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Re-evaluation Decision

RVD2022-17

# Chlorothalonil and Its Associated End-use Products, Used as a Preservative in Paints

*Final Decision*

*(publié aussi en français)*

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## Table of Contents

Re-evaluation decision for chlorothalonil and associated end-use products, used as a preservative in paint .....	1
Re-evaluation decision for chlorothalonil (used as a material preservative in paints) .....	2
Next steps .....	3
Other information .....	4
Evaluation Approach .....	5
List of abbreviations .....	9
Appendix I Registered material preservative products containing chlorothalonil in Canada as of 6 September 2022 .....	10
Table 1 Chlorothalonil products used as preservatives in paints that do not require label amendments .....	10
Table 2 Chlorothalonil products used as preservatives in paints that require label amendments .....	10
Appendix II List of commenters to PRVD2020-07.....	11
Appendix III Comments and Responses .....	12
Appendix IV Label amendments for material preservative products containing chlorothalonil .....	17

## Re-evaluation decision for chlorothalonil and associated end-use products, used as a preservative in paint

Under the authority of the [Pest Control Products Act](#), all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA), on behalf of the Minister of Health, to ensure that they continue to have acceptable risk to human health and the environment, and have acceptable value. The re-evaluation considers available data and information<sup>1</sup> from pesticide registrants, published scientific reports, existing assessments, other governments, and international regulatory authorities, as well as comments received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative framework, risk assessment and risk management approach, are provided under the section of Evaluation Approach of this document.

This document forms part of a re-evaluation assessment of several active ingredients used as preservatives in paints, coatings and related uses. As per [Re-evaluation Note REV2018-02, Approach for the Re-Evaluation of Pesticides Used as Preservatives in Paints, Coatings and Related Uses](#), the paint-related uses of sodium omadine, chlorothalonil, dazomet, folpet and ziram were evaluated separately from other uses and relied on data provided by the registrants and the Antimicrobial Exposure Assessment Task Force II (AEATF II). This approach was adopted in order to obtain and review paint-related studies, have risk assessments more reflective of current and realistic exposure scenarios and to allow for a consistent approach to the risk assessment and risk management for these uses. In the absence of scenario-specific data, paint studies/data were used as surrogates for the assessment of building materials and adhesives.

Chlorothalonil is used as a dry-film material preservative against bacterial and fungal contamination or spoilage of paint. All other registered uses of chlorothalonil (that is, agricultural and turf uses) were evaluated separately (Re-evaluation Decision RVD2018-11, *Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses*). Currently registered products for use as a material preservative containing chlorothalonil can be found in the [Pesticide Product Information Database](#) and in Appendix I.

The Proposed Re-evaluation Decision PRVD2020-06, *Chlorothalonil and Its Associated End-use Products, Used as a Preservative in Paints*<sup>2</sup> containing the evaluation of the material preservative uses of chlorothalonil and proposed decision, was published on 9 July 2020 for a 90-day consultation period. An additional 60 days for consultation was provided in response to requests from stakeholders to accommodate time constraints imposed by pandemic measures; the 150-day consultation period ended on 6 December 2020. PRVD2020-06 proposed continued registration with mitigation measures for primary handlers (that is, closed transfer system for liquid formulations; additional personal protective equipment (PPE) and a reduction in amount

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<sup>1</sup> Canada. Health Canada. *Information Note – Determining Study Acceptability for use in Pesticide Risk Assessments*. Ottawa, 2019. (Internet: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/determining-study-acceptability-pesticide-risk-assessments.html>; cited October 2022.)

<sup>2</sup> “Consultation statement” as required by subsection 28(2) of the *Pest Control Products Act*.

handled per person per day for solid formulations) and for secondary handlers (that is, a reduction in the maximum rate of chlorothalonil used for solvent-based paint and exterior latex paint, and additional personal protective equipment for professional painters using an airless sprayer (all paint types), coupled with a product stewardship/outreach program).

Health Canada received comments relating to the health and value assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments did not result in a revision to the risk assessments; therefore, no changes were made to the proposed re-evaluation decision as described in PRVD2020-06.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2020-06; no further information was used in the final re-evaluation decision. Therefore, the complete reference list of all information used in this final re-evaluation decision is set out in PRVD2020-06.

This document presents the final re-evaluation decision<sup>3</sup> for the material preservative uses of chlorothalonil, including the required amendments (risk mitigation measures) to protect human health, as well as label amendments required to bring labels to current standards. All products containing chlorothalonil for use as a material preservative that are registered in Canada are subject to this re-evaluation decision.

## **Re-evaluation decision for chlorothalonil (used as a material preservative in paints)**

Health Canada has completed the re-evaluation of the material preservative uses of chlorothalonil. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing chlorothalonil is acceptable with mitigation measures. An evaluation of available scientific information found that the material preservative uses of chlorothalonil meet current standards for protection of human health and have acceptable value when used according to revised conditions of registration, which includes new mitigation measures. Environmental exposure from the material preservative uses of chlorothalonil is expected to be minimal. Label amendments, as summarized below and listed in Appendix IV, are required.

### **Risk mitigation measures**

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of the material preservative uses of chlorothalonil, are summarized below. Refer to Appendix IV for details.

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<sup>3</sup> “Decision statement” as required by subsection 28(5) of the *Pest Control Products Act*.

## **Human health – Risk Mitigation**

To mitigate risks to primary handlers (mixers/loaders) manufacturing latex paints (interior and exterior) and solvent-based paints:

- Additional personal protective equipment (chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves and a respirator) is required together with reducing the amount of active ingredient handled per worker per day to 4.51 kg a.i. for the commercial-class solid dust products; and
- Closed transfer systems are required for the commercial-class liquid products.

To mitigate risks to secondary (professional and residential) handlers applying latex and solvent-based paints using an airless sprayer:

- Reduction of the maximum registered label rates from 9.8 g a.i./L (exterior latex paint) and 11.8 g a.i./L (solvent-based paint) to 8.5 g a.i./L for exterior latex paints and solvent-based paints; and
- For professional handlers, additional personal protective equipment (cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, a painter's hat 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) for solvent-based paint and latex paints (interior and exterior).

Implementation of product stewardship/outreach plan.

## **Next steps**

### **Pest control products requiring label amendments**

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry. This 24-month period also applies to the requirement that manufactured paint products containing the preservative chlorothalonil must be labelled with the stipulation that professional painters wear personal protective equipment when using an airless sprayer (refer to Appendix IV).

Health Canada has determined that the identified risks from the use of chlorothalonil as a material preservative under the current conditions of use were from longer-term exposure durations and therefore, the potential risks to human health are considered acceptable during the 24-month time period required to implement the required mitigation measures.

## Chlorothalonil-treated articles

[Information Note – Treated Articles](#)<sup>4</sup> (September 2022) provides regulatory requirements for articles that have been treated with pesticides. The import and sale of paint treated with chlorothalonil at the unamended label rates and without the newly required PPE for professional painters is permitted during the 24-month implementation period. However, after 24 months, the import and sale of paint treated at the unamended label rates and without the requirement for PPE (for professional painters using airless sprayers) on the label will be prohibited; all paint sold after 24 months must be treated at the new label rates and bear the PPE requirements.

Refer to Appendix I for details on specific products impacted by this decision.

## Product stewardship/outreach plan

The product stewardship/outreach plan is intended to inform professional painters of the requirement for additional personal protective equipment (coveralls, chemical-resistant gloves, painter's hat and respirator) to mitigate risks when applying paint using airless sprayers. The plan will also have the general goal of increasing awareness of the presence of pesticide preservatives in paint and how to reduce health risks for painters. Health Canada is creating communication materials for this outreach plan.

Registrants are required to notify paint manufacturers of the new paint labelling requirements related to PPE for professional painters using an airless sprayer. Paint manufacturers are required to directly label paint cans with the required label statements.

## Other information

Any person may file a notice of objection<sup>5</sup> regarding this decision on Chlorothalonil and Its Associated End-use Products, Used as a Preservative in Paints within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact Health Canada's [Pest Management Information Service](#).

The relevant confidential test data on which the decision is based (as referenced in PRVD2020-06) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact Health Canada's [Pest Management Information Service](#).

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<sup>4</sup> Canada. Health Canada. *Information Note – Treated Articles*. Ottawa, 2022. (Internet: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html>; cited October 2022.)

<sup>5</sup> As per subsection 35(1) of the *Pest Control Products Act*.

## Evaluation Approach

### Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* (or the Act) subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if conditions of registration can be established to prevent unacceptable risks to human health and the environment.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

**health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

**environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration

**value**, in respect of a pest control product, means 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.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.



## Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in *A Framework for Risk Assessment and Risk Management of Pest Control Products*.<sup>6</sup> A high-level overview is provided below.

### i) Assessing Potential Health Risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks<sup>7</sup>.

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01.<sup>8</sup>

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<sup>6</sup> Canada. Health Canada. *PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products, 2021* (Internet: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/risk-management-pest-control-products.html>, cited October 2022).

<sup>7</sup> Canada. *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, 2000* (Internet: <https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html>, cited October 2022).

<sup>8</sup> Canada. Health Canada. *Science Policy Note: The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides, 2008* (Internet: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2008/application-uncertainty-factors-pest-control-products-act-factor-human-health-risk-assessment-pesticides-spn2008-01.html>, cited October 2022).

Assessments estimate potential health risks to defined populations<sup>9</sup> under specific exposure conditions. They are conducted in the context of the registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or exposure when interacting with treated pets. Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

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<sup>9</sup> Consideration of Sex and Gender in Pesticide Risk Assessment, 2020 (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/consideration-sex-gender-pesticide-risk-assessment-infographic.html>, cited October 2022).

During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered. An assessment of the benefits associated with the pesticide may also be conducted to demonstrate its value in the current context, and to identify potential alternatives.

### **Risk management**

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing, frequency and method of application), personal protective equipment, pre-harvest intervals, restricted entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the re-evaluation decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*. Implementation of post-market decisions follow the framework articulated in the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*.<sup>10</sup>

Following a decision, continuous oversight activities such as post-market review, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

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<sup>10</sup> PMRA Regulatory Directive DIR2018-01 *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2018/dir2018-01-policy-cancellations-amendments.html>).

## List of abbreviations

AEATF II	Antimicrobial Exposure Assessment Task Force II
CPCA	Canadian Paint and Coatings Association
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
REV	Re-evaluation Note
RVD	Re-evaluation Decision
USEPA	United States Environmental Protection Agency

## Appendix I Registered material preservative products containing chlorothalonil in Canada as of 6 September 2022

**Table 1 Chlorothalonil products used as preservatives in paints that do not require label amendments**

Registrant	Registration number	Product name	Marketing class
Adama Agricultural Solutions Canada Ltd.	31763	Adama Chlorothalonil Technical	T
Bayer CropScience Inc.	24915	Tattoo Manufacturing Use Product	M
Sipcam Agro USA, Inc.	27059	Chlorothalonil Technical Fungicide	T
	29354	Chlorothalonil Technical AG	T

T = technical grade active ingredient; M = manufacturing concentrate;

**Table 2 Chlorothalonil products used as preservatives in paints that require label amendments**

Registrant	Registration number	Product name	Marketing class
Arch Chemicals, Inc	27057.03	Densil C-98	C
Buckman Laboratories of Canada Ltd.	27058.02	Busan 1192D Microbicide	C
Sostram Corporation	27057	Clortram P-98M	C
	27058	Clortram F-40	C
Troy Chemical Corporation	27057.02	Fungitrol 960S Fungicide	C
	27058.03	Fungitrol 404-DS Fungicide	C
Global Biocides Solutions	34538	Biotrend CTL98-P	C

T = technical grade active ingredient; C = commercial; M = manufacturing concentrate;

**Note:** Discontinued products and products with submissions for discontinuation not included. Technical products where the registrant indicated that they did not support paint-related uses are not included.

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**Appendix II List of commenters to PRVD2020-07**

List of commenters' affiliations for comments submitted in response to PRVD2020-07

<b>Category</b>	<b>Commenter</b>
Industry association	Canadian Paint and Coatings Association (CPCA)
Registrant	Troy Chemical Corporation

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## Appendix III Comments and Responses

Health Canada received comments during the public consultation for the chlorothalonil proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

### 1.0 Comments Related to Health Canada Processes and Policies

#### 1.1 Comments related to harmonization of Health Canada and United States Environmental Protection Agency (USEPA) timelines and decisions:

Comments were submitted by the Canadian Paint and Coatings Association (CPCA) expressing the importance of a more aligned North American review process for biocides to maintain fair trade and access to a sufficient number of biocides in both countries for all paint manufacturers.

##### Health Canada response

As outlined in the chlorothalonil proposed re-evaluation decision document (PRVD2020-06), Health Canada relied on data provided by the registrant and the Antimicrobial Exposure Assessment Task Force II (AEATF II) to conduct the risk assessments for each of the active ingredients in the paint cluster. Health Canada has engaged with AEATF II and the USEPA on science matters prior to and following the submission of this data.

Health Canada continues to communicate with its USEPA counterparts on science-related topics. Health Canada has also shared the outcome of its paint preservative assessments and proposed decisions with the USEPA and other regulatory authorities.

#### 1.2 Comments related to the re-evaluation process and paint-related antimicrobials

Comments were submitted regarding the re-evaluation process with respect to antimicrobials for use as paint preservatives in general. These comments included topics such as socio-economic cost impact, transparency, research and development, and the method of assessment for antimicrobials.

##### Health Canada response

Health Canada considered a science-based risk assessment and risk management approach for this re-evaluation; risk mitigation measures were implemented to address potential risks related to human health. Comments regarding Health Canada's re-evaluation process and protocols in general are beyond the scope of the re-evaluation of the material preservative uses of chlorothalonil and cannot be adequately addressed in this document.

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## **2.0 Comments related to the health risk assessment**

### **2.1 Comments related to toxicology reference values used in the human health risk assessment**

The registrant disagreed with several toxicology reference values used in the human health risk assessment. In particular, the registrant disagreed with the selection of the toxicology reference values for assessing risks via the dermal and inhalation routes.

#### **Health Canada response**

The complete toxicology re-evaluation review of chlorothalonil was summarized previously in Proposed Re-evaluation Decision PRVD2011-14, Chlorothalonil, with amendments published in Re-evaluation Note REV2016-06, Chlorothalonil – Amendment to the Proposed Re-evaluation Decision, which underwent public consultation. Comments received on PRVD2011-14 and REV2016-06 were reviewed and addressed in Re-evaluation Decision RVD2018-11, Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses. No new toxicology data were provided in response to PRVD2020-06; therefore, the previously established toxicology reference values for chlorothalonil are not being revisited at this time. For more information on the toxicology assessment, please refer the documents listed above.

### **2.2 Comments related to occupational/residential exposure**

#### **2.2.1 Comment related to Health Canada's assessment of the exposure studies**

A comment was received from the CPCA expressing concern about the major limitations identified by Health Canada following the review of the AEATF II study reports, even though the protocols/studies were approved beforehand by Health Canada and the USEPA. Moreover, the comment stated that these limitations led Health Canada to apply safety factors in the calculation of unit exposure values, noting that additional safety factors should only be applied following appropriate risk evaluations that are linked to actual related incidents and applied in a transparent manner.

#### **Health Canada response**

While limitations have been identified within the individual exposure studies (for example, brush and roller and airless sprayer studies), the unit exposure values derived from each study align closely between Health Canada and the USEPA and no additional safety factors were applied to the risk assessments to account for these limitations. In turn, Health Canada has considered this information in the risk assessments, along with the other information, based on a weight-of-evidence approach. This approach is in alignment with Health Canada's standard policy for evaluating risks.



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### **2.2.2 Comment related to the monitoring events (MEs) selected for the inhalation risk assessment for primary handlers in manufacturing facilities using liquid pour scenarios**

A comment was received regarding the use of the inhalation unit exposures from all MEs in the liquid pour study, noting that three of these MEs poured smaller volumes of material preservatives, which are not reflective of the larger containers and open buckets that would be used to transfer liquid chlorothalonil in an industrial setting. In turn, the inhalation unit exposure value was recalculated based on the MEs which only poured medium and large volumes of preservative.

#### **Health Canada response**

When assessing exposure studies, Health Canada calculates both dermal and inhalation unit exposure values by normalizing the individual exposures of each ME by the amount of active ingredient handled by the same ME. An arithmetic mean assuming a lognormal distribution is then calculated for each route of exposure.

It should be noted that no inhalation risks of concern were identified for primary handlers manufacturing paints and related uses and using the liquid open pour scenario. Risks of concern were driven by the dermal exposures where the calculated dermal MOEs were magnitudes lower than the target MOE (see Appendix III, Table 1 of the PRVD2020-06).

### **2.2.3 Comment related to the amount of paint applied per day using airless sprayer by residential users**

One comment referred to the new information from an American Coatings Association (ACA) survey which indicates the maximum amount of paint applied by residential handlers using an airless sprayer is 10 gallons (38 L) per year.

#### **Health Canada response**

The referenced survey, indicating that the maximum amount of paint applied per year is 10 gallons (38 L), was not provided to Health Canada. In the absence of this information, no refinements to the residential risk assessments are possible. New information can be submitted to Health Canada for consideration via a pre-market submission.

### **2.2.4 Comment related to the use of airless sprayer for indoor application of paint by residential users**

One comment stated that the airless sprayer is rarely used for interior residential application of paint.

#### **Health Canada response**

The source of this information was not provided, and no data were submitted regarding the frequency of use of airless sprayers by residential users for indoor application of paint. Considering that airless sprayers can be purchased online or at various retail stores, potential risks associated with their use cannot be disregarded.

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## 2.3 Comment related to the lack of incident reports

A comment was received from the CPCA stating that no incident reports were noted in any of the assessment monographs, which normally justify the decision to impose drastic reductions of use levels and/or cancellations of use.

### Health Canada response

A low number or a lack of incidents cannot be used to imply an absence of risks of concern. Secondary (professional and residential) handlers applying or using paints are likely unaware that these products have been treated with a material preservative. Therefore, the true burden of any observed adverse effect from exposure to the preservative, resulting from the application of paint, is unknown. Underreporting of incidents and barriers to reporting have been documented in many areas including pesticides (Prado et al., 2017<sup>11</sup>; Bell et al., 2005<sup>12</sup>). Health Canada, therefore, considers all available data and scientific information to ensure that registered pesticides continue to meet current health and environmental safety standards and continue to have value.

## 3.0 Comment related to the value assessment

### 3.1 Comment related to limited or no alternatives to material preservative active ingredients

Stakeholders emphasized that there are limited or no alternatives to some active ingredients used as material preservatives and indicated challenges with the registered alternatives (for example, higher cost, lower effectiveness, undesirable effects such as yellowing of paints).

### Health Canada response

Health Canada acknowledges that there are limitations to alternative active ingredients registered for certain material preservative uses. Health Canada considers the value of currently registered uses of chlorothalonil to be acceptable, however, information related to the value of registered alternatives cannot be used to negate required risk mitigation measures.

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<sup>11</sup> Prado J.B., Mulay P.R., Kasner E.J., Bojes H.K. and Calvert, G.M. (2017). Acute pesticide-related illness among farmworkers: Barriers to reporting to Public Health Authorities. *Journal of Agromedicine*, 22(4): 395-405.

<sup>12</sup> Bell, E.M., Sandler, D.P., and Alavanja, M.C. (2006). High Pesticide exposure events among farmers and spouses enrolled in the Agricultural Health Study. *Journal of Agricultural Safety and Health*, 12(2):101-116.

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## **4.0 Comment related to the Product Stewardship/Outreach Program development for the paint cluster**

### **4.1 Comment regarding the development and implementation of the product stewardship/outreach program:**

Comments received were in favour of a stewardship/outreach program, however, the details of the plan and the implementation timeline were questioned. Questions were raised on how the stewardship/outreach program will impact the safety margins for the risk assessment and who is responsible for developing the program. Recommendations for developing the stewardship/outreach program were also received. These recommendations included having PMRA act as lead developer of any personal protective equipment (PPE) guidance material with input from paint associations, painter groups and industry. In addition, there were recommendations for recurring educational awareness campaigns and performance evaluations with workplace monitoring to ensure ongoing compliance. Considerations for developing labelling, general PPE guidance and educational awareness campaigns were also suggested.

#### **Health Canada response**

The Paint Cluster Stewardship/Outreach Program is intended to inform professional painters of the requirement for additional personal protective equipment (coveralls, chemical-resistant gloves, painter's hat and respirator) to mitigate risks when applying paint using airless sprayers. The program will also have the general goal of increasing awareness of the presence of pesticide preservatives in paint and how to reduce health risks for all painters.

The Stewardship/Outreach Program will consist of an educational campaign to increase awareness of the presence of pesticide preservatives in paint and the new labelling on paint containers. This outreach will be directed mainly towards professional painters but is also intended for all paint users. The educational material will be developed primarily by Health Canada with consideration of the comments received from stakeholders.

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## **Appendix IV Label amendments for material preservative products containing chlorothalonil**

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

### **Personal protective equipment**

Label statements must be amended (or added) to include the following directions to the appropriate labels, unless the current label mitigation is more restrictive:

#### **1.1 For all commercial class suspension products**

Use a closed transfer system when mixing and loading. A closed transfer system is defined as a procedure for removing a pesticide from its original container, rinsing the emptied container and transferring the pesticide and rinse solution through connecting hoses pipes, and coupling that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution. Furthermore, the closed transfer system must be equipped with a dry coupling system that is designed to drip less than 2 mL per coupling.

#### **1.2 For all commercial class dust products**

Wear chemical-resistant coveralls over a long-sleeved shirt, and long pants, chemical-resistant gloves, socks, chemical-resistant footwear 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 during mixing, loading, clean-up and repair.

“DO NOT mix and load more than [4.51 kg a.i. to be reported as a product equivalent value]\* per person per day when mixing and loading. This restriction is in place to minimize exposure to individual handlers. Mixing and loading may need to be performed over multiple days or using multiple handlers.”

\* As indicated by the square brackets above, the active ingredient amount in this statement (in other words, 4.51 kg a.i.) is to be converted into the corresponding amount of product by the registrant for each product label.

#### **1.3 Manufactured paint products containing the preservative chlorothalonil must be labelled with the following information:**

Professional painters USING AN AIRLESS SPRAYER must wear cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, a painter’s hat, 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.

## **DIRECTIONS FOR USE**

For all uses of latex exterior and solvent-based paints:

Reduce the maximum application rates to 8.5 g a.i./L. The rate of chlorothalonil is to be converted into the corresponding product rate by the registrant for each product label.