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Halohydantoins

Interim Registration Review Decision
Case Number 3055

June 2021

Approved by: _____

Anita Pease
Director
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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the Agency) Interim Registration Review Decision (ID) for halohydantoins (PC Codes 006315, 006317, 006322, 006333, 028500, 028501, 128826, 128989 and 606315; case 3055), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. PC Code 128989 no longer has any active registrations, and PC Code 606315, a recently registered new active ingredient in March 2020, was incorporated into this case after the initial issuance of the GDCIs and publication of the DRA. 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 the halohydantoins, see EPA's public docket (EPA-HQ-OPP-2013-0220) 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 EPA is issuing an ID for halohydantoins 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). As discussed in Section III. B. 1., the Agency has evaluated risks to endangered and threatened (listed) species and is making a "no effect" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under section 7(a)(2) of the Endangered Species Act (ESA)[5] is not required. Before completing registration review, EPA will also complete endocrine screening for the halohydantoins under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6] See the Halohydantoins Proposed Interim Registration Review Decision, Appendix D for additional information about the endocrine screening for the registration review of the

[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).

halohydantoins. Additionally, under the FFDCA section 408, a pesticide chemical residue is considered unsafe if it is not covered by a tolerance or exemption. Because the FIFRA standard for registration requires a finding that the uses on food are consistent with the 408 safety standard, a final decision cannot be made for the registration review indicating that the pesticide meets the FIFRA standard until such tolerances or exemptions are issued. Therefore, EPA is publishing this ID in recognition that the final decision for the registration review of halohydantoins will be based on the establishment of the requisite tolerances or exemptions, unless such uses are removed from the labels. Refer to Section III. A. 3. for details.

The halohydantoins registration review case includes eight active ingredients: four dihalodialkylhydantoins (PC Codes 006315, 006317, 028501 and 128826), which were evaluated in the 2007 Registration Eligibility Decision (RED) for dihalodialkylhydantoins. The case also includes three other dihalodialkylhydantoins (PC Codes 006322, 006333 and 128989), one monohalodialkylhydantoin (PC Code 028500) and one dialkylhydantoin (606315) that were registered after November 1, 1984 – the reregistration cut-off date. Because this case contains both monohalo- and dihalohydantoins, this case is referred to herein as halohydantoins.

There are 90 registered halohydantoin products, which are used for microbial control in water and water systems. They are used as disinfectants in commercial and residential swimming pools, spas, and hot tubs; as sanitizers for treatment of toilet bowl water in homes; and for controlling bacterial and fungal contamination in a variety of industrial water systems (i.e., industrial cooling water systems, pulp and paper mill process water, wastewater treatment systems, air washer water systems, sewage systems, industrial processing water), and aquatic areas (i.e., ornamental ponds). In addition, halohydantoins are used as sanitizers for hard surfaces, egg washing, fruit and vegetable washing, and drinking water disinfection.

This document is organized in five sections:

- *Introduction* (summarizing the ID and responding to public comments);
- *Use and Usage* (discussing how and why the halohydantoins are used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *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. Updates Since the Proposed Interim Decision was Issued

In October 2020, EPA published the Proposed Interim Decision (PID) for the halohydantoins. This section provides updates since the PID. After receiving comments on the PID, the Agency is updating the mitigation measures for occupational handlers. EPA has determined that the risk of concern for occupational handlers applying powders and granules in water treatment scenarios can be resolved by using a closed-loading system. Additionally, the data deficiencies have been updated following communications with the Halohydantoins Task Force. Registrants with approved waivers for the inhalation toxicity study are no longer required to submit those data. In

addition, the Agency is providing additional information regarding the status of the bromate formation in swimming pools study. Additional information can be found in section III. A. 4. Human Health Data Needs.

The Agency did not assess risk to swimmers from exposure to bromate in swimming pools, spas and hot tubs. The Agency has determed it necessary to remove the outdoor pool use from halohydantuion labels and add label language to direct hot tub and spa users to cover their units when not in use. Please see section III. A. 1. and IV. A. for further discussion of these changes.

B. Summary of Halohydantoins Registration Review

On June 26, 2013, the Agency formally initiated registration review for the halohydantoins with the opening of the registration review docket for the case.[7] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of the halohydantoins:

- June 2013 - The *Halohydantoins Preliminary Work Plan* (PWP*)* was posted to the docket for a 60-day public comment period.

- December 2013 - The *Halohydantoins Final Work Plan* (FWP) was issued. During the public comment period on the PWP, 29 comments were received by the Agency. Comments received on the PWP resulted in a modification to the anticipated data needs detailed in the halohydantoins FWP.

- March 2017 – The following Generic Data Call-Ins (GDCIs) for halohydantoins were issued for data needed to conduct the registration review risk assessments: GDCI-006315-1606, GDCI-006317-1699, GDCI-028500-1701, GDCI-028501-1702, GDCI-128826-1703, GDCI-128989-1704 and GDCI-006322-1700. A repeat-dose inhalation toxicity study (870.3465) was not received by the Agency and remains outstanding. The Agency relied upon available data and used conservative assumptions to complete the risk assessments for the halohydantoins. The Agency intends to waive this study based on the mitigation described in Section IV. A. 2.

- April 2017 – The *Halohydantoins Amended Final Work Plan*, although signed in February, was posted to the docket. Changes were made to anticipated data needs based on food contact uses. Additionally, data requirements from the Reregistration Eligibility Decision (RED) were incorporated into the registration review Generic Data Call-In (GDCI).

- May 2020 - The Agency announced the availability of the *Draft Risk Assessment for the Halohydantoins Registration Review* for a 60-day public comment period. Five comments were received during the comment period from a registrant task force as well as from various local water boards. The comments did not change the risk assessments or registration review timeline for the halohydantoins.

[7] 40 C.F.R. § 155.50

- October 2020- The Agency announced the availability of the *Halohydantoins Proposed Interim Registration Review Decision* for a 60-day public comment period. Four comments were received during the comment period from a registrant, a registrant task force and two comments from California-based water boards. These comments and the Agency's responses are summarized below.

- June 2021 – The Agency has completed the *Halohydantoins Interim Registration Review Decision* (ID) and will announce its availability in the Federal Register.

C. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period for the *Halohydantoins Proposed Interim Registration Review Decision*, which opened on October 23, 2020 and closed on December 22, 2020, the Agency received public comments from four sources: the Center for Biocide Chemistries' Halohydantoins Work Group (representing eight registrants), the Bay Area Clean Water Agencies (BACWA), the San Francisco Bay Regional Water Quality Control Board, and the registrant Lonza, LLC. Substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized below. The Agency thanks all commenters for their comments and has considered them in developing this ID.

Comment Submitted by the Center for Biocide Chemistries' Halohydantoins Work Group (Docket ID: EPA-HQ-OPP-2013-0220-0028):

Comment: The Center for Biocide Chemistries' Halohydantoins Work Group submitted a comment to the docket related to the risk mitigation strategy and data requirements. The work group requested clarification of the particle sizes that would be impacted by the occupational handler mitigation measures. Additionally, the work group inquired about the status of two data requirements.

EPA Response: The Agency is clarifying that the particle sizes impacted by the occupational handler mitigation measures are powders and granules; pellets, tablets and pucks are not impacted. If the physical formulations identified by registrants in documentation submitted at the time of registration indicate the product is in a powder or granule, the mitigation measures will apply. Additional details can be found in section IV. A. 2. Additionally, information regarding the repeat-dose inhalation toxicity study (870.3465) and a bromate formation study for swimming pools (SS-1129) has been updated throughout this document to indicate that both studies will no longer be required once the necessary mitigation measures are implemented as described in section III. A. 4.

Comments Submitted by the Bay Area Clean Water Agencies (BACWA) and the San Francisco Bay Regional Water Quality Control Board (Docket IDs: EPA-HQ-OPP-2013-0220-0029 and EPA-HQ-OPP-2013-0220-0030):

Comment: Both of these commenters expressed their appreciation for the language that was proposed to be added to labels of halohydantoin products applied to swimming pools, spas, hot tubs, and fountains. These commenters recommended the addition of the following language in comments posted to the docket under the *Draft Risk Assessment for the Halohydantoins Registration Review*:

> "Before draining a treated pool, spa, hot tub, or fountain, contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated pool or spa water to any location that flows to a gutter or storm drain or natural water body unless discharge is allowed by state and local authorities."

EPA Response: The EPA thanks the Bay Area Clean Water Agencies and the San Francisco Bay Regional Water Quality Control Board for their comments and continued input throughout the registration review process. The recommended language will be added to the appropriate halohydantoin labels. Additional information related to the label language can be found in Appendix B.

Comment Submitted by the Registrant, Lonza, LLC (Docket ID: EPA-HQ-OPP-2013-0220-0027):

Comment: In response to the mitigation strategy that was proposed by the EPA in the PID, the registrant, Lonza, LLC., commented to request that occupational handlers only apply halohydantoin products in powder and granule formulations via closed loading systems, rather than the restrictions EPA had proposed in the PID for powder and granule product formulations for all end uses.

EPA Response: The EPA agrees that this mitigation strategy is appropriate for the occupational uses of halohydantoin products, since it would result in negligible inhalation exposure to occupational handlers. The mitigation strategy has been updated accordingly. Additional details can be found in section IV. A. 1.

II. USE AND USAGE

Halohydantoin products are used for microbial control in water and water systems. In particular, they are used as disinfectants in commercial and residential swimming pools, spas, hot tubs, and fountains; as sanitizers for treatment of toilet bowl water in homes; and for controlling bacterial and fungal contamination in a variety of industrial water systems (i.e., industrial cooling water systems, pulp and paper mill process water, wastewater treatment systems, air washer water systems, sewage systems, industrial processing water), and aquatic areas (i.e., ornamental ponds). In addition, halohydantoins are used as sanitizers for hard surfaces, egg washing, fruit and vegetable washing, and drinking water disinfection. There are 90 active registrations that contain one or more of the halohydantoins.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of halohydantoins. For additional details on the human health assessment for halohydantoins, see the *Draft Risk Assessment for the Halohydantoins Registration Review*, which is available in the public docket (EPA-HQ-OPP-2013-0220) at regulations.gov.

1. Risk Summary and Characterization

A summary of the Agency's human health risk assessment was presented in the PID. No risks of concern were identified for dietary exposures, residential handlers, residential post-application exposures, occupational post-application exposures, aggregate or cumulative exposures. Inhalation risks of concern were identified for occupational handlers applying halohydantoin products in powder or granule form to public pools, paper/paper mill systems, commercial and industrial water-cooling systems, and industrial water processing water. No dermal risks of concern were identified.

Since the PID was published, the Agency has considered post-application risk to swimmers from the formation of bromate, which is a degradation product of halohydantoins. These risks were not considered at the time of the DRA or PID. An acceptable bromate formation study was not received by the Agency for use in the risk assessment. However, the Agency has done a bromate exposure assessment for another bromate forming compound, the inorganic halides, and has concluded that the bromate assessment for the inorganic halides is applicable to the halohydantoins for three reasons: (1) the chemistry of both the inorganic halides and the halohydantoins are the same in terms of antimicrobial mode of action; (2) both release bromide ion into the pool water; and (3) the use rates are comparable; therefore, the bromate concentrations in water should be roughly equivalent. In lieu of the bromate formation data, the Agency conducted a conservative analysis of risk for bromate formation in swimming pools using current inorganic halide product labels. Since complete conversion to bromate is unlikely, and the actual amount of conversion is unknown, the bromate water concentration in swimming pool water corresponding to a cancer risk of 1.0×10^{-6} was back calculated. Based on these back calculations, bromate water concentrations of 5 µg/liter and 18 µg/liter for competitive and recreational swimmers, respectively, correspond to a cancer risk of 1×10^{-6}. Similar to the inorganic halides, halohydantoin pool products have an application rate greater than 18 µg/liter; therefore, EPA has determined that there are potential risks of concern for the outdoor swimming pool use pattern of halohydantoin products that contain bromine. The risks only exist for outdoor swimming pools because the bromate ion is formed under UV light exposure.

The spa and hot tub exposure scenario differs from the pool use scenario because spa and hot tub users are expected to generally keep their heads above the water line, the amount of water ingested by spa and hot tub users from movements like splashing is expected to be negligible, and the duration of exposures are expected to be minimal as compared to the swimmer scenario.

In addition, hot tubs and spas are generally covered when not in use, as a way to preserve heat in the hot tub or spa and keep them clean, and those covers are expected to keep out the UV light that is needed to form bromate. Similarly, bromate is not expected to form in indoor pools, spas, and hot tubs, and is therefore not of concern for those uses.

For additional details on the human health assessment for the halohydantoins, see the *Draft Risk Assessment for the Halohydantoins Registration Review*, which is available in the public docket at regulations.gov under docket ID EPA-HQ-OPP-2013-0220.

2. Human Incidents

OPP's Incident Data System (IDS) includes reports of alleged human health incidents from various sources, including mandatory FIFRA Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS.

Based on a search of the IDS for severe incidents (i.e., those classified as deaths or 'major') from 2014 to May 3, 2021, there was one severe incident identified that involved only halohydantoins. This incident (I030445-00001), classified as 'major', was the result of an intentional misuse (i.e., suicide attempt). There were 23 additional incidents classified as 'moderate' from this time period involving halohydantoins reported to the Agency. For one of these incidents, it is unknown whether an additional active ingredient other than a halohydantoin was present.

The Agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

3. Tolerances

EPA anticipates the need to update an existing tolerance exemption for 1,3-dibromo-5,5-dimethylhydantoin for its use as an active or inert ingredient in antimicrobial formulations as established under FFDCA Section 408. The Agency intends to propose that the tolerance exemption under 40 CFR 180.940(a) be updated to include the metabolites and degradates dimethylhydantoin (DMH) and ethylmethylhydantoin (EMH), which result from the use of 1,3-dibromo-5,5-dimethylhydantoin and other halohydantoin active ingredients, in this case used as food contact surface solutions. Details on tolerance exemptions and proposed actions are shown in Table 1. Additional information on tolerances and tolerance exemptions for the halohydantoins can be found in section 3.4.1 of the *Draft Risk Assessment for the Halohydantoins Registration Review*.[8]

Table 1: Summary of Proposed Tolerance Actions

[8] *Draft Risk Assessment for the Halohydantoins Registration Review*. www.regulations.gov; Docket ID EPA-HQ-OPP-2013-0220

1,3-dibromo-5,5-dimethylhydantoin: Summary of Tolerance Actions				
40 CFR Section	**Tolerance Exemption**	**Chemical CAS #**	**Maximum Residue Level**	**Recommended Action**
180.1346	Exemption from the requirement of a tolerance when used in treatment solutions of raw agricultural commodities in treatment facilities.	1,3-dibromo-5,5-dimethylhydantoin (CAS # 77-48-5), including metabolites and degradates resulting from the use of 1,3-dibromo-5,5-dimethylhydantoin	None Specified	None; retain existing tolerance exemption
180.940 (a)	For active and inert ingredients for use in antimicrobial formulations - Food contact surface solutions: For use in public eating places, dairy-processing equipment, and food-processing equipment and utensils.	1,3-dibromo-5,5-dimethylhydantoin CAS # 77-48-5	None Specified	Amend existing tolerance exemption to say: "1,3-dibromo-5,5-dimethylhydantoin (CAS # 77-48-5), including metabolites and degradates resulting from the use of 1,3-dibromo-5,5-dimethylhydantoin"

4. Human Health Data Needs

The halohydantoin toxicological database is complete except for a repeat-dose inhalation toxicity study (870.3465) and a bromate formation study for swimming pools (SS-1129). In lieu of a repeat dose study, the Agency used an acute inhalation study and added a 10-fold uncertainty factor. The repeat-dose inhalation toxicity study (870.3465) was called in through the GDCIs as described in Section I. B. As described in Section I. A., some registrants received a waiver for this data requirement due to the formulation of their products as tablets, which results in negligable inhalation exposure. The Agency is requiring that products formulated as powders and granules are applied to public pools, paper/paper mill systems, commercial and industrial water-cooling systems, and industrial water processing water by occupational handlers using a closed loading system. Using a closed-loading system will result in little to no inhalation exposures. Once product labels have been updated with this language, the repeat-dose inhalation toxicity study will no longer be required. For additional details, see Section IV. A. 2.

Additionally, the bromate formation in swimming pools data requirement (SS-1129) was not satisfied before the completion of the draft risk assessment. The halohydantoins registrants intended to cite the study submitted for the inorganic halides registration review case.[9] This study was submitted during the comment period for the draft risk assessment for the inorganic halides during registration review; however, it was deemed unacceptable by the Agency due to questionable validity as detailed further in the Agency Memo: *Agency's Response to the Bromate Work Group's Response to Review of Bromate Photolysis in Simulated Swimming Pools Study* located in the inorganic halides docket EPA-HQ-OPP-2009-0168 at www.regulations.gov.

[9] Docket ID EPA-HQ-OPP-2009-0168 at www.regulations.gov

In this interim decision, the Agency is requiring that all halohydantoin products, that contain active ingredients with bromine (PC codes 006315, 006317, 006322, 006333 and 128989) remove the outdoor swimming pool use and add label language for outdoor hot tubs and spas. Once these label amendments have been made, the bromate formation in swimming pools study will no longer be required. If registrants wish to add an outdoor pool use for products with bromine-containing halohydantoins, then completion of an acceptable bromate formation in swimming pool study is necessary to refine the estimated exposure and associated potential risks.

Although not all data requirements were met, the Agency believes that available data were sufficient for conducting a risk assessment and making this ID.

B. Ecological Risks

The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of the halohydantoins. For additional details on the ecological risk assessment for the halohydantoins, see the *Registration Review Draft Risk Assessment for the Halohydantoins*, which is available in the public docket at www.regulations.gov under docket ID EPA-HQ-OPP-2013-0220.

1. Risk Summary and Characterization

A summary of the Agency's ecological risk assessement was presented in the PID. Based on the environmental fate data, exposure to halohydantoins will be to their degradates, DMH or EMH. Although halohydantoins are generally highly toxic to aquatic organisms, their degradates (DMH and EMH) are practically non-toxic and thus pose minimal risks to nontarget organisms. A screening level down-the-drain analysis was completed in the 2013 *Halohydantoins Final Work Plan*.[10] For there to be risks to nontarget organisms, more than 300,000,000 kg DMH or EMH per year would have to enter domestic wastewater treatment plants to result in an exceedance of one day for the acute concentration of concern (COC) for listed freshwater fish and invertebrates and an exceedance of 20 days for the chronic COC for freshwater fish.

Based on the 2017 Kline report, the total annual volume production of halohydantoins is 27.7 million pounds (12.5 million kg).[11] Therefore, it is not possible to reach the amount needed to result in risks of concern for listed species. Additionally, based on the amount of halohydantoins used and the lack of toxicity of the degradates to nontarget organisms, no ecological risks are anticipated from the registered uses of the halohydantoins. Based on the current uses of the halohydantoins, exposure to terrestrial organisms, including pollinators, are not likely, and no risks are expected.

For the reasons outlined above, the EPA is making a "no effect" determination for the halohydantoins under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required for

[10] *Halohydantoins Final Work Plan*. Docket ID EPA-HQ-OPP-2013-0220; www.regulations.gov
[11] *Specialty Biocides 2016: United States Market Analysis*. Kline Group. 2017.

the current uses of halohydantoins in antimicrobial products. Should the use pattern or usage information relied upon within the draft risk assessment change, then the Agency may need to re-evaluate this determination.

2. Ecological Incidents

There were no reported ecological incidents for halohydantoins in the Agency's Incident Data System (IDS) as of May 3, 2021.

The Agency will continue to monitor ecological incident information as it is reported to the Agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

There are no ecological or environmental fate data gaps for the halohydantoins. All data requirements have been met with either submitted data or approved waivers. Therefore, no additional data are required at this time.

C. Benefits Assessment

According to the 2017 Kline Report, halohydantoins are the third most widely used biocide in water treatment applications in the United States at over 27 million pounds or 7.6% of the total market by volume.[12] The largest use of halohydantoin products is for treating recreational water, such as pools, spas, and hot tubs, though they account for less than 10% of biocides used in recreational water by weight. Additionally, whereas chlorine is often recommended for use in swimming pools, bromine is the preferred chemical for hot tubs and spas, thus the different halohydantoin products may be used differently depending on the chemical makeup of the active ingredients.[13] There are 10.4 million residential and 309,000 public swimming pools in the United States, all of which require regular water treatment to prevent unwanted microbial growth.[14]

Water cooling systems are the next largest consumer of halohydantoin products. Halohydantoins are valuable for this application because they can be used in tandem with other active ingredients including bromides or bleach as they work well at a higher pH. On their own, halohydantoin products cause less erosion to cooling water systems than chlorine bleach or chloroisocyanurates.[15]

Other active ingredients used in similar use sites as the halohydantoins include chloroisocyanurates, lithium hypochlorite (LiClO), sodium bromide (NaBr), glutaraldehyde, monochloramine, polixetonium chloride (WSCP) and quaternary ammonium compounds (quats).

[12] *Specialty Biocides 2016: United States Market Analysis*. Kline Group. 2017.
[13] https://lesliespool.com/blog/bromine-vs-chlorine-for-spas-hot-tubs.html
[14] *Specialty Biocides 2016: United States Market Analysis*. Kline Group. 2017.
[15] *Specialty Biocides 2016: United States Market Analysis*. Kline Group. 2017.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

In the Registration Review Draft Risk Assessment that was completed for the halohydantoins, human health risks were identified for occupational handlers via the inhalation route of exposure for various large-scale water treatment applications. The Agency has engaged with registrants in order to better understand how products are applied and handled and what mitigation strategies will most effectively address the identified risks of concern. The EPA has determined that it is necessary for occupational handlers to apply halohydantoin products formulated as powders or granules within closed loading systems in order to reduce the risk of inhalation exposure.

Additionally, the Agency has determined that there are human health risks of concern for the use of bromine-containing halohydantoin products in outdoor swimming pools. Therefore, the Agency has determined that it is necessary to cancel the outdoor swimming pool use. The Agency has determined it necessary to add language directing users to cover outdoor hot tubs and spas when not in use to prevent the formation of bromate ion to limit potential exposure to outdoor hot tub and spa users.

The Agency has also determined that label language is necessary for products with pool, spa, hot tub, and fountain uses to instruct users to contact local wastewater treatment plant, and storm drain authorities before discharging treated water. Even though the EPA does not anticipate ecological risks resulting from the use of halohydantoin products, the Agency is proposing this label language in order to align with other pool products undergoing registration review.

No additional mitigation is needed at this time for ecological exposures. Due to a lack of toxicity to nontarget aquatic organisms and a lack of exposure to terrestrial organisms (including pollinators), ecological risks from halohydantoins are not expected.

1. Mitigation Measure for Halohydantoin Swimming Pool Products Formulated with Bromine

To address human health risk concerns, the Agency has determined it is necessary to remove the outdoor pool use site for products containing the following halohydantoin active ingredients, which contain bromine: 1-bromo-3-chloro-5,5-dimethylhydantoin (006315), 1,3-dibromo-5,5-dimethylhydantoin (006317), 3-bromo-1-chloro-5,5-dimethylhydantoin (006322), bromochloro-5,5-dimethylhydantoin (006333), and bromochloro-5-ethyl-5 methylhydantoin (128989). This mitigation measure is necessary due to the formation of bromate ion from these active ingredients under UV exposure. The Inorganic Halides Registration Review Draft Risk Assessment stated that bromate ion has been characterized by the Agency as a probable human carcinogen and provided additional details. A reduction in use rate is not feasible due to the low level of bromate cancer risk at concentrations of 5 µg/liter and 18 µg/liter for competitive and non-competitive recreational swimmers. Thus, removal of this use is necessary to mitigate the cancer risks of concern. Considering the post-application risks to swimmers and the low benefits

in pools in comparison to spas and hot tubs, the Agency has determined that the continued registration of the outdoor pool use does not meet the FIFRA standard. Given the lack of UV light exposure and subsequent bromate ion formation in indoor pools, the indoor pool use site may be retained.

As an additional precautionary measure, the Agency has determined it is necessary to add clarifying label language on spa and hot tub products containing the above listed halohydantoin active ingredients due to the potential for the formation of bromate ion under UV light exposure. The spa and hot tub exposure scenario differs from the pool use scenario because spa and hot tub users are expected to generally keep their heads above the water line, the amount of water ingested by spa and hot tub users from movements like splashing is expected to be negligible, and the duration of exposure is expected to be minimal compared to the swimmer scenario. Although the amount of bromate ion formed in hot tubs is uncertain, the Agency has determined that the outdoor hot tub use continues to meet the FIFRA standard based on the lower duration of use and negligle amounts of hot tub water expected to be ingested by hot tub users as compared to the amounts estimated in the swimming pool assessment. In addition, hot tubs are generally covered when not in use and this is expected to limit the UV light needed to form bromate. Based on the low potential for exposure, the Agency has determined that the outdoor spa and hot tub use continues to meet the FIFRA standard provided additional label language is added to reduce the exposure to sunlight and thus formation of bromate. The indoor spa and hot tub use site may be retained without additional restrictions.

The registrants who will be impacted by these measures have been contacted and are aware of the Agency's determination of necessary changes to the label language. Those who have offered feedback are in agreement with the Agency's strategy.

- Add the following instruction to the Directions for Use label section:
    - "This product is not for use in outdoor pools."
    - "Outdoor hot tubs and spas must be covered when not in use."

2. Mitigation Measure for Halohydantoin Products Formulated as Powders or Granules

To mitigate the occupational handler inhalation risks of concern, the Agency has determined that it is necessary for occupational handlers to apply halohydantoin products formulated as powders and granules in closed loading systems. Inhalation risks of concern were identified for halohydantoin products formulated as powders and granules, whereas inhalation exposures from pellets, tablets and pucks are expected to be negligible. Accordingly, if the documentation that was submitted to the Agency at the time of registration indicates that the product is formulated as a powder or granule, then label language is required to restrict application to use in a closed loading system. For those halohydantoin products are already formulated as pellets, tablets and pucks, no label changes would be necessary for these products. If registrants believe that the physical form listed on EPA registration documents is incorrect, they may submit a PRIA amendment along with new data confirming the physical form of the product in question. The

registrants who are impacted by these measures have been contacted and are aware of the Agency's determination of necessary changes to the label language. Those who have offered feedback are in agreement with the Agency's strategy.

3. Mitigation Measure for the Discharge of Water Treated with Halohydantoin Products

In order to align with discharge instructions being added for other water treatment products undergoing registration review, the Agency has determined that it is necessary for halohydantoin products used to treat swimming pools, spas, hot tubs, and ornamental fountains to include the following label language:

> "Before draining a treated [pool], [spa], [hot tub], or [fountain], contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated [pool], [spa], [hot tub], or [fountain] water to any location that flows to a gutter or storm drain or natural water body unless discharge is allowed by state and local authorities."

The registrants were made aware of this label language in the PID and have not provided additional feedback.

B. Tolerance Actions

The EPA intends to revise the existing exemption at 40 CFR Section 180.940(a) to include the metabolites and degradates of 1,3-dibromo-5,5-dimethylhydantoin and other halohydantoin active ingredients, in this case used as food contact surface solutions as part of the tolerance exemption.[16] EPA will use its FFDCA rulemaking authority to pursue tolerance changes. Refer to Section III. A. 3. for details.

C. Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing *The Halohydantoins Interim Registration Review Decision*. Except for the Endocrine Disruptor Screening Program (EDSP) component of this case and the need to establish tolerances or exemptions from the requirement of a tolerance for halohydantoins under FFDCA Section 408, the Agency has made the following interim decision: (1) no additional data are required at this time; and (2) changes to the affected registrations or their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of the halohydantoins. The Agency's final registration review decision for the halohydantoins will be dependent upon the result of the Agency's EDSP FFDCA § 408(p) determination and establishment of tolerances or exemptions from the requirement of a

[16] *Draft Risk Assessment for the Halohydantoins Registration Review*. www.regulations.gov; Docket ID EPA-HQ-OPP-2013-0220

tolerance under FFDCA Section 408. As covered in Section III. B. 1., the Agency has made a "no effect" determination for the registered uses of the halohydantoins under the ESA.

D. Data Requirements

The halohydantoin human health toxicological database is complete except for a repeat-dose inhalation toxicity study. The Agency used an acute inhalation toxicity study in order to complete the DRA. Waiver requests for this data requirement were approved for some registrants based on the formulations of their products. For all other registrants, this study will no longer be required once product labels are updated to instruct occupational handlers to use a closed loading system when applying products formulated as powders and granules to public pools, paper/paper mill systems, commercial and industrial water-cooling systems, and industrial water processing water.

The Agency does not anticipate calling-in additional data for the halohydantoins at this time.

V. NEXT STEPS AND TIMELINE

Within 60 days following issuance of this Interim Registration Review Decision in EPA's public docket, registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the Halohydantoins Interim Registration Review Decision and EPA regulations at 40 C.F.R. Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the halohydantoins Interim Registration Review Decision and 40 C.F.R. Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Peter Bergquist at one of the following addresses, provided the labels and application are submitted within the required timeframe:

By US mail:
US EPA, OPP/Antimicrobials Division (7510P)
c/o Front End Processing
Attn: Reevaluation Team Leader, PM 36
1200 Pennsylvania Ave NW

Docket Number EPA-HQ-OPP-2013-0220
www.regulations.gov

Washington, DC 20460

By express or courier service:
US EPA, OPP/Antimicrobials Division (7510P)
c/o Front End Processing
Room S-4910, One Potomac Yard (South)
Attn: Reevaluation Team Leader, PM 36
2777 South Crystal Drive
Arlington, VA 22202

Appendix A: Summary of Actions for the Halohydantoins

Registration Review Case: 3055
PC Codes: 006315, 006317, 028500, 028501, 128826, 128989, 006322
006333 and 606315

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions	Comment (use to briefly clarify or elaborate on risk or mitigation)
Residential Post-Application (outdoor)	Treated water in outdoor swimming pools	Ingestion (incidental oral)	Chronic	Cancer	Deletion of outdoor pool uses	Only required for products containing these active ingredients: 006315, 006317, 006322, 006333, 128989
Residential Post-Application (outdoor)	Treated water in outdoor hot tubs and spas	Ingestion (incidental oral)	Chronic	Cancer	Instruct hot tub and spa users to always cover their hot tubs and spas when not in use	Only required for products containing these active ingredients: 006315, 006317, 006322, 006333, 128989
Occupational Handlers	Powders and granules applied in various large-scale water treatment applications	Inhalation	Short, intermediate and long-term	Rales, labored breathing, nasal area red matting, hypothermia and prostrate posture.	Instruct occupational handlers to apply halohydantoin products formulated as powders and granules using a closed loading system	Risks based on acute inhalation toxicity study.

Appendix B: Labeling Changes for Halohydantoin Products

Description	Label Language for Halohydantoin Products	Placement on Label
Use Deletion of Outdoor Pool Use for Products Containing PC Codes 006315, 006317, 006322, 006333 and 128989	"This product is not for use in outdoor pools."	Direction for use
For end use formulations used to treat commercial and residential hot tubs and spas (containing PC Codes 006315, 006317, 006322, 006333 and 128989)	"Outdoor hot tubs and spas must be covered when not in use."	Direction for Use
Label Language for Halohydantoin Products formulated as powders and granules that are being applied in public pools, paper/paper mill systems, commercial and industrial water-cooling systems, and industrial water processing water	"Halohydantoin products formulated as powders and granules must be applied by occupational handlers using a closed loading system."	Directions for Use
Label Language for Halohydantoin Products Used in Pools, Spas, Hot Tubs, and Ornamental fountains	"Before draining a treated [pool], [spa], [hot tub], or [fountain], contact your local sanitary sewer and storm drain authorities and follow their discharge instructions. Do not discharge treated [pool], [spa], [hot tub], or [fountain] water to any location that flows to a gutter or storm drain or natural water body unless discharge is allowed by state and local authorities."	Directions for Use