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Proposed Registration Decision

PRD2019-06

Chlorine Generating Devices, Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400

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Overview

Proposed Registration Decision for the chlorine generating devices Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400. These devices use potassium chloride as a precursor to generate free available chlorine, which can be used to control biofilm and plant pathogens within greenhouse irrigation lines.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health and value assessments of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable¹ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value² when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of the Canada.ca website at Canada.ca/pesticides.

¹ "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

² "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, Health Canada's PMRA will consider any comments received from the public in response to this consultation document.³ Health Canada will then publish a Registration Decision⁴ on Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Are Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400?

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 are chlorine-generating devices used to control biofilm and plant pathogens within greenhouse irrigation lines. They generate free available chlorine in the forms of chlorine, hypochlorous acid, and hypochlorite by electrolysis of chloride, using potassium chloride as a precursor. The process is similar to the operating principle for chlorine generating devices for salt water pools and spas. There are three models of Chlorinsitu II proposed for registration, models 24, 200 and 400, that all operate on the same principle, but have different outputs of free available chlorine and can treat different volumes of irrigation water.

Health Considerations

Can Approved Uses of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 Affect Human Health?

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 are unlikely to affect human health when they are used according to label directions.

Potential exposure to free available chlorine and electrolytic by-products generated by Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 may occur through the diet (food and water) or when working in a greenhouse where the free available chlorine is produced and stored. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

⁴ "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

The end-use products are devices that generate free available chlorine as disinfectants in greenhouse irrigation lines. The free available chlorine circulates in the irrigation systems at levels between 1–4 mg/L. Health Canada recommends that drinking water distribution systems maintain an operational range of free chlorine residual between a detectable level and 5 mg/L.

Residues in Water and Food

Dietary risks from food and water are acceptable.

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 generate free available chlorine that circulates at low concentrations (1–4 mg/L) in greenhouse irrigation water. Health Canada (2009) suggests that drinking water distribution systems in Canada maintain an operational range of free chlorine residual between a detectable level and 5 mg/L and indicates that chlorine and hypochlorite salts are not expected to accumulate or bioconcentrate in the food chain due to their water solubility and high reactivity. It is anticipated that health risks of concern from the consumption of food commodities that have been watered with irrigation water treated with free available chlorine are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is acceptable.

There are no residential uses for these devices. Residential bystanders are not expected to come into contact with circulating free available chlorine. Therefore, risk due to residential and bystander exposure is acceptable.

Occupational Risks From Handling Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400

Occupational risks are acceptable when Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 are used according to the label directions, which include protective measures.

During loading, individuals can come into direct contact with potassium chloride but worker exposure is not expected to result in health risks of concern. Due to the closed and automated nature of the devices, no applicator exposure is expected. Maintaining the device in a state of good repair and using high quality ($\geq 99\%$ purity) potassium chloride should prevent build-up of ions on the electrolytic electrodes of the device. In turn, this should eliminate the need for any cleaning of the device with strong acids that could damage the electrodes and result in the release of metals into the electro-chemically activated water. Occupational bystander exposure to free

available chlorine and additional by-products generated by the device(s) are also not expected to occur due to the nature of the application. Precautionary and engineering statements on the label and operation manual are considered adequate to protect individuals from occupational exposure.

In the event of a faulty system where high concentrations of free available chlorine are released, the Precautions section of the secondary display panel will state that workers must wear coveralls over a long-sleeved shirt, long pants, socks and chemical-resistant footwear, chemical-resistant gloves, goggles, and a respirator with a NIOSH⁵-approved organic vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides. This precautionary statement is also included in the operation manual.

Exposure from postapplication activities is expected to be low, and not of concern.

Environmental Considerations

An environmental assessment was not required for Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 as they have no outdoor uses, nor will treated greenhouse irrigation waters come into contact with surface or groundwater.

Value Considerations

What Is the Value of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400?

These devices, by generating chlorine, offer a valuable option for the treatment of greenhouse irrigation water.

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 generate chlorine, which is effective at controlling bacteria that can form biofilms within irrigation lines and reduce the flow of water to greenhouse plants. Water is a valuable resource and many greenhouses re-use the water from their drip and floor or table flood irrigation systems. This practice can increase the risk of transferring plant pathogens to the crops. Chlorine, added at levels similar to those in swimming pools, is an effective means of controlling plant pathogens and significantly reducing their numbers within the irrigation water delivered to the greenhouse crops. Furthermore, as a precursor to chlorine generation, potassium chloride is used, which is an important fertilizer component.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

⁵ National Institute for Occupational Safety and Health

The key risk-reduction measures being proposed on the labels and in the operation manuals of Chlorinsitu II 24, Chlorinsitu II 200, and Chlorinsitu II 400 to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Electrolytic chlorine generators require precautionary labelling due to the fact that they generate hydrogen which is highly flammable and explosive. The signal words “WARNING – Operating Chlorinsitu II (24, 200 or 400) without water flow through the cell can cause a build-up of flammable gases which can result in FIRE OR EXPLOSION” are required on the principal display panels of the labels for Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400.

A Precautions section is to be added to the secondary display panel with the statement “In the event of a faulty system where high concentrations of free available chlorine are released, workers must wear coveralls over a long-sleeved shirt, long pants, socks and chemical-resistant footwear, chemical-resistant gloves, goggles, and a respirator with a NIOSH-approved organic vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides.”

The Directions of Use section of the secondary display panel will include the statement “Hydrogen produced during the electrolysis process must be discharged to the outside atmosphere via a closed system.”

Labels on replacement hypo cells for Chlorinsitu II devices will require the following text on the principal display panels “Read the Label and Operation Manual of the chlorine generating device Chlorinsitu II (24, 200 or 400) before using.”

Next Steps

Before making a final registration decision on Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, Health Canada’s PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada’s response to these comments.

Other Information

When Health Canada makes its registration decision, it will publish a Registration Decision on Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA’s Reading Room (located in Ottawa).

Science Evaluation

1.0 Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, their Properties and Uses

1.1 Directions for Use

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 are for the control of biofilm and plant pathogens within greenhouse irrigation waters. The chlorine generated by the device is added to the mixing/storage tank to a maximum of 4 parts per million (ppm) free available chlorine. The levels of free available chlorine are measured at the dripper just before the irrigation water is used on the crops. It is recommended to maintain a level of 1–2 ppm of free available chlorine at the furthest point in the drip line system. Measurements are taken at least twice weekly and adjusted as necessary. Free available chlorine levels can be measured using standard diethyl-p-phenylenediamine (DPD) tablets.

1.2 Mode of Action

Free available chlorine is an oxidizing biocide that kills a broad range of microbes including bacteria, fungi and viruses, by the oxidation of critical cell components and enzymes.

2.0 Impact on Human and Animal Health

2.1 Toxicology Summary

A detailed review of publicly available toxicological data for the electrolytic products and by-products generated by Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 as well as the chemical components used in their construction was conducted. The database is considered complete and includes reported toxicity study endpoints currently required for hazard assessment purposes for non-conventional chemical pesticides. In addition, published United States Environmental Protection Agency (USEPA) and Health Canada documents were utilized.

High quality ($\geq 99\%$ purity) potassium chloride is used as the starting materials for generating free available chlorine. Potassium chloride is a skin and eye irritant but not a skin sensitizer. The USEPA Reregistration Eligibility Decision (RED) document for chlorine gas (1999) classifies chlorine, hypochlorous acid and hypochlorites as highly acutely toxic by the oral, dermal, and inhalation routes, corrosive to eyes and skin, and dermal sensitizers. Chlorate and chlorite are potential by-products of the electrolysis system. Potassium chlorate is of slight acute oral toxicity in rats and is of low acute oral toxicity in mice. Chlorates and chlorites can be formed in the presence of hypochlorite solutions.

Incident Reports

As of 1 March 2019, no human, domestic animal or environment incidents involving chlorine generating devices were submitted to the PMRA.

2.2 Occupational, Residential and Bystander Exposure and Risk Assessment

2.2.1 Use Description

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 are in situ salt electrolysis devices designed to generate free available chlorine at a concentration of 4 g/L or 4000 ppm in the form of hypochlorite (ClO^-), hypochlorous acid (HClO), and chlorine (Cl_2) from potassium chloride in order to control bacterial biofilms, plant viruses, moulds and algae in agricultural (greenhouse) irrigation water. After electrolysis, electro-chemically activated water containing free available chlorine is pumped into an electro-chemically activated water storage tank and then metered into the irrigation water at a 1:1000 dilution or 4 ppm in order to prevent contamination in the irrigation lines of drip irrigation systems or flood floor and flood table irrigation systems.

The devices differ in their maximum output. Chlorinsitu II 24 has a maximum output of 0.53 kg of free available chlorine and is able to disinfect 6000 L of irrigation water per hour. Chlorinsitu II 200 has a maximum output of 4.4 kg of free available chlorine and is able to disinfect 50 000 L of irrigation water per hour while Chlorinsitu II 400 has a maximum output of 8.8 kg of free available chlorine and is able to disinfect 100 000 L of irrigation water per hour.

2.2.2 Mixer, Loader, and Applicator Exposure and Risk

Workers can be exposed to potassium chloride when manually loading the salt into the appropriate collection tank. There are no mixing and applying activities. Worker exposure to potassium chloride is not expected to result in health risks of concern.

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 have automatic valves, level controls and sensors to control the direction of flow of the system and minimize human handling. The system is run with a programmable logic controller or industrial computer and the operators can control the entire system at the computer control box or with a remote control modem. Therefore no applicator exposure is expected.

A precautionary statement is required on the labels of the Chlorinsitu II devices as electrolytic chlorine generators can produce and release hydrogen gas: “WARNING: Operating Chlorinsitu II (24, 200 or 400) without water flow through the cell can cause a build-up of flammable gases which can result in FIRE OR EXPLOSION.” No personal protective equipment is required during use of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, however the Precautions section of the secondary display panel is required to state that “In the event of a faulty system where high concentrations of free available chlorine are released, workers must wear coveralls over a long-sleeved shirt, long pants, socks and chemical-resistant footwear, chemical-resistant gloves, goggles, and a respirator with a NIOSH-approved organic vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides.” The statement “Hydrogen produced during the electrolysis process must be discharged to the outside atmosphere via a closed system.” is required under the Directions of Use section.

Following label and operation manual instructions for the end-use products that aim to mitigate exposure are considered adequate to protect individuals from risk due to occupational exposure. Overall, occupational risks for handlers and loaders are acceptable when label and operating manual directions are followed which include personal protective equipment in the event of a faulty system where high concentrations of free available chlorine are released.

2.2.3 Postapplication Exposure and Risk

Postapplication activities involve the operator measuring the concentration of the metered electro-chemically activated water entering the greenhouse mixing/storage tanks and checking chlorine residues in the irrigation water once or twice a week. The electro-chemically activated water is added into the irrigation water at a free available chlorine concentration of 4 ppm, and chlorine residues at the furthest point in the drip line system are expected to be 1–2 ppm.

Operators or workers involved in daily greenhouse operations could be exposed to electro-chemically activated water at the drip points or from contact with the flood tables, but the concentration of free available chlorine at these points should be within 1–4 ppm. Exposure from postapplication activities is expected to be low, and not of concern.

A restricted-entry interval is not required.

2.2.4 Residential and Bystander Exposure and Risk

There are no residential uses for these devices. Consequently, a risk assessment for residential exposure was not required.

Greenhouse irrigation water is oversupplied and recycled for re-use. Worker exposure to large volumes of undiluted electro-chemically activated water is not expected as the Chlorinsitu II system has automatic valves, level controls and sensors to control the direction of flow of the system and minimize human handling and exposure.

Bystander exposure is not expected to pose a health risk of concern because Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 will be used in a greenhouse where bystanders are not expected to be present.

2.3 Food Residue Exposure Assessment

2.3.1 Food

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 generate free available chlorine in the form of hypochlorite, hypochlorous acid, and chlorine that circulate at low concentrations (1–4 ppm) in greenhouse irrigation water. Health Canada's Guidelines for Canadian Drinking Water Quality, Technical Document for chlorine (2009) indicates that the suggested operational range for free available chlorine in Canadian drinking water is between detectable levels and 5 mg/L (or 5 ppm). The range of free available chlorine generated by Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 is within the acceptable range of Canadian drinking water distribution

systems. It is not anticipated that dietary exposure to residues of free available chlorine in/on greenhouse crops will result in health risks of concern.

2.3.2 Drinking Water

Diluted electro-chemically activated water circulating through greenhouse irrigation lines will not come into contact with surface or groundwater.

The risk due to exposure from drinking water is acceptable.

2.3.3 Acute and Chronic Dietary Risks for Sensitive Subpopulations

Calculations of acute reference doses (ARfDs) and acceptable daily intakes (ADIs) are not required for free available chlorine. As a result, there is no need to apply uncertainty factors to account for intra- and interspecies variability, or have a margin of exposure required. Further factoring of consumption patterns among infants and children, special susceptibility in these subpopulations, and cumulative effects on infants and children, does not apply. As a result, the PMRA has not used a margin of exposure approach to assess risks to human health.

2.3.4 Aggregate Exposure and Risk

Based on available information, there is reasonable certainty that no harm will result from aggregate exposure of residues of free available chlorine or electrolytic by-products generated by Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 to the general Canadian population, including infants and children, when the end-use products are used as labelled. This includes all anticipated dietary (food and drinking water) exposures and all other non-occupational exposures (dermal and inhalation) for which there is reliable information.

2.3.5 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, a cumulative health assessment was undertaken. While free available chlorine may share a common moiety with other chlorine-based active ingredients, the potential health risks from cumulative exposure to free available chlorine are acceptable when levels remain within the range permitted in Canadian drinking water distribution systems.

2.3.6 Maximum Residue Limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine that the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. This maximum amount of residues expected is then legally specified as an MRL under the *Pest Control Products Act* for the purposes of adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure the food Canadians eat is safe.

Free available chlorine (chlorine, hypochlorous acid, and hypochlorite) levels generated by Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 fall within the range set by Canadian drinking water guidelines (between a detectable level and 5 mg/L), therefore, no MRL is required on crops irrigated with electro-chemically activated water.

3.0 Value

Chlorine is a well-known oxidizing biocide that has been used for many decades as a slimicide to control biofilm in industrial process waters, as a sanitizer for pools, spas and hard surfaces and as a treatment for potable water. It is effective at controlling a broad spectrum of microorganisms, including plant pathogens and bacteria that form biofilms, at rates of 1–4 ppm of free available chlorine. Data were provided from laboratory trials designed to demonstrate the maximum output of chlorine over an hour that each of the three Chlorinsitu II models was capable of generating.

There are currently no biocides registered specifically for use in greenhouse irrigation lines. Furthermore, there are a limited number of sanitizer products registered to control plant pathogens in greenhouses. The registration of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 will provide an effective means to control biofilm and spread of plant pathogens through greenhouse irrigation water.

Typically, electrolytic chlorine generators, such as those registered for use in swimming pools, use sodium chloride as a precursor. However, sodium build-up can have negative impacts on plant growth. The use of potassium chloride as the precursor with these devices, not only avoids potential problems with sodium buildup, but also provides the plant an essential fertilizer component.

4.0 Pest Control Product Policy Considerations

4.1 Toxic substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, such as, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, the free available chlorine (chlorine, hypochlorous acid and hypochlorite) generated by Chlorinsitu II 24, Chlorinsitu II 200, and Chlorinsitu II 400 were assessed in accordance with the PMRA Regulatory Directive DIR99-03⁶ and evaluated against the Track 1 criteria. The free available chlorine generated by the Chlorinsitu II devices did not meet TSMP criteria.

4.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical as well as formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.⁷ The list is used as described in the PMRA Notice of Intent NOI2005-01⁸ and is based on existing policies and regulations including DIR99-03 and DIR2006-02,⁹ and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Chlorinsitu II 24, Chlorinsitu II 200, and Chlorinsitu II 400 do not contain or generate formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

5.0 Summary

5.1 Human Health and Safety

Publicly available information on potassium chloride and free available chlorine (chlorine, hypochlorous acid and hypochlorite) were adequate to qualitatively identify the toxicological hazards that may result from human exposure to the starting material and generated products from use of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400. Potassium chloride, required by the device, is a skin and eye irritant but not a skin sensitizer. The generated products, chlorine, hypochlorous acid and hypochlorites, are highly acutely toxic by the oral, dermal, and inhalation routes, corrosive to eyes and skin, and dermal sensitizers.

Greenhouse operators and workers are not expected to be exposed to free available chlorine or large volumes of undiluted electro-chemically activated water as the Chlorinsitu II system has automatic valves, level controls and sensors to control the direction of flow of the system and minimize human handling and exposure. Greenhouse workers are only required to add potassium

⁶ DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the *Toxic Substances*

⁷ SI/2005-114

⁸ NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*

⁹ DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

chloride to the system. There is potential for postapplication exposure to operators or workers involved in daily greenhouse operations to diluted electro-chemically activated water at the drip points or from contact with the flood tables. Label and operation manual instructions for Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 aim to mitigate exposure and are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

There are no residential uses for these devices.

Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 generate free available chlorine in the form of chlorine, hypochlorous acid and hypochlorite at levels which fall within the range set by Canadian drinking water guidelines. Consequently, a maximum residue limit is not required on food crops irrigated with electro-chemically activated water generated from Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 devices.

5.2 Value

The information provided in support of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 was adequate to demonstrate its ability to control biofilms from forming or plant pathogens from spreading through greenhouse irrigation lines. As there are no currently registered products for this specific use in greenhouses, Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400 and the chlorine they generate will be valuable in improving greenhouse plant health.

6.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing registration for the sale and use of Chlorinsitu II 24, Chlorinsitu II 200 and Chlorinsitu II 400, to control biofilm and plant pathogens within greenhouse irrigation waters.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document No.	Reference
2822274	2017, Owners Manual for Chlorinsitu II 200 - English, DACO: 5.14
2822276	2017, Product Information Dossier, DACO: 10.2.3.2(F),5.1,5.2
2827456	2017, Owners Manual for Chlorinsitu II 24 - English, DACO: 5.14
2827468	2017, Owners Manual for Chlorinsitu II 400 - English, DACO: 5.14
2945489	2018, Company Response to Clarification Request, DACO: 5.2
2945490	2018, Response to Clarification Request, DACO: 7.8
2949946	2018, 5.2 Installation Response, DACO: 5.2
2949947	2018, 5.2 Metals Released to ECA-Water, DACO: 5.2
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