested concentration in avian chronic studies; therefore, at concentrations above 1000 mg a.i./kg-diet, risk is uncertain. For seed treatment uses, several EECs for seeds treated with captan at rates of 3.2 fl oz/100 lbs. seeds exceeded the non-definitive avian No Adverse Effect Concentration (NOAEC) of 1000 mg a.i./kg-diet from a chronic mallard study. Therefore, the Agency cannot preclude risk concerns for seed treatment applications at rates above 3.2 fl. oz/100 lbs. seed due to a lack of information on captan toxicity at corresponding doses greater than 1000 mg a.i./kg-diet. No potential risk concerns were identified for scenarios with EECs less than 1000 mg a.i./kg-diet (associated with application rates below 3.2 fl. oz per 100 lbs. seed).

Terrestrial Invertebrates. Captan is a non-systemic broad-spectrum fungicide registered on a variety of agricultural and non-agricultural crops, some of which are bee attractive and require the use of managed pollinators. Tier I toxicity data for captan are available for acute exposure for adult and larval honey bees; however, no chronic toxicity data are available for adults or larvae. The Tier I pollinator assessment, based on the available data, concluded that acute risk of mortality to adult honey bees is low; however, there are potential risk concerns for larvae on an acute exposure basis at the maximum agricultural (almonds) and non-agricultural (ornamentals) application rates (RQs ranged from 4.3-10.2). An incident involving captan described honey bee brood losses and deformities associated with application to almonds in California. This incident was classified with a certainty index of 'probable,' although the legality of the use was undetermined. There was no information on reported use of other pesticides that could be potentially associated with this incident.

EPA proposes that Tier 1 larval and adult honey bee chronic toxicity data are needed for captan. Pending the results of the chronic larval and adult honey bee Tier I studies, additional higher-tier data (*e.g.*, nectar and pollen residue data and/or semi-field studies at environmentally relevant concentrations) may be useful for refining the understanding of potential exposure of bees from these uses, and the extent of risk at the colony level.

Terrestrial Plants. EPA has not identified any potential risks of concern for terrestrial plants associated with use of captan. The available terrestrial plant toxicity studies for captan showed no adverse effects at the highest tested treatment level (4.55 lbs. a.i./A). The maximum captan application rate for an orchard crop is 4.5 lbs. ai/A (for almonds). When EPA assumes exposure to the highest tested concentration, the resulting RQs do not exceed the LOC.

ii. Aquatic Risks

EPA estimated the potential risk associated with captan use for both freshwater and estuarine/marine fish, invertebrates, and aquatic plants. Risk estimates (RQs) were compared with EPA's Level of Concern (LOC) for non-listed species. The acute and chronic LOCs for fish and aquatic invertebrates are 0.5 and 1.0 respectively, and for aquatic plants the LOC is 1.0.

In the 2018 ERA, EPA identified potential acute risk concerns for freshwater fish exposed to captan from aerial application to orchards and from aerial and ground applications to apples. The RQs ranged from 0.02 to 0.53, with an LOC of 0.5. However, these risk estimates were based on an incorrect maximum application rate of 6 lbs. a.i./A for apples. When the Agency corrected the maximum single application rate for agricultural uses, there were no LOC exceedances associated with the apple use. EPA did not identify any potential risk concerns for aquatic invertebrates (either benthic or water-column) or aquatic plants (vascular and non-vascular). Due to the rapid degradation of captan in water by hydrolysis, chronic exposure in aquatic environments is expected to be low.

In 2003, EPA initiated formal consultation with NMFS on the effects of captan and other pesticides on Pacific salmonids through the transmittal[34], of a final Biological Evaluation.[35] NMFS issued a formal Biological Opinion in 2011, concluding that continued use of pesticide products containing captan would not jeopardize listed Pacific salmonids or destroy or adversely modify their designated critical habitats. The 2011 BiOp described reasonable and prudent measures, which are listed in Section IV of this document, to minimize unintentional harm or death that could result from the legal use of captan to individuals of these listed species and their critical habitats.

2. Ecological Incidents

EPA reviewed OPP's Incident Data System (IDS) on October 25, 2017, for ecological incidents associated with use of captan. Between 1967 and 2017, the IDS reported a total of 14 such incidents, with certainty categories of possible, probable, or highly probable. These incidents were considered as part of the weight of the evidence for captan and they support the risk conclusions for nontarget organisms. Incidents classified as unlikely or unrelated to captan exposure were excluded from this total. The aggregate IDS reported 38 minor plant incidents associated with captan use. Based on the low frequency of captan incidents and probability of their occurrence in nontarget organisms, EPA is not concerned that captan presents an imminent risk at this time. The Agency intends to monitor ecological incidents for captan and will conduct additional analyses if necessary. Specific incidents are summarized below. For details, see the August 21, 2018, ERA, *Captan: Preliminary Ecological Risk Assessment for Registration Review.*

3. Ecological and Environmental Fate Data Needs

At this time, the ecological effects and environmental fate database for captan is considered complete with the exception of an independent laboratory validation for the environmental chemistry analytical method for water. This independent laboratory validation has been submitted to EPA and is in review. The available fate and effects data were sufficient to conduct the 2018 ERA and the 2019 and 2021 ERA addenda and are adequate to support this PID. An

[34] See https://www3.epa.gov/pesticides/endanger/litstatus/effects/captan-letter.pdf
[35] See Captan Analysis of Risks to Endangered and Threatened Salmon and Steelhead (December 2003) at https://www3.epa.gov/pesticides/endanger/litstatus/effects/captan-analysis.pdf

additional environmental chemistry analytical method was required for water because the limit of quantification is higher than the lowest aquatic toxicity effect level of concern.

In addition, because the two avian chronic toxicity studies for captan only tested up to 1000 mg/kg diet, there is considerable uncertainty regarding risk conclusions for some seed treatment uses with EECs that were greater than the highest tested concentration in the study (> 1000 mg a.i./kg-diet or 3.2 fl oz/100 lbs seed). Therefore, EPA intends to issue a future Data Call-In for an additional avian chronic toxicity study (OSCPP Guideline 850.2300) that covers avian dietary concentrations up to the maximum seed treatment application rate (12 fl oz/100 lb seed or 3750 mg a.i./kg-diet).

Furthermore, given the uncertainties surrounding potential risks to terrestrial invertebrates, additional data may be necessary to fully evaluate chronic risks to nontarget terrestrial invertebrates, especially pollinators. Although the Agency identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for captan, the problem formulation and registration review DCI for captan were both issued prior to the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[36]. This 2014 guidance lists pollinator studies that were not included in the captan registration review DCI.

At this time, EPA is proposing that that additional Tier 1 larval and adult honey bee chronic toxicity data be required through EPA's DCI authority. After receiving and reviewing the Tier 1 studies, EPA will determine whether additional higher tier pollinator data, such as the Tier 2 nectar and pollen residue data and/or semi-field studies, are needed for captan. The additional pollinator studies that could be required for captan are listed in Table 1.

Table 1: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
Non-Guideline	Honey bee adult chronic oral toxicity
Non-Guideline	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

C. Benefits Assessment

Captan is a phthalimide fungicide classified within Group M04 by the Fungicide Resistance Action Committee (FRAC) (FRAC, 2021). It acts on multiple biochemical sites within target pests, so it is also known as a "multi-site" fungicide, in contrast to many other fungicides, which act on a single biochemical "site" within the pest. This has implications for resistance

[36] Available at https://www.epa.gov/sites/production/files/201406/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

management benefits, which are further discussed below. It is a protectant fungicide, a term referring to its ability to protect plants from fungal infections when applied prior to the manifestation of infection symptoms. It suppresses fungal growth by direct contact with spores on plant foliage or fruit. Specific benefits of captan in high use agricultural sites are summarized below. These sites include orchard crops (i.e., pome and stone fruits), berries (i.e., blueberries, caneberries, and strawberries), grapes, ornamentals, and ginseng. Additional details may be found in the supporting documents located in the captan public docket, EPA-HQ-OPP-2013-0296 at www.regulations.gov.

1. Orchard Crops

i. Pome Fruits (apples and pears)

Captan use in pome fruit is concentrated in eastern apple production in the U.S.; captan is not used in western apple production or in pears due to lack of pest pressure. Captan has a long history as an effective control for apple scab and is a backbone of the apple disease control spray programs for this pest, so the benefit of captan use for apple production is significant. Captan also controls anthracnose, flyspeck, powdery mildew, rot, rust, and sooty blotch in apples. In apples, captan is the leading fungicide, in terms of acreage treated, for control of apple scab. Apple scab is the most common serious disease of apple in the U.S. and is a major disease for eastern apple growers. The apple scab pathogen may cause significant defoliation and infected fruit are unfit for fresh market. The application timing of captan depends on apple scab disease pressure and weather conditions, and captan is commonly applied as a summer cover spray. One of captan's benefits is that is has a rain-fast quality that can persist during rainy, wet periods. Fungicide resistance management is a significant concern since apple scab has a propensity to develop resistance against fungicides having a single-site mode of action. Although two other multi-site fungicides, mancozeb and ziram, are registered for use on apples, they are not as effective as captan for apple scab control. In addition, mancozeb has a long pre-harvest interval and is limited to early season use. EPA has proposed cancellation of use of ziram on apples in the Proposed Interim Decision for that chemical.[37] Although captan is also labeled as a post-harvest fruit treatment for pome fruit, multiple alternative fungicides that are more efficacious in controlling fungal decay of fruit during storage are available and preferred by packing houses. For more details, please see *Captan Usage, Pest Management Benefits, and Impacts of Possible Mitigation on Apple* in the public docket.

ii. Stone Fruits (peaches, tart cherries, plums/prunes)

In stone fruit, captan is used from bloom to harvest but is most important as a "cover spray" that is applied after bloom until harvest. Captan provides benefits to stone fruit growers in terms of reduced fungal control costs and fungicide resistance management for blossom blight/brown rot (*Monilinia spp.*), peach scab (*Cladosporium carpophilum*), and cherry leaf spot (*Blumeriella jaapii*) in peaches and tart cherries. In warm and humid climates, brown rot is the most important disease of stone fruit and the primary reason for fungicide application. If captan were not

[37] See docket EPA-HQ-2015-0528 for the Ziram Proposed Interim Decision. The Agency has proposed canceling all conventional agricultural uses of ziram.

available, peach and tart cherry growers would need to use more expensive alternative fungicides; plum/prune growers would have alternative fungicides available with similar efficacy and cost. In addition, if captan were not available, resistance to some of the likely single-site MOA alternative fungicides could develop rapidly, particularly with the brown rot pathogens, a genus that is well known for developing resistance. Although captan is also labeled as a post-harvest fruit treatment for cherries, multiple alternative fungicides that are more efficacious in controlling fungal decay of fruit during storage are available and preferred by packing houses. For more details, please see *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for the Fungicide Captan* in the public docket.

2. Berries and Grapes

i. Blueberries

In blueberry, captan is used in disease management programs throughout the growing season for mummy berry, *Botrytis* fruit and flower blight, *Exobasidium* leaf and fruit spot, Anthracnose leaf spot and ripe rot, blueberry rust, *Alternaria* rot, and *Phomopsis* cane blight. As blueberries are most valuable when sold for fresh-market consumption, diseases that cause fruit damage, such as mummy berry, *Botrytis, Exobasidium,* Anthracnose, and *Alternaria* fruit rots, are important to prevent, as fruit damage can cause the harvest to be unmarketable. Foliar diseases, such as Anthracnose and *Exobasidium* leaf spots and blueberry rust, can result in defoliation that leads to poor bud and fruit development, reducing yields. *Phomopsis* twig blight is also important to control, as it can cause loss of twigs and subsequent yield losses or, when severe, death of entire plants. Fungicide resistance is a concern, particularly in *Botrytis* and *Exobasidium* diseases; therefore, captan, as a multisite fungicide, is an important tank-mix addition to delay the development of pathogen populations with resistance to single-site fungicides. Other multisite fungicides registered in blueberry are lime sulfur and ziram; however, lime sulfur can only be applied after harvest and during the dormant period, and ziram has low efficacy compared to captan and cannot be used later than 3 weeks after full bloom. Moreover, EPA has proposed cancelling the use of ziram on blueberry. Thus, captan is particularly important for resistance management in blueberry because it is the only efficacious multisite fungicide available during the growing season. For more details, please see *Benefits of Captan in Caneberries, Blueberry, and Grape, and Impacts of Potential Mitigation* in the public docket.

ii. **Caneberries**

Captan is applied to caneberries (e.g., raspberry, blackberry) primarily to control diseases caused by the fungal pathogen *Botrytis cinerea,* including gray mold, fruit rot, and blossom blight. Captan is also applied to caneberries for management of *Anthracnose*, consistent with recommendations from university extension. As caneberries are most valuable when sold for fresh-market consumption, diseases that cause fruit damage, such as *Botrytis* and anthracnose, are important to prevent, as fruit damage can cause a crop to be unmarketable, resulting in economic losses. *Botrytis* blossom blight is also important to prevent, as blighted flowers will not produce fruit and will sporulate, leading to subsequent fruit rots and yield losses. Although captan may not be as effective as newer site-specific fungicides for management of *Botrytis* diseases*,* it has the lowest risk of resistance development and thus is important to quell

development of resistance to single-site fungicides in fungal populations. Other multisite fungicides registered in caneberry are lime sulfur, sulfur, and copper. Sulfur and copper both have low or no efficacy on captan's target diseases. Lime sulfur, while efficacious on most of captan's target diseases, is substantially more expensive than captan, cannot be used on raspberries during the growing season, and is not recommended for management of *Botrytis* diseases, rendering it an insufficient alternative to captan in most scenarios. For more details, please see *Benefits of Captan in Caneberries, Blueberry, and Grape, and Impacts of Potential Mitigation* in the public docket.

iii. Strawberries

Captan is effective against important fungal pathogens of strawberry including gray mold (*Botrytis cinerea),* anthracnose (*Colletotrichum* spp.), and leaf spot disease (*Mycosphaerella fragariae*). *Botrytis cinerea* infections can kill blossoms and can infect fruits resulting in rot during storage. *Colletotrichum* spp. infects strawberry foliage, runners, crowns and fruits which can result in reduced fruit yields and fruit rot during storage. *Mycosphaerella* spp. infects leaves, fruits, and runners. The most noticeable symptoms are small round spots on strawberry leaves; leaf spot disease can result in significant yield losses under high disease pressure. Captan is a desirable fungicide for strawberry producers for its multisite mode of action, low risk of resistance development in fungal pathogens, and affordability relative to registered alternative fungicides used by growers. Thiram is the only other registered multisite mode of action fungicide for strawberry. Thiram is less efficacious than captan when targeting anthracnose in California and Florida, and less efficacious on *Botrytis* gray mold in California. Moreover, EPA has proposed to cancel the foliar use of thiram on strawberry.[38] As with the other crops discussed in this section, it can also be an important rotational component for fungicide resistance management programs to help delay/prevent resistance development against single-site mode of action fungicides that are used during the strawberry season. For more details, please see *Use, Usage, Benefits, Impacts of Potential Risk Mitigation and Summary of Public Comments for Captan Use in Strawberry* in the public docket.

iv. Grapes

In East Coast grape production, captan has good to excellent efficacy on *Phomopsis* cane and leaf spot and downy mildew; the *2017 Pest Management Strategic Plan for Grapes in the Northeast* indicates that captan is a standard material for management of *Phomopsis* cane and leaf spot. The University of California (UC) Integrated Pest Management (IPM) program recommends that growers use protectant fungicides, such as captan, to prevent fungal trunk diseases, such as esca or *Phomopsis*. Surveys of California growers indicate that captan is used in wine and table grapes exclusively for control of esca. Trunk diseases of grape are important to prevent, because once an infection is established within a plant, fungicides cannot eradicate it, and the plant must be pruned or removed, depending on the location and severity of the infection. Downy mildew is also an important pathogen of grape, as it can infect leaves, inflorescences, and young berries, and lead to significant yield losses if not managed by fungicides such as captan.

[38] EPA has proposed to cancel all foliar uses of thiram in strawberry. See *Thiram Proposed Interim Decision* in docket EPA-HQ-OPP-2015-0433.

Other multisite fungicides registered in grape include coppers, mancozeb, sulfur, lime sulfur, and ziram; however, these multisite fungicides are generally regarded as inferior to captan with regard to pest control, efficacy, crop safety, and/or preharvest interval. Furthermore, EPA has proposed cancelling use of ziram on grapes.[39] For more details, please see *Benefits of Captan in Caneberries, Blueberry, and Grape, and Impacts of Potential Mitigation* in the public docket.

3. Ginseng and Ornamentals

i. Ginseng

Captan is considered an essential chemical for commercial ginseng production, offering unique benefits to users by providing effective protection against major fungal diseases impacting ginseng production, which include *Phytophthora* root and crown rot, *Alternaria* leaf and stem blight, and *Botrytis* blight. The dry flowable (DF) captan formulation is preferred in commercial ginseng production and is typically applied by groundboom at the labeled maximum single application rate of 3 lbs. ai/acre, with re-application intervals of every two to three weeks, and six total applications per season. Growers use captan to maintain a constant fungicidal protective coverage throughout ginseng's multi-year growing season. In the absence of captan, users would most likely experience crop yield losses due to disease pressure, because currently available fungicides registered for ginseng to treat the same target pests as captan are already being used with captan, have seasonal label application restrictions, and/or have a higher risk of developing disease resistance. These alternatives, which include mandipropamid, fluopicolide, oxathiapiprolin, chlorothalonil, and mancozeb, are currently used alongside captan. For more information, please see *Amended: Captan Use, Usage, and Pest Management Benefits, and Impacts of Potential Mitigation on Ginseng and Ornamental Use Sites,* available in the public docket.

ii. Ornamentals

In ornamental use sites, captan is labeled to treat a range of fungal diseases in a variety of ornamental crops, including those in residential use sites. Target diseases include damping-off, petal blight, tuber rot, *Alternaria* leaf spot, rust, *Botrytis* flower blight, *Septoria* leafspot, black spot, and white mold. However, based on feedback received from stakeholders, captan provides low benefits to the production of ornamentals as it has been displaced in the ornamental industry by newer and more effective fungicidal active ingredients to treat target pests, limiting its use to treat younger plants and seedling in commercial production, and to personal use in residential ornamentals.

4. Resistance Management Benefits

Captan is often used alone or in tank mixtures with single-site fungicides as part of a resistance management plan. Because captan has a multi-site mode of action, it is less prone to fungicide resistance, unlike fungicides with a single site of action. There have been no reports of fungicide resistance associated with captan since it was first registered in 1951. Depending on the crop,

[39] See *Ziram Proposed Interim Decision* in docket EPA-HQ-2015-0568.

other multi-site fungicides may also be available: primarily chlorothalonil and mancozeb. However, these other multi-site fungicides may not always be appropriate substitutes for captan due to various factors such as restrictions on the timing of applications or effectiveness against a particular target pest in a given crop. For example, chlorothalonil cannot be used in stone fruits after the shucks split (essentially resulting in prohibition of use after fruit begins to develop), and mancozeb[40] is not as effective as captan for apple scab control.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

EPA has identified potential risk concerns to human health and nontarget organisms associated with use of captan. In the 2018 HHRA and three subsequent addenda, EPA identified potential risk concerns for pesticide handlers and re-entry workers who are exposed to captan through their work in agriculture, nurseries and greenhouses, fruit packing houses, in seed and seed piece treatment facilities, and during on-farm seed treatment. The Agency also identified potential risk concerns associated with residential use products, but this has been addressed by registrants through a voluntary product cancellation and deletion of home and garden sublabels. In the 2018 ERA and subsequent addenda, the Agency identified potential risks to nontarget mammals, birds, insect pollinators, fish and other aquatic organisms associated with use of captan. The Agency has concluded that these potential risks must be mitigated to meet the FIFRA and FFDCA registration standard for captan based on the risk summary and characterization in Sections III.A. and III.B. of this document.

EPA identified potential residential and aggregate risk concerns associated with captan home and garden products containing more than 12% active ingredient, therefore, all registrants of products containing more than 12% captan active ingredient have voluntarily cancelled these products or amended the product registrations, effective November 15, 2021. (See 86 FR 63,019.) EPA approved these label amendments in February 2022.

To mitigate potential occupational risk concerns for pesticide handlers and re-entry workers, EPA is proposing label changes that would eliminate aerial application of the DF/WDG and WP formulations of captan on certain crops; reduce application rates for apples, peaches, nectarines, cherries, and grapes; and specify additional personal protective equipment, engineering controls; and change REIs[41]. For pesticide handlers who apply captan via mechanically pressurized handgun, the Agency is proposing a limit on the amount handled for growers who are unable to reduce the application rate due to pest pressures. For orchard crops EPA is also proposing optional reductions in area treated per day for airblast application that will reduce risk to growers and applicators who do not have ready access to engineering controls. The Captan Task Force has agreed to these mitigation measures. Although EPA expects that there will be some potential occupation risks of concern for captan, even after implementation of these risk mitigation

[40] Mancozeb also has a 77 day preharvest interval on apples, limiting the application window.

[41] Because captan is a corrosive eye irritant (Toxicity Category I), the default REI assigned under WPS is 48 hours. See 40 CFR 156.208(c)(2). This is the minimum REI that could be assigned to captan.

measures, the Agency believes that the high benefits of captan outweigh the risks and that the remaining risks are not unreasonable in light of the high benefits of captan.

To mitigate potential risk concerns for nontarget organisms, the Agency is proposing to prohibit aerial application of the WP and DF/WDG formulations of captan on orchard, berry, and vineyard crops, which constitute the majority of captan usage; reduce application rates for apples, peaches, nectarines, cherries, and grapes; require the addition of mandatory and advisory spray drift statements and mandatory environmental hazard statements to captan labels; and require that seed treatment products contain instruction to label treated seed with bag tags. EPA is also proposing to terminate all use of captan on turf, grasses, grass substitutes, and lawn seedbeds for all registered captan products. Last, EPA is in the process of implementing the 2011 NMFS BiOp describing the impacts of captan on salmonids in the Pacific Northwest states of California, Idaho, Oregon, and Washington. The Captan Task Force has agreed to this mitigation.

Although EPA expects that there will be some potential ecological risks of concern for captan, even after implementation of these risk mitigation measures, the Agency believes that the high benefits of captan outweigh the risks and that the remaining risks are not unreasonable in light of the high benefits of captan.

In evaluating potential risk mitigation for captan, EPA considered current use patterns, risks, and benefits, under the risk-benefit provisions of FIFRA. Although there are risks of concern associated with the use of captan, with the adoption of the proposed mitigation measures, the Agency believes that the benefits of captan use, including its efficacy, its multisite mode of action and its lack of resistance, outweigh any remaining worker and ecological risks. For more information on the benefits of captan, see Section IIIC of this document. This conclusion is explained in more detail in Section IV.E. of this document.

The expected impacts of the proposed mitigation on captan users are presented below by mitigation measure. Section IV.B. of this document summarizes mitigation by use site. EPA encourages submission of comments about these and any other possible impacts of the proposed mitigation to the public docket for this PID, EPA-HQ-OPP-2013-0296.

1. Percent Active Ingredient in Consumer Products

All currently registered captan product registrations with greater than 12% active ingredient have been voluntarily canceled or amended to remove the home and garden sublabel. At this time, the only registered captan home and garden product contains 11.7% active ingredient. EPA has identified risk concerns for consumer home and garden products containing more than 12% active ingredient but not for products containing less than 12% active ingredient.

2. Termination of Uses and Application Methods

All Turf Uses. To address a data deficiency, potential risk to adults and children (both residents and bystanders), and potential risks to nontarget organisms, EPA proposes to terminate all remaining registered uses of captan on turf-related use sites including, all grasses, grass substitutes, and lawn seed beds. These include but are not limited to dichondra, St. Augustine

grass, lawn seedbeds, and ornamental grasses. The registration review DCI for captan included a requirement for a turf transferable residue (TTR) study. However, the technical registrants chose not to develop the data necessary to support the turf use and instead opted to remove most, but not all, turf uses from the captan product labels. Therefore, given the potential risk concerns identified for the remaining use of captan on turf, ornamental grasses, grass substitutes, and lawn seedbeds, and any other turf-like[42] uses, as well as potential risk concerns for nontarget organisms, the Agency is proposing to terminate all remaining turf-like uses described above. These uses were not assessed in the HHRA, ERA, or the HHRA and ERA addenda because most of the turf uses had been voluntarily removed from product labels before EPA initiated the captan risk assessment process; however, the Agency anticipates risk concerns for any remaining turf uses.

Aerial Application with Certain Formulations. To address potential inhalation risk concerns for captan mixers and loaders who are supporting aerial application of DF/WDG and WP formulations, EPA is proposing that this application method be prohibited and removed from captan DF/WDG and WP product labels for almonds, apples, apricots, blueberries, cherries, grapes, nectarines, peaches, plums/prunes, and strawberries. This prohibition will completely mitigate risk concerns for mixers/loaders who support aerial applicators. The aerial application prohibition for DF/WDG and WP formulations will also partially mitigate acute risk concerns for freshwater fish and chronic risk to mammals by reducing environmental exposure. Aerial application will continue to be allowed for liquid formulations because there were no occupational risks identified for this formulation. Because very little captan is currently applied by air[43] and because the proposal allows growers to continue to apply liquid captan products by air, EPA expects the impacts of this mitigation measure on users to be minor.

3. PPE and Engineering Controls

PF50 Respirator Requirement for Certain Handlers. To address inhalation risk concerns for pesticide mixers and loaders, EPA is proposing to increase the level of respiratory protection from a PF10 respirator to a PF50 respirator for certain exposure scenarios. These include:

- Mixing and loading for the DF/WDG formulation to support airblast and groundboom applications to orchard crops (when workers wear a PF10 respirator, MOEs range from 8 to 18, but are all greater than the LOC of 30 with a PF50 respirator),
- Mixing and loading for the WP formulation to support airblast and groundboom applications to orchard crops when captan is applied at rates greater than or equal to 4 lbs. ai/A (when workers wear a PF10 respirator, MOEs range from 26 to 29, but are greater than the LOC with a PF50 respirator),
- Seed treatment workers involved in more than one activity when treating certain seeds[44] (when workers wear a PF10 respirator, MOEs range from 12 to 29; but are greater than the LOC with a PF50 respirator),

[42] Including but not limited to lawns, lawn seed beds, ornamental grasses, and grass substitutes such as dichondra.
[43] According to the Kinetic database about 1% of captan is applied by air. Kynetec USA, Inc. 2020. AgroTrak® Study. iMap Software. Database Subset: 2015-2019. [Accessed January 2021].
[44] Seeds of alfalfa, clover, trefoil, barley, rye, corn, cotton, cowpeas, oats, sorghum, soybean, and strawberry.

- Fruit dipping workers mixing and loading DF/WDG and WP for mixing a post-harvest fruit dip solution for apples, cherries, and pears (when workers wear a PF10 respirator, MOEs are 4.5 and 15, respectively, but are 22 and 73 with a PF50 respirator), and
- Fruit packing workers handling apples, cherries, and pears treated with captan post-harvest (when workers wear a PF 10 respirator, the MOE is 13, with a PF50 respirator, the MOE is 63, greater than the LOC).

The MOEs resulting from the use of a PF50 respirator for these activities can be found in the second and third HHRA addenda. EPA anticipates impacts to captan users associated with the requirement of a PF50 respirator for mixers and loaders of DF/WDG and WP formulations.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. For example, the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. PF50 respirators, in particular, could cost[45] growers approximately $1,500 per respirator, per person, with additional costs for replacement cartridges and annual fit testing. The Worker Protection Standard (WPS) requires users of respirators to have a fit test done annually; in 2015, EPA estimated this procedure to cost about $180. These costs may have increased since this cost was estimated in 2015. If a pesticide handler currently using captan does not have a respirator, then this person will have to purchase a respirator, hire a professional applicator who already has this PPE, or use an alternative fungicide[46] without this requirement. Costs may be different if a handler typically uses other chemicals requiring a respirator in the production system or as part of the business. This would eliminate the cost of additional fit testing but there would be an increased cost of purchasing filters for the respirator more frequently.

The PF50 respirator requirement for post-harvest applications may limit the use of captan as a post-harvest dip treatment for apples, cherries, and pears. However, this post-harvest dip treatment is not a high-benefit use of captan. Cost-effective alternatives are already used.

Updated Respirator Statement. In addition to proposing the requirement for a PF50 respirator, EPA proposes updating the respirator statement currently on captan product labels (see Appendix B). The proposed clarification does not fundamentally change the PPE that workers currently must use.

EPA's HHRA assumes National Institute for Occupational Safety and Health (NIOSH) protection factors[47] in estimating the inhalation risks and the risk reduction associated with

[45] Three sources of PF50 respirators include (1) Airgas. 2021. PAPR Respiratory Protection. Available at: https://www.airgas.com/Safety-Products/Respiratory-Protection/PAPR/category/344; (2) Fisher Science. 2021. PAPR Systems. Available at: https://www.fishersci.com/us/en/browse/90136215/papr-systems, and (3) Grainger. 2021. PAPR System Kit, Versaflo. Available at: https://www.grainger.com/product/3M-PAPR-System-Kit-475M36. EPA accessed these in March 2021.

[46] Alternative fungicides are listed in Section III.C. of this document and in the benefits assessments, which are in the captan docket, EPA-HQ-OPP-2013-0296.

[47] NIOSH protection factors assume that respirators are used according to OSHA's standards.

different respirators.[48] If the respirator does not fit properly, EPA's proposed PPE mitigation for captan may not reduce risks as detailed above and may result in unreasonable adverse effects for the pesticide handler.

Enclosed Cabs for Airblast Applicators for Orchard Crops who Apply Captan at rates of 3 lbs. ai/A or higher. To address dermal and inhalation risk concerns for pesticide handlers who apply captan to certain orchard crops[49] using airblast equipment, the Agency is proposing to require use of an enclosed tractor cab. Use of enclosed cabs would result in a change to inhalation MOEs, from the range of 15 to 23 for orchard crops, when captan is applied at 3 lbs. ai/A and above, to MOEs greater than the LOC of 30. (See Table 1 in Appendix F for details.) This mitigation would completely address EPA's risk concerns. The Captan Task Force has agreed to this mitigation, provided that growers have an alternative option, which is a reduction in the area treated, described in Section IV.A.4 of this document. For apples, the Agency expects this mitigation to impact about 13% of the apple acres using captan to control apple scab at a rate higher than 3.0 lbs. ai per acre.[50] Growers who currently use higher rates of captan on their apple acres might face impacts from switching to a more expensive, alternative multisite fungicide like copper as a replacement for late season applications. For early season applications, the likely alternative is mancozeb which is similar in cost per acre; low to now grower impacts would be expected. For late season applications, the likely alternative is copper, which is more expensive than captan, therefore, growers might be impacted by the higher cost of the alternative fungicide. For peaches, about 8% of grower might be impacted. EPA is also proposing application rate reductions for certain crops (see Section IV.A.4.). If those rate reductions are implemented, almonds would be the sole crop with an application rate greater than 3 lbs. ai/A, and the only crop affected by this mitigation proposal. However, because only a small number of almond acres are treated with captan (1-3% crop treated) and because effective alternatives are available, EPA anticipates little to no impact from this restriction.

Enclosed Cabs for Airblast Application to Blueberries and Caneberries. To address inhalation risk concerns for pesticide handlers who apply captan to highbush blueberries, EPA is proposing to require use of an enclosed tractor cab. This requirement would be impactful for the majority of caneberry and blueberry growers that do not already have enclosed cabs. Growers who do not already have the appropriate equipment would either have to purchase the equipment, hire a commercial firm to make captan applications, likely at an increased cost, or find an alternative fungicide which could be more expensive and/or less efficacious.

Alternatively, applicators may use an open cab, PF10 respirator, single layer PPE, and chemical resistant gloves but are limited to treating 35 acres/day for blueberries and 40 acres/day for caneberries. This mitigation would completely address EPA's risk concerns, and the Captan Task

[48] Proper fit and use of respirators are essential to accomplish the protections respirators are intended to provide. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection. 29 C.F.R. § 1910.134.

[49] Orchard crops with an application rate of 3 lbs. ai/A or higher include almonds, apples, cherries, nectarines, and peaches.

[50] For details, see the March 30, 2022, memo, *Captan Usage, Pest Management Benefits and Impacts of Proposed Mitigation for Use on Pome Fruit*, available in the public docket (EPA-HQ-OPP-2013-0296).

Force has agreed to the mitigation. Given typical airblast spray practices which make it unlikely that a caneberry or blueberry grower would treat an area greater than the acreage limitations, it is unlikely that this limitation will preclude these growers from using captan. If a grower was impacted by acreage limitations because they need to treat a large area, they would need to hire more people who can apply captan, spend multiple days in a row on fungicide applications, or switch to an alternative fungicide without acreage limitations. However, typical airblast spray practices make it unlikely that a caneberry or blueberry grower would treat an area greater than the acreage limitation.

Chemical Resistant Eyewear. To address known hazards with eye injury associated with use of captan, EPA is proposing to continue the requirement for applicators to wear chemical-resistant eyewear. This will completely address potential eye injury, as demonstrated by a decrease in incident reports associated with eye injury. Applicators who are using an enclosed cab are not required to wear chemical-resistant eyewear when they are inside the enclosed cab.

Double Layer and Chemical-Resistant Gloves for Seed Treatment. To address potential risk concerns for on-farm planter box treatment of soybean seeds, EPA is proposing the addition of a second layer of PPE, such as coveralls or a chemical resistant apron, with the continued use of chemical-resistant gloves. For workers wearing a single layer of PPE and chemical-resistant gloves, dermal MOEs range from 74 (for soybeans) to 740. With a second layer of PPE, the worst-case dermal MOE is 150, above the LOC of 100, and no longer of concern. This mitigation completely addresses the risk concern. This requirement may impose a cost on pesticide handlers and growers for the cost of the PPE; however, the Agency expects these costs and any other associated impacts of this requirement to be minor.

Updated Glove Statement. EPA is proposing to update the gloves statements on all captan labels to be consistent with Chapter 10 of the Label Review Manual.[51] The glove statements should no longer include any references to specific categories in EPA's chemical-resistance category selection chart and should specify the appropriate type of chemical resistant glove for use with each captan product.[52]

Updated Labeling for Water Soluble Packaging. EPA is proposing updated directions for use language be added to labels for captan products in water-soluble packaging. These updated directions for use are expected to improve label clarity. This in turn is expected to ensure proper use of these products and to minimize exposure to occupational handlers.

4. Reduction in Application Rate, Area Treated, and/or Amount Handled

Application Rate Reductions for Certain Crops. To address both inhalation risk to pesticide handlers and post-application dermal risk to workers re-entering treated areas, the Agency is proposing application rate reductions for apples, cherries, peaches, nectarines, and grapes. EPA is proposing a maximum application rate of 3 lbs. ai/A for apples, cherries, nectarines, and peaches and a maximum application rate of 1.75 lbs. ai/A for grapes. These rate reductions,

[51] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual.
[52] For specific label language, see Appendix B.

combined with the requirement for a PF50 respirator and/or an enclosed cab, will reduce inhalation risk for these crops to above EPA's level of concern (LOC of 30), as shown in Appendix F of this document. These rate reductions will also allow shorter REIs for hand-thinning orchard fruit crops and grapes (compared to the 30-day REIs that EPA estimated in the 2018 HHRA).

The Agency anticipates that most stone fruit growers will be unaffected by the rate reduction. All captan-treated acres for tart cherries, the type of cherry where captan is used, are already treated at rates below the proposed 3 lbs. ai/A rate maximum. For peach and nectarine growers, approximately 8% of treated acres will be affected by the rate reduction because these acres are currently treated at a rate greater than 3 lbs. ai/A. Growers who currently use higher rates of captan on their peaches and nectarines might face impacts from switching to more expensive alternatives as well as enhanced resistance among pests because likely alternatives are single site chemistries.[53]

EPA anticipates that in most situations, grape growers who currently use captan will be unaffected by the proposed rate reduction; however, the Agency acknowledges that the proposed rate may be ineffective in the face of high disease pressure, especially near the end of the growing season. In this situation, growers may see reduced disease control from captan applications and may need to supplement with another fungicide, most likely in a tank mix with captan to avoid any development of fungicide resistance in captan's target pest(s). For apples, EPA expects a rate reduction from 4.0 lbs. ai to 3.0 lbs. ai per acre to impact about 13% of the apple acres using captan to control apple scab at a rate higher than 3.0 lbs. ai per acre.

Reduction in Acreage Treated by Airblast for Orchard Crops. As an alternative for growers who do not have access to, or cannot use an enclosed cab in their orchards, EPA is proposing a reduction of the of acreage treated by each handler by airblast each day (24-hour time period). The acreage limit varies by crop and is described in detail in Section IV.B of this document. The airblast applicator would be required to wear a PF10 respirator, single layer PPE, and chemical resistant gloves. This alternate mitigation will completely address EPA's risk concerns for airblast applicators. Growers with orchards larger than 30 acres will have to choose between limiting applications to only 30 acres per day, investing in enclosed cab equipment or hiring a commercial firm to make captan applications, or using an alternative fungicide at a higher per acre cost. Based on orchard sizes in the Census of Agriculture, a maximum daily application limit of 30 acres could impact up to 9% of tart cherry orchards, 7% of nectarine orchards, 5% of peach orchards, and 7% of plum/prune orchards (USDA NASS, 2017) if those orchards are already using captan.

Reduction in Amount Handled by Applicators Using Mechanically Pressurized Handgun. To address dermal risk concerns for pesticide handlers who apply captan using a mechanically pressurized handgun, EPA is proposing a limit to the amount of captan solution handled per applicator per day (24-hour time period). This limit varies by crop and is described in detail in Section IV.B. of this document. For stone fruit and berry crops, the Agency anticipates minimal

[53] For details, see the March 18, 2022, memo, *Assessment of Usage, Benefits and Impacts of Proposed Mitigation in Stone Fruit Production for the Fungicide Captan.*

impacts for most operations because the most likely situation under which captan would be applied by mechanically pressurized handgun is in small orchards or plantings under severe pest pressure when dilute spraying is necessary.

5. Changes to Restricted-entry Intervals (REIs)

EPA is proposing changes to REIs to protect workers performing high-contact activities, including girdling and turning vines for table grapes, and working with handset irrigation used in ornamental nurseries following captan application. For table grapes, EPA is proposing a 5-day REI for girdling and turning. The MOE is 96 on the 5th day after captan application. For ornamentals, EPA is proposing an 8-day REI for work on handset irrigation. The MOE is 92 on the 8th day after captan application (and 100 on the 10th day). Although these proposed activity-based REIs for table grapes and ornamentals result in MOEs less than the LOC of 100, these longer REIs will address most risk concerns for re-entry workers exposed to captan on foliage. For orchard crops, a longer REI is not needed, provided that application rate reductions are implemented as described herein. For grapes, the Agency expects minor impacts from the lengthened REIs as the affected activities either no longer occur in commercial grape production or do not occur during the time when growers would apply captan. For ornamentals, impacts will be negligible because handset irrigation is seldom used.

6. Endangered Species

EPA has determined that the following language is necessary to address the 2011 NMFS BiOp on the effects of captan on endangered and threatened Pacific salmonids. EPA intends to implement these statements on all product labels, as these best management practices are expected to reduce off-target movement and further protect listed species and provide for a more streamlined nationwide ESA assessment and consultation process.

- ***"Reporting Ecological Incidents****: To report ecological incidents, including mortality, injury, or harm to plants and animals, call [*insert registrant phone number*]."*

- **Windspeed restrictions** – "Do not apply when wind speeds exceed 10 mph."

- **Rain restrictions** – "Do not apply this product when soil is saturated. Do not apply when a storm event likely to produce runoff from the treated area is forecasted (by NOAA/National Weather Service, or other similar forecasting service) to occur within 48 hours following application."

EPA is continuing to discuss with NMFS other aspects of the 2011 BiOp and will consider comments on the PID in the context of such discussions.

In addition to the above label language, EPA is proposing that the following statement be added to all labels to streamline implementation of additional risk reduction measures that may be identified during the nationwide consultation process.

"*Endangered Species Protection Requirements*: *It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species, under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult* ***http://www.epa.gov/espp/****, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product."*

7. Spray Drift Management

EPA proposes adding mandatory and advisory spray drift management language to captan labels to reduce off-target spray drift and consistently protect against a baseline level of spray drift across all captan products.[54]

The Agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all captan products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of captan.

EPA is proposing the following spray drift mitigation language to be included on all captan product labels for products applied by liquid spray application. The proposed spray drift language is intended to be mandatory and enforceable and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The Agency is also providing recommendations which allow captan registrants to standardize all advisory language on captan product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once effective.

- Applicators must not spray during temperature inversions.
- For aerial applications, do not apply when wind speeds exceed 10 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- For aerial applicators, if the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.

[54] Reducing spray drift will decrease environmental exposure and risk to nontarget organisms. Although EPA is not making a listed species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of captan. For specific label language, see Appendix B.

- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For airblast applications, nozzles directed out of the orchard must be turned off in the outer row.
- For air blast applications, applications must be directed into the canopy foliage.

In addition to including the spray drift restrictions on captan labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all captan labels where such information currently appears. The proposed new language above, which cites ASABE S572.3, eliminates the need for VMD information.

Prohibiting applications during inversions could result in delays to intended applications and, more generally, reduce the amount of time users have to apply captan. Management of production activities would be more complex. Additionally, inversions are difficult to detect, and compliance with this mitigation may be difficult for growers.

Mitigations associated with aerial application are expected to have low to no impact on growers because aerial application of captan is rare.

Wind conditions vary across the U.S. and wind speed restrictions could prevent timely applications of captan. However, it is already a best management practice for pesticide applicators using airblast sprayers to apply at wind speeds less than 10 mph. Due to the fine nature of the droplets produced by airblast sprayers, high wind speeds greatly reduce the coverage and consequently the efficacy of a pesticide. EPA expects the impact of the wind speed restriction for ground applications to be minor.

For airblast applications, the requirement to turn off the nozzles directed out of the orchard and requiring applications to be directed into the canopy foliage is expected to have little impact on growers, as these are already standard practices.

8. Nontarget Organism Advisory Statements

EPA is proposing nontarget organism advisory statements to reduce nontarget risk concerns for captan. These include risk concerns for terrestrial organisms, including mammals, birds, and pollinating insects. Based on the incomplete data available, EPA is uncertain how much risk captan presents to pollinators, which may be exposed to captan from residues in pollen or nectar through spray drift. EPA prioritizes protecting pollinators, including by reducing spray drift and educating growers about potential indirect adverse effects of pesticides (including captan) on foliage and habitat of nontarget organisms.

9. Resistance Management

The Agency proposes adding resistance-management language to captan labels to reduce the development of pesticide resistance. Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management, EPA intends to propose pesticide resistance measures for existing chemicals during registration review and for new chemicals and new uses

at the time of registration. To combat pesticide resistance, resistance management experts recommend using pesticides with different chemical modes of action against the same target pest population as part of integrated pest management (IPM) programs. This approach may prevent or delay target pest populations from developing resistance to a particular mode of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

Adding this language will provide pesticide users with easy access to important information on maintaining the effectiveness of pesticides—including captan—thereby preserving the benefits of captan and other useful pesticides. EPA does not expect this language to affect the risks or benefits of captan.

B. Summary of Crop and Use Specific Mitigation

EPA's mitigation proposals for major agricultural crops treated with captan and other registered uses of captan are summarized below. These proposals are listed by the major types of formulated captan products: DF/WDG, liquid, and WP. The proposal for the following crops and other registered uses describes the risk issues to be addressed by mitigation, the mitigation proposal, whether the mitigation completely addresses the risk, and the potential impacts of the mitigation.

1. Proposed Mitigation for Orchard Crops

EPA's mitigation proposal for orchard crops (almonds, apples, apricots, cherries, nectarines, peaches, plums, and prunes) is as follows:

- Prohibit aerial application of DF/WDG and WP formulations.
- Reduce maximum application rate for apples, peaches, and nectarines, from 4 to 3 lbs. ai/A.
- Reduce maximum application rate for cherries from 3.16 lbs. to 3 lbs. ai/A.
- Require PF50 respirator, single layer, and chemical-resistant gloves for handlers mixing/loading DF/WDG and WP formulations for airblast application.
- Require enclosed cabs and single layer PPE for airblast applicators.
    - Alternative option: applicator may use an open cab and PF10 respirator but is limited to treating 30 acres/day for all crops (apples, peaches, nectarines, and cherries) except for almonds.
        - For almonds, an applicator using an open cab and PF10 respirator may only treat 20 acres/day.
- Require enclosed cabs and single layer PPE for groundboom applicators treating all orchard or PF10 respirator and single layer PPE.
- Require PF10 respirator and limit amount handled by applicators using mechanically pressurized handguns.
    - Almonds ≤ 220 gal/day
    - Apples, nectarines, and peaches ≤ 245 gal/day
    - Cherries ≤ 315 gal/day
    - Apricots ≤ 395 gal/day

  - Plums and prunes ≤ 325 gal/day
- No changes to current REI (default WPS REI based on acute toxicity).

For the post-harvest use of captan as a fruit dip for apples, cherries, and pears, fruit sorters and packers must wear a PF50 respirator. All other packing house workers wear a PF10 respirator. Inhalation MOEs range from 1.3 (with no respirator) to 63 (with a PF50 respirator), and the LOC is 30. Therefore, this mitigation will completely address inhalation risk concerns from this scenario.

2. Proposed Mitigation for Berries and Grapes

EPA's mitigation proposal for berries (blueberries, caneberries, and strawberries) is as follows:

- Prohibit aerial application of DF/WDG and WP formulations. Aerial application is allowed for liquid formulations.
- Require PF50 respirator for mixing/loading DF/WDG formulation only for airblast and groundboom application as well as single layer PPE and chemical-resistant gloves.
- Require enclosed cabs and single layer PPE for airblast applicators treating blueberries.
  - Alternative option: applicator may use an open cab, PF10 respirator, single layer PPE, and chemical resistant gloves but is limited to treating 35 acres/day for blueberries and 40 acres/day for caneberries.
- Require PF10 respirator, single layer PPE, and chemical-resistant gloves for groundboom application to blueberries, caneberries, and strawberries.
- Require PF10 respirator, single layer PPE, chemical-resistant gloves, and limit to amount handled for mechanically pressurized handgun to ≤ 395 gal/day for blueberries.

EPA's mitigation proposal for grapes is as follows:

- Maximum application rate reduction for all formulations: from 2 lbs. ai/A to 1.75 lbs. ai/A.
- Airblast application:
  - Require PF50 respirator for mixing/loading DF/WDG formulation only for airblast application as well as single-layer PPE and chemical-resistant gloves.
  - Require single-layer PPE, gloves, and PF10 respirator for airblast applicators. Alternatively, applicators may use enclosed cabs.
- Mechanically pressurized handgun:
  - For all formulations, mixers/loaders/and applicators must wear a PF10 respirator and chemical-resistant gloves.
  - Limit amount handled to 485 gal/day.
- Post-application:
  Re-entry workers who are girdling and turning table grapes must observe a 5-day REI.

3. Proposed Mitigation for Ornamentals and Ginseng

EPA's mitigation proposal for ornamentals is as follows:

- For groundboom application, mixers and loaders using the DF/WDG and WP formulations must wear a PF50 respirator, single layer PPE, and chemical-resistant gloves. The PF50 respirator will increase inhalation MOEs for mixers/loaders using DF/WDG formulations from 5.5 to 27; for workers using WP formulations, the PF50 respirator increases the inhalation MOE from 18 to 89. The level of concern is 30. EPA believes that the mitigated risk of 27 is not unreasonable given the high benefits of captan to ginseng growers, especially for disease control and resistance management, further described in Section III.C. of this document and the limited field size, which may result in lower risks.
- Groundboom applicators (for all formulations) must wear a PF10 respirator, single layer, gloves (current label PPE) OR use enclosed cabs and wear single layer PPE.
- For application with mechanically pressurized handgun, mixer/loader/applicator must wear single layer, gloves, PF10 respirator (current label PPE) and limit amount handled to ≤ 75 gal/day for greenhouse and nursery ornamentals.
- For dip tank treatment, hand dipping is prohibited.
- For post-application re-entry activities:
  - Workers must observe an 8-day REI for handset irrigation.
  - There is no change to the REI for other activities.

4. Proposed Mitigation for Seed Treatment

EPA has identified risk concerns for commercial seed treatment workers who are performing multiple activities during the workday, including applying captan to seeds, bagging treated seeds, and sewing bags closed. When these workers wear PF10 respirators, inhalation MOEs are less than LOC, ranging from 12 to 29 (the LOC is 30). To address these potential inhalation risks, the Agency is proposing to require use of PF50 respirators by workers performing more than one activity in a day, which will result in MOEs above the LOC of 30. Workers who are performing only one activity during the workday must wear PF10 respirators. As noted in Section IV.A.3. of this document, PF50 respirators are expensive, with a potential cost of $1,500 per respirator, per person, with additional costs for replacement cartridges and annual fit testing. PF10 respirators also have costs associated with replacement cartridges and annual fit testing.

EPA also has identified potential risks of concern for on-farm seed treatment using planter box loaders and applicators. Dermal MOEs for the on-farm planter box scenarios range from 74 to 740 for workers wearing the single layer of clothing and chemical resistant gloves required on current captan product labels. On-farm risks of concern are limited to planter box treatment of soybean seeds (31,000 to 34,000 lbs. of seed treated daily). Therefore, the Agency is proposing to require a double layer of protective clothing (coveralls or apron), which increases the MOE from 74 to greater than the LOC of 100.

In addition, to address the potential nontarget risks to wildlife who consume seeds treated with captan, EPA is proposing to include additional language on seed bag tags, through the addition of such language on the captan product labels registered for seed treatment using commercial

equipment.[55] The new language would require commercial users to ensure that bag tags are printed to accompany the treated seed and that such bag tags include the following statements:

- Bury or collect all treated seeds spilled during loading to protect wildlife.
- Plant treated seed into the soil to the recommended minimum depth or greater to minimize exposure.
- DO NOT plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- To report ecological incidents, including mortality, injury, or harm to plants and animals, call *[insert registrant phone number]."* Note: Each end-use registrant is required to provide a phone number for its products.
- This seed expires on [insert date] and may not be stored for use past this date.
- Consistent with USDA requirements under the Federal Seed Act,
    - All seeds treated with a Toxicity Category I product (EPA signal word DANGER) must be labelled with "POISON" in red letters and skull and crossbones.
    - This seed has been treated with captan *[list all active ingredients, specific product(s) used to treat seed and the EPA registration number(s)]*.
    - Do not use for food, feed, or oil purposes.

All other label requirements related to personal protective equipment, storage, and disposal of treated seeds remain and must be listed on the seed bag tag. EPA is proposing that captan products registered for both commercial and on-farm seed treatment using commercial equipment must comply with these requirements, which are best practices consistent with Chapter 18 of the *EPA Pesticide Label Review Manual.*[56] If seed treated with captan is distributed or sold without such bag tags labeled as described above, the seed would not meet the conditions of the FIFRA treated article exemption because the pesticide used to treat the seed requires such language on the bag tags. Therefore, the distribution and sale of such seed would be distribution and sale of an unregistered pesticide, a violation of FIFRA section 12.

C. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA has sought to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the exposure to captan.

[55] This applies to any seeds treated with commercial equipment that are packaged for sale or distribution, whether in a commercial facility or on farm.
[56] https://www.epa.gov/sites/production/files/2017-10/documents/chap-18-sep-2013_0.pdf

One community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle captan or may be exposed to captan when mixing, loading, or applying captan to orchard crops, berries and grapes, ornamentals and ginseng. In addition, farmworkers may be exposed to captan during commercial or on-farm seed treatment. The Agency has found risks of concern for occupational handlers, re-entry workers, and fruit packing house workers, as described in detail in Section III.A. and IV.A. and IV.B. of this document. EPA has also evaluated the risks to people living adjacent to treated fields, which may include many farmworker families, and has not found risks of concern for captan from spray drift of captan from treated orchards and fields. EPA has also evaluated risk to residential handlers (such as homeowners) and adults/children who may be exposed to residues after pesticide application and has found risks of concern that have been addressed by voluntary product cancellations and use deletions. With the mitigation described in Sections IV.A. and IV.B. of this document, EPA is addressing the risks of concern according to the FQPA and FIFRA standards. The risks and benefits of captan relative to the FIFRA standard for worker risk are described in detail in Sections III.C. and IV.A. and IV.B. of this document.

The Agency requests information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to captan compared to the general population or who may otherwise be disproportionately affected by the use of captan as a pesticide.

D. Tolerance Actions

1. Tolerance Expression

The Agency plans to exercise its FFDCA authority to update the tolerance expression to appropriately cover the metabolites and degradates of captan and to specify the residues to be measured for each commodity for enforcement purposes. EPA anticipates amending the tolerance expression to read as follows:

> §180.103(a)(1) *General.* Tolerances are established for residues of captan, including its metabolites and degradates in and on the commodities in the table below. Compliance is to be determined by measuring only captan, (3a,4,7,7a-tetrahydro-2-[(trichloromethyl)thio]-1*H* -isoindole-1,3(2*H*)-dione).
>
> §180.103(a)(2) Tolerances are established for residues of captan, (3a,4,7,7a-tetrahydro-2-[(trichloromethyl)thio]-1*H*-isoindole-1,3(2*H*)-dione) including its metabolites and degradates. Compliance is to be determined by measuring only the metabolite tetrahydrophthalimide, (4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione).

2. Changes to Commodity Definitions and Tolerance Levels

EPA also plans to exercise its FFDCA authority to update commodity definitions, crop groups, and tolerance levels, for captan through future rulemaking. The Agency expects to propose the

changes to captan tolerances summarized in Table 2 below after implementation of the mitigation measures described in this document.

Table 2. Captan 40 CFR §180.103 Summary of Anticipated Tolerance Actions			
Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments *Correct Commodity Definition*
Raw Agricultural Commodities in 40 CFR §180.103 (a)(1)			
Almond	0.25	0.3	Increase to harmonize with Codex
Almond, hulls	75.0	75	Change to Rounding
Apple	25.0	25	Change to Rounding
Raw Agricultural Commodities			
Apple	25.0	25	Change to Rounding
Apricot	10.0	10	Change to Rounding
Blueberry	20.0	20	Change to Rounding
Caneberry subgroup 13-07A	--	25	Establish new tolerance for *Caneberry subgroup 13-07A*; concomitant with revoking tolerance for *Caneberry subgroup 13A*; Change to Rounding
Caneberry subgroup 13A	25.0	Revoke	
Cherry, sweet	50.0	50	Change to Rounding
Cherry, tart	50.0	50	
Grape	25.0	25	Change to Rounding
Nectarine	25.0	25	Change to Rounding
Okra	0.05	Revoke	Move to *Crop Group 8-10*
Peach	15.0	20	Increase to Harmonize with Codex
Pear	25.0	25	Change to Rounding
Plum, prune, fresh	10.0	10	Change to Rounding
Strawberry	20.0	20	Change to Rounding
Vegetable, leafy, except Brassica, group 4	0.05	Revoke	Crop group update
Vegetable, *Brassica* head and stem, group 5-16	--	0.05	Establish new tolerance for vegetable, Brassica, head and stem, group 5-16 concomitant with revocation of tolerance for *vegetable, Brassica, leafy, group 5*
Vegetable, *Brassica* leafy, group 5	0.05	Revoke	
Vegetable, bulb, group 3-07	--	0.05	Crop group conversion/revision
Vegetable, bulb, group 3	0.05	Revoke	
Vegetable, fruiting, group 8-10	--	0.05	Crop Group Update
Vegetable, fruiting, group 8	0.05	Revoke	
Vegetable, leaf petiole, subgroup 22B	--	0.05	Establish new tolerance for crop group 22B to cover residues on celtuce and Florence fennel (These were previously covered by a crop group tolerance for *subgroup 4B*

Table 2. Captan 40 CFR §180.103 Summary of Anticipated Tolerance Actions			
Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments *Correct Commodity Definition*
Vegetable, leafy, group 4-16	--	0.05	Establish new tolerance for *vegetable, leafy, except Brassica, group 4*
Vegetable, leafy, except *Brassica*, group 4	0.05	Revoke	
Livestock Feed Commodities			
Cattle, meat	0.20	0.2	Conformation with OECD rounding classes
Cattle, meat byproducts	0.30	0.3	
Goat, meat	0.30	0.3	
Goat, meat byproducts	0.30	0.3	
Hog, meat	0.20	0.2	
Hog, meat byproducts	0.30	0.3	
Horse, meat	0.20	0.3	
Horse, meat byproducts	0.30	0.3	
Milk	0.10	0.1	
Sheep, meat	0.20	0.2	
Sheet, meat byproducts	0.30	0.3	

3. International Harmonization

The U.S. tolerance expression for captan (parent captan for raw agricultural commodities) is harmonized with Canadian and Codex MRLs. However, because the U.S. tolerance expression for livestock commodities includes captan and its degradate THPI, it cannot be harmonized.

Codex has established Maximum Residue Levels (MRLs) for captan residues in/on almonds; blueberries; cherries; cucumber; dried grapes (including currants, raisins, and sultanas); grapes; melons, except watermelon; nectarine; peach; plums (including fresh prunes); pome fruits; potato; raspberries, red, black; spices, roots and rhizomes; strawberry; and tomato.

EPA plans to increase the tolerance for captan residues in or on almonds from 0.25 to 0.3 ppm and the tolerance for peach from 15 to 20 ppm to harmonize with Codex. The tolerance for captan on *vegetable*, *root and tuber, group 1*, is harmonized with the Codex MRL for potato at 0.05 ppm. However, Codex does not have MRLs for carrot, radish, or sugar beet, which are also included in *vegetable, root and tuber, group 1*. EPA is unable to harmonize the U.S. tolerances for captan with Codex MRLs for blueberries, cherries, cucumber, dried grapes, (fresh) grapes, melons, nectarines, plums, pome fruits, potato, raspberries, and strawberries for various reasons. A detailed analysis of differences between US tolerances for captan and the Codex and Canadian MRLs may be found in Appendix E.

E. Proposed Interim Registration Review Decision for Captan

EPA is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency has made the following proposed interim decision for captan: (1) EPA proposes that no additional data are required at this time and (2) EPA proposes that captan does not meet the registration standard without changes to the affected registrations and their labeling. EPA has determined

that the mitigation proposed in Sections IV.A. and IV.B. of this document and Appendices A and B are sufficient to address certain risk concerns.

The Agency conducted detailed draft HHRA and ERA for captan. In these risk assessments, EPA identified several risks associated with continuing to register captan, including potential risks to residential handlers and adults and children entering residential areas treated with captan,[57] potential occupational handler and post-application risks, and potential risk to birds, mammals, and pollinating insects. To address the potential risks of concern, registrants voluntarily canceled or amended the associated product registrations. In addition, EPA is proposing to prohibit the use of home and garden products containing more than 12% captan, label changes that would terminate aerial application of the WP and DF/WDG formulations of captan for certain crops, additional personal protective equipment and changes to REIs, or optional reductions in amount handled and area treated, environmental hazard and spray drift statements to captan labels, and label changes to address generic labeling requirements for all registered captan products and uses. These are described in detail in Section IV of this document. Any remaining risks associated with use of captan are outweighed by the benefits of captan as described below and in Section III.C.

EPA has also determined that continuing to register captan provides high benefits to growers, especially for orchard crops, berries, ginseng, and grapes. Captan is a multi-site phthalamide fungicide classified within FRAC Group M4. It controls/suppresses fungal growth by direct contact with foliage or fruit. Because captan has multi-site and protectant modes of action, it is not associated with fungicide resistance, unlike most other fungicides registered on the same crops. There have been no reports of fungicide resistance associated with captan since it was first registered in 1951. There are other multi-site fungicides registered for these crops, but they may be limited by application timing or other restrictions and/or have lower efficacy against the pathogens targeted by captan. In addition, captan is less expensive than many other fungicides. Therefore, captan has high benefits when used in or on orchard crops, berries, and ginseng.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[58] Here, EPA proposes that captan does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A. and Appendices A and B. These changes are necessary to mitigate unreasonable adverse effects on human health and the environment. The proposed changes to handler PPE and REIs for re-entry mitigate EPA's risk concerns for adverse effects on human health described in Section III of this document. The proposed restrictions on aerial application mitigate adverse effects to both human health and the environment. The proposed environmental hazard

[57] As described in Section I.A. of this document, registrants voluntarily canceled or amended product registrations associated with the residential risk concerns prior to completion of this PID.

[58] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" (FIFRA's risk-benefit standard) and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the FFDCA safety standard"). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

statements and revisions to spray drift labeling also mitigate adverse effects on the environment. Although some ecological risks may remain after implementation of these measures, the Agency believes that the benefits of captan use to agriculture (described in Section III.C. of this document) outweigh its risks.

During registration review, EPA also considers whether a pesticide continues to meet the FFDCA standard of a "reasonable certainty of no harm." Section III.A. of this document summarizes the Agency's assessment of risks from aggregate exposure to captan via residues in food and drinking water or from bystander exposure or residential use. It also addresses whether captan is a member of a class of chemicals sharing a common mechanism of action (as defined by FQPA) and whether a cumulative risk assessment is necessary. Section IV.A.1. of this document describes registrant actions and an EPA proposal to address the residential and aggregate risk concerns identified. Therefore, in this PID, EPA proposes to determine that there is no human dietary risk from registered uses of captan that is inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA assessed captan's potential aggregate risks, including dietary (food and water) and non-occupational residential exposures. Although EPA initially found risks exceeding the Agency's levels of concern[59] for non-occupational residential exposure to both adults and children from certain captan end-use products registered for home and garden use, registrants of these products have voluntarily canceled these products or amended the product registrations to terminate home and garden sublabels to address the Agency's risk concerns. Therefore, EPA proposes to conclude that there is a reasonable certainty that no harm would result from aggregate exposure to captan, including all anticipated dietary exposures and all other exposures for which there is reliable information and that captan's residues are safe. EPA intends to retain the captan tolerances and to proceed with the actions[60] identified in Table 2, as EPA's analysis indicates that such modifications would also be safe.

In this PID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of captan. Similarly, the Agency is not making a complete endangered species finding, although the proposed mitigation is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range or critical habitat co-occur with the use of captan. The Agency will complete a nationwide listed-species assessment and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services and make an EDSP determination before issuing a final registration review decision for captan. For more information, see Appendices B and C.

EPA previously required data to support antimicrobial uses of captan in GDCI-081301-1381. After the captan technical registrants amended product registrations to delete these uses, the Agency waived the antimicrobial data requirements. EPA also required a turf transferable residue study in a separate DCI for conventional uses of captan, GDCI-081301-1383. The

[59] *Captan. Human Health Draft Risk Assessment in Support of Registration Review* (September 2018), ***Captan.*** *Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* (March 2, 2021), and ***Captan.*** *Second Addendum to the Human Health Draft Risk Assessment in Support of Registration Review with Updated Occupational and Residential Exposure Assessment* (November 3, 2021).
[60] Tolerance changes will be implemented through a future rulemaking in accordance with FFDCA § 408.

registrants have not fulfilled this data requirement; instead, they requested a data waiver, and most registrants amended their product registrations to delete all turf and turf like uses.[61] EPA has waived the TTR data requirement[62] for registrants who have amended their labels. As part of this proposed interim decision, EPA is proposing that any remaining products containing turf and turf like uses be amended to delete these uses.

Through this registration review, the Agency has identified the need for additional honey bee data to evaluate risk to insect pollinators. Therefore, at this time, EPA proposes that registrants submit additional Tier 1 chronic toxicity data for both larval and adult honey bees. The Agency will issue a DCI to establish a timeline for submitting this data.

V. NEXT STEPS AND TIMELINE

A Federal Register Notice will announce the availability of the Captan PID and open a 60-day comment period. The Agency may issue an Interim Registration Review Decision (ID) for captan after the close of this comment period if commenters do not submit significant comments or additional information that lead the Agency to change the proposed interim decision in Section IV.C, above. EPA may make a final registration review decision for captan without previously issuing an ID. However, a final registration review decision for captan will only be made after EPA completes (1) a nationwide endangered species determination and any necessary consultation with the Services, and (2) an EDSP determination.

If EPA posts an ID to the public docket, the captan registrants must submit amended product labels, which include the label changes described in Appendices A and B and requests for amendment of their product registrations within 60 days.

[61] During registration review, the registrants may request a waiver of data requirements by requesting an extension of an existing waiver or by requesting a new waiver from EPA. 40 C.F.R. § 152.91.
[62] Letters waiving the TTR data requirement may be found in the captan docket, EPA-HQ-OPP-2013-0296.

Appendix A: Summary of Proposed Actions for Captan

Registration Review Case #: 0120
PC Code: 081301
Chemical Type: Fungicide
Chemical Family: Phthalamide
Mode of Action: FRAC Group M4

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
• Occupational handler	Handling products and applying spray solution containing product	Dermal Inhalation	Short Term	Reproductive toxicity Respiratory effects	Reduce rate Prohibit aerial application Additional PPE Engineering controls Limit amount handled Limit area treated	Mitigation varies by crop, formulation, and application method
• Occupational post application	Residues on treated foliage	Dermal	Short Term	Severe acute toxicity (eyes and skin) Reproductive toxicity Respiratory effects	Longer REI for high contact activities	Grapes and Ornamentals only
• Nontarget organisms	Spray drift and runoff, treated seeds	Dermal Ingestion	Acute Chronic	Reproductive toxicity Indirect effects	Mandatory and advisory spray drift measures Requirement to bury or dispose of treated seed spilled on field	
• Endangered Species (Pacific salmonids in CA, OR, WA, and ID)	Residues in surface water from runoff and spray drift	Ingestion	Acute Chronic	Reproductive toxicity Indirect effects	Implement 2011 NMFS salmonid BiOp RPMs	

Appendix B: Proposed Labeling Changes for Captan Products

Description	Proposed Label Language for Captan Products	Placement on Label
Technical and Manufacturing Use Products		
Use prohibitions	"Do not formulate into products labeled for use on turf, St Augustine grass or any other lawn or ornamental grasses, lawn seed beds, or dichondra." "Do not formulate into products labeled for antimicrobial use."	**Directions for Use**
Endangered Species Protections	"This product may only be formulated into end-use products that contain the following language on their labeling when they are released for shipment:" *"ENDANGERED SPECIES PROTECTION REQUIREMENTS"* (to be placed at the beginning of the Directions for Use section of all end-use product labels) *"It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species, and certain threatened species, under the Endangered Species Act Section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult http://www.epa.gov/espp/, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product."*	**Directions for Use**
End Use Products		
Application Prohibitions	"Not for use on dichondra, grasses or grass substitutes, lawns, lawn seed beds, turf, or turf like grasses."	**Use Restrictions**
Mode of Action Group Number	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP"** in the second column • Include the **MODE/MECHANISM/SITE OF ACTION CODE** in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is **SITE OF ACTION)** • Include the type of pesticide (i.e., **FUNGICIDE** in the fourth column.	**Front Panel, upper right quadrant.** All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.

Description	Proposed Label Language for Captan Products	Placement on Label
	CAPTAN **GROUP** **M04** **FUNGICIDE**	
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	**Personal Protective Equipment (PPE)**
PF50 Respirator **Commercial Use Labels, DF/WDG and WP formulations only** **(Does not apply to liquid formulations)**	**Note to registrant**: Pesticide handlers mixing and loading WP and DF/WDG formulations for airblast and groundboom application must wear a PF50 respirator to address inhalation risk concerns. Either a full- or half-face elastomeric respirator, with appropriate cartridges, which reduce inhalation exposure by 99%, may be used to fulfill this proposed requirement.	**Personal Protective Equipment (PPE)**
PF50 Respirator **Fruit Packing Houses**	**Post-Harvest Fruit Dip Use of Captan on Apples, Cherries, and Pears** **Note to registrant**: Workers mixing and loading DF/WDG and WP captan for mixing a post-harvest fruit dip solution for apples, cherries, and pears must wear a PF50 respirator to address inhalation risk concerns.	**Personal Protective Equipment (PPE)**
PF50 Respirator **Fruit Packing Workers** **Sorters and Packers Only**	**Post-Harvest Fruit Dip Use of Captan on Apples, Cherries, and Pears** Fruit packing workers who are sorting and packing apples, cherries, or pears treated with captan must wear a PF50 respirator to address inhalation risk concerns. Either a full- or half-face elastomeric respirator, with appropriate cartridges, which reduce inhalation exposure by 99%, may be used to fulfill this proposed requirement.	**Personal Protective Equipment (PPE)** ***and*** **Directions for Use**
PF50 Respirator **Seed Treatment Labels Only** *For Seed Treatment Using Commercial Equipment*	**Note to Registrant:** In commercial seed treatment facilities and for on-farm treatment using commercial equipment, pesticide handlers using captan who are treating alfalfa, clover, trefoil, barley, rye, corn, cotton, cowpeas, oats, sorghum, soybean, or strawberry seed and performing more than one activity in a day must wear a PF50 respirator to address inhalation risk concerns. Either a full- or half-face elastomeric	**Personal Protective Equipment (PPE)**

Description	Proposed Label Language for Captan Products	Placement on Label
	respirator, with appropriate cartridges, which reduce inhalation exposure by 99%, may be used to fulfill this proposed requirement.	
PF10 Respirator **Seed Treatment Labels Only** Seed Treatment Using Commercial Equipment	**Note to Registrant:** In commercial seed treatment facilities and for on-farm treatment using commercial equipment, pesticide handlers using captan in seed treatment facilities who are performing only one activity in a day must wear a PF10 respirator	**Personal Protective Equipment (PPE)**
Seed Treatment Products **(On Farm Seed Treatment Using Hopper Box)** Double layer PPE for certain seeds	**Note to Registrant:** For on-farm seed treatment using a hopper box, handlers treating bean and wheat seeds must wear double layer PPE, such as coveralls or a chemical resistant apron.	**Personal Protective Equipment (PPE)**
Updated Respirator Language for PF10 Respirators	**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language: "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 HE filters." For respiratory protection from organic vapor **and** particulates (or aerosols), use the following language: "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	**Personal Protective Equipment (PPE)**
Updated Respirator Language for PF50 respirators	**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language: "Wear a minimum of a NIOSH-approved elastomeric full face particulate respirator with any N*, R or P filter."	**Personal Protective Equipment (PPE)**

Description	Proposed Label Language for Captan Products	Placement on Label
	Note to registrant: For respiratory protection from organic vapor a**nd** particulates (or aerosols), use the following language: "Wear a minimum of a NIOSH-approved elastomeric full mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved full face gas mask with OV canisters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	
Non-target Organism Advisory **(Residential Product Label)**	"This pesticide is toxic to fish and aquatic invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area." "Do not apply directly to water or to areas where water is present. Do not contaminate water when disposing of container or rinsate."	**Environmental Hazards**
Non-target Organism Advisory **(All Commercial Product Labels)**	"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 washwater or rinsate." "This pesticide is toxic to fish and aquatic invertebrates." "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	**Environmental Hazards**
Non-target Organism Advisory **(Seed Treatment Products)**	"Treated seed exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading."	**Environmental Hazards** on bag tag for treated seed (Seed treatment products only)
Endangered Species Protection **Applies to all end-use products**	"*Endangered Species Protection Requirements*: *It is a Federal offense to use any pesticide in a manner that results in an unauthorized "take" (e.g., kill or otherwise harm) of an endangered species and certain threatened species, under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult* ***http://www.epa.gov/espp/****, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product."*	**Environmental Hazards** under the heading "Endangered Species Protection"

Description	Proposed Label Language for Captan Products	Placement on Label
Endangered Species Protection **Applies to all end-use products**	"Reporting Ecological Incidents: To report ecological incidents, including mortality, injury, or harm to plants and animals, call *[insert registrant phone number]."* Note: Each end-use registrant is required to provide a phone number for its products.	**Environmental Hazards** *and* **DIRECTIONS FOR USE**
Endangered Species Protection **Applies to all end-use products**	**Windspeed restrictions** – "Do not apply when wind speeds exceed 10 mph." **Rain restrictions** – "Do not apply this product when soil is saturated. Do not apply when a storm event likely to produce runoff from the treated area is forecasted (by NOAA/National Weather Service, or other similar forecasting service) to occur within 48 hours following application."	**DIRECTIONS FOR USE**
Restricted Entry Interval (REI)	"Do not enter or allow workers to enter during the restricted-entry interval (REI). The REI and exceptions are listed in the Directions for Use associated with the crop." "Notify workers of the exception (including when entry is permitted for each of the tasks named in the exception)."	**AGRICULTURAL USE REQUIREMENTS Box**
Restricted Entry Interval (REI) **Table Grapes**	"Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 5 days for girdling and turning table grapes grown on T trellises."	**DIRECTIONS FOR USE** **Below GENERAL USE PRECAUTIONS** (List under specific crops)
Restricted Entry Interval (REI)	"Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 8 days for handling, maintaining, moving, or repairing handset irrigation for ornamental crops."	
Rate Reductions	Orchard Crops • Reduce maximum application rate for apples, peaches, and nectarines from 4 to 3 lbs. ai/A. • Reduce maximum application rate for cherries from 3.16 to 3 lbs. ai/A. <u>Grapes</u> • Reduce maximum application rate from 2 to 1.75 lbs. ai/A. • Specify new maximum rate in both terms of lbs. ai/A and product to be applied	**DIRECTIONS FOR USE** **Below GENERAL USE PRECAUTIONS** (List under specific crops)

Engineering Controls
Enclosed Cabs
(Airblast application to orchard crops)
	<u>Orchard Crops</u>
	• Airblast Applicators must use an enclosed cab
	  ○ Alternatively, for all orchard crops except almond, airblast applicators may use an open cab and PF10 respirator with an area treated limit of 30 A/day
	  ○ For almonds, applicators may use an open cab and PF10 respirator with an area treated limit of 20 A/day.
		DIRECTIONS FOR USE
		Below GENERAL USE PRECAUTIONS
		Engineering Controls
		(List under specific crops)

Description	Proposed Label Language for Captan Products	Placement on Label
Engineering Controls **Enclosed Cabs** **(Airblast application to blueberries and caneberries)**	Blueberries • Airblast Applicators must use an enclosed cab ○ Alternatively, airblast applicators may use an open cab and PF10 respirator with an area treated limit of 35 acres/day for blueberries and 40 acres/day for caneberries	**DIRECTIONS FOR USE** **Below GENERAL USE PRECAUTIONS** Engineering Controls (List under specific crops)

Application with Mechanically pressurized handgun to fruit and nut crops	• Applicators must wear a PF10 respirator and single layer PPE
	• Applicators must limit the amount handled
	  ○ Almonds ≤220 gal/day
	  ○ Apples, nectarines, and peaches ≤245 gal/day
	  ○ Apricots and cherries ≤ 490 gal/day
	  ○ Plums and prunes ≤ 325 gal/day
	  ○ Grapes ≤ 490 gal/day
	  ○ Blueberries and caneberries ≤ 390 gal/day
		Directions for Use
		(List under specific crops)

Application with Mechanically pressurized handgun to ornamentals	• Applicators must limit the amount handled to ≤ 100 gal/day	**Directions for Use** **(List under specific crops)**
Post-Harvest Fruit Dip	• Fruit sorters and packers must wear PF50 respirator; all other workers must wear a PF10 respirator.	**Directions for Use** **(List under specific crops)**
Root Dip **(For peach trees, roots, and tubers)**	• Hand dipping is prohibited	**Directions for Use** **(List under specific crops)**
Seed Treatment Products **(Treatment with Commercial Equipment)** Applies to both seed treatment in commercial facilities and on-farm seed treatment using commercial equipment when treated seed is bagged for distribution.	• Product label must instruct both commercial and on-farm users to print bag tags for treated seed that must accompany the treated seed and (1) mandate that users bury or collect all treated seeds spilled during loading, plant seeds at the correct depth, avoid broadcast planting of treated seed, dispose of excess treated seed by planting away from bodies of water, and avoid contaminating water bodies with planter box rinsate; (2) continue to advise, consistent with USDA requirements under the Federal Seed Act, that treated seed may not be used in food, feed, or processed products, such as oil; and (3) identify the EPA registration number(s) for the pesticide product(s) used to treat the seed and an expiration date for the seeds beyond which the treated seeds may no longer be stored for use. • "Any seed treated with captan that is sold or distributed without a bag tag including the following language (Seed Bag Labeling Requirements) is an unregistered pesticide, in violation of FIFRA section 12."	**Directions for Use**

Description	Proposed Label Language for Captan Products	Placement on Label
Seed Treatment Product Labeling (To Appear on Bag Tags for Treated Seed when seed is to be sold or distributed)	• All seeds treated with a Toxicity Category I product (EPA signal word DANGER) must be labelled with "POISON" in red letters and skull and crossbones. "Treated with Captan POISON" (In red) • Applies only to seeds bagged for sale or distribution	**Directions for Use** **Seed Bag Labeling Requirements**
Seed Treatment Product Labeling (To Appear on Bag Tags for Treated Seed when seed is to be distributed)	"SEED BAG LABELING REQUIREMENTS" "THE FEDERAL SEED ACT REQUIRES THAT BAGS CONTAINGING TREATED SEEDS SHALL BE LABELED WITH THE FOLLOWING STATEMENT(S). • This seed has been treated with *[insert product name(s) and EPA Reg, No(s)., containing captan (list all pesticide active ingredients used to treat seed)]*. • DO NOT use for food, feed, or oil." "THE U.S. ENVIRONMENTAL PROTECTION AGENCY REQUIRES THE FOLLOWING STATEMENTS ON BAGS CONTAINING SEEDS TREATED WITH *[insert product name(s) and EPA reg. No(s).]:* • This seed expires on [insert date] and may not be stored for use past this date. • Treated seeds exposed on soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading. • Plant treated seed into the soil to the recommended minimum depth or greater to minimize exposure. • DO NOT plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds. • Dispose of all excess treated seed by burying seed away from bodies of water. • Do not contaminate bodies of water when disposing of planting equipment wash water." • "Reporting Ecological Incidents: To report ecological incidents, including mortality, injury, or harm to plants and animals, call *[insert registrant phone*	**Directions for Use** **Seed Bag Labeling Requirements font size 8 points or above**

Description	Proposed Label Language for Captan Products	Placement on Label
	number].” Note: Each end-use registrant is required to provide a phone number for its products. Please note that all other requirements on current captan labels must also be listed on the seed bag tag. These include provisions related to endangered species, environmental hazards, personal protective equipment, storage, and disposal.	
Resistance-management for fungicides and bactericides The pesticide resistance management labeling applies to all conventional outdoor pesticide products.	Include resistance management label language for fungicides/bactericides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year). See section 3 (Scope) of the PRN to determine whether the resistance management measures outlined in the PRN apply to your product.	**Directions for Use**, prior to directions for specific crops
Spray Drift Management Application Restrictions **(Liquid formulations only)** **Registrants:** Remove this text from labels for DF/WDG and WP Formulations	**“MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy unless a greater application height is necessary for pilot safety. • Applicators must select nozzle and pressure that deliver medium or courser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 641 (ASABE S641). If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply when wind speeds exceed 10 mph at the application site. If the windspeed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters • Do not apply during temperature inversions.”	**Directions for Use**, below the **AGRICULTURAL USE REQUIREMENTS** box Under the heading “**MANDATORY SPRAY DRIFT MANAGEMENT**” Placement for these statements should be before crop-specific directions for use.
Spray Drift Management Application Restrictions for all products that allow airblast applications	**“MANDATORY SPRAY DRIFT MANAGEMENT** **Airblast applications:** • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 10 miles per hour at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions.”	**Directions for Use**, below the **AGRICULTURAL USE REQUIREMENTS** box Under the heading “**MANDATORY SPRAY DRIFT MANAGEMENT**”

Description	Proposed Label Language for Captan Products	Placement on Label
Spray Drift Management Application Restrictions for all products that are applied as liquids and allow ground boom applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators must select nozzle and pressure that deliver medium or courser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572). • Do not apply when wind speeds exceed 15 mph at the application site. Do not apply during temperature inversions."	**Directions for Use**, below the **AGRICULTURAL USE REQUIREMENTS** box Under the heading "**MANDATORY SPRAY DRIFT MANAGEMENT**"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. 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. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight.	**Directions for Use**, below the **AGRICULTURAL USE REQUIREMENTS** box and the "**MANDATORY SPRAY DRIFT MANAGEMENT**" labeling

Description	Proposed Label Language for Captan Products	Placement on Label
	BOOM HEIGHT – Ground Boom ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Captan Products	Placement on Label
Additional Required Labelling Action **Applies to all products delivered via liquid spray applications**	Remove information about volumetric mean diameter from all labels where such information currently appears.	DIRECTIONS FOR USE SPRAY DRIFT MANAGEMENT
All DF/WDG and WP Products		
PF50 Respirator	All mixers and loaders supporting airblast application must wear a PF50 Respirator.	**Personal Protective Equipment**
Prohibition of Aerial Application to captan DF/WDG and WP products	"Do not apply to almonds, apples, apricots, blueberries, cherries, grapes, nectarines, peaches, plums/prunes, or strawberries by air."	Directions for Use, Directly Above Spray Drift Management
WP Products Packaged in Water Soluble Bags		
Directions for mixing/loading captan WP products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 C.F.R. 170.607(d)]. Handling Instructions Follow these steps when handling pesticide products in WSPs. 1. Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may,	

Description	Proposed Label Language for Captan Products	Placement on Label
	in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions. 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved, and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label." For Toxicity Category I and II products: "**ENGINEERING CONTROLS STATEMENT** Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant	

Description	Proposed Label Language for Captan Products	Placement on Label
	apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down." For Toxicity Category III and IV products: "**ENGINEERING CONTROLS STATEMENT** Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."	

Appendix C: Listed-Species Assessment

This Appendix provides general background about the Agency's assessment of risks from pesticides to endangered and threatened (listed) species under the Endangered Species Act (ESA). Additional background specific to captan appears at the conclusion of this Appendix.

In 2015, EPA, along with the Services—the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) released their joint Interim Approaches for assessing risks to listed species from pesticides. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on listed species. Since that time, the agencies have been continuing to work to improve the consultation process.

EPA initially conducted biological evaluations (BEs) using the interim method on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned as the start of an iterative process. Later that year, NMFS issued a final biological opinion for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion. EPA recently received a draft revised biological opinion on these pesticides from NMFS and posted it for public comment.[63] In February 2022, EPA also received a final malathion biological opinion[64] from FWS, which the Agency plans to implement according to the 18-month timeframe specified in the opinion.

After receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* ("Revised Method") in March 2020.[65] During the same timeframe, EPA also released draft BEs for carbaryl and methomyl, which were the first to be conducted using the Revised Method. To date, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, and glyphosate.

The 2018 Farm Bill established a FIFRA Interagency Working Group (IWG) to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes

[63] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

[64] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions

[65] https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084

representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[66] The agencies continue to work collaboratively, consistent with Congress's intent in creating the IWG.

In January 2022, EPA announced a policy[67] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use will not jeopardize listed species or adversely modify their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In 2011, NMFS released a Biological Opinion specific to listed Pacific salmon and steelhead species for various pesticides, including captan. EPA is in the process of implementing this Biological Opinion (BiOp) as part of its registration review process. In 2007, the Agency transmitted its final biological evaluation and initiated formal consultation with FWS on the effects of captan on the California Red Legged Frog. EPA has not yet received a biological opinion from FWS. The Agency will complete a nationwide listed species assessment and any necessary consultation with the Services before completing the captan registration review.

[66] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act

[67] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for captan, the Agency reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), captan is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

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

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. Captan is on list 1 and the review conclusions are available in the captan public docket (see EPA-HQ-OPP-2013-0296). A second list of chemicals identified for EDSP screening was published on June 14, 2013,[68] and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, visit the EPA endocrine disruption website.[69]

[68] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[69] https://www.epa.gov/endocrine-disruption

EPA's EDSP is actively pursuing the application of new approach methods (NAMs) to create a more efficient and robust screening program. In October 2020, EPA underwent a reorganization and the EDSP was moved to the Office of Pesticide Programs. This reorganization provides better alignment of the EDSP with the procedures and methods used by the program offices. On July 28, 2021, the Office of Inspector General (OIG) released its new report on the EDSP and made ten recommendations. EPA is also developing a strategic planning document for EDSP which will be available for public comment in 2022. EPA expects additional documents for public release in 2021-2023 that address aspects of EDSP chemical determinations. EPA looks forward to working with stakeholders and the scientific community to accelerate the implementation of this important program into pesticide risk assessments and decision making.

In this PID, EPA is making no human health or environmental safety findings associated with the EDSP screening of. Before completing this registration review, the Agency will make an EDSP FFDCA § 408(p) determination."

Appendix E: Tolerance Harmonization

EPA has treaty obligations with the World Trade Organization to harmonize U.S. pesticide tolerances with Codex MRLs wherever possible. For captan, the Agency has conducted an analysis to determine differences between U.S. tolerances established in 40 CFR §180.302 and the MRLs established by Codex Alimentarius, to support harmonization between U.S. tolerances and Codex MRLs, and to explain why certain US tolerances can't be harmonized with Codex. A summary of this analysis is provided below.

EPA is unable to harmonize the U.S. tolerances in 40 CFR §180.302 for fruiting vegetables or for cucurbits because the current tolerance is significantly lower than the Codex and Canadian MRLs. The U.S. tolerance for vegetable, fruiting crop group 8, which includes tomato, pepper, eggplant, and related commodities, is 0.05 ppm, and cannot be harmonized with the Canadian and Codex tolerance of 5 ppm on tomato. Likewise, EPA is not able to harmonize the U.S. tolerance of 0.05 ppm for cucurbit crop group with the Codex MRLs of 3 ppm for cucumber or 10 ppm for melon (except watermelon). Canada does not have established MRLs on these commodities, and neither Canada nor Codex have MRLs on summer squash.

The Agency is unable to harmonize U.S. tolerances for captan in or on apple, apricot, blueberry, caneberry, sweet and tart cherry, grape, nectarine, plum, or strawberry with both Codex and Canada because the US tolerance values are significantly higher than MRLs established by Canada and Codex. Canada has an established apple MRL at 5.0 ppm, and Codex has an established apple MRL at 15 ppm. The established U.S. tolerance is 25 ppm. Therefore, EPA is not able to harmonize the U.S. apple tolerance with the international MRLs.

Canada has established an apricot MRL at 5.0 ppm. The established U.S. tolerance is 10 ppm. Therefore, EPA is not able to harmonize the U.S. apricot tolerance with the Canadian MRL.

Canada has established blueberry MRLs at 5.0 ppm each for both highbush and lowbush blueberries; the Codex MRLs are 20 ppm on these same commodities. The established U.S. tolerance of 20 ppm on blueberry is harmonized with Codex.

The Agency is unable to harmonize the U.S. tolerance of 25 ppm on Caneberry, crop subgroup 13-07A, with the Codex MRL of 20 ppm or the Canadian MRL of 5 ppm on raspberry. Neither Canada nor Codex have MRLs established on blackberry.

Canada has established MRLs on sweet cherry and tart cherry at 5.0 ppm each. Codex has established MRLs on sweet cherry and tart cherry at 25 ppm each. The established U.S. tolerances on sweet and tart cherries are 50 ppm each. Because the international MRLs are lower than the established U.S. tolerances for cherries, EPA is unable to harmonize these tolerances.

Canada has an established MRL on grape at 5.0 ppm. Codex has an established MRL on grape at 25 ppm. The established U.S. tolerance on grape of 25 ppm is harmonized with Codex.

Canada has an established MRL on nectarine at 5 ppm. Codex has an established MRL for nectarine at 3.0 ppm. The established U.S. tolerance for nectarine is 25 ppm. Therefore, EPA unable to harmonize the nectarine tolerance.

Canada has an established MRL on grape at 5.0 ppm. Codex has an established MRL on grape at 25 ppm. The established U.S. tolerance on grape of 25 ppm is harmonized with Codex.

Canada has an established MRL on strawberry at 5.0 ppm. Codex has an established MRL for strawberry at 15 ppm. The established U.S. tolerance is 20 ppm. Because the international MRLs are lower than EPA tolerances, the Agency is unable to harmonize the strawberry tolerance.

The U.S. tolerance of 10 ppm on plums is harmonized with Codex (plums, including fresh prunes) but not with Canada; the Canadian MRL is 5 ppm.

For all other individual crops, crop groups, and livestock commodities with U.S. tolerances; neither Codex nor Canada have established MRLs; therefore, harmonization is not possible. For complete details of the international MRL levels and harmonization recommendations, see *Captan. Human Health Draft Risk Assessment in Support of Registration Review* and *Draft Human Health Risk Assessment (Appendix E)* in the public docket, EPA-HQ-OPP-2013-0296.

Appendix F: Summary of Captan Worker Risk Estimates After Mitigation

Table 1. Summary of Captan Risk Estimates for Occupational Handlers Reflecting Proposed Rate Reductions

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
Apples, Peaches, Nectarines	40 acres (standard assumptions)	4.00 lb ai/A Airblast and Groundboom (M/L)	DF/WDG	4,000	5,100	3,300	**8.9**	45	**3.1**
			Liquid	5,500	7,100	6,900	370	1,800	730
			WP	3,600	6,300	3,300	**29**	150	**3.1**
		Airblast Applicator	Spray	130	140	14,000 (EC/Gloves)	**17**	85	120
		Groundboom Applicator	Spray	13,000	16,000	41,000 (EC/Gloves)	240	1,200	400
	40 acres	3.00 lb ai/A (reduced rate) Airblast and Groundboom (M/L)	DF/WDG	5,400	6,800	4,300	**12**	59	**4.1**
			Liquid	7,400	9,500	9,100	490	2,400	970
			WP	4,800	8,400	4,300	39	190	**4.1**
		Airblast Applicator	Spray	170	190	19,000 (EC/Gloves)	**23**	110	160
		Groundboom Applicator	Spray	17,000	22,000	54,000 (EC/Gloves)	310	1,600	530
	1,000 gallons Solution (standard assumptions)	0.20 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/WDG Liquid WP	**81**	120	ND	**7.3**	37	ND
	245 gallons Solution (amount handled limit)	0.20 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/WDG Liquid WP	330	500	ND	30	150	ND

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
	325 gallons solution (amount handled limit + reduced rate)	0.150 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/WDG Liquid WP	330	500	ND	30	150	ND
	350 acres	4.00 lb ai/A Aerial (M/L)	Liquid only	630	820	780	42	210	83
		Aerial Applicator	Spray	ND	ND	11,000 (EC/G)	ND	ND	190
		Aerial Flagger	Spray	2,000	2,300	ND	45	230	ND
		3.00 lb ai/A Aerial (M/L)	Liquid only	840	1,100	1,000	56	280	110
		Aerial Applicator	Spray	ND	ND	15,000 (EC/G)	ND	ND	250
		Aerial Flagger	Spray	2,600	3,000	ND	60	300	ND
Cherries	40 acres	3.16 lb ai/A Airblast and Groundboom (M/L)	DF	5,100	6,400	4,100	**11**	56	**3.9**
			Liquid	7,000	9,100	8,700	460	2,300	920
			WP	4,600	8,000	4,100	37	180	**3.9**
		Airblast Applicator	Spray	170	180	18,000 (EC/G)	**22**	110	150
		Groundboom Applicator	Spray	16,000	21,000	52,000 (EC/G)	300	1500	510
	40 acres	3.00 lb ai/A Airblast and Groundboom (M/L)	DF	5,400	6,800	4,300	**12**	59	**4.1**
			Liquid	7,400	9,500	9,100	490	2,400	970
			WP	4,800	8,400	4,300	39	190	**4.1**
		Airblast Applicator	Spray	170	190	19,000 (EC/G)	**23**	110	160
		Groundboom Applicator	Spray	17,000	22,000	54,000 (EC/G)	310	1,600	530
	1,000 gallons Solution	0.158 lb ai/gal	DF/ Liquid/	100	160	ND	**9.4**	47	ND

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
	(standard assumptions)	Mechanically Pressurized Handgun (M/L/A)	WP						
	315 gallons Solution (standard assumptions)	0.158 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	490	ND	30	150	ND
	325 gallons solution (amount handled limit + reduced rate)	0.150 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	500	ND	30	150	ND
	350 acres	3.16 lb ai/A Aerial (M/L)	Liquid only	800	1,000	990	53	260	100
		Aerial Applicator	Spray	ND	ND	14,000 (EC/G)	ND	ND	240
		Aerial Flagger	Spray	2,500	2,800	ND	57	290	ND
		3.00 lb ai/A Aerial (M/L)	Liquid only	840	1,100	1,000	56	280	110
		Aerial Applicator	Spray	ND	ND	15,000 (EC/G)	ND	ND	250
		Aerial Flagger	Spray	2,600	3,000	ND	60	300	ND
Grapes	40 acres	2.04 lb ai/A Airblast and Groundboom (M/L)	DF	7,900	9,900	6,400	**18**	87	**6**
			Liquid	11,000	14,000	13,000	710	3,600	1,400
			WP	7,100	12,000	6,400	57	290	**6**
		Airblast Applicator	Spray	260	280	28,000 (EC/G)	33	170	230
		Groundboom Applicator	Spray	25,000	32,000	80,000 (EC/G)	460	2,300	780
	40 acres	1.75 lb ai/A	DF	9,300	12,000	7,400	**20**	100	**7**

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
		Airblast and Groundboom (M/L)	Liquid	13,000	16,000	16,000	840	4,200	1,700
			WP	8,300	14,000	7,400	66	330	7
		Airblast Applicator	Spray	300	320	33,000 (EC/G)	39	190	270
		Groundboom Applicator	Spray	29,000	38,000	93,000 (EC/G)	540	2,700	910
	1,000 gallons Solution (standard assumptions)	0.102 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	160	240	ND	14	72	ND
	485 gallons Solution (amount handled limit)	0.102 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	300	450	ND	30	150	ND
	570 gallons solution (amount handled limit + reduced rate)	0.0875 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	490	ND	30	150	ND
	350 acres	2.04 lb ai/A Aerial (M/L)	Liquid only	1,200	1,600	1,500	82	410	160
		Aerial Applicator	Spray	ND	ND	22,000 (EC/G)	ND	ND	370
		Aerial Flagger	Spray	3,900	4,400	ND	89	440	ND
		1.75 lb ai/A Aerial (M/L)	Liquid only	1,400	1,900	1,800	95	480	190
		Aerial Applicator	Spray	ND	ND	26,000 (EC/G)	ND	ND	430
		Aerial Flagger	Spray	4,500	5,100	ND	100	520	ND

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
Almonds	40 acres (standard assumptions)	4.50 lb ai/A Airblast and Groundboom (M/L)	DF	3,600	4,500	2,900	**8**	40	**2.7**
			Liquid	4,900	6,300	6,100	320	1,600	650
			WP	3,200	5,700	2,900	**26**	130	**2.7**
		Airblast Applicator	Spray	120	130	13,000 (EC/G)	**15**	75	100
		Groundboom Applicator	Spray	11,000	15,000	36,000 (EC/G)	210	1,000	360
	1,000 gallons solution (standard assumptions)	0.225 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	**72**	110	ND	**6.6**	33	ND
	220 gallons solution (amount handled limit)	0.225 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	500	ND	30	150	ND
Plums/Prunes	1,000 gallons solution (standard assumptions)	0.15 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	110	160	ND	**9.8**	49	ND
	325 gallons solution (amount handled limit)	0.15 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	500	ND	30	150	ND
Blueberries	40 acres (standard assumptions)	2.50 lb ai/A Airblast and Groundboom (M/L)	DF	6,400	8,100	5,200	**14**	71	**4.9**
			Liquid	8,900	11,000	11,000	580	2,900	1,200
			WP	5,800	10,000	5,200	47	230	**4.9**

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
		Airblast Applicator	Spray	210	230	23,000 (EC/G)	27	140	190
		Groundboom Applicator	Spray	21,000	26,000	65,000 (EC/G)	380	1,900	640
	1,000 gallons Solution (standard assumptions)	0.125 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	130	200	ND	12	59	ND
	395 Gallons Solution (amount handled limit)	0.125 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	500	ND	30	150	ND
Apricots	40 acres (standard assumptions)	2.50 lb ai/A Airblast and Groundboom (M/L)	DF	6,400	8,100	5,200	14	71	4.9
			Liquid	8,900	11,000	11,000	580	2,900	1,200
			WP	5,800	10,000	5,200	47	230	4.9
		Airblast Applicator	Spray	210	230	23,000 (EC/G)	27	140	190
		Groundboom Applicator	Spray	21,000	26,000	65,000	380	1,900	640
	1,000 gallons Solution (standard assumptions)	0.125 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	130	200	ND	12	59	ND
	395 Gallons Solution (amount handled limit)	0.125 lb ai/gal Mechanically Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	330	500	ND	30	150	ND

Crop	Amount Handled/ Area Treated[1]	Application Rate[2]	Formulation[3]	Dermal MOEs[4] (LOC = 100)			Inhalation MOEs[4] (LOC = 30)		
				Single Layer/ Gloves	Double Layer/ Gloves	Closed Cab/ No Gloves[5]	PF10 Respirator	PF50 Respirator	Closed Cabs/ No Respirator[6]
Ornamentals (Greenhouse)	175 gallons solution (standard assumption)	0.0123 lb ai/gal Mechanically-Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	4,300	5,200	ND	**13**	66	ND
	78 gallons solution (standard assumption)	0.0123 lb ai/gal Mechanically-Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	9,600	12,000	ND	30	150	ND
Ornamentals (Nursery)	300 gallons solution (standard assumption)	0.0123 lb ai/gal Mechanically-Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	2,500	3,000	ND	**7.8**	39	ND
	78 gallons solution (standard assumption)	0.0123 lb ai/gal Mechanically-Pressurized Handgun (M/L/A)	DF/ Liquid/ WP	9,600	12,000	ND	30	150	ND

Shaded in grey – scenarios conducted with standard assumptions and maximum application rates.
[1] Exposure Science Advisory Council Policy #9.2.
[2] Assessment based on maximum registered application rates for each crop (refer to Table E.1. from the 1st addendum (B. Lee, *et al.*, 03/02/2021, D453333)).
[3] DF = Dry flowable; WP = wettable powder. Aerial applications have not been assessed for DF or WP per PRD's request, based on PRD's proposed mitigation to prohibit those use patterns.
[4] EC/No G = Engineering controls (water soluble packets) without gloves. For aerial applicators, EC/G = engineering control (enclosed cockpits) with gloves; data are not available for enclosed cockpits without gloves for aerial applicators.
[5] EC/No G = Engineering controls (enclosed cabs) without respirator.

Table 2. Summary of Captan Inhalation Risk Estimates for Airblast Applicators with Reduced Application Rates and Reduction in Area Treated

Crop	Application Rates	Area Treated[3]	Inhalation MOEs[4] (LOC = 30)	
			PF10-R	EC/No R
Apples, Peaches, Nectarines	4.00 lb ai/A[1]	40 acres	**17**	120
	3.00 lb ai/A[2]	40 acres	**23**	160
		36 acres	**25**	170
		30 acres	30	210
Cherries	3.16 lb ai/A[1]	40 acres	**22**	150
	3.00 lb ai/A[2]	40 acres	**23**	160
		36 acres	**25**	170
		30 acres	30	210
Grapes	2.04 lb ai/A[1]	40 acres	33	230
	1.75 lb ai/A[2]	40 acres	39	270

[1] Current maximum single application rates based on registered labels; refer to Table E.1. (B. Lee, *et al.*, 03/02/2021, D453333) and proposed reduced rates.
[2] Proposed application rates informed by BEAD division.
[3] The standard assumptions for orchard/vineyard area treated is 40 acres.
[4] Inhalation MOE = Inhalation POD (mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

Table 3. Summary of Captan Inhalation Risk Estimates for Airblast Applicators with Reduced Area Treated

Crop	Application Rates[1]	Area Treated[2]	Inhalation MOEs[3] (LOC = 30)	
			PF10-R	EC
Almonds	4.50 lb ai/A	40 acres	**15**	100
		24 acres	**25**	170
		20 acres	30	210
Blueberries	2.50 lb ai/A	40 acres	**27**	190
		36 acres	30	210

[1] Current maximum single application rates based on registered labels; refer to Table E.1. (B. Lee, *et al.*, 03/02/2021, D453333).
[2] The standard assumptions for orchard/vineyard area treated is 40 acres.
[3] Inhalation MOE = Inhalation POD (mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

Table 4. Summary of Captan Dermal Risk Estimates for Re-entry Workers at Reduced Rates

Table 3.1. Occupational Post-Application Dermal Risk Estimates at Reduced Application Rates					
Crop	**Worker Re-entry Activity**	**Current Maximum Application Rates[1]**	**Timepoint when MOE ≥ LOC**	**Proposed Reduced Application Rate**	**Timepoint[2] when MOE > LOC**
Apples, Peaches, Nectarines	Hand thinning	4 lb ai/A	Day 6	3 lb ai/A	Day 0 (MOE = 100)
Cherries	Hand thinning	3.16 lb ai/A	Day 1	2.05 lb ai/A	Day 0 (MOE = 160)
Grapes, wine/juice	Tying, training, hand harvesting, leaf pulling[3]	2.04 lb ai/A	Day 3 (MOE	1.75 lb ai/A	Day 1 (MOE = 94) Day 2 (MOE = 110)
Grapes, table	Girdling and turning[4]	2.04 lb ai/A	Day 8	1.75 lb ai/A	Day 5 (MOE = 96) Day 6 MOE = 110)

[1] Current maximum single application rates based on registered labels.
[2] Days after treatment (DAT).
[3] MOEs are 94 at DAT1 and 78 at DAT0.
[3] MOEs are 96 at DAT5 and 82 at DAT4.