Proposed Re-evaluation Decision PRVD2020-05

Folpet and Its Associated End-use Products, Used as a Preservative in Paints and Vinyl Plastics

Consultation Document

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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 folpet used as a preservative in paints and vinyl plastics, 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 folpet for use as a preservative in paints and vinyl plastics 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.

Folpet is a dry-film material preservative used to control bacterial and fungal degradation in solvent-based paints and vinyl plastics (gaskets, roof membranes, exterior vinyl products including artificial leather for outdoor seating, truck covers, industrial tents and outdoor architectural fabrics). All other registered uses of folpet (that is, as a fungicide on food and ornamental crops) were evaluated separately (Proposed Re-evaluation Decision PRVD2018-05, *Folpet and Its Associated End-use Products*; Re-evaluation Decision RVD2020-02, *Folpet and Its Associated End-use Products for Agricultural Uses*).

Outcome of Science Evaluation

With respect to human health, risks of concern were identified for primary handlers (industrial manufacturers) handling folpet as a material preservative and for secondary handlers (professional and residential) using folpet-treated paint.

Therefore, mitigation measures are proposed for mixing/loading folpet (that is, additional personal protective equipment and a reduction of the amount handled per person per day) and the use of folpet in paint is proposed for cancellation. Exposure from the remaining use as a material preservative in vinyl plastics is unlikely to affect human health when used according to the revised label directions.

Proposed Regulatory Decision for Folpet

Under the authority of the *Pest Control Products Act* and based on the evaluation of currently available scientific information, Health Canada is proposing that use of folpet as a material preservative in vinyl plastics is acceptable for continued registration in Canada, provided that the proposed risk mitigation measures are in place. The use of folpet as a material preservative in paint has not been shown to be acceptable and is proposed for cancellation.

Human Health

To mitigate risks to secondary handlers (professional and residential):

- Cancel the use of folpet in solvent-based paints.

To mitigate risks to primary handlers (industrial manufacturers) manufacturing vinyl plastics:

- For the commercial-class solid product, require additional protective equipment (chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear and a respirator) when mixing and loading, together with reducing the amount of active ingredient handled per worker per day to 648 g a.i./person/day.

International Context

Folpet is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the United States, the European Union, Mexico and New Zealand. No decision by an OECD-member country to prohibit all uses of folpet for health or environmental reasons has been identified.

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 period[1] 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 available information database of folpet and support refined risk assessment. In addition, stakeholders may consider providing information on risk management options for folpet (for example, additional personal protective equipment (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 and other data/information that may allow further refinement of the risk assessment:

- Refined daily amounts of paint manufactured and treated with preservatives in Canada
- Chemical-specific dermal absorption studies conducted with paint formulations

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

Science Evaluation

1.0 Introduction

Folpet is a dry-film material preservative in solvent-based paints and vinyl plastics. All other registered uses of folpet (that is, as a fungicide on food and ornamental crops) were evaluated separately (Proposed Re-evaluation Decision PRVD2018-05, *Folpet and Its Associated End-use Products*; Re-evaluation Decision RVD2020-02, *Folpet and Its Associated End-use Products for Agricultural Uses*). Only human health (exposure) and value assessments related to the use of folpet as a material preservative are presented herein; these assessments replace those previously presented in PRVD2018-05 for this specific use. Environmental exposure from this use is expected to be minimal.

Appendix I lists all folpet 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 PRVD2018-05 and RVD2020-02.

2.2 Dietary Exposure and Risk Assessment

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

2.3 Exposure from Drinking Water

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

2.4 Residential and Occupational Exposure and Risk Assessment

Residential and occupational 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 Residential and Occupational Risk Assessment

See PRVD2018-05.

Dermal Absorption

As a single acceptable guideline dermal absorption study was not available for folpet, a weight-of-evidence approach for estimating the dermal absorption was taken. The human in vivo study suggested that dermal absorption was low (7%), which is supported by the physical-chemical properties and the dermal toxicity studies; however, there were major limitations with this study.

Low dermal absorption is also supported by the rat in vivo studies. For the low dose group with a 10 hour exposure period, dermal absorption was reported to be 18% including skin bound residues. For the longer 72 hour exposure duration, dermal absorption was less than 15%, not including skin bound residues. However, not all residues in the skin are expected to be available for absorption, based on the low radioactivity in the blood, urine, faeces and carcass compared to the amount in the skin (53-100% of the absorbed dose) in one of the rat in vivo studies (PMRA# 1347829), the majority of the absorbed dose found in the skin (80-93%) in the in vitro study, and the physical-chemical properties.

Using a weight-of-evidence approach from the dermal absorption studies, physical/chemical properties, and the dermal toxicity studies, a decreased dermal absorption value from 100% to 7% is supported for mixers/loaders handling the folpet material preservative and a decrease to 20% is supported for all post-application scenarios. This is not expected to underestimate exposure, as it is greater than the dermal absorption observed in the rat in vivo studies.

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

The following postapplication scenarios were assessed:

- Individuals applying solvent-based paints preserved with folpet;
- Individuals who contact surfaces treated with paints preserved with folpet; and
- Individuals who contact vinyl plastic products preserved with folpet.

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.

Paints and Vinyl Plastic Products

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

- Applying paints with paint brush and roller;
- Applying paints with an airless sprayer; and
- Dermal contact with impregnated vinyl plastics.

Paints

Chemical-specific exposure data were not available for folpet 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 m^2), 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 means based on the arithmetic mean (AMu) of all test subjects.

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 the AMu of all test subjects. 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.

The 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 USEPA 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 or roller and approximately three 5-gallon cans (56.78 L total) when using an airless sprayer.

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, calculated MOEs for residential handlers applying paint using a brush and roller met the target MOEs at the lowest label rate only, but did not meet the target MOEs at the maximum or minimum label rates when applying paint using an airless sprayer. Therefore, risks were not shown to be acceptable. To mitigate this risk, it is proposed that the use of folpet as a preservative in paints be cancelled. See Appendix II, Table 1 for more information.

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 folpet 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 folpet was not required.

Vinyl plastics

For plastic products that contain folpet, a qualitative postapplication risk assessment was conducted, considering the conclusions of the paint transferable residue studies. Risks were considered to be acceptable, as contact with the treated plastic products (gaskets, roof membranes and exterior vinyl products) is expected to be minimal with very low amounts of folpet available at the material surface for transfer and exposure.

Bystander Exposure

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

2.4.3 Occupational Exposure and Risk Assessment

There is potential for exposure to folpet 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 folpet.

2.4.3.1 Mixer, Loader and Applicator Exposure and Risk Assessment

Industrial Uses (Material Preservative)

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

Exposure to folpet 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 and vinyl plastics are formulated as solids. Therefore, the following scenario was assessed:

- Mixing/transfer of solids, open pour

Chemical-specific exposure data were not available for folpet for this scenario. However, solid pour exposure studies (PMRA# 2834812) were submitted by the AEATF II.

These solid pour studies were designed to determine the dermal and inhalation exposures to occupational workers (primary handlers) when open pouring two 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 solid pour study were combined with the default amounts of paint and vinyl plastics handled/treated per day by workers in manufacturing facilities to estimate exposures. The amounts of paint handled/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 (9388 kg based on paint density of 1.24 kg/L) of paint per day. In the case of vinyl manufacturing facilities, the registrant submitted information stating that an average of 55 kg of folpet may be handled per day when treating vinyl plastics.

Calculated MOEs for mixing/transfer of solids (in manufacturing facilities) did not reach the target MOE, and, therefore, risks were not shown to be acceptable. To mitigate this risk, it is proposed that workers wear chemical-resistant coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and chemical-resistant footwear and a respirator, during mixing, loading, clean-up and repair and handle no more than 648 g of folpet/person/day when manufacturing vinyl plastics. Appendix III, Table 1 summarizes the calculated MOEs for mixers/loaders.

2.4.3.2 Postapplication Worker Exposure and Risk Assessment

Downstream postapplication workers in industrial settings are expected to be wearing personal protective equipment (PPE) as required by law under occupational health and safety, which would limit potential exposure. Furthermore, the use of folpet as a preservative of solvent-based paints and vinyl plastics is limited to mixing and loading, which is largely automated. Therefore, a quantitative risk assessment for downstream workers in industrial facilities involved with the manufacturing of paints and vinyl was not conducted.

Exposure (professional secondary handlers) to folpet-treated paints and vinyl plastics were the postapplication occupational scenarios assessed in this review.

Solvent-Based Paint Uses

There is potential exposure for professional painters applying paints preserved with folpet.

Exposure to folpet in paints 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 paint using paint brush and roller; and
- Applying paint using an airless sprayer.

The 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 (equivalent to 23.19 kg, based on paint density of 1.24 kg/L) using a brush and roller (2001 PMRA survey) and 120 L per day (equivalent to 232.5 kg, based on paint density of 1.24 kg/L) using an airless sprayer (PMRA# 2992785).

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

Calculated MOEs did not reach the target MOEs for either scenario and, therefore, are of concern. Even with additional mitigation measures (for example, additional PPE for professional painters using airless sprayer), risks were not shown to be acceptable at the lowest label rate. Therefore, it is proposed that the use of folpet in solvent-based paints be cancelled. Appendix III, Table 2 summarizes the calculated MOEs for professional painters.

Vinyl Plastic Uses

Exposure to folpet can occur when workers contact products manufactured from vinyl plastics preserved with folpet. While there is no data available to quantify potential postapplication exposure to workers handling treated vinyl plastic products, exposure is expected to be low, as contact with these treated products is expected to be low and intermittent, gloves are likely to be worn, and very low amounts of folpet would be available at the material surface for transfer and exposure. Based on the above considerations, potential risk to postapplication workers contacting vinyl plastics preserved with folpet during the manufacture of such products, or when using these manufactured products, is considered to be acceptable.

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.

In the case of folpet-impregnated vinyl plastics, there is no postapplication residential risk of concern anticipated; therefore, an aggregate exposure and risk assessment is not required.

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. The cumulative risk assessment for thiophosgene, a metabolite of both folpet and captan, was presented in PRVD2018-05, and was not of concern. Given the low potential for dermal postapplication exposure from contacting treated vinyl plastics containing folpet, the low potential for cumulative toxicity and the low likelihood of co-exposure, no further assessment was required.

2.7 Incident Reports

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

3.0 Value Assessment

Folpet is registered for use as a material preservative in solvent-based paints and vinyl plastics. It is incorporated into the products during manufacturing, to provide protection from bacterial and fungal degradation.

This active ingredient is effective at controlling the various micro-organisms responsible for degrading solvent-based paints and vinyl plastics, when used as currently directed on the registered product labels.

Protection of these products is important to industry as degradation of the products 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 folpet and associated end-use products in the manufacturing of vinyl plastics are shown to be acceptable with the proposed mitigation measures (see proposed revised label directions under Appendix IV). However, risks were not shown to be acceptable for secondary professional and residential handlers applying solvent-based paints using a brush and roller or an airless sprayer. Therefore, cancellation of the paint use is proposed.

4.2 Value

Folpet is used to control bacterial and fungal degradation in solvent based paint and vinyl plastics in order to prevent deleterious effects imposed on the product by the degrading organisms. Alternatives are available for industry to utilize.

List of Abbreviations

µg	microgram
% w/w	percent weight per weight
AEATF II	Antimicrobial Exposure Assessment Taskforce II
a.i.	active ingredient
AMu	geometric mean based on the arithmetic mean
BIT	1,2-benzisothiazolin-3-one
bw	body weight
CF	conversion factor
g	gram(s)
IOM	Institute of Occupational Medicine
kg	kilogram(s)
L	litre(s)
m	metre(s)
m^2	square metre(s)
mg	milligram(s)
min	minute(s)
mL	millilitre(s)
MOE	margin of exposure
NOAEL	no observed adverse effect level
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
REV	Re-evaluation Note
USEPA	United States Environmental Protection Agency

Appendix I Products Used as Preservatives in Solvent-Based Paints and Vinyl Plastics

Table 1 Folpet Products Used as Preservatives in Solvent-Based Paints and Vinyl Plastics as of 29 November 2019

Registrant	Registration Number	Product Name	Marketing Class
Adama Agricultural Solutions Canada Ltd.	22040	FOLPAN FOLPET TECHNICAL	T
Troy Chemical Corporation	15605	FUNGITROL 11 POWDER	C
	32928	FUNGITROL 11E	C

T = technical grade active ingredient; C = commercial
Note: Discontinued products and products with submissions for discontinuation not included.

Appendix II Non-Occupational (Residential) Risk Assessment

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

Scenario	Application rate (g a.i./kg 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)[e]		
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal[f]	Inhalation[g]	Combined[h]
Shorts, short-sleeved shirt, no gloves										
Brush and roller	9.59	90	237445	17.3	0.05	0.00002	0.05	187	71823	187
	4.80	45	237445	17.3	0.03	0.00001	0.03	374	143646	374
Airless sprayer	9.59	674	196244	2169	0.33	0.018	0.35	30	77	29
	4.80	337	196244	2169	0.17	0.009	0.17	60	153	157

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 300; combined: 300).

[a] Application rate = Product application rate (1.0% [max] and 0.5% [min] w/w) × a.i. guarantee × CF (1000 g/kg)

[b] Amount handled per day for each type of painting equipment = Application rate × amount of paint applied/day (7.58 L using brush and roller and 56.7 L using airless sprayer) × paint density (1.24 kg/L)

[c] Unit exposure values from AEATF II brush and roller and airless sprayer studies

[d] Daily exposure = [Amount handled per day × Unit exposure value × Absorption (20% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

[e] MOE = NOAEL/Daily exposure

[f] Dermal NOAEL of 10 mg/kg bw/day from a rabbit development study and target MOE of 300.

[g] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and target MOE of 300.

[h] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the developmental endpoint identified in the oral developmental toxicity study. Target MOE is 300.

Appendix III Occupational Risk Assessment

Table 1 Occupational Long-Term Exposure and Risk Assessment for Use of Folpet in Manufacturing Facilities Using Solid, Open Pour Scenario

Use	Application rate (g a.i./kg product)[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]		
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal[f]	Inhalation[g]	Combined[h]
Single layer, chemical-resistant gloves, respirator										
Paint	9.59	90029	585	57.571	0.0461	0.0648	0.1109	217	22	90
	4.80	45014	585	57.571	0.0231	0.0323	0.0554	434	43	180
Vinyl plastics	2.40 - 9.59	54431	585	57.571	0.0279	0.0392	0.0670	359	36	149
Chemical-resistant coveralls over single layer, chemical-resistant gloves, respirator										
Paint	9.59	90029	198	57.571	0.0156	0.0648	0.0804	641	22	124
	4.80	45014	198	57.571	0.0078	0.0324	0.0402	1282	43	249
Vinyl plastics	2.40 - 9.59	54431	198	57.571	0.0094	0.0392	0.0486	1060	36	206
	n/a	648	198	57.571	0.0001	0.0005	0.0006	89074	3002	17283

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 3000; combined: 300)

[a] Application rate = Product application rate (1.0% [max] or 0.5% [min] w/w for paint and 1.0% [max] or 0.25% [min] w/w for vinyl plastics) × a.i. guarantee × CF (1000 g/kg)

[b] For paint: Amount handled per day = Application rate x maximum amount of paint treated per day (7571 L) × paint density (1.24 kg/L). For vinyl: 54431 g a.i./day based on applicant submitted information or 648 g a.i./day, which is the maximum allowable amount of a.i. handled per day per person for MOEs to be acceptable.

[c] Unit exposure values from the AEATF II solid pour study

[d] Daily exposure = [Amount handled per day × Unit exposure value × Absorption (7% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

[e] MOE = NOAEL/Daily exposure

[f] Dermal NOAEL of 10 mg/kg bw/day from a rabbit development study and a target MOE of 300.

[g] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and a target MOE of 3000.

[h] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposure could contribute to the developmental endpoint identified in the oral developmental toxicity study. Target MOE is 300.

Table 2 Professional Painter Long-Term Exposure and Risk Assessment

Scenario	Application rate (g a.i./kg product)[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]		
			Dermal	Inhalation	Dermal	Inhalation	Combined	Dermal[f]	Inhalation[g]	Combined[h]
Single layer, no gloves										
Brush and roller	9.59	223	175871	17.3	0.0980	0.00005	0.0981	102	29036	102
	4.80	111	175871	17.3	0.0490	0.00002	0.0490	204	58071	204
Airless sprayer	9.59	1427	65937	2169	0.2352	0.0387	0.2739	43	36	37
	4.80	714	65937	2169	0.1176	0.0193	0.1370	85	72	73
Cotton coveralls over single layer, chemical-resistant gloves, painter's hat, respirator										
Airless sprayer	4.80	714	7402	217	0.0132	0.0019	0.0151	757	724	661

Shaded cells indicate where the MOE is less than the target MOE (dermal: 300; inhalation: 1000; combined: 300)

[a] Application rate = Product application rate (1.0% [max] or 0.5% [min] w/w for paint) × a.i. guarantee × CF (1000 g/kg)

[b.] Amount of active ingredient handled per day = application rate × amount of paint handled per day (18.75 L for brush and roller and 120 L for airless sprayer) × paint density (1.24 kg/L)

[c] Unit exposure values from the AEATF II brush and roller and airless sprayer studies

[d] Daily exposure = [Amount handled per day × Unit exposure value × Absorption (20% dermal or 100% inhalation) × CF (1 mg/1000 µg) × CF (1 kg/1000 g)]/80 kg bw

[e] MOE = NOAEL / Exposure

[f] Dermal NOAEL of 10 mg/kg bw/day from a rabbit development study and a target MOE of 300.

[g] Inhalation NOAEL of 1.4 mg/kg bw/day from a rat inhalation study and a long-term target MOE of 3000.

[h] Combined MOE = NOAEL/ (dermal exposure + inhalation exposure), as both the dermal and inhalation exposures could contribute to the developmental endpoint identified in the oral developmental toxicity study. Target MOE is 300.

Appendix IV Proposed Label Amendments for Products Containing Folpet

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

Cancellation of Uses

The following uses are proposed for cancellation. All references to the use of folpet as a material preservative for these uses must be removed from all technical and end-use product labels:

- Paints
- Stains
- Coatings

1.0 Label Amendments for Commercial Class End-use Product Containing Folpet

1.1 Clarification of Vinyl Uses

Uses of folpet in vinyl products must be clarified on the product label. Use description of vinyl products should include:

- Gaskets
    - Refrigerator gaskets
    - Window gaskets for homes and cars
- Roof membranes
- Exterior vinyl products
    - Artificial leather for outdoor seating
    - Truck covers
    - Industrial tents
    - Outdoor architectural fabrics

2.0 PRECAUTIONS

2.1 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:

Replace,

"Wear an approved pesticide respirator."

With,

"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 and loading, clean-up and repair."

Limit the amount of active ingredient handled to 648 g per person per day when mixing and loading. These restrictions are in place to minimize exposure to individual handlers. Application may need to be performed over multiple days or by multiple handlers.

References

A. Information Considered for the Occupational and Residential Assessment

List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
1347829	1990, A study of dermal penetration of C-14 folpet in the rat, DACO: 5.8

Published Information

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

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.
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 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.
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.

PMRA Document Number	Reference
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.
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.