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Proposed Re-evaluation Decision

PRVD2020-06

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

Consultation Document

(publié aussi en français)

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Table of Contents

Proposed Re-evaluation Decision	1
Outcome of Science Evaluation.....	1
Proposed Regulatory Decision for Chlorothalonil.....	2
International Context	2
Next Steps.....	2
Science Evaluation.....	4
1.0 Introduction.....	4
2.0 Human Health Assessment	4
2.1 Toxicology Summary.....	4
2.2 Dietary Exposure and Risk Assessment.....	4
2.3 Exposure from Drinking Water	4
2.4 Occupational and Residential Exposure and Risk Assessment	4
2.4.1 Toxicology Reference Values for Occupational and Residential Risk Assessment ...	5
2.4.2 Residential Exposure and Risk Assessment	5
2.4.3 Occupational Exposure and Risk Assessment	7
2.5 Aggregate Exposure and Risk Assessment.....	11
2.6 Cumulative Assessment.....	11
2.7 Related Incident Reports.....	12
3.0 Value Assessment	12
4.0 Conclusion of Science Evaluation	12
4.1 Human Health	12
4.2 Value.....	12
List of Abbreviations	13
Appendix I Products Used as Preservatives in Paints, Coatings and Related Uses.....	14
Table 1 Chlorothalonil Products Used as Preservatives in Paints, Coatings and Related Uses, as of 2 October 2019.....	14
Appendix II Non-Occupational Risk Assessment.....	15
Table 1 Residential Non-Cancer (Short-Term) Exposure and Risk Assessment.....	15
Table 2 Residential Cancer Exposure and Risk Assessment	15
Appendix III Occupational Risk Assessment.....	17
Table 1 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment for Primary Handlers in Manufacturing Facilities Using Liquid, Open Pour Scenario	17
Table 2 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment for Primary Handlers in Manufacturing Facilities Using Solid, Open Pour Scenario.....	17
Table 3 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment to Professional Painters.....	18
Appendix IV Aggregate Exposure and Risk Assessment.....	20
Table 1 Aggregate Non-Cancer Risk Assessment	20
Table 2 Aggregate Cancer Risk Assessment.....	20
Appendix V Proposed Label Amendments for Products and New Labelling Required for Treated Paint Containing Chlorothalonil	21
References.....	22

Proposed Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports, and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

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.

This document presents the proposed regulatory decision for the re-evaluation of chlorothalonil used as a preservative in paints, including the proposed risk mitigation measures to further protect human health, as well as the science evaluation on which the proposed decision was based. All products registered in Canada containing chlorothalonil for use as a preservative in paints are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period, during which the public, including the pesticide manufacturers and stakeholders, may submit written comments and additional information to [Health Canada](#). The final re-evaluation decision will be published taking into consideration the comments and information received.

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*).

Outcome of Science Evaluation

With respect to human health, risks of concern were identified for primary handlers (industrial manufacturers) handling chlorothalonil as a material preservative and for secondary handlers (professional and residential painters) applying chlorothalonil-treated paint using an airless sprayer. Therefore, mitigation measures for primary handlers (that is, closed transfer system for liquid formulations; additional personal protective equipment (PPE) and a reduction in amount 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)) are proposed.

Proposed Regulatory Decision for Chlorothalonil

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that products containing chlorothalonil for use as a material preservative in paint are acceptable for continued registration in Canada, provided that the proposed risk mitigation measures are in place.

Human Health

To mitigate risks to primary handlers (mixers/loaders/applicators) 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 4.51kg 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 respirator) coupled with an outreach/stewardship program (for solvent-based paint and latex paints (interior and exterior)).

International Context

Chlorothalonil is currently acceptable for use in some other Organization for Economic Cooperation and Development (OECD) member countries, including Australia, Mexico, New Zealand and the United States. The approval of chlorothalonil was not renewed for use as a plant protection product in the European Union. The European Union's decision (April 2019) was based on human health and environmental concerns for the agricultural use of chlorothalonil, with a grace period for use ending in May 2020.

Next Steps

The public, including the registrants and stakeholders, are encouraged to submit additional information that could be used to refine risk assessments during the 90-day public consultation period¹ upon publication of this proposed re-evaluation decision.

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of the re-evaluation decision document,² which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Additional Scientific Information

No additional scientific data are being requested. However, during the consultation period, the registrants and other stakeholders may consider submitting the following information that may address uncertainties in the database of chlorothalonil and support a refined risk assessment. In addition, stakeholders may consider providing information on risk management options for chlorothalonil (for example, additional PPE, engineering controls).

The evaluation of any additional data would be based on the scientific merit and relevance to the risk assessment. While additional data may reduce uncertainty in the risk assessment, continued registration of any uses would be based on the acceptability of risk assessed using a science-based approach.

Additional detailed use description information that may allow further refinement of the risk assessment:

- Refined daily amounts of paint manufactured and treated with preservatives in Canada

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Chlorothalonil is used as a dry-film material preservative in paint. All other registered uses of chlorothalonil (that is, agricultural and turf uses) were evaluated separately (Proposed Re-evaluation Decision PRVD2011-14, *Chlorothalonil*; Re-evaluation Note REV2016-06, *Chlorothalonil: Amendment to the Proposed Re-evaluation Decision*; Re-evaluation Decision RVD2018-11, *Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses*). Only human health (exposure) and value assessments related to the use of chlorothalonil as a material preservative are presented herein. Environmental exposure from this use is expected to be minimal.

Appendix I lists all chlorothalonil products that are registered for use as material preservatives under the authority of the *Pest Control Products Act*.

2.0 Human Health Assessment

2.1 Toxicology Summary

See PRVD2011-14, REV2016-06 and RVD2018-11.

2.2 Dietary Exposure and Risk Assessment

There are no food uses associated with the preservative uses of chlorothalonil; therefore, no dietary exposure is anticipated.

2.3 Exposure from Drinking Water

Residues of chlorothalonil in potential drinking water sources are not anticipated as a result of the preservative uses.

2.4 Occupational and Residential Exposure and Risk Assessment

Occupational and residential risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

2.4.1 Toxicology Reference Values for Occupational and Residential Risk Assessment

Dermal Absorption

For the use of chlorothalonil as a preservative, a new dermal absorption study (PMRA# 1166247) was submitted. In this study, 1% ¹⁴C-chlorothalonil in latex-based paint or in alkyd covering stain (0.1 µg/cm²) was applied to the back of male rats for periods of 8 hours (washed and terminated), 24 hours (washed and terminated) and 24 hours (washed and maintained for an additional 24 hours). For the paint, total recovery was 99-105% with 97-102% in skin washes, 0.64-1.62% in skin and 0.58-0.99% absorbed (urine, feces, cage wash, blood and carcass). For the stain, total recovery was 89-96%, with 84-95% in skin washes, 0.56-1.52% in skin and 0.78-2.97% absorbed. Based on the findings of the study, a dermal absorption factor of 1% was determined to be appropriate for the chlorothalonil risk assessment for paint preservatives.

The 19% dermal absorption factor, based on the rat in vivo study and established under REV2016-06 was used for all primary handler (mixer/loader) risk assessments.

2.4.2 Residential Exposure and Risk Assessment

Residential risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

A residential applicator assessment for the chlorothalonil preservative itself was not required since there are no registered domestic-class pesticide products for paint-related material preservatives. Residential handling of paint-related material preserved with chlorothalonil is considered a postapplication scenario.

The following postapplication scenarios were assessed:

- Individuals applying latex and solvent-based paints (interior and exterior) preserved with chlorothalonil; and
- Individuals who contact surfaces treated with paints preserved with chlorothalonil.

2.4.2.1 Residential Postapplication Exposure and Risk Assessment

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation and/or incidental oral (non-dietary ingestion) routes as a result of handling a product that has been treated with a pesticide, or being in a residential environment that has been previously treated with a pesticide.

There is potential for short-term exposure for residential handlers (≥16 years old) applying products preserved with chlorothalonil. The following scenarios were assessed:

- Applying paints with paint brush and roller;
- Applying paints with an airless sprayer; and
- Dermal contact with painted surfaces.

Paint (Exterior and Interior) Uses

Chemical-specific exposure data were not available for chlorothalonil for the painting scenarios. However, a brush and roller study (PMRA# 2849401) and an airless sprayer study (PMRA# 3003682) were submitted by the Antimicrobial Exposure Assessment Task Force II (AEATF II).

The brush and roller study was designed to quantify dermal and inhalation exposures to both occupational and residential painters while applying paint, containing an antimicrobial, using a brush or roller. The study monitored 18 test subjects using a brush and/or roller in six identical rooms in a warehouse space. The surrogate non-volatile active ingredient used in this study was 1,2-benzisothiazolin-3-one (BIT). The total amount of paint handled (8.520 to 9.940 kg), the time spent while painting (48 to 172 min), and the surface area painted (25 to 82.5 m²), were all measured. Dermal exposures were measured using inner and outer cotton whole body dosimeters, painter's hat, hand washes (all subjects did not wear gloves) and face and neck wipes. Inhalation exposures were measured using air sampling tubes. Separate dermal unit exposure values were generated for residential painters wearing a short-sleeved shirt and shorts and for occupational workers wearing a long-sleeved shirt, long pants and no gloves. The inhalation unit exposure values for both occupational and residential handlers were generated for each individual performing light activities. The total dermal and inhalation unit exposure values were presented as geometric mean based on the arithmetic mean (AMu) of all test subjects. Dermal unit exposure values were calculated with and without method efficiency adjustment (MEA) for hand wash and face and neck wipes.

The airless sprayer study was designed to quantify exposure to painters using airless sprayers. The study monitored 18 test subjects divided into 3 groups based on volume of paint sprayed (37.9 L, 56.8 L and 114 L). The surrogate active ingredient used in this study was propiconazole (PON). Within each group, subjects were subdivided into groups based on dose concentration (0.12% PON or 1.2% PON). All test subjects were occupational painters who had experience painting and handling airless sprayer equipment. The study was conducted in a warehouse facility constructed into three separate modules representing two residential spaces and one commercial office space. All subjects were required to open paint buckets, strain and pour the paint into the equipment and apply paint to the walls, ceiling and other surfaces of the modules. Test subjects wore a long-sleeved shirt and long pants over a 100% cotton dosimeter, as well as a half-face respirator, goggles, shoes and a painter's hat over a dosimeter placed on their head. The test subjects did not wear gloves. Dermal deposition was corrected to account for skin protected by a half-face respirator and goggles. Separate dermal unit exposure values were generated for residential painters wearing a short-sleeved shirt and shorts and for occupational workers wearing a long-sleeved shirt, long pants and no gloves. The inhalation unit exposure values for both occupational and residential handlers were generated for each individual performing light activities. The total dermal and inhalation unit exposure values were presented as geometric means of the arithmetic mean (AMu) of all test subjects. Dermal unit exposure values were calculated with and without method efficiency adjustment (MEA) for hand wash and face and neck wipes. There were a number of limitations with the study; however, these did not preclude the use of this study to establish unit exposure values for painting with airless sprayers.

For the non-cancer risk assessment, dermal unit exposure values without MEA and inhalation unit exposure values from the brush and roller and airless sprayer studies were combined with the default amounts of paint handled per day from the US EPA 2012 Residential SOP (PMRA# 2409268), where a residential painter may apply up to two 1-gallon cans (7.58 L total) daily when using a brush and roller and approximately three 5-gallon cans (56.7 L total) when using an airless sprayer. With the availability of a dermal absorption study using a paint formulation, for the cancer risk assessment, dermal unit exposure values with MEA and inhalation unit exposure values from the same studies, were combined with the same default values mentioned above.

Using the unit exposure values from these studies, assuming the clothing scenario of a residential handler to be shorts and a short-sleeved shirt, together with the default amounts handled, non-cancer and cancer risks were shown to be acceptable for residential handlers applying paint using a brush and roller. When applying solvent-based paints and latex exterior paints using an airless sprayer, non-cancer and cancer risks were not shown to be acceptable. To mitigate these risks, it is proposed that the maximum application rates for solvent-based paints and latex exterior paints be reduced to 8.5 g a.i./L. Appendix II, Tables 1 and 2 summarizes the calculated MOEs and lifetime cancer risks.

To determine the potential transfer of preservative residues from a painted surface, transferable residue studies (PMRA#s 2967976 and 2883917) were submitted by the AEATF II. The studies demonstrated that the transfer of residues onto the skin following contact with a painted surface is minimal. Hence exposure to chlorothalonil is expected to be negligible. Based on the findings of these studies, a quantitative residential postapplication risk assessment for contact with a treated surface for chlorothalonil used in paint was not required and the potential residential postapplication risk is considered to be acceptable.

Bystander Exposure

Bystander exposure is expected to be negligible for the preservative uses of chlorothalonil.

2.4.3 Occupational Exposure and Risk Assessment

There is potential for exposure to chlorothalonil in occupational scenarios when workers handle the pesticide during the mixing and loading process in industrial (manufacturing) settings, and for postapplication exposure to workers handling products treated with chlorothalonil.

2.4.3.1 Mixer, Loader and Applicator Exposure and Risk Assessment

There is potential for exposure to chlorothalonil in occupational scenarios in industrial settings when workers handle the commercial-class chlorothalonil products during the mixing and loading process to manufacture solvent and latex-based paints.

Exposure to chlorothalonil from its use in manufacturing facilities is expected to be long-term in duration (that is, >180 days), via the dermal and inhalation routes.

The commercial class products registered for use in the manufacturing of paints are formulated as liquids (suspensions) and solids (dust). Therefore, the following scenarios were assessed:

- Mixing/transfer of liquids, open pour;
- Mixing/transfer of solids, open pour

Chemical-specific exposure data were not available for chlorothalonil for these scenarios. However, the liquid pour (PMRA#s 2296582 and 2296584) and solid pour (PMRA# 2834812) exposure studies were submitted by the AEATF II.

The liquid pour study was designed to determine the dermal and inhalation exposures to occupational workers during manual open pouring of a non-volatile liquid containing an antimicrobial product.

Three different liquid pouring scenarios were considered in the study: use of conventional containers with no design modifications, reduced-splash or “no-glug” containers, and pouring into a trigger spray bottle. The trigger spray bottle scenario was not considered relevant to paint-related manufacturing. Two non-volatile active ingredients, formulated as soluble concentrates, didecyl dimethyl ammonium chloride (DDAC) and C¹⁴-alkyl dimethyl benzyl ammonium chloride (C¹⁴-ADBAC) were used. The conventional and reduced-splash container scenarios included pouring a range of various amounts of active ingredient handled at different heights using various sized pouring and receiving containers. In this study, 18 subjects that performed 36 monitoring events (MEs) using the two surrogate active ingredients were monitored for dermal and inhalation exposures. Eighteen MEs poured DDAC, and eighteen MEs poured C¹⁴-ADBAC. Each subject performed two MEs, one for pouring from a conventional container and the second from a reduced-splash container. Container sizes were based on the typical product containers currently in the market. To account for different pouring heights, the receiving containers were placed randomly either on a table or on the floor. The receiving container sizes were variable and ranged from 3.785 or 7.571 L buckets to 189 L low-walled plastic troughs.

Subjects wore inner and outer cotton dosimeters. An air sampling pump was attached to the belt of the subject, and an OVS air sampling tube was placed in the subject’s breathing zone. The face and the neck were wiped with gauze and exposure to the rest of the head was extrapolated based on the ratio of the surface area of the face/neck to that of the rest of the head (all subjects were provided with safety glasses). Hand washes were conducted following the removal of the gloves; residues on the chemical-resistant gloves were not quantified. Total dermal exposure was calculated by summing the residues on the inner and outer dosimeters (based on the clothing scenario), face/neck wipes and hand wash samples for each monitoring event (ME). The inhalation unit exposure values for occupational handlers were generated for each individual performing light activities. The unit exposure values for each ME were generated by normalizing the total dermal and inhalation exposure by the amount of active ingredient handled. Inhalation exposure data are presented for workers not wearing respiratory protection.

To assess occupational exposure for scenarios where individuals handled conventional and reduced-splash containers, dermal unit exposure values were generated based on a single layer (long-sleeved shirt and long pants) plus chemical-resistant gloves. However, unit exposure values

could not be generated for different levels of personal protective equipment, as exposure to the body was already minimal and below the level of quantification for most MEs. Therefore, adding additional protective equipment is not expected to significantly change exposure. The total dermal and inhalation unit exposure values for pouring from conventional containers and reduced-splash containers were presented as the AMu.

Similarly, the solid pour studies were designed to determine the dermal and inhalation exposures to occupational workers (primary handlers) when open pouring two different solid formulations (powder and granules) containing an antimicrobial.

Four different pouring scenarios were considered in this study. Two scenarios involved pouring powder and granular formulations in an occupational setting and the other two considered pouring powder and granular formulations in a residential setting. Study details are provided for the occupational scenarios only. The surrogate active ingredient used was cyanuric acid (1,3,5-triazine-2,4,6-triol, CAS number 108-80-5). Eighteen occupational workers poured the solid products into an indoor mix tank. Each subject was randomly assigned two monitoring numbers to account for two consecutive monitoring events, starting with the granules followed by the powder formulation to minimize the potential for cross contamination. All scenarios included manual pouring and/or scooping from different heights, using various sized containers.

Dermal exposure was measured using inner and outer cotton whole body dosimeters, hand washes, and face and neck wipes. All subjects were also given safety glasses and a dust mask. Subjects in the occupational scenario wore chemical-resistant gloves. Inhalation exposures were measured using IOM air sampling tubes (Institute of Occupational Medicine).

Separate dermal unit exposure values were generated for occupational workers wearing different levels of personal protective equipment. The inhalation unit exposure values for occupational handlers were generated for each individual performing light activities. The total dermal and inhalation unit exposure values were presented as the AMu of all test subjects.

The unit exposure values from the liquid and solid pour studies were combined with the default amounts of paint treated per day by workers in manufacturing facilities to estimate exposures. The amounts of paint treated per day were based on the USEPA Antimicrobial Division Draft Summary of Amounts Handled or Treated for Occupational Handler Scenarios,³ where it was assumed that facilities may treat up to 7571 L of paint per day.

³ PMRA# 3084493. USEPA (2018). Summary of Amounts Handled or Treated for Occupational Handler Scenarios. EPA: Washington, DC.

Non-cancer and cancer risks were not shown to be acceptable when mixing/transferring the liquid suspension and solid dust formulations. To mitigate these risks, it is proposed that closed transfer systems be used for handling the commercial-class liquid suspension products. For dust formulations, it is proposed that additional PPE (chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves and a respirator) be required, coupled with a reduced amount of active ingredient handled per person per day of 4.51 kg a.i./person/day. Appendix III, Tables 1 and 2 summarize the calculated MOEs and lifetime cancer risks for mixers/loaders (primary handlers) for liquid and solid open pour scenarios, respectively.

2.4.3.2 Postapplication Worker Exposure and Risk Assessment

Downstream postapplication workers in industrial settings are expected to be wearing PPE as required by law under occupational health and safety, which would limit potential exposure. Therefore, a quantitative risk assessment for downstream workers in industrial facilities involved with the manufacturing of paints was not conducted.

Exposure (professional secondary handlers) to chlorothalonil-treated solvent and latex-based paints were the postapplication occupational scenarios assessed in this review.

Paint (Exterior and Interior) Uses

There is potential exposure for professional painters applying paint preserved with chlorothalonil.

Exposure to chlorothalonil in paint is expected to be long-term in duration (that is, >180 days), via the dermal and inhalation routes.

Based on the use pattern, the following major scenarios were identified for professional painters:

- Applying paints using paint brush and roller; and
- Applying paints using an airless sprayer.

With the availability of a dermal absorption study using a paint formulation, the dermal unit exposure values with MEA and inhalation unit exposure values from the above brush and roller and airless sprayer exposure studies were combined with the default amounts of paint applied per day: 18.75 L per day using a brush and roller (2001 PMRA survey) and 120 L per day using an airless sprayer (PMRA#2992785).

When applying solvent-based paint and latex (interior and exterior) paints using a brush and roller, non-cancer and cancer risks were shown to be acceptable at the maximum registered label rates.

When applying solvent-based paint and latex (interior and exterior) paints using an airless sprayer, non-cancer and cancer risks were not shown to be acceptable. To mitigate these risks, it is proposed to reduce the maximum rates for solvent-based paint and latex (exterior only) paint to 8.5 g a.i./L and to require additional PPE (cotton coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, a painter's hat and respirator) for professional painters using an airless sprayer. Appendix III, Table 3 summarizes the calculated MOEs and lifetime cancer risks for professional painters (secondary handlers).

Based on the findings of the paint transferable residue study, a quantitative occupational postapplication risk assessment for professional secondary handlers contacting treated surfaces for chlorothalonil used in paint was not required.

2.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

The aggregate non-cancer risk was shown to be acceptable for inhalation exposure resulting from the application of latex-based interior paint using an airless sprayer. Aggregate non-cancer risk assessment was not shown to be acceptable for the application of latex-based exterior and solvent-based interior and exterior paints using an airless sprayer. However, aggregate exposure is expected to be overestimated and not of concern, given that solvent-based interior paints are intended to be applied in high moisture areas such as kitchens and bathrooms where the use of an airless sprayer may not be a general practice. Furthermore, the inhalation risk assessment also did not account for air dilution in an outdoor environment or ventilation in an indoor environment.

In addition, while the aggregate cancer risk exceeded 1×10^{-6} , given the considerations listed above and the conservative assumptions used in the dietary (for example, inclusion of residue data for crops no longer on the label) and painter exposure assessments (for example, 50 years of painting), the aggregate cancer risk is not expected to be of concern. See Appendix IV, Tables 1 and 2.

2.6 Cumulative Assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative effects of pest control products that have a common mechanism of toxicity. Accordingly, an assessment of a potential common mechanism of toxicity with other pesticides was undertaken for chlorothalonil. Chlorothalonil is a member of the aromatic fungicide class. Non-occupational exposure to other fungicides within this class is not expected to occur in Canada. The primary mode of action for chlorothalonil via the oral route in mammals involves the generation of nephrotoxic cysteine S-

conjugates through a bioactivation process in the kidney.⁴ The PMRA did not identify information indicating that chlorothalonil shares a common mechanism of toxicity with other pesticides to which exposure is expected to occur in Canada; therefore, no cumulative health risk assessment is required at this time.

2.7 Related Incident Reports

As of 20 December 2019, no human or domestic animal incidents involving chlorothalonil as a material preservative were submitted to the PMRA.

3.0 Value Assessment

Chlorothalonil is registered as a material preservative in paints. It is incorporated into the final product during manufacturing, to provide protection from bacterial and fungal degradation.

This active ingredient is effective at controlling the various micro-organisms responsible for degrading paint, when used as currently directed on the registered product labels.

Protection of paint is important to industry as degradation can lead to a failure of the product to perform its intended purpose, discoloration, odour formation or other complications arising from bacterial or fungal growth.

4.0 Conclusion of Science Evaluation

4.1 Human Health

With respect to human health, the health risks associated with the use of chlorothalonil and associated end-use products in solvent and latex-based paints (exterior and interior) are shown to be acceptable with the proposed mitigation measures for these uses (see proposed revised label directions under Appendix V).

4.2 Value

Chlorothalonil is used to control bacterial and fungal degradation in solvent and latex-based paints (interior and exterior), in order to prevent deleterious effects imposed on the product by the degrading organisms. Alternatives are available for industry to utilize.

⁴ PMRA# 3080957. United States Environmental Protection Agency, 2012, Chlorothalonil: Human Health Assessment Scoping Document in Support of Registration Review, DACO: 12.5.4.

List of Abbreviations

µg	microgram
% w/w	percent weight per weight, concentration of solute in solution
a.i.	active ingredient
ADBAC	alkyl dimethyl benzyl ammonium chloride
ADD	average daily dose
AEATF II	Antimicrobial Exposure Assessment Task Force II
AMu	geometric mean based on the arithmetic mean
BIT	1,2-benzisothiazolin-3-one
bw	body weight
CF	conversion factor
cm	centimetre(s)
DDAC	didecyl dimethyl ammonium chloride
g	gram(s)
kg	kilogram(s)
L	litre(s)
LADD	lifetime average daily dose
m	metre(s)
m ²	square metres
ME	monitoring event
mg	milligram(s)
min	minute(s)
mL	millilitre(s)
MOE	margin of exposure
NOAEL	no observed adverse effect level
OVS	OSHA Versatile Sampler
PMRA	Pest Management Regulatory Agency
PON	propiconazole
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 Products Used as Preservatives in Paints, Coatings and Related Uses

Table 1 Chlorothalonil Products Used as Preservatives in Paints, Coatings and Related Uses, as of 2 October 2019.

Registrant	Registration Number	Product Name	Marketing Class
3313045 Nova Scotia Company	29647	ROCIMA 404D MICROBICIDE	C
Adama Agricultural Solutions Canada Ltd.	31763	ADAMA CHLOROTHALONIL TECHNICAL	T
Arch Chemicals, Inc	27057.03	DENSIL C-98	C
Bayer Cropscience Inc.	24915	TATTOO MANUFACTURING USE PRODUCT	M
Buckman Laboratories of Canada Ltd.	27058.02	BUSAN 1192D MICROBICIDE	C
Sipcam Agro USA, Inc.	27059	CHLOROTHALONIL TECHNICAL FUNGICIDE	T
	29354	CHLOROTHALONIL TECHNICAL AG	T
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

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.

Appendix II Non-Occupational (Residential) Risk Assessment

Table 1 Residential Non-Cancer (Short-Term) Exposure and Risk Assessment

Product Type	Scenario	Application rate (g a.i./L paint) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)		Margin of exposure ^e (MOE)	
				Dermal	Inhalation	Dermal	Inhalation	Dermal ^f	Inhalation ^f
Shorts, short-sleeved shirt, no gloves									
Latex - Exterior Paints	Brush and roller	10.0	76	237445	17.30	0.225	0.00002	2666	91482
	Airless sprayer	10.0	567	196244	2169	1.39	0.015	431	98
		8.5	482	196244	2169	1.18	0.013	508	115
Latex - Interior Paints	Brush and roller	5.0	38	237445	17.30	0.1122	0.00001	5332	182963
	Airless sprayer	5.0	284	196244	2169	0.070	0.008	863	195
Solvent-based Interior and Exterior Paints	Brush and roller	11.8	89	237445	17.30	0.265	0.00002	2268	77814
		11.8	667	196244	2169	0.164	0.018	367	83
	Airless sprayer	8.5	482	196244	2169	1.18	0.013	508	115

Shaded cells indicate where the MOE is less than the target MOE (100)

^a Application rate = As listed on registered labels. Reduced rate of 8.5 g a.i./L reflects the rate that was shown to be acceptable.

^b Amount handled per day for each type of painting equipment = Application rate × maximum amount of paint applied/day (7.58 L using brush and roller and 56.7 L using airless sprayer)

^c Unit exposure values from AEATF II brush and roller and airless sprayer studies; dermal unit exposure values were not adjusted for method efficiency

^d Daily exposure = [Amount handled per day × Unit exposure value × Absorption × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw. Absorption not required for dermal exposure; 100% absorption for inhalation exposure.

^e MOE = NOAEL/Daily exposure

^f Dermal NOAEL of 600 mg/kg bw/day from a rat dermal toxicology study and target MOE of 100.

^g Inhalation NOAEL of 1.50 mg/kg bw/day from a rat oral study and target MOE of 100.

Table 2 Residential Cancer Exposure and Risk Assessment

Product Type	Scenario	Application rate (g a.i./L paint) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		ADD (mg/kg bw/day) ^d			LADD ^e (mg/kg bw/day)	Cancer Risk ^f
				Dermal	Inhalation	Dermal	Inhalation	Combined		
Shorts, short-sleeved shirt, no gloves										
Latex - Exterior Paints	Brush and roller	10.0	76	309602	17.3	0.029	0.00002	0.0030	0.000021	2 × 10 ⁻⁷
	Airless sprayer	10.0	567	229378	2169	0.0163	0.015	0.0316	0.00022	2 × 10 ⁻⁶
		8.5	482	229378	2169	0.014	0.013	0.027	0.00019	1 × 10 ⁻⁶
Latex - Interior Paints	Brush and roller	5.0	38	309602	17.3	0.0015	0.000008	0.0015	0.00001	8 × 10 ⁻⁸
	Airless sprayer	5.0	284	229378	2169	0.0081	0.0077	0.0158	0.00011	8 × 10 ⁻⁷
Solvent-based Exterior and Interior Paints	Brush and roller	11.8	89	309602	17.3	0.0034	0.00002	0.0035	0.000024	2 × 10 ⁻⁷
		11.8	667	229378	2169	0.019	0.018	0.0372	0.000261	2 × 10 ⁻⁶
	Airless sprayer	8.5	482	229378	2169	0.014	0.013	0.027	0.00019	1 × 10 ⁻⁶

Shaded cells indicate where the cancer risk is greater than 1 × 10⁻⁶

^a Application rate = As listed on registered labels. Reduced rate of 0.87 kg/100 L reflects the rate that was shown to be acceptable.

^b Amount handled per day for each type of painting equipment = Application rate × maximum amount of paint applied/day (7.58 L using brush and roller and 56.7 L using airless sprayer)

^c Unit exposure values from AEATF II brush and roller and airless sprayer studies; dermal unit exposure values were adjusted for method efficiency

^d Average Daily Dose (ADD) = [Amount handled per day × Unit exposure value × Absorption (1% Dermal or 100% Inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

^e Lifetime Average Daily Dose (LADD) = Combined Average Daily Dose (ADD) × frequency of exposure (4 days/year) × exposure duration (50 years) / (365 days/year × life expectancy (78 years))

^f Cancer risk = LADD × q₁* (7.66 × 10⁻² (mg/kg bw/day)⁻¹)

Appendix III Occupational Risk Assessment

Table 1 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment for Primary Handlers in Manufacturing Facilities Using Liquid, Open Pour Scenario

Use	Application rate (g a.i./L) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)			Margin of Exposure (MOE) ^e			LADD ^h (mg/kg bw/day)	Cancer Risk ⁱ
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal ^f	Inhalation ^f	Combined ^g		
Single layer, chemical-resistant gloves												
Latex Exterior Paint	10	75731	1922	5.08	0.346	0.005	0.351	4	312	4	0.123	9×10^{-4}
Latex Interior Paint	5	75731	1922	5.08	0.173	0.002	0.175	9	623	9	0.0616	5×10^{-4}

Shaded cells indicate where the MOE is less than the target MOE (100) and the cancer risk is greater than 1×10^{-5}

^a Application rate = As listed on registered labels

^b Amount handled per day = Application rate × maximum amount of paint treated/day (7571 L)

^c Unit exposure values from AEATF II liquid, open pour scenario

^d Daily exposure = [Amount handled per day × Unit exposure value × Absorption (19% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

^e MOE = NOAEL/Daily exposure

^f Dermal and inhalation NOAEL of 1.5 mg/kg bw/day from a rat oral toxicology study and target MOE of 100.

^g Combined MOE = NOAEL / Combined daily exposure and target MOE of 100

^h Lifetime Average Daily Dose (LADD) = Combined daily exposure × frequency of exposure (250 days/year) × exposure duration (40 years) / (365 days/year × life expectancy (78 years))

ⁱ Cancer risk = LADD × q₁* (7.66×10^{-2} (mg/kg bw/day)⁻¹)

Table 2 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment for Primary Handlers in Manufacturing Facilities Using Solid, Open Pour Scenario

Use	Application rate (g a.i./L) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)			Margin of Exposure (MOE) ^e			LADD ^h (mg/kg bw/day)	Cancer Risk ⁱ
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal ^f	Inhalation ^f	Combined ^g		
Single layer, chemical-resistant gloves												
Latex - Exterior Paint	9.8	74194	585.30	575.71	0.103	0.534	0.637	15	3	2	0.224	1.7×10^{-3}
Latex - Interior Paint	4.9	37097	585.30	575.71	0.052	0.267	0.318	29	6	5	0.112	9×10^{-4}
Solvent - based Exterior and Interior Paints	11.8	89033	585.30	575.71	0.124	0.641	0.764	12	2	2	0.269	2×10^{-3}

Use	Application rate (g a.i./L) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)			Margin of Exposure (MOE) ^e			LADD ^h (mg/kg bw/day)	Cancer Risk ⁱ
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal ^f	Inhalation ^f	Combined ^g		
Chemical-resistant coveralls over single layer, chemical-resistant gloves, respirator												
Latex - Exterior Paint	9.8	74194	198	57.571	0.035	0.053	0.088	43	28	17	0.031	2 × 10 ⁻⁴
Latex - Interior Paint	4.9	37097	198	57.571	0.017	0.027	0.044	86	56	34	0.016	1 × 10 ⁻⁴
Solvent - based Exterior and Interior Paints	11.8	89033	198	57.571	0.042	0.064	0.106	36	23	14	0.037	3 × 10 ⁻⁴
All Paints	n/a	4510	198	57.571	0.002	0.003	0.005	707	462	280	0.002	1 × 10 ⁻⁵

Shaded cells indicate where the MOE is less than the target MOE (100) and the cancer risk is greater than 1 × 10⁻⁵

^a Application rate = Product application rate (kg/100L) × a.i. guarantee × CF (1000 g / kg)

^b Amount handled per day = Application rate × maximum amount of paint treated/day (7571 L paint treated/day). The maximum allowable amount of a.i. handled per day per person for MOEs to be acceptable is 4510 g a.i./day.

^c Unit exposure values from AEATF II solid, open pour scenario

^d Daily exposure = [Amount handled per day × Unit exposure value × Absorption (19% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

^e MOE = NOAEL/Daily exposure

^f Dermal and inhalation NOAEL of 1.5 mg/kg bw/day from a rat oral toxicology study and target MOE of 100.

^g Combined MOE = NOAEL / Combined daily exposure and target MOE of 100

^h Lifetime Average Daily Dose (LADD) = Combined daily exposure × frequency of exposure (250 days/year) × exposure duration (40 years) / (365 days/year × life expectancy (78 years))

ⁱ Cancer risk = LADD × q₁* (7.66 × 10⁻² (mg/kg bw/day)⁻¹)

Table 3 Non-Cancer (Long-Term) and Cancer Exposure and Risk Assessment to Professional Painters

Product Type	Scenario	Application rate (g a.i./L paint) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)			Margin of exposure (MOE)			LADD ^h (mg/kg bw/day)	Cancer Risk ^e
				Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal ^f	Inhalation ^f	Combined ^g		
Long pants, long-sleeved shirt, no gloves													
Latex - Exterior Paints	Brush and roller	10.0	187	247470	17.3	0.0058	0.00004	0.0058	259	37082	257	0.0005	4 × 10 ⁻⁶
	Airless sprayer	10.0	1200	99297	2169	0.015	0.032	0.047	101	46	32	0.0042	3 × 10 ⁻⁵
		8.5	1020	99297	2169	0.013	0.028	0.040	118	54	37	0.0035	3 × 10 ⁻⁵
Cotton coverall over long pants, long-sleeved shirt, chemical-resistant gloves, respirator													
	Airless sprayer	8.5	1020	12991	217	0.0017	0.003	0.004	906	542	339	0.0004	3 × 10 ⁻⁶
Long pants, long-sleeved shirt, no gloves													
Latex - Interior Paints	Brush and roller	5.0	94	247470	17.3	0.003	0.00002	0.003	518	74164	515	0.0002	2 × 10 ⁻⁶
	Airless sprayer	5.0	600	99297	2169	0.007	0.016	0.024	201	92	63	0.0021	2 × 10 ⁻⁵
		Cotton coverall over long pants, long-sleeved shirt, chemical-resistant gloves, respirator											
	Airless sprayer	5.0	600	12991	217	0.001	0.0016	0.0026	1540	922	577	0.0002	2 × 10 ⁻⁶

Product Type	Scenario	Application rate (g a.i./L paint) ^a	Amount handled per day (g a.i./day) ^b	Unit exposure value ^c (µg/kg a.i.)		Daily exposure ^d (mg/kg bw/day)			Margin of exposure (MOE)			LADD ^d (mg/kg bw/day)	Cancer Risk ^e
				Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal ^f	Inhalation ^f	Combined ^g		
Solvent - based Interior and Exterior Paints	Long pants, long-sleeved shirt, no gloves												
	Brush and roller	11.8	220	247470	17.3	0.0068	0.00005	0.0068	221	31542	219	0.0006	5 × 10 ⁻⁶
	Airless sprayer	11.8	1411	99297	2169	0.018	0.038	0.056	86	39	27	0.0049	4 × 10 ⁻⁵
		8.5	1020	99297	2169	0.013	0.028	0.004	118	54	37	0.0035	3 × 10 ⁻⁵
	Cotton coverall over long pants, long-sleeved shirt, chemical-resistant gloves, respirator												
Airless sprayer	8.5	1020	12991	217	0.0017	0.0028	0.0044	906	542	339	0.0004	3 × 10 ⁻⁶	

Shaded cells indicate where the MOE is less than the target MOE (100) and cancer risks are greater than 1 × 10⁻⁵

^a As listed on registered labels. Reduced rate of 8.5 kg/L reflects the rate that was shown to be acceptable.

^b Amount handled per day for each type of painting equipment = Application rate × maximum amount of paint applied/day (18.7 L using brush and roller and 120 L using airless sprayer)

^c Unit exposure values from AEATF II brush and roller and airless sprayer studies; dermal unit exposure values were adjusted for method efficiency

^d Daily exposure = [Amount handled per day × Unit exposure value × Absorption (1% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

^e MOE = NOAEL/Daily exposure

^f Dermal and inhalation NOAEL of 1.5 mg/kg bw/day from a rat dermal toxicology study and target MOE of 100.

^g Combined MOE = NOAEL / Combined daily exposure and target MOE of 100

^h Lifetime Average Daily Dose (LADD) = Combined daily exposure × frequency of exposure (250 days/year) × exposure duration (10 years) / (365 days/year × life expectancy (78 years))

ⁱ Cancer risk = LADD × q₁* (7.66 × 10⁻² (mg/kg bw/day)⁻¹)

Appendix IV Aggregate Exposure and Risk Assessment

Table 1 Aggregate Non-Cancer Risk Assessment

Subpopulation	Inhalation exposure ^a	Dietary exposure ^b	Combined exposure ^c	MOE
Individuals applying paint using an airless sprayer + dietary exposure	0.013	0.0047	0.018	84

^a. Inhalation exposure to residential painters applying latex exterior and solvent-based interior and exterior paints, treated with chlorothalonil at the reduced maximum application rate of 8.5 g ai/L, and using an airless sprayer

^b. Chronic (non-cancer) dietary exposure for the general population (PRVD2011-14)

^c. MOE = Aggregate NOAEL / Combined exposure where Aggregate NOAEL is 1.5 mg/kg bw/day based on the rat oral toxicology study and Target MOE of 100. For painters, the aggregate risk is not expected to be of concern given conservative assumptions used in dietary (for example, monitoring data based on the current use pattern) and painter (for example, applying maximum volume of latex-based exterior or solvent-based interior and exterior paint using an airless sprayer) exposure assessments

Table 2 Aggregate Cancer Risk Assessment

Subpopulation	Residential lifetime cancer risk ^a	Dietary lifetime cancer risk ^b	Aggregate cancer risk ^c
Individuals applying paint using an airless sprayer + dietary exposure	1×10^{-6}	8×10^{-7}	2×10^{-6}

^a. Lifetime cancer risk (dermal and inhalation) for residential painters applying solvent-based and latex exterior paints, treated with chlorothalonil at the reduced maximum application rate of 8.5 g ai/L, and using an airless sprayer

^b. Dietary cancer risk for the general population (PRVD2011-14)

^c. Aggregate cancer risk = Residential cancer risk + dietary cancer risk, the PMRA Level of Concern is 1×10^{-6} . For painters, the aggregate cancer risk is not expected to be of concern given conservative assumptions used in dietary (for example, inclusion of residue data for crops no longer on the label) and painter exposure assessments (for example, 50 years of painting)

Appendix V Proposed Label Amendments for Products and New Labelling Required for Paint Containing Chlorothalonil

1.0 Label Amendments for Commercial Class End-use Products Containing Chlorothalonil

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

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 Suspensions

Use a closed transfer system when mixing and loading.

1.2 For All Commercial Class Dust Products

Wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and 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.

Limit the amount of active ingredient handled per day to 4.51 kg per person per day. These restrictions are in place to minimize exposure to individual handlers. Application may need to be performed over multiple days or by using multiple handlers.

1.3 Manufactured paint products (EPs) 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 during paint application.

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

References

A. Information Considered for the Occupational and Residential Assessment

Study/Information Submitted by Registrant

PMRA Document Number	Reference
1166247	Study With Rats to Define the Dermal Absorption of [¹⁴ C]Chlorothalonil Formulated in Alkyd Covering Stain and Latex Base Paints. DACO: 4.5.9

Published Information

PMRA Document Number	Reference
2409268	USEPA (2012a). Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC. Revised October 2012. Section 10.

AEATF II Studies:

PMRA Document Number	Reference
2834812	A Study for Measurement of Potential Dermal and Inhalation Exposure During Manual Pouring of Two Solid Formulations Containing an Antimicrobial. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA07.
2296582	A Study for Measurement of Potential Dermal and Inhalation Exposure during Manual Pouring of a Liquid Containing an Antimicrobial. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA05.
2849401	A Study for Measurement of Potential Dermal and Inhalation Exposure During Application of a Latex Paint Containing an Antimicrobial Pesticide Product Using a Brush and Roller for Indoor Surface Painting. Antimicrobial Exposure Assessment Task Force II (AEATF II), Washington, DC. January 31, 2018. (AEATF II) Project ID: AEA09.
3003682	A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA10.

PMRA Document Number	Reference
2967976	Analysis of Propiconazole Used as an In-Can Paint Preservative in Wall Wipe Samples Collected from Dried Paint During An Airless Paint Monitoring Study. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II (AEATF II). (AEATF II) Project ID: AEA10.
2883917	Analysis of 1,2-Benzisothiazolin-3-one (BIT) in Background Wall Wipe Samples from Indoor Wall Surfaces Painted with Latex Paint Using a Brush and Roller (Non-GLP). Antimicrobial Exposure Assessment Taskforce II (AEATF II), Washington, DC. (AEATF II) Project ID: AEA19.
2296584	A Study for Measurement of Potential Dermal and Inhalation Exposure During Manual Pouring of a Liquid Containing an Antimicrobial. Supplemental Report – Supplement 1, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA05.
2992785	2017, Study Design: A Study for Measurement of Potential Dermal and Inhalation Exposure During the Application of Paint Containing an Antimicrobial using an Airless Sprayer. American Chemistry Council, Antimicrobial Exposure Assessment Task Force II, Washington, DC. (AEATF II) Project ID: AEA10.