



Irgarol

Proposed Interim Registration Review Decision Case Number 5031

September 2020

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Table of Contents

I.	INTRODUCTION	4
A.	Summary of Irgarol Registration Review	5
II.	USE AND USAGE	6
III.	SCIENTIFIC ASSESSMENTS	7
A.	Human Health Risks.....	7
1.	Risk Summary and Characterization	7
2.	Human Incidents and Epidemiology	8
3.	Tolerances.....	8
4.	Human Health Data Needs	8
B.	Ecological Risks.....	9
1.	Risk Summary and Characterization	9
2.	Ecological Incidents	9
3.	Ecological and Environmental Fate Data Needs	9
C.	International Maritime Organization (IMO) Environmental Actions for Irgarol	10
1.	IMO Timeline	10
D.	Alternative Antifoulant Active Ingredients.....	10
	Table 1: Comparison of Antifoulant Paint and Coatings.....	12
IV.	PROPOSED INTERIM REGISTRATION REVIEW DECISION	14
A.	Proposed Risk Mitigation and Regulatory Rationale.....	14
1.	Proposed Removal of Antifoulant Paint Uses for Irgarol.....	14
2.	Proposed Occupational and Residential Handler Mitigation for the Airless Sprayer Application of Algacidal Preserved Paint for Irgarol	14
3.	Proposed Occupation Handler Mitigation for the Open Pouring of Irgarol Powder Formulations.	15
B.	Tolerance Actions	15
C.	Proposed Interim Registration Review Decision	15
D.	Data Requirements	15
V.	NEXT STEPS AND TIMELINE.....	15
A.	Proposed Interim Registration Review Decision	15
B.	Implementation of Mitigation Measures	16
	Appendix A: Summary of Proposed Actions for Irgarol.....	17
	Appendix B: Propose Labeling Changes for Irgarol Products.....	19
	Appendix C: Endangered Species Assessment.....	20

Appendix D: Endocrine Disruptor Screening Program 22

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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Proposed Interim Registration Review Decision (PID) for Irgarol (Cybutryne) (PC Code 128996, case 5031), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose 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. Additional information on irgarol, can be found in the EPA's public docket (EPA-HQ-OPP-2010-0003) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the 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. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at <https://www.epa.gov/pesticide-reevaluation>. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing a PID for irgarol 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). The agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to develop methodologies for conducting national threatened and endangered (listed) species assessments for pesticides in accordance with the Endangered Species Act (ESA) Section 7, also identified as § 7 in this document. Therefore, although the EPA has not yet fully evaluated risks to federally listed species, the agency will complete its listed species assessment and any necessary consultation with the Services for irgarol prior to completing the irgarol registration review. Likewise, the agency will complete endocrine screening for irgarol, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the irgarol registration review.

The agency has been working with the International Maritime Organization (IMO) that is proposing to ban cybutryne (irgarol). When the proposal to ban cybutryne (irgarol) was first

considered at the IMO in 2017, the U.S. Coast Guard consulted with EPA offices (Office of Chemical Safety and Pollution Prevention, Office of Water, and Office of International and Tribal Affairs) and other federal agencies. Following consideration of the technical merit of the proposal, current market demand and alternatives, and the anticipated support at the IMO for the proposal, the Coast Guard – with concurrence from EPA and other federal agencies – in 2019 expressed “no objection” to the recommendation to go forward with a comprehensive proposal to a ban on the antifoulant paint use. For further discussion on EPA’s proposed strategy to align with the IMO ban, see Section III C.

Irgarol, also referred to as cybutryne, (PC Code 128996) is used as an algaecide, fungicide, antifouling agent, microbicide, microbiostat, molluscicide, and slimicide. Products containing irgarol are registered for use as an antifoulant paint on boat hulls and as a material preservative in paints, caulks, coatings, sealants, grouts, vinyl roofing, roof coatings, cements, stucco, wood stains, adhesives, plasters, and incorporated into boat hulls themselves.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA’s responses; *Use and Usage*, which describes how and why irgarol is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA’s risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for the EPA’s PID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Irgarol Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for irgarol (1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N’- (1,1-dimethylethyl)-6-(methylthio)-) also called cybutryne, with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of irgarol.

- March 31, 2010 - The Irgarol *Preliminary Work Plan* (PWP), was posted to the docket for a 60-day public comment period. No comments were made that impacted the schedule or risk assessment needs.
- September 2010 - The *Final Work Plan* (FWP) for irgarol was issued.
- September 2014 GDCI-128996-1425 - A Generic Data Call-In (GDCI) for irgarol was issued for data needed to conduct the registration review risk assessments. All data have been submitted.

- February 2020 - The agency announced the availability of the *Registration Review Draft Risk Assessment for Irgarol (also called Cybutryne)* for a 60-day public comment period. No public comments were received.
- July 2020 – *The Revised Inhalation Risk Assessment for the Irgarol Registration Review DRA* was completed. The inhalation risk assessment was revised to include the 90-day inhalation toxicity study that was submitted after the irgarol draft risk assessment was conducted. Based on the 90-day inhalation toxicity study, inhalation risks were reduced, but not completely eliminated (See Sections 4 and 5 in the document). The revised inhalation risk assessment document will be posted in the docket at the same time as the proposed interim decision (PID).
- September 2020 - The agency has completed the *Irgarol Proposed Interim Registration Review Decision* and will announce its availability in the Federal Register in the docket for a 60-day public comment period.

II. USE AND USAGE

Irgarol containing products are currently registered for use in antifoulant paints for boat and/or vessel hulls in both marine and freshwater settings; as a algicidal preservative in paints, caulks, coatings, sealants, grouts, vinyl roofing, roof coatings, stucco, wood stains, adhesives, plasters; and is incorporated into boat hulls themselves. In antifouling paints, irgarol is often combined with copper, or copper compounds such as cuprous oxide or copper thiocyanate. While irgarol effectively controls algae, copper is effective at controlling aquatic animals such as mussels and barnacles. Irgarol is a s-triazine algaecide used in combination with copper in antifoulant paint as a “booster” biocide, intended to diminish algae growth on ship hulls. In material preservative products, irgarol is often combined with carbendazim (MBC), chlorothalonil, and/or DCOIT (3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-).

Currently, there are six registrants with 16 active products in this case; one is a technical product and 15 are end-use products. The end use products are formulated as solid concentrate powders, liquid concentrates, ready to use liquids (*i.e.*, paints) and pressurized liquids (*i.e.*, paints in spray cans). Four of the end-use products are irgarol only and contain between 2 and 98.6% irgarol. The other 11 are combinations of cuprous oxide + irgarol, cuprous oxide + carbendazim + DCOIT or copper thiocyanate + irgarol containing between 0.8 and 3.5% irgarol. Ten end-use products are antifoulant paint formulations that contain 0.49 to 2.38% irgarol. According to Kline and Company (2016), irgarol (listed as triazine), accounted for 1.4% of average market pricing of selected antifoulant marine coatings in the US. According to Kline and Company (2004), which lists irgarol specifically, the annual sales were 3.5 million dollars. Kline and Company (2004) also indicated that irgarol is used primarily for yachts as a booster for copper based marine antifoulant coatings. Although irgarol compounds are the least expensive active among co-biocides, it is predicted to witness slow growth for issues related to high toxicity and low biodegradability (2016).

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of irgarol. For additional details on the human health assessment for irgarol, see the *Irgarol Human Health and Ecological Draft Risk Assessment*, and the *Irgarol Revised Inhalation Risk Assessment* which are available in the public docket (EPA-HQ-OPP-2010-0003) at www.regulations.gov.

1. Risk Summary and Characterization

Dietary (Food + Drinking Water) Risks

There are no human health risks from oral exposures to irgarol as there are no dietary uses or drinking water or incidental oral exposures.

Residential Handler Risks

There was no inhalation risk of concern for antifoulant paint use in the initial risk assessment or revised inhalation risk assessment; however, dermal risks of concern were identified for antifoulant paint applied with a brush and roller. The margin of exposure (MOE) of 65 for painting the largest size recreational boat (i.e., 30 ft long) without wearing gloves is of concern because it is less than the target MOE of 100. Residential inhalation handler risks evaluated for other smaller treated boats ranging from 14 ft to 20 ft long were greater than the MOE of 100 and not of concern.

Residential handler inhalation exposure risk was identified during the 'Do It Yourself' (DIY) application rate of 3.94% irgarol as an algicidal preservative in paints. The MOE of 19 is of concern because it is less than the level of concern (LOC) of 30 for both brush/roller and airless sprayer methods of application.

Residential Post-Application Risks

There are no residential post-application risks of concern.

Occupational Handler Risks

Occupational handler inhalation risk was identified during the commercial application of irgarol-containing antifoulant paints applied to large vessels such as cargo ships, cruise ships and large pleasure boats (i.e., mega yachts) that ranged between 90 to 680 ft. The inhalation exposures were calculated as air concentrations using the average 8-hour time weighted average for each

trial/job combination. The MOE of 15 applied by spray men is of concern for all large boat sizes because it is less than the LOC of 30.

Occupational handler exposure risk was identified during the open pour powder addition of irgarol as a preservative during paint manufacturing and commercial application of irgarol as an algicidal preservative in paints. The product with the lowest application rate of 0.46% irgarol (EPA Reg No. 707-312) is not of concern since all MOEs are above the target MOE. The product with the highest application rate of 3.94% irgarol (EPA Reg No. 40810-15) has the greatest risks to occupational handlers for these uses. The inhalation MOEs of 0.6 for open pour powder to preserve paints at 3.94% irgarol and 5.8 for airless spray application of paints containing 3.94% irgarol, are of concern because they are less than the target MOE of 30. Occupational handler dermal risks for airless spray application of paint containing 3.94% irgarol is of concern since the MOE of 51 is less than the target MOE of 100.

Occupational Post-Application Risks

There are no occupational post-application risks of concern.

Aggregate Risks

There are no exposures via the oral route. Exposures to irgarol can occur via the inhalation and dermal routes from antifoulant paint used by DIY boat painters and from algicidal preservative paint used by residential painters. It is extremely unlikely that a residential painter would paint their boat with irgarol antifoulant paint and their house with irgarol preserved paint on the same day; therefore, an aggregate risk assessment is not needed for irgarol.

Cumulative Risks

The EPA has not made a common mechanism of toxicity to humans finding as to irgarol and any other substance (*e.g.*, other S-triazines) and it does not appear to produce a toxic metabolite produced by other substances. Therefore, the EPA has not assumed that irgarol has a common mechanism of toxicity with other substances for this assessment.

2. Human Incidents and Epidemiology

The search of the Incident Data System (IDS) did not include any reports in the database as of August 2020. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

3. Tolerances

There are no tolerances, tolerance exemptions or FDA clearances for irgarol and none are required for this PID.

4. Human Health Data Needs

The agency does not anticipate calling in any further data for irgarol.

B. Ecological Risks

A summary of the agency's ecological risk assessment is presented below. The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of Irgarol. For additional details on the ecological assessment for irgarol, see the Registration review *Irgarol Human Health and Ecological Draft Risk Assessment* which is available in the public docket at www.regulations.gov under docket ID EPA-HQ-OPP-2010-0003.

The EPA is currently working with its federal partners and other stakeholders to implement an interim approach for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats are finalized, the agency will complete its endangered species assessment for Irgarol. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

1. Risk Summary and Characterization

The agency has determined that irgarol is highly toxic to freshwater fish, aquatic invertebrates and both freshwater and marine plants. Leaching from paints applied to boat hulls will expose aquatic organisms to parent irgarol and its primary triazine degradation product. Risks to aquatic plants exceed the level of concern for non-listed species based on modeling using the environmental fate data and median release rates of parent irgarol from treated paints in saltwater environments. Because risks were identified for algae, it was determined that there is also a potential for risk to coral from the antifouling paint use of irgarol. However, the modelled exposure concentrations do not exceed any acute or chronic level of concern for fish or aquatic invertebrates. Even though the use as a material preservative may result in leaching, a terrestrial ecological risk assessment was not conducted because, treated building materials are spatially dispersed and not expected to occur in any one concentrated area. Therefore, overall terrestrial exposure is expected to be minimal, and irgarol is practically nontoxic to terrestrial receptors (including pollinators).

2. Ecological Incidents

The search of the Incident Data System (IDS) did not include any reports in the database as of August 2020. The agency will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database is complete, and no data is anticipated to be called in at this time.

C. International Maritime Organization (IMO) Environmental Actions for Irgarol

The IMO is the United Nations technical organization responsible for setting safety, environmental, and other standards for international shipping.

The U.S. Coast Guard formally represents the U.S. Government in the work of the IMO. It establishes U.S. negotiating positions in close consultation with EPA, National Oceanic Atmospheric Administration (NOAA), Department of State, Navy, Maritime Administration (MARAD), Department of Justice, and other federal entities.

When the proposal to ban cybutryne (irgarol) was first considered at the IMO in 2017, the Coast Guard consulted with EPA offices (Office of Chemical Safety and Pollution Prevention, Office of Water, and Office of International and Tribal Affairs) as well as NOAA, Navy, Department of State, Department of Transportation, and other federal entities. Following consideration of the technical merit of the proposal, current market demand and alternatives, and the anticipated support at the IMO for the proposal, the Coast Guard – with concurrence from EPA and other federal entities – in 2019 expressed “no objection” to the recommendation to go forward with a comprehensive proposal to a ban on the antifoulant paint use.

During the discussions of the proposal at IMO meetings, the Coast Guard and NOAA representatives noted strong support, even among industry entities, for the recommended ban. EPA’s subsequent conversations with industry counterparts, e.g., the American Coatings Association, confirmed that industry agreed that the IMO’s risk assessment was rigorous and well done and that industry groups do not oppose the ban.

1. IMO Timeline

The recommended IMO timeline¹ for the ban on use of irgarol as an antifoulant paint is still tentative and shifting. The proposed date for prohibition of new applications of irgarol is currently scheduled to be effective as of October 2025 and the requirement for sealing of existing irgarol-containing coatings after October 2030. The agency has been in communication with all the irgarol registrants, and they concur with the cancellation of their antifoulant paint uses of irgarol, preferably along the same timelines of the IMO (See Section IV for proposed mitigation).

D. Alternative Antifoulant Active Ingredients

Without the protection of an effective antifoulant paint coat, a boat may be subject to biofouling, that is, the hull may become colonized by algae, barnacles, or similar species. A boat that is biofouled will consume more energy and fuel to propel it through the water due to increased drag. Aside from the costs to boat owners, this also increases fuel-related pollution. In cases of

¹ <http://www.imo.org/en/MediaCentre/MeetingSummaries/MEPC/Pages/MEPC-74th-session.aspx>

excessive fouling, damage to the hull and moving parts of the boat such as propellers is expected to occur. Additionally, the maneuverability and performance of the boat is impaired, creating safety concerns. The severity of fouling varies greatly with water temperature, salinity, pH, nutrient content and geographic region all playing a role. As an ecological concern, biofouled boats that travel to different marinas may cause recreational boaters to unknowingly transport invasive species.

It is estimated that approximately one-third of the U.S. adult population participates in recreational boating annually (combining both freshwater and saltwater uses). Recreational boats comprise the U.S.' largest boat fleet, far outnumbering U.S. merchant shipping, commercial fishing, passenger traffic, and Armed Services fleets. The agency does not have data to indicate the percentage of recreational boaters who use antifoulant products but assumes this is a large proportion of boaters. The irgarol registrants have identified zinc pyrithione, tralopyril and DCOIT as alternatives. Table 1 provides a comparison of antifoulant paint and coatings.

Table 1: Comparison of Antifoulant Paint and Coatings

Type of Paint	Description	Frequency of Application (approx.) ¹	Advantages	Disadvantages
Cuprous oxide (Case 4025, PC Code 025601) ²	Copper-based biocide	2-3 years	Low in cost Widely available Broad-spectrum biocide No human health risks of concern	Toxicant to non-target aquatic species Copper persists in environment
Irgarol (Case 5031, PC Code 128996) ²	Organic algicide	< 2 years	Effective against algae Slower leach rate than other biocides listed in table based on median of release rates	Human health and ecological risks of concern Ecological risk to non-target aquatic plants and coral Must be combined with other antifoulant
DCOIT (Case 5023, PC Code 128101) ²	Organic, metal-free biocide	< 2 years	Broad-spectrum biocide Low VOC ⁴ emissions Does not persist in environment Minimal bioaccumulation Stripping of old paint not required	Human health and ecological risks of concern Requires professional application More frequent application required
Zinc pyrithione (Case 2480, PC Code 088002) ²	Zinc-based biocide	≤ 2 years	Broad-spectrum biocide	Human health risks are being reevaluated. ³ Toxicant to non-target aquatic species Pyrithione persists in environment More frequent application required More coats of paint required
Econea™/Tralopyril (Case 5114, PC Code 119093) ²	Organic, metal-free biocide	< 2 years	Does not persist in environment Effective against macrofouling	Human health and ecological risks of concern More frequent application required Must be combined with other antifoulant
Silicone antifoulant coatings (Case: N/A, PC Code: N/A)	Soft non-biocide	5-10 years	Longevity Scrubbing, dry docking does not compromise effectiveness Broad-spectrum effectiveness Can be cleaned at same frequency as copper	More expensive up-front cost Stripping off old paint layer required Not widely available Toxicity not evaluated by the agency Not a registered antimicrobial antifoulant use.
Epoxy antifoulant coatings (Case: N/A, PC Code: N/A)	Hard non-biocide	5-10 years	Longevity Scrubbing, dry docking does not compromise effectiveness Broad-spectrum effectiveness	More expensive up-front cost Stripping off of old paint layer required Not widely available Require more frequent cleaning Toxicity not evaluated by the agency

¹The lifespan of any AFC system is subject to the conditions in which the craft is used and frequency of hull cleaning, thus an approximate range is provided.

Docket Number EPA-HQ-OPP-2010-0003

www.regulations.gov

² Currently undergoing registration review.

³ This case does not have a completed risk assessment for registration review; thus, the agency has not made a risk determination. Human health studies have been identified as necessary to assess safety for paint applicators (occupational and residential handlers).

⁴ Volatile Organic Compound

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

In evaluating potential risk mitigation for the applications of irgarol, the agency has considered the risks and benefits. EPA has determined that there are human health and ecological risks of concern from the use of irgarol in antifoulant paints, preserved paint, and as a materials preservative. However, the agency has also identified areas where risk mitigation measures are appropriate and is proposing to implement label changes for antifoulant paints and preserved paints containing irgarol. Mitigation measures are expected to greatly reduce human health and ecological risks of concern from the use of irgarol in antifoulant and preserved paints. The agency has notified registrants of the proposed mitigation measures to address the risks of concern and the registrants are in general agreement with the agency's proposed mitigation.

1. Proposed Removal of Antifoulant Paint Uses for Irgarol

To mitigate occupational handler inhalation and dermal human health risk as well as the freshwater and marine ecological exposure risks to aquatic plants that affect coral reefs, the agency is proposing to remove the antifoulant paint use of irgarol. The agency has been working with the registrants who are planning to cancel their antifoulant paint uses of irgarol along the same timelines of the IMO (see Section III.C.). EPA understands the most recent IMO recommendation is to ban the use of irgarol (cybutryne) as an antifoulant paint with no new applications as of October 2025 and no existing irgarol-containing coatings after October 2030 unless sealed. Therefore, the agency is proposing that registrants with product labels that include marine and freshwater antifoulant paints uses must request removal of those uses by September 30, 2023. If the products are only registered for antifoulant paint uses, then registrants must submit a voluntary cancellation request by September 30, 2023. The timing for the FIFRA 6(f) process and allowing for use of existing stocks is estimated to take 2 years; therefore, the antifoulant paints uses will be effectively cancelled by October 2025, which aligns with current IMO recommendations. Once all labels are received, the agency will use its FIFRA 6(f) authority to officially cancel the antifoulant paint uses.

The agency would like stakeholder feedback on this proposed timeframe during the comment period for this PID.

2. Proposed Occupational and Residential Handler Mitigation for the Airless Sprayer Application of Algicidal Preserved Paint for Irgarol

To mitigate the potential inhalation and dermal risks for both residential and occupational handlers applying irgarol-preserved paints via airless sprayer, the agency is proposing to lower the maximum allowed application rate to 0.76 % a.i. by weight. This rate is not the lowest level of 0.046% found in the revised risk assessment²; however, it is low enough to mitigate the painter risks. This paint product is useful for building materials, stucco, sealants, and coatings.

² Revised Inhalation Risk Assessment for the Irgarol Registration Review DRA. July 16, 2020.

3. Proposed Occupation Handler Mitigation for the Open Pouring of Irgarol Powder Formulations.

The agency is proposing water-soluble packaging for powder formulations of irgarol to mitigate dermal and inhalation risks of concern.

B. Tolerance Actions

There are no tolerances or exemptions from the requirement of tolerances required for irgarol.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the agency has made the following PID: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are required at this time, as described in Section IV. A and Appendices A and B.

In this PID, the agency is making no human health or environmental safety findings associated with the EDSP screening of irgarol, nor is it making a complete endangered species finding. Although the agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of irgarol. The agency's final registration review decision for irgarol will be dependent upon the result of the agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

The agency does not anticipate calling-in additional data for registration review of irgarol.

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for irgarol and will allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the agency to change its PID, the EPA may issue an interim registration review decision for irgarol. However, a final decision for irgarol may be issued without the agency having previously issued an interim decision. A final decision on the irgarol registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination, and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the irgarol registrants must submit amended labels (except antifoulant uses, see below) that include the label changes described in Appendices A and B. The revised labels and requests for amendment of registrations must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

The agency is proposing that registrants with product labels that include marine and freshwater antifoulant paints uses must request removal of those uses by September 30, 2023. If the products are only registered for antifoulant paint uses, then registrants must submit a voluntary cancellation request by September 30, 2023.

Appendix A: Summary of Proposed Actions for Irgarol

Registration Review Case#: 5031 PC Code: 128996 Chemical Type: antifoulant, microbicide, molluscicide, slimicide, fungicide					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Residential Handler Airless Sprayer	Application of paint	Inhalation Dermal	Short	Upper respiratory tract irritation Irritation	Decrease Application Rate
Occupational Handler Airless Sprayer	Application of paint	Inhalation Dermal	Short Intermediate	Upper respiratory tract irritation Irritation	Decrease Application Rate
Occupational Handler Open pour powders	Open pouring of powders to preserve paints	Inhalation	Short Intermediate	Upper respiratory tract irritation	Water-Soluble packaging

Residential Handler Brush and roller	Application of antifoulant paint	Dermal	Short	Irritation	Cancel the antifouling paint use
Occupational Handler	Application of antifoulant paint	Inhalation Dermal	Short Intermediate	Upper respiratory tract irritation Irritation	Cancel the antifouling paint use
Aquatic Plants (and indirectly Corals)	Leaching of antifoulant paint	Leaching	Acute Sub-chronic Chronic	Risks to aquatic plants and coral bleaching	Cancel the antifoulant paint use

Appendix B: Propose Labeling Changes for Irgarol Products

Description	Proposed Label Language for Irgarol Products	Placement on Label
<p>Lower the application rates for formulated algicidal paints, coatings, stucco, stains and caulks to inhibit or control the growth of algae on the treated formulations</p>	<p>The maximum allowed application rate is 0.76 % irgarol by weight.</p>	<p>Directions for Use</p>
<p>Formulated powders put into water-soluble packages</p>	<p>Water-soluble packaging is required for powder formulations.</p>	<p>Directions for Use</p>
<p>Removal of the antifoulant paint uses for ecological risks and occupational and residential handler risks</p>	<p>Antifoulant paint uses must be removed from labels by submitting a label amendment to the agency by September 30, 2023. Products that are only registered for antifoulant paints uses must request voluntary cancellation by September 30, 2023.</p>	<p>N/A</p>

Appendix C: Endangered Species Assessment

In 2013, EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) 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 to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, 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* (i.e., Revised Method) in March 2020.³ During the same timeframe, EPA also released draft BEs for carbaryl and methomyl, which were the first to be conducted using the Revised Method.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group (IWG) to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role in this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019. The recommendations from the IWG and progress on implementing those recommendations are outlined in reports to Congress.⁴

Given that the agencies are continuing to work toward implementation of the Revised Method to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for irgarol does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this PID, EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of irgarol. This will allow EPA to focus its future evaluations on the types of species

³ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084>

⁴ <https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act>

Docket Number EPA-HQ-OPP-2010-0003
www.regulations.gov

where the potential for effects exists once the Revised Method has been fully implemented. Once that occurs, the Revised Method will be applied to subsequent analyses for irgarol as part of completing this registration review.

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, the 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, the 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 irgarol, the EPA 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), irgarol is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

The 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 the 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, the 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. A second list of chemicals identified for EDSP screening was published on June 14, 2013,⁵ 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, please visit the EPA website.⁶

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

⁵ See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

⁶ <https://www.epa.gov/endocrine-disruption>