Re-evaluation Decision RVD2022-16

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

Final Decision

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Re-evaluation decision for folpet and associated end use products, used as a preservative in paints and vinyl plastics

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

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

Folpet is a dry-film material preservative used to control bacterial and fungal degradation in solvent-based paints, stains and coatings 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 (Re-evaluation Decision RVD2020-02, *Folpet and Its Associated End-use Products for Agricultural Uses*). Currently registered products for use as a material preservative containing folpet can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2020-05, *Folpet and Its Associated End-use Products, Used as a Preservative in Paints and Vinyl Plastics*[2] containing the evaluation of the material preservative uses of folpet and proposed decision, was published on 9 July 2020 for a 90-day consultation period. An additional 60 days for consultation was provided in response to requests from stakeholders to accommodate time constraints imposed by pandemic measures; the

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

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

150-day consultation period ended on 6 December 2020. PRVD2020-05 proposed continued registration of folpet as a material preservative in vinyl plastic with mitigation measures for primary handlers (that is, additional personal protective equipment and a reduction of the amount handled per person per day) and cancellation of the use of folpet as a material preservative in paint.

Health Canada received comments relating to the health and value assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments did not result in revisions to the risk assessments; therefore, no changes were made to the proposed re-evaluation decision as described in PRVD2020-05.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2020-05; no further information was used in the final re-evaluation decision. Therefore, the complete reference list of all information used in this final re-evaluation decision is set out in PRVD2020-05.

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

Re-evaluation decision for folpet (used as a material preservative in paint and vinyl plastics)

Health Canada has completed the re-evaluation of the material preservative uses of folpet. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing folpet is acceptable with mitigation measures. An evaluation of available scientific information found that the use of folpet as a material preservative in vinyl plastics meets current standards for protection of human health and has acceptable value when used according to revised conditions of registration, which includes new mitigation measures. Environmental exposure from the material preservative uses of folpet is expected to be minimal. The use of folpet in solvent-based paints, stains and coatings is cancelled since health risks were not shown to be acceptable when used according to the current conditions of registration, or when additional mitigation is considered. Label amendments, as summarized below and listed in Appendix IV, are required.

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

Risk mitigation measures

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

Human health – Risk Mitigation

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

- Cancel the use of folpet in solvent-based paints, stains and coatings; this use will be removed from product labels through amendment

The following risk-reduction measures are required for continued registration of folpet products used as material preservative in vinyls in Canada**.**

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

- For the commercial-class soluble powder/dust products, require additional personal 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.

Next steps

Pest control products requiring label amendments

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

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

Folpet-treated articles

Information Note – Treated Articles[4] (September 2022) provides regulatory requirements for articles that have been treated with pesticides.

The import and sale of paint treated with folpet is permitted during the 24-month implementation period. However, after 24 months, the import and sale of folpet-treated paint will be prohibited.

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

Other information

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

The relevant confidential test data on which the decision is based (as referenced in PRVD2020-05) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the Health Canada's Pest Management Information Service.

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

[5] As per subsection 35(1) of the *Pest Control Products Act*.

Evaluation approach

Legislative framework

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

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

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

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

> **health risk**, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.
>
> **environmental risk**, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration
>
> **value**, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

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

Risk and value assessment framework

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

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

i) Assessing Potential Health Risks

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

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

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

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

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

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

ii) Assessing risks to the environment

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

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

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

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

iii) Value assessment

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

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

Risk management

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

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

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

[10] Health Canada. PMRA Regulatory Directive DIR2018-*01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review*, 2018 (Internet: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2018/dir2018-01-policy-cancellations-amendments.html, cited October 2022)

List of abbreviations

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

Appendix I Registered material preservative products containing folpet in Canada as of 7 September 2022

Table 1 Folpet products used as preservatives in paints and vinyl plastics that do not require amendments

Registrant	Registration number	Product name	Marketing class
Sharda Cropchem Limited	34281	Sharda Folpet Technical	T
Troy Chemical Corporation	34226	Plastiguard 642VP	C*

T = technical grade active ingredient; C = commercial; * Product has required mitigation on label.

Table 2 Folpet products used as preservatives in paints and vinyl plastics that require amendments

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 List of commenters to PRVD2020-05

List of commenters' affiliations for comments submitted in response to PRVD2020-05

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

Appendix III Comments and responses

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

1.0 Comments related to Health Canada processes and policies

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

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

Health Canada response

As outlined in the folpet proposed re-evaluation decision document (PRVD2020-05), Health Canada relied on data provided by the registrant and the Antimicrobial Exposure Assessment Task Force II (AEATF II) to conduct the risk assessments for each of the active ingredients in the paint cluster. Health Canada has engaged with the AEATF II and the USEPA on science matters prior to and following the submission of this data.

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

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

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

Health Canada response

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

2.0 Comments related to the health risk assessment

2.1 Comments related to the toxicology assessment

2.1.1 Comment related to toxicology reference values used in the human health risk assessment

The registrant disagreed with several toxicology reference values used in the human health risk assessment. In particular, the registrant disagreed with the determination of the *Pest Control Products Act* factor of threefold, the use of the developmental toxicity study for long-term dermal risk assessment, the use of the 28-day inhalation study for inhalation risk assessment.

Health Canada response

The complete toxicology re-evaluation review of folpet was summarized previously in Proposed Re-evaluation Decision PRVD2018-05, *Folpet and Its Associated End-use Products*, which underwent public consultation. Comments received on PRVD2018-05 were reviewed and addressed in Re-evaluation Decision RVD2020-02, *Folpet and Its Associated End-use Products for Agricultural Uses*. No new toxicology data were provided in response to PRVD2020-05; therefore, the previously established toxicology reference values for folpet are not being revisited at this time. For more information on the toxicology assessment, please refer PRVD2018-05, RVD2020-02.

2.2 Comments related to occupational/residential exposure

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

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

Health Canada response

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

2.2.2 Comment related to the use of airless sprayer for indoor application of paint by residential users

One comment referred to the fact that the airless sprayer is not used by residential users for the indoor application of paint. The comment further stated that if solvent-based paint were to be used in a home, adequate ventilation would be used to increase the air changes within the home and reduce any potential residential exposure.

Health Canada response

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

2.2.3 Comment related to the selection of the dermal absorption values

A comment was received noting that a dermal absorption value of 7% should be used for all occupational and residential scenarios as this value was used by Health Canada for the manufacturing scenario and by the USEPA for all scenarios in their most recent risk assessment. This value is supported by data, including a rat in vivo study and the recent triple pack of dermal absorption studies, which indicates that the anticipated dermal absorption is less than 10% for the tested folpet formulations.

Health Canada response

The entire database of folpet dermal absorption studies was considered in the selection of dermal absorption values for folpet. This included one in vivo human study, three in vivo rat studies and a triple pack of dermal absorption studies. The rat in vivo study and triple pack studies specifically noted in the comment were included in the database. This rat in vivo study was considered to be unacceptable by Health Canada due to the large variability of radioactivity in the applied dose (coefficients of variation up to 89% between samples), large variability in mass balance (37–291%), and high amounts of radioactivity in the application device and the non-occlusive cover (6–173%).

Conversely, Health Canada considered the triple pack studies acceptable and applied the North American triple pack approach as outlined in SPN2016-02.[11] In this approach, if the dermal absorption in the rat in vitro study is shown to be a good predictor of rat in vivo dermal absorption (in other words, a rat in vitro/rat in vivo ratio of one or greater), then the in vitro methodology is considered to be acceptable and a dermal absorption value can be selected from the human in vitro study. However, as only agricultural products were tested in the triple pack studies, human in vitro study results were considered inappropriate for selecting the dermal absorption values for material preservative products, as the formulants differ between the two product types and formulants are known to impact dermal absorption.

[11] Health Canada, 2016. Science Policy Note SPN2016-02, Dermal Absorption: Position Papers from the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG)

The available dermal absorption studies allowed the determination of activity-specific dermal absorption values for workers performing different activities who would be exposed to different concentrations of folpet. For example, workers in manufacturing facilities would be exposed to the end-use product directly, while secondary handlers would be exposed to the diluted products, such as in paint and building materials. Since the percent dermal absorption depends on the concentration of folpet deposited on the skin, different dermal absorption values were determined for primary and secondary handlers.

For primary workers handling end-use products in industrial manufacturing facilities, a 7% dermal absorption value was selected in PRVD2020-05 from the human in vivo study. This study was conducted using technical folpet in acetone, which is considered to be representative of the registered material preservative end-use products. The doses tested in this study (7500–10 600 µg/cm^2) were similar to that estimated for workers handling end-use products during manufacturing (9590 µg/cm^2).

For secondary handlers such as professional or residential painters, the dermal absorption of 7% from the human in vivo study was not considered to be appropriate, as the percent of dermal absorption of folpet increases with decreasing concentration/dose, and the concentration of folpet in paint and similar products is lower than that in the manufacturing end-use products. Therefore, a dermal absorption value was selected from studies where the tested dose was similar to that estimated for secondary handlers working with diluted products such as paint (59–119 µg/cm^2). As a guideline dermal absorption study relevant to diluted material preservative products was not available, a weight-of-evidence approach was used to select a dermal absorption value of 20% from the two acceptable rat in vivo studies. Although this value may be conservative (that is an upper bound estimate of dermal absorption), further refinement was not possible with the currently available folpet data.

2.2.4 Comment related to the limited use of solvent-based paints

A comment was received noting the steady drop in the volume of solvent-based paint sold in Canada since the 1980s, which now apparently account for only 5% of the total volume of sales. The comment further noted that solvent-based paints are applied infrequently compared to waterborne products, but they are mostly applied by professional and residential contractors, who do not apply them at the same daily rate for any given job (75–80% in quantity compared to water-based products).

Health Canada response

The source of this information was not provided, and no data were submitted supporting the statement, nor was any sales information on different types of paint shared with Health Canada for consideration as a refinement of the risk assessments for professional and residential painters.

2.3 Comment related to the lack of incident reports

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

Health Canada response

A low number or a lack of incidents cannot be used to imply an absence of risks of concern. Secondary (professional and residential) handlers applying or using paint or vinyl products are likely unaware that these products have been treated with a material preservative. Therefore, the true burden of any observed adverse effect from exposure to the preservative, resulting from the application/use of paint or vinyl plastics, is unknown. Underreporting of incidents and barriers to reporting have been documented in many areas including pesticides (Prado et al., 2017[12]; Bell et al., 2005[13]). Health Canada, therefore, considers all available data and scientific information to ensure that registered pesticides continue to meet current health and environmental safety standards and continue to have value.

3.0 Comment related to the value assessment

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

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

Health Canada response

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

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

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

Appendix IV Label amendments for material preservative products containing folpet

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

Cancellation of uses

The following uses are cancelled. 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 products 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 applicable uses:

- 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."

"DO NOT mix and load more than [648 g a.i. to be reported as a product equivalent value]* per person per day when mixing and loading. These restrictions are in place to minimize exposure to individual handlers. Mixing and loading may need to be performed over multiple days or using multiple handlers."

* As indicated by the square brackets above, the active ingredient amount in this statement (in other words, 648 g a.i.) is to be converted into the corresponding amount of product by the registrant for each product label.