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Re-evaluation Decision

RVD2023-07

Piperonyl Butoxide and Its Associated End-use Products

Final Decision

(publié aussi en français)

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Table of Contents

Re-evaluation decision for piperonyl butoxide	2
Risk mitigation measures.....	3
Implementation of the re-evaluation decision	5
Health considerations	6
Environmental considerations	7
Next steps	7
Other information	9
Legislative framework.....	10
Risk management	12
Science evaluation update.....	14
1.0 Revised health risk assessment	14
1.1 Toxicology summary	14
1.2 Dietary exposure and risk assessment.....	14
1.3 Occupational and non-occupational exposure and risk assessment.....	14
1.4 Aggregate exposure and risk assessment.....	15
1.5 Cumulative assessment	15
1.6 Health incident reports.....	16
2.0 Revised environmental risk assessment.....	16
3.0 Value assessment	17
4.0 Conclusion of science evaluation.....	17
List of abbreviations	19
Appendix I Registered products containing piperonyl butoxide in Canada	21
Table 1 Products containing piperonyl butoxide requiring expedited label amendments as a result of re-evaluation (18-month implementation timeline) ¹	21
Table 2 Products containing piperonyl butoxide requiring expedited cancellation as a result of re-evaluation (18-month phase-out period) ¹	28
Table 3 Products containing piperonyl butoxide requiring label amendments as a result of re-evaluation (24-month implementation timeline) ¹	30
Table 4 Products containing piperonyl butoxide cancelled as a result of re-evaluation (36-month phase-out period)	38
Table 5 Products containing piperonyl butoxide that do not require label amendments as a result of re-evaluation	39
Appendix II List of commenters to PRVD2020-09	41
Appendix III Comments and responses	42
Table 1 Updated toxicology study summary for the 12-month dietary toxicity study in dogs exposed to piperonyl butoxide.....	44
Appendix IV Label amendments for products containing piperonyl butoxide	55
Table 1 Maximum rates for indoor surface-directed applications for commercial-class products.....	57
Table 2 Label statements for piperonyl butoxide commercial-class product by use scenario.....	58
Table 3 Maximum rates for indoor surface-directed applications for domestic-class products.....	72
Table 4 Label statements for piperonyl butoxide domestic-class product by use scenario ...	72

Appendix V	Revised occupational and non-occupational exposure and risk assessments for piperonyl butoxide	79
Table 1	Summary of mitigation required based on the revised assessment.....	82
Table 2	Occupational mixer/loader/applicator exposure and risk assessment.....	84
Table 3	Postapplication worker exposure and risk assessment.....	87
Table 4	Residential applicator exposure and risk assessment.....	88
Table 5	Residential postapplication dermal exposure and risk assessment – outdoor areas and outdoor and indoor/non-commercial greenhouse plants.....	91
Table 6	Residential postapplication dermal exposure and risk assessment – indoor environments (short- to intermediate-term).....	93
Table 7	Residential postapplication dermal exposure and risk assessment – indoor environments (long-term, for bed bugs)	95
Table 8	Residential postapplication dermal exposure and risk assessment – mattresses (long-term, for bed bugs).....	96
Table 9.1	Residential postapplication inhalation exposure and risk assessment for outdoor space sprays (liquid) and indoor space sprays (liquid and total release foggers)	96
Table 9.2	Residential postapplication short-term inhalation exposure from aerosols – refined using air concentration estimates for pressurized product (outdoor).....	98
Table 9.3	Residential postapplication short-term inhalation exposure from aerosols – refined using air concentration estimates for pressurized product (indoor).....	98
Table 10	Residential postapplication inhalation exposure and risk assessment (metered release applications).....	100
Table 11	Residential postapplication hand-to-mouth incidental oral exposure and risk assessment.....	100
Table 12	Postapplication incidental soil ingestion exposure and risk assessment for children (1 to <2 years)	102
Table 13	Short- to intermediate-term residential postapplication object-to-mouth exposure and risk assessment for children (1 to <2 years).....	102
Table 14	Long-term residential postapplication object-to-mouth exposure and risk assessment for children (1 to <2 years) – expansion of assessed rates - indoor environment surface applications (bed bugs).....	104
Appendix VI	Revised aggregate exposure and risk assessments for piperonyl butoxide	105
Table 1	Short- to intermediate-term aggregate exposure and risk assessment	105
Table 2	Long-term aggregate oral exposure and risk assessment for children (1 to <2 years) – indoor environment bed bug applications (soft surfaces).....	108
Appendix VII	References considered following publication of PRVD2020-09	109

Re-evaluation decision for piperonyl butoxide and associated end-use products

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 information¹ 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 Evaluation Approach of this document.

Piperonyl butoxide is a synergist that is always co-formulated with a pesticide (mainly pyrethrins and synthetic pyrethroids) to enhance the effectiveness of the co-formulated active ingredients. Products containing piperonyl butoxide are used to control a broad spectrum of insect pests on a wide variety of sites, including commercial and domestic agricultural and structural uses, and fish in bodies of water. Piperonyl butoxide is a component of the integrated pest management of common household pests, such as bed bugs, cockroaches, fleas, and indoor ants. Products containing piperonyl butoxide are available in various formulations including dusts, pressurized products, pastes, solutions, and emulsifiable concentrates. Currently registered products containing piperonyl butoxide can be found in the [Pesticide Product Information Database](#) and in Appendix I.

The Proposed Re-evaluation Decision PRVD2020-09, *Piperonyl Butoxide and Its Associated end-use Products*² containing the evaluation of piperonyl butoxide and proposed decision was published 17 September 2020 for a 90-day consultation period. An additional 75 days for consultation was provided in response to requests from stakeholders to accommodate time constraints imposed by pandemic measures; the consultation period ended on 1 March 2021.

A request for data under section 19 of the *Pest Control Products Act* to confirm that application rates and use directions on product labels were consistent with the rates used in the health risk assessments was also issued on the day of publication of PRVD2020-09. The deadline for the required data was also extended to 1 March 2021 due to requests from registrants and stakeholders. The data were used to inform a revised use pattern analysis, which confirmed use sites, crops, formulations, application equipment, rates, container sizes, active ingredient concentration, number of applications and application intervals. The revised use pattern is considered for the updated science evaluations for human health and the environment.

¹ Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*

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

PRVD2020-09 proposed continued registration for most uses provided the additional risk mitigation measures are in place. The proposed risk mitigation measures included increased personal protective equipment (PPE); limit on the amount of active ingredient handled per day for commercial-class products; 2-hour re-entry interval after indoor residential applications; precautionary statements to protect pollinators and the environment; and spray buffer zones. The proposed uses for cancellation for commercial products included uses on pastures, direct application to stored grain and seeds, direct application to ponds, lakes, reservoirs, and streams; spot-on application to poultry; space spray application while livestock, other than poultry, are present; and broadcast application for bed bug control on commercial-class dust and pressurized product labels. The proposed uses for cancellation for domestic products included all garden and greenhouse food uses; all pressurized products used as total release foggers; indoor uses on domestic-class product labels; indoor space spray uses (not including metered release) on pressurized product labels; and all claims related to killing lice on non-host sites.

Health Canada received comments and information 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 and new data/information resulted in revisions to the occupational and non-occupational exposure assessments, aggregate exposure risk assessment, and environmental risk assessment (see Science Evaluation Update) and resulted in changes to the proposed re-evaluation decision as described in PRVD2020-09.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2020-09, and further information used in the re-evaluation decision is listed in Appendix VII of this document. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in PRVD2020-09 and the information set out in Appendix VII herein.

This document presents the final re-evaluation decision³ for the re-evaluation of piperonyl butoxide, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing piperonyl butoxide that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation decision for piperonyl butoxide

Health Canada has completed the re-evaluation of piperonyl butoxide. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of many uses of piperonyl butoxide is acceptable. An evaluation of available scientific information found that some uses of piperonyl butoxide products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration, which includes new mitigation measures.

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

The following uses of piperonyl butoxide are cancelled since health risks or value were not shown to be acceptable when used according to the current conditions of registration, or when additional mitigation is considered:

- Domestic-class pressurized products used as total release foggers (including lock-valve mechanisms)
- Domestic-class pressurized products used in metered-release devices
- Space spray uses on domestic-class liquid product labels
- Domestic handler applications using handheld or stationary fogging/misting equipment on liquid domestic-class products
- Uses on pastures; direct application to bulk or bagged stored grain; direct application to ponds, lakes, reservoirs, and streams; space spray application while livestock, other than poultry, are present; and garden and greenhouse food uses on domestic-class labels
- Claims related to killing lice on mattresses, bedding, furniture, and garments.

Label amendments, as summarized below and listed in Appendix IV, are required.

Risk mitigation measures

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

Human health

Risk mitigation:

To protect consumers, bystanders or workers the following uses are cancelled:

- All domestic-class pressurized products used as total release foggers (including lock-valve mechanisms).
- All domestic-class pressurized products used in metered-release devices.
- Space spray uses on domestic-class liquid product labels.
- Domestic handler applications using handheld or stationary fogging/misting equipment on liquid domestic-class products

Data were not available to support certain uses that could result in dietary exposure; therefore, the following risk-reduction measures are required:

- Cancellation of: uses on pastures; direct application to bulk or bagged stored grain; direct application to ponds, lakes, reservoirs, and streams; space spray application while livestock, other than poultry, are present; and garden and greenhouse food uses on domestic-class product labels.
- Limit the application rate of space spray applications while poultry are present.

- Dust application is to be limited to areas that do not affect food, feed, or livestock used to produce food commodities (for example, voids, non-food areas).

To minimize dietary risk to Canadians, the following risk reduction measures are required:

- Revocation of the maximum residue limit (MRL) of 20 ppm on raw cereals, to reduce dietary exposure from residues in cereal grains.
- The number of applications for all outdoor uses (for example: campgrounds, roadsides, and grassy areas) are to be reduced such that the yearly cumulative rate is less than 1100 g a.i./ha, to reduce dietary exposure from residues in drinking water.
- Structural labels are to be updated as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Update*, to reduce dietary exposure from residues in food or feed after a location is treated with a structural product.

To protect consumers, and bystanders (including children) who may be using the product or entering treated sites, the following risk reduction measures are required:

- For surface spray applications, label directions must be added or revised to specify the pests controlled, the application rate and application type (for example, perimeter/spot, crack and crevice) that were shown to have acceptable risk in the human health risk assessment (Appendix IV, Tables 1 and 3). This includes label statements that clearly define and establish the conditions of use for residential areas where children may be present versus non-residential areas where children are not expected to be present.
- Limit the application rate for commercial-class products used as a broadcast surface spray and mosquito abatement, and in metered release devices.
- A 2-hour re-entry interval for commercial-class products applied as an indoor space spray (liquid and pressurized products, excluding metered release products). The commercial applicator is responsible for notifying the occupants and others of the re-entry period requirement.
- Limit the application rate for domestic-class pressurized products used as an indoor space spray.
- A label statement prohibiting use of handheld and stationary fogging/misting equipment on liquid domestic-class labels.
- A label statement prohibiting use of domestic-class greenhouse end-use products in commercial greenhouses.
- Additional label statements for domestic and commercial-class products used as structural pest control products as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates*.

To protect workers using commercial-class products or entering treated sites following application of commercial-class products, the following risk reduction measures are required:

- Increased personal protective equipment (PPE).
- Limit the amount of product handled per day.
- Restricted-entry intervals (REIs) for outdoor ornamentals.
- Re-entry intervals for all other sites.

To protect pets treated with sprays or shampoos containing piperonyl butoxide, the following risk reduction measures are required:

- Label statements to inform consumers of the possible side effects that may be expected in their pets following use.
- Label statements to prohibit the use of other companion animal products with the same active ingredient(s).

Environment

Risk mitigation:

To protect the environment, the following risk-reduction measures are required:

- Standard environmental hazard statements to inform uses of the potential toxic effects on bees, beneficial arthropods, and aquatic organisms.
- Precautionary statements and additional application instructions on product labels with foliar applications (commercial and domestic) to prevent terrestrial plant damage/death.

Value

- Cancellation of label claims related to killing lice on mattresses, bedding, furniture, and garments.

Label improvements to meet current standards:

Health

- Label statements for domestic- and commercial-class products used as structural pest control products are required to be updated as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates*.
- Label statements for domestic-class products used on companion animals are required to be updated as per DIR2002-01, *Canadian Label Improvements for Pesticides used on Companion Animals*.

Implementation of the re-evaluation decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides general timelines for implementation of post-market decisions.

When a re-evaluation or special review decision requires cancellation of pest control products, consistent with Health Canada's *Information Note: update on implementation of post-market decisions* (2021), Health Canada will immediately cancel pest control product registrations on the date of a decision made under paragraph 21(2)(b) of the *Pest Control Products Act*.

If there are no serious and imminent risks to human health or the environment, Health Canada will allow for a phase-out period consistent with the Cancellation Policy and will impose any conditions necessary for carrying out the purposes of the *Pest Control Products Act* under the authority of paragraph 21(5)(a) of the *Pest Control Products Act*.

Health considerations

Risks to human health from exposure to a pesticide are estimated by comparing potential exposures with the most relevant endpoint from toxicology studies, with standard protection factors incorporated to further protect human health, including the most sensitive population. These factors provide an inherent level of protection from exposures that could result in adverse effects to human health. Furthermore, Health Canada applies additional protection factors if warranted by the hazard profile of the pesticide or by the quality and completeness of the underlying data. When risks of concern are identified in the human health exposure scenarios, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce potential risks would be required.

For piperonyl butoxide products co-formulated with pyrethrins/synthetic pyrethroids, 234 human incident reports involving 48 products were received between 2007 and 2022 and were considered to be possibly related to the reported product when used according to the label. For the majority of human health incidents, reported symptoms included respiratory effects (such as cough, nasal congestion, and respiratory irritation), skin or eye irritation, tingling mouth or skin, nausea, dizziness, or headache. These effects were associated mostly with domestic-class products used in indoor sites, and were mainly minor in severity, were of short duration and resolved quickly without medical treatment. For these domestic-class indoor products associated with human incidents, as well as registered domestic products with similar formulations and use pattern, the required label amendments must be implemented no later than 18 months after the publication date of this re-evaluation decision (Appendix I, Table 1). For domestic-class indoor products that have been cancelled (Appendix I, Table 2), product cancellations are in effect as of the date of this decision document with an 18-month phase-out period. During this 18-month phase-out period, continued possession, handling, storage, and use of existing stock in Canada at the time of cancellation of these products (Appendix I, Table 2) will be authorized under paragraph 21(5)(a) of the *Pest Control Products Act*.

For the products requiring amendments listed in Appendix I, Table 3, label amendments must be implemented no later than 24 months after the publication date of this re-evaluation decision.⁴ Products listed in Appendix I, Table 4 are cancelled as of the date of this decision with a 3-year phase-out period authorized under paragraph 21(5)(a) of the *Pest Control Products Act*. During this 3-year phase-out period, continued possession, handling, storage, and use of existing stock in Canada at the time of cancellation of these products (Appendix I, Table 4) will be authorized under paragraph 21(5)(a) of the *Pest Control Products Act*.

⁴ The 24-month timeline is consistent with guidance for label amendments on other companion animal product types (in other words, spot-on type products – see 2019 PMRA Guidance Document, *Label Improvements for Spot-on Pesticides Used on Companion Animals*).

In addition, for the products subject to cancellation in Appendix I, Table 4 there are no serious and imminent risks identified or expected during the phase-out period.

This approach prioritizes the implementation of mitigation measures for products associated with human incident reports as well as the cancellation of products that are similar in use. This will facilitate the practical and orderly implementation of mitigation measures through label amendments and cancellations.

Potential and relative health risks for products containing piperonyl butoxide are acceptable during these implementation periods for label amendments.

Environmental considerations

To comply with this decision, the required amendments (mitigation measures and label updates) to protect the environment must be implemented on product labels no later than 24 months after the publication date of this re-evaluation decision. The risks identified are considered acceptable because they are not expected to cause irreversible harm over the label implementation period. Potential effects of piperonyl butoxide include a localized reduction in aquatic organism and pollinator abundance. Affected populations have the potential to recover following implementation of the additional restrictions, which will reduce overall exposure. Recovery is expected because risks to these non-target organisms are geographically limited to areas where these piperonyl butoxide products are applied and areas adjacent to application sites. The presence of unaffected non-target organisms in areas where piperonyl butoxide products are not being used will further facilitate recovery since unaffected organisms can move back into areas where effects may have occurred. Overall, the risk to these organisms is acceptable over the period required to implement the mitigation measures.

For the restricted class product subject to cancellation there are no serious and imminent risks identified or expected. The product label indicates the product is toxic to aquatic organisms and can only be used following consultation and permitting from Provincial and Federal Fish and Wildlife Agencies. As such, use is monitored, and environmental impacts are considered during the permit application process. Therefore a 3-year phase out period for this cancelled product is acceptable.

Next steps

To comply with this decision, the required pest control product amendments and cancellations must be made within the timelines described in this section. This decision is applicable to all products containing piperonyl butoxide, see Appendix I for details.

Amendments to product registrations

- 1) For pest control products listed in Appendix I, Table 1:** The required amendments (risk mitigation measures and label updates) to domestic-class products with indoor uses identified in Appendix I, Table 1 must be implemented no later than 18-months after the final decision publication. Accordingly, both registrants and retailers will have up to 18-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 18-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.

- 2) **For pest control products listed in Appendix I, Table 3:** Any remaining products, not described above, requiring label amendments (risk mitigation measures and label updates) (Appendix I, Table 3) must be implemented 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.

Cancellation of product registrations

- 1) **For pest control products listed in Appendix I, Table 2:** As of the date of this decision document, some domestic-class products with indoor uses are cancelled pursuant to paragraph 20(1)(b) of the *Pest Control Products Act* (Appendix I, Table 2). An 18-month phase-out period is established to deplete existing stocks in Canada.

During this phase-out period, continued possession, handling, storage, and use of existing stock in Canada of these products will be authorized under paragraph 21(5)(a) of the *Pest Control Products Act* as per the schedule below:

- Authorized for sale (of existing stocks in Canada) by registrant six (6) months from the date of decision, followed by;
- Authorized for sale by retailer/distributor (if applicable) six (6) months from the last date of sale by registrant, followed by; and
- Authorized for use six (6) months from the last date of sale by retailer/distributor.

- 2) **For pest control products listed in Appendix I, Table 4:** As of the date of this decision document, some products, not described above, are cancelled pursuant to paragraph 20(1)(b) of the *Pest Control Products Act* (Appendix I, Table 4) with a 3-year phase-out period to deplete existing stocks in Canada. During this period, continued possession, handling, storage, and use of existing stock in Canada of these products will be authorized under paragraph 21(5)(a) of the *Pest Control Products Act* as per the schedule below:

- Authorized for sale (of existing stocks in Canada) by registrant one (1) year from the date of decision, followed by;
- Authorized for sale by retailer/distributor (if applicable) one (1) year from the last date of sale by registrant, followed by; and
- Authorized for use one (1) year from the last date of sale by retailer/distributor.

Products that have a phase-out period will be listed as “Phase-out” in the Public Registry for the duration of their authorization. During the phase-out period, importing or manufacturing of cancelled pest control products containing piperonyl butoxide in Canada is prohibited (Appendix I, Tables 2 and 4).

In addition, registrants are required to continue to comply with sales and incident reporting obligations (relating to all pest control products containing piperonyl butoxide) during the phase-out period for the pest control products in Appendix I, Tables 2 and 4.

Other information

Any person may file a notice of objection⁵ regarding this decision on piperonyl butoxide and its associated end-use products 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 PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2020-09 and in Appendix VII of this document) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact PMRA's Pest Management Information Service.

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 human health and the 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

Assessments estimate potential health risks to defined populations⁹ 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.

⁶ *PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products*

⁷ *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks – August 1, 2000*

⁸ *Science Policy Note: The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*

⁹ *Consideration of Sex and Gender in Pesticide Risk Assessment*

ii) Assessing risks to the environment

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

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

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

iii) Value assessment

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

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 continued 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 PMRA Regulatory Directive DIR2018-01 *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*

Science evaluation update

Based on the comments and additional information received during consultation, Health Canada revised the human health, and environmental assessments.

1.0 Revised health risk assessment

1.1 Toxicology summary

The toxicology assessment for piperonyl butoxide was previously conducted and summarized in PRVD2020-09. The toxicology-related comments received during the consultation period for PRVD2020-09 pertained to the points of departure selected by Health Canada for the oral, dermal and inhalation risk assessments, and included scientific rationales pertaining to the reference values. Overall, the review of the information and comments submitted did not result in a change to the reference values established for the human health risk assessment outlined PRVD2020-09. Detailed responses to comments are presented in Appendix III.

1.2 Dietary exposure and risk assessment

In PRVD2020-09, certain uses that could result in dietary exposure were proposed for cancellation due to lack of supporting data, or due to dietary risks that were not shown to be acceptable.

No data or comments were received to address the dietary assessment of piperonyl butoxide. Updates to product use information were provided during the consultation; however, they did not result in changes to the dietary assessment. Therefore, the required mitigation measures stemming from the dietary assessment are consistent with those stated in PRVD2020-09.

Label changes resulting from the dietary assessment are included in Appendix IV. Changes to MRLs will be published in a Proposed Maximum Residue Limit (PMRL) document for consultation.

1.3 Occupational and non-occupational exposure and risk assessment

In PRVD2020-09, risks were not shown to be acceptable for domestic-class pressurized products used as total release foggers; indoor dust uses, and indoor space spray uses on domestic-class products; outdoor flying insect control uses for all pressurized products; and broadcast application for bed bug control on commercial-class dust and pressurized products. These uses were proposed for cancellation. Risks were shown to be acceptable for all other uses with proposed mitigation measures such as limits on the application rate, increased personal protective equipment (PPE), restrictions on the amount of active ingredient handled per day and restricted entry intervals or re-entry intervals, including a 2-hour re-entry interval for space spray in residential areas.

As outlined in PRVD2020-09, additional data were required under section 19 of the *Pest Control Products Act* to confirm that application rates and use directions on product labels are consistent with the rates used in the health risk assessments. As a result of the information received from

registrants in response to this data call-in, the occupational and non-occupational risk assessment of piperonyl butoxide for most uses was revised to reflect the clarifications to the currently registered use pattern, such as areas of use, application equipment, application rates, concentration of piperonyl butoxide in registered products and application intervals. In addition, comments, and data specific to occupational and non-occupational exposure were received during the PRVD consultation period and considered in the revised risk assessment (Appendix V). This information was incorporated into the revised assessment to the extent possible. The data included an outdoor air monitoring study, which was used to revise the postapplication inhalation assessment for outdoor space spray applications using pressurized products. The indoor space spray studies using pressurized products were also revisited based on comments received from registrants.

As a result of the comments and data, many of the outcomes of the occupational and non-occupational risk assessments and proposed mitigation in PRVD2020-09 have changed and the following uses are cancelled:

- Domestic-class pressurized product application using total release foggers (including lock-valve mechanism)
- Domestic-class pressurized products used in metered-release devices
- Space spray uses on domestic-class liquid product labels
- Domestic handler applications using handheld or stationary fogging/misting equipment on liquid domestic-class products

All remaining registered uses are acceptable for continued registration provided that the mitigation measures outlined in Appendix IV are followed.

Health Canada responses to specific comments are located in Appendix III. Details of the revised occupational and non-occupational risk assessments are presented in Appendix V.

1.4 Aggregate exposure and risk assessment

The aggregate exposure and risk assessment was updated to include those uses and scenarios for which route-specific risks are shown to be acceptable. Exposure from use of piperonyl butoxide in residential areas was aggregated with dietary exposure from food and drinking water.

Aggregate risks were shown to be acceptable for all currently registered uses, including those in indoor residential environments, provided the use pattern changes and mitigation measures outlined in Appendix IV are followed. Details of the revised aggregate risk assessments are presented in Appendix VI.

1.5 Cumulative assessment

No new information was received during the consultation period related to cumulative risk. As concluded in PRVD2020-09, Health Canada did not identify information indicating that piperonyl butoxide shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative health risk assessment at this time.

1.6 Health incident reports

Subsequent to the publication of PRVD2020-09, Health Canada received 30 additional human incidents and 69 additional domestic animal incidents involving piperonyl butoxide co-formulated with other active ingredients (mainly pyrethrins and synthetic pyrethroids). The adverse effect and exposure patterns noted in the current sub-set of incidents (in other words, from 19 November 2019 to 3 February 2022) are similar to those observed in the incident report review summarized in PRVD2020-09.

In general, piperonyl butoxide incidents mostly involved products for use on companion animals followed by products used at residential sites.

The review of incidents involving co-formulated piperonyl butoxide spray or shampoo products for use on companion animals point to a concern of adverse effects in cats and dogs even when the products are used according to label directions. Therefore, the labels of all piperonyl butoxide spray or shampoo products (co-formulated with pyrethrins or synthetic pyrethroids) must be updated to inform the consumer of possible side effects in pets that can be expected following the use of these products. In addition, the labels must contain statements that contraindicate the use of other companion animal products with the same active ingredient as the co-formulated piperonyl butoxide spray (or shampoo) product and remove any label language that allows for the re-application of the product before the end of the effective control period. The label requirements (see Appendix IV) are similar to those outlined in the 2019 PMRA Guidance Document, *Label Improvements for Spot-on Pesticides Used on Companion Animals*. Furthermore, the product labels must be amended to reflect the statements outlined in DIR2002-01, *Canadian Label Improvements for Pesticides used on Companion Animals*, to address the deficiencies or inconsistencies noted in the precautionary and use direction statements across the various registered products.

The review of human and domestic animal incidents involving co-formulated piperonyl butoxide products for use at residential sites indicates a potential for incidental oral, inhalation and/or dermal exposure of people and pets to piperonyl butoxide even when products are used according to the label directions. The current label language on piperonyl butoxide products that were most frequently reported in incidents was found to be somewhat vague and non-specific (for example, products do not clearly specify or define the type of surface-directed treatment allowed). Therefore, mitigation measures, as outlined in Appendix IV, are required to inform the consumer of the potential effects that can be expected following the use of piperonyl butoxide products co-formulated with pyrethrins or synthetic pyrethroids. Additionally, label amendments as outlined in the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates* are required for all domestic-class piperonyl butoxide products (co-formulated with pyrethrins or synthetic pyrethroids), in order to reduce the potential for dermal and/or inhalation exposure of people and pets during the use of these products in enclosed areas.

2.0 Revised environmental risk assessment

Additional use information was requested in accordance with section 19 of the *Pest Control Products Act* after the publication of PRVD2020-09. A rate of application higher than what was assessed in the re-evaluation for pyrethrins and piperonyl butoxide was provided. The revised

use information results in a five-fold increase of the rate relative to the maximum rate used in the environmental risk assessment for mosquito control products assessed in PRVD2020-09. The revised risk assessment for piperonyl butoxide indicates the risks have not been shown to be acceptable at this rate for several non-target organisms. The broad-based nature of this risk along with the relatively large risk quotients indicates that impacts may occur at an ecosystem level. Environmental exposure to pyrethrins at this rate was not shown to be acceptable either and is discussed in detail in RVD2023-06. Therefore, the maximum rate of commercial-class outdoor mosquito fogging will be limited to the rate outlined in the revised occupational and non-occupational exposure risk assessment (Appendix V).

3.0 Value assessment

Comments received in response to PRVD2020-09 did not result in a change in the value assessment. Therefore, the value assessment and conclusions are consistent with PRVD2020-09.

4.0 Conclusion of science evaluation

The review of the information and comments submitted during the consultation period did not result in a change to the toxicology reference values established for the human health risk assessment outlined in PRVD2020-09. Dietary exposure mitigation measures remain consistent with those in the proposed re-evaluation decision, including the revocation of the maximum residue limit for raw cereals. The occupational and non-occupational risk assessment, including residential exposure, was revised to include new use sites, application equipment, rates, container sizes, piperonyl butoxide concentration, number of applications and application intervals. This risk analysis determined that most uses are acceptable except for domestic-class pressurized product – total release foggers, domestic-class liquid application using handheld and stationary fogging/missing equipment, domestic-class automatic metered release devices, and domestic-class indoor space sprays using liquid products. For acceptable uses, various risk mitigation measures are required. Aggregate exposure was revised to include uses and scenarios for which route-specific risks were shown to be acceptable, as well exposure as a result of use in residential areas was aggregated with dietary exposure. All aggregate risks were found to be acceptable with the required mitigation measures. In addition, similar to what was proposed in PRVD2020-09, it is required that all labels of domestic-class products (co-formulated with pyrethrins or pyrethroids) contain best practice statements and label amendments.

The environmental risks were re-assessed based on maximum application rates received from the data call-in. The revised environmental risk assessment determined a maximum application rate for outdoor mosquito fogging applications was required. The environmental risks of piperonyl butoxide for all other uses were found to be acceptable when used according to the revised label directions and required mitigation measures.

Piperonyl butoxide, as a co-formulant, was determined to have value except for label claims related to killing lice on mattresses, bedding, furniture, and garments as noted in PRVD2020-09. The revised risk assessments, as noted above, will require mitigation that will have limited impact on the use pattern(s) for some uses.

In conclusion of this science evaluation, most uses of piperonyl butoxide are acceptable for continued registration provided the risk mitigation measures outlined in this final decision are implemented.

List of abbreviations

♂	males
♀	females
↑	increased
↓	decreased
AC	air concentration
ACH	air exchanges per hour
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
AHPD	amount handled per day
a.i.	active ingredient
ALP	alkaline phosphatase
AP	amount applied
AR	application rate
ATPD	area treated per day
BAY	propoxur
BB	bed bug
bw	body weight
bwg	body weight gain
cm ²	centimeter squared
CR	chemical resistant
CXF	cyfluthrin
DACO	data code
DFR	dislodgeable foliar residue
DU	dust
ET	exposure time
F	fraction of chemical available in outdoor air
g	gram
ha	hectares
HH AB/MB	handheld airblast/mistblower
Hct	hematocrit
HtM	hand-to-mouth
IPM	integrated pest management
IR	inhalation rate
kg	kilogram(s)
kPa	kilopascal
L	litre(s)
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
LOQ	limit of quantification
m ²	meters squared
m ³	meters cubed
max com	maximum concentration
mg	milligram(s)
MGD	di-n-propyl isocinchomeronate
MGK	N-octyl bicycloheptene dicarboximide
M/L/A	mixer/loader/applicator

MOE	margin of exposure
MPHG	mechanically pressurized handgun
MPHS	mechanically pressurized handheld sprayer for mists, aerosols, and fogs
MPHW	manually pressurized handwand
MPR	(s)-methoprene
MR	metered-release pressurized product
MRL	maximum residue limit
NDETF	Non-Dietary Exposure Task Force
NEO	tetramethrin
NOAEL	no observed adverse effect level
NIOSH	National institute for Occupational Safety and Health
OtM	object-to-mouth
PBU	piperonyl butoxide
PCO	pest control operator
PFL	permethrin
PHG	D-phenothrin
PJV	Pyrethrins Joint Venture
PMRA	Pest Management Regulatory Agency
PMRL	proposed maximum residue limit
PP	pressurized product
PPE	personal protective equipment
PPID	pesticide product information database
PRX	pyriproxifen
PRVD	Proposed Re-evaluation Decision
psi	pound per square inch
PYR	pyrethrins
RBC	red blood cell
REI	restricted entry interval
ROT	rotenone
RTU	ready to use
SIF	silicon dioxide (present as 00% diatomaceous earth) – fresh water fossils
SIL	silica aerogel
SOP	standard operating procedure
T	target margin of exposure
TC	transfer coefficient
TR	transferable residue
TRF	pressurized products that can be used as a total release fogger
TTR	turf transferable residue
TWA	time weighted average
ULV	ultra low volume
µm	micrometer(s)
USEPA	United States Environmental Protection Agency

Appendix I Registered products containing piperonyl butoxide in Canada

Table 1 Products containing piperonyl butoxide requiring expedited label amendments as a result of re-evaluation (18-month implementation timeline)¹

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
9021	Domestic	Rolf C. Hagen Inc.	Living World Bird Bath for Caged Birds	Pressurized Product	PBU ² (0.18%) PYR ³ (0.09%) MGK ⁴ (0.30%)
9749	Domestic	S.C. Johnson and Son, Limited	Raid House & Garden Bug Killer	Pressurized Product	PBU (1.21%) PYR (0.25%)
13074	Domestic	Premier Tech Brighton Ltd	Pro Professional Ant and Roach Pyroduct	Dust	PBU (1.0%) PYR (0.2%)
14633	Domestic	McLaughlin Gormley King Company	Pyroicide Ready-to-Use Liquid Insecticide	Solution	PBU (1.0%) PYR (0.1%)
15180	Domestic	McLaughlin Gormley King Company	Pyroicide Aqueous Garden Spray	Solution	PBU (0.2%) PYR (0.02%)
15181	Domestic	McLaughlin Gormley King Company	Pyroicide Aqueous Plant Spray Insecticide	Solution	PBU (0.2%) PYR (0.02%)
15488	Domestic	Puroguard Insecticides Ltee	Puroguard House & Garden Insecticide Dust	Dust	PBU (1.0%) PYR (0.2%)
16282	Domestic	Premier Tech Brighton Ltd	Pro Professional Aerosol Insecticide	Pressurized Product	PBU (4.0%) PYR (0.5%)
17953	Domestic	PLZ Corp.	K-G House & Garden Insect Killer I	Pressurized Product	PBU (0.8%) PYR (0.2%)
18074	Domestic	Puroguard Insecticides Ltee	Puroguard Insecticide	Solution	PBU (1.0%) PYR (0.1%)
18504	Domestic	PLZ Corp.	K-G House Plant Insecticide I	Pressurized Product	PBU (1.0%) PYR (0.2%)
19004	Domestic	Maheu & Maheu Inc.	Maheu & Maheu Insecticide Dust	Dust	PBU (1.0%) PYR (0.2%)
19460	Domestic	Woodstream Canada Corporation	Safer's Flea & Tick Spray/R.T.U.	Solution	PBU (0.60%) PYR (0.06%)
19485	Domestic	PLZ Corp.	K-G Flying Insect Killer I	Pressurized Product	PBU (3.2%) PYR (0.4%)
19748	Domestic	McLaughlin Gormley King Company	Flying Insect Killer IB	Pressurized Product	PBU (1.93%) PYR (0.4%)
20720	Domestic	Woodstream Canada Corporation	Safer's Flea & Tick Spray (R.T.U.)	Solution	PBU (0.60%) PYR (0.06%)
20848	Domestic	Woodstream Canada Corporation	Safer's Attack Roach & Crawling Insect Killer	Dust	PBU (1.0%) PYR (0.4%) SIF ⁴ (74.9%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
21088	Domestic	S.C. Johnson and Son, Limited	Raid House & Garden Bug Killer Pressurized Spray	Pressurized Product	PBU (1.93%) PYR (0.4%)
21455	Domestic	PLZ Corp.	K-G Flea & Tick Spray for Dogs & Cats VII	Pressurized Product	PBU (0.1%) PYR (0.106%) PFL ⁵ (0.050%) MGK (0.168%)
22169	Domestic	S.C. Johnson and Son, Limited	Raid House & Garden Bug Killer Trigger Spray	Emulsifiable Concentrate	PBU (0.97%) PYR (0.2%)
23053	Domestic	Premier Tech Ltd.	Wilson Flower, Vegetable and Ornamental RTU BUG-X	Solution	PBU (0.2%) PYR (0.02%)
23061	Domestic	S.C. Johnson and Son, Limited	Raid Max House & Garden Bug Killer 2	Pressurized Product	PBU (1.01%) PYR (0.25%)
23185	Domestic	Premier Tech Ltd.	Green Earth Bio-Mist Garden Insect Killer	Solution	PBU (0.2%) PYR (0.02%)
23300	Domestic	Premier Tech Ltd.	Green Earth Bio-Mist Insect Killer	Solution	PBU (9.22%) PYR (0.96%)
23352	Domestic	Puroguard Insecticides Ltee	The Exterminator Insecticide Dust	Dust	PBU (1.0%) PYR (0.2%)
23356	Domestic	Puroguard Insecticides Ltee	The Exterminator PY-42	Solution	PBU (1.0%) PYR (0.1%)
23502	Domestic	PLZ Corp.	K-G Insecticide Pressurized Spray	Pressurized Product	PBU (5.0%) PYR (0.5%)
24201	Domestic	S.C. Johnson and Son, Limited	Raid Yard Guard 1 Bug Killer	Pressurized Product	PBU (0.97%) PYR (0.176%) NEO ⁶ (0.081%)
24211	Domestic	Woodstream Canada Corporation	Safer's Attack Houseplant & Garden Insecticide	Solution	PBU (0.2%) PYR (0.02%)
24330	Domestic	Vétoquinol N.-A. Inc.	Veto-Mist II Fly Killer Insecticide	Pressurized Product	PBU (10.0%) PYR (1.75%)
24428	Domestic	W.F. Young Inc.	Absorbine FLYS-X Ready to Use Insecticide	Solution	PBU (1.0%) PYR (0.1%)
24784	Domestic	Farnam Companies, Inc.	Bronco Water-base Equine Fly Spray	Solution	PBU (0.5%) PYR (0.05%) PFL (0.10%)
24864	Domestic	PLZ Corp.	K-G Multi Purpose Insecticide Spray II	Pressurized Product	PBU (1.0%) PYR (0.25%)
24892	Domestic	Acuity Holdings, Inc.	Konk 493 Insect Blaster Pressurized Spray	Pressurized Product	PBU (5.0%) PYR (0.5%)
24979	Domestic	Chasse-Moustique Buzz-Up	Buzz-Up! House & Garden Insect Killer	Pressurized Product	PBU (0.8%) PYR (0.2%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
25181	Domestic	S.C. Johnson and Son, Limited	OFF! Area Bug Spray (Yard & Deck)	Pressurized Product	PBU (0.97%) PYR (0.176%) NEO (0.081%)
25495	Domestic	Maheu & Maheu Inc.	Maheu & Maheu Flying Insect Killer	Pressurized Product	PBU (3.2%) PYR (0.4%)
26669	Domestic	Acuity Holdings, Inc.	Konk House & Garden Bug Killer	Pressurized Product	PBU (1.0%) PYR (0.25%)
26720	Domestic	Premier Tech Ltd.	Green Earth Homecare Flying and Crawling Insect Killer	Pressurized Product	PBU (0.8%) PYR (0.2%)
26909	Domestic	S.C. Johnson and Son, Limited	Raid EarthBlends Multi-Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
27175	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Go Green Doktor Doom Indoor/Outdoor Insecticide Spray	Pressurized Product	PBU (1.25%) PYR (0.25%)
27177	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Crawling Insect Killer	Pressurized Product	PBU (1.25%) PYR (0.25%)
27547	Domestic	Empack SprayTech Inc.	Blaze Flying Insect Killer	Pressurized Product	PBU (2.0%) PYR (0.4%)
27945	Domestic	S.C. Johnson and Son, Limited	Raid EarthBlends Ant & Spider Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
28465	Domestic	Kuus Inc.	Knock Down X-Max Flying & Crawling Insect Killer (0.5 Pyrethrin from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (5.0%) PYR (0.5%)
28466	Domestic	Kuus Inc.	Knock Down Indoor and Plant Max Flying & Crawling Insect Killer (0.25 Pyrethrin from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (1.25%) PYR (0.25%)
28970	Domestic	Les Produits de Controle Superieur Inc / Superior Control Products Inc	Pro-Maxx The Garden & House Protector	Pressurized Product	PBU (1.0%) PYR (0.25%)
29045	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Multi-Purpose Insecticide Spray	Pressurized Product	PBU (1.25%) PYR (0.25%)
29046	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Go Green Doktor Doom Spider Mite Knockout I	Pressurized Product	PBU (0.8%) PYR (0.2%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
29047	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Professional Aerosol Insect Killer	Pressurized Product	PBU (4.0%) PYR (0.5%)
29322	Domestic	S.C. Johnson and Son, Limited	Raid Max Home Insect Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
29323	Domestic	S.C. Johnson and Son, Limited	Raid Spider Blaster Bug Killer 5	Pressurized Product	PBU (1.01%) PYR (0.25%)
29324	Domestic	S.C. Johnson and Son, Limited	Raid Max Flying Insect Killer 3	Pressurized Product	PBU (1.01%) PYR (0.25%)
29339	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Sleep Tight Bed Bug Killer II	Pressurized Product	PBU (1.25%) PYR (0.25%)
29485	Domestic	Premier Tech Ltd.	Schultz Houseplant & Indoor Garden Insect Spray	Solution	PBU (0.2%) PYR (0.02%)
29521	Domestic	Can-Vet Animal Health Supplies Ltd.	Bugwacker 600	Pressurized Product	PBU (5.0%) PYR (0.5%)
29633	Domestic	Kuus Inc.	Knock Down Bed Bug Killer 0.25% Pyrethrins from Chrysanthemum Flower Pyrethrum	Pressurized Product	PBU (1.25%) PYR (0.25%)
29691	Domestic	Kuus Inc.	Knock Down Max House Plant Insect Killer (0.25% Pyrethrins from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (1.25%) PYR (0.25%)
29692	Domestic	Kuus Inc.	Knock Down Total Home & Indoor Garden Insect Killer	Pressurized Product	PBU (1.25%) PYR (0.25%)
29693	Domestic	Kuus Inc.	Knock Down Total Spider Mites Killer 0.25% Pyrethrins from Chrysanthemum Flower Pyrethrum	Pressurized Product	PBU (1.25%) PYR (0.25%)
29759	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom "Go Green" Premium Quality Pyrethrin Insecticide Powder	Dust	PBU (1.0%) PYR (0.2%)
29800	Domestic	Gardex Chemicals Ltd.	Gardex Py Dust-Bug Kill Maxx	Dust	PBU (1.0%) PYR (0.2%)
29950	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Premium Quality #1 "No Flies on Us" Insect Destroyer	Pressurized Product	PBU (5.0%) PYR (0.5%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
29955	Domestic	Kuus Inc.	Protex Bed Bug Killer .25% Pyrethrin form Chrysanthemum Flower Pyrethrum	Pressurized Product	PBU (1.25%) PYR (0.25%)
29983	Domestic	Can-Vet Animal Health Supplies Ltd.	Tick-End	Solution	PBU (0.60%) PYR (0.06%)
30032	Domestic	Kuus Inc.	Knock Down Professional KD120P Flying & Crawling Insect Killer	Pressurized Product	PBU (5.0%) PYR (0.5%)
30355	Domestic	S.C. Johnson and Son, Limited	Raid® Ant Roach & Earwig Bug Killer 19	Pressurized Product	PBU (0.48%) PYR (0.2%) CXF ⁷ (0.05%)
30356	Domestic	S.C. Johnson and Son, Limited	Raid® Spider Blaster Bug Killer 4	Pressurized Product	PBU (0.48%) PYR (0.2%) CXF (0.05%)
30357	Domestic	S.C. Johnson and Son, Limited	Raid Max® Crawling Insect Bug Killer 3	Pressurized Product	PBU (0.48%) PYR (0.2%) CXF (0.05%)
30368	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Go- Green Multipurpose Indoor Insect Control II	Pressurized Product	PBU (1.25%) PYR (0.25%)
30418	Domestic	UR-Can Inc.	Onguard PD5	Pressurized Product	PBU (5.0%) PYR (0.5%)
30439	Domestic	Kuus Inc.	Professional Knock Down Bedbug, Ant, Cockroach, Flea & Tick Insect Killer 0.25% Pyrethrins from Chrysanthemum Flower Pyrethrum	Pressurized Product	PBU (1.25%) PYR (0.25%)
30640	Domestic	S.C. Johnson and Son, Limited	Raid® Spider Blaster Bug Killer	Pressurized Product	PBU (0.48%) PYR (0.2%) CXF (0.05%)
30641	Domestic	S.C. Johnson and Son, Limited	Raid Mosquito and Fly Killer 1	Pressurized Product	PBU (1.01%) PYR (0.25%)
30980	Domestic	Camco	Super Kill Flying and Crawling Insect Killer	Pressurized Product	PBU (3.2%) PYR (0.4%)
31110	Domestic	Acuity Holdings, Inc.	Kong Bed Bug Killer	Pressurized Product	PBU (5.0%) PYR (0.5%)
31119	Domestic	Hartz Canada Inc.	Hartz Ultraguard Plus Flea & Tick Home Spray	Solution	PBU (1.0%) PRX ⁸ (0.015%) PHG ⁹ (0.40%)
31143	Domestic	Kuus Inc.	Knock Down Dust Devil Crawling & Flying Insect Control & Killer Dust	Dust	PBU (1.0 %) PYR (0.2%) SIF ¹⁰ (74.0%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
31295	Domestic	Kuus Inc.	Knock Down Eco Flying and Crawling Liquid Insect Killer (0.1% Pyrethrins from Chrysanthemum Flower Pyrethrum)	Solution	PBU (1.0%) PYR (0.1%)
31397	Domestic	Business Helpers' Depot Inc.	Gotcha Indoor/Outdoor Surface & Space Insecticide Spray	Pressurized Product	PBU (1.0%) PYR (0.1%)
31402	Domestic	Business Helpers' Depot Inc.	Fight Back Blood Sucking Parasite Killer	Pressurized Product	PBU (1.5%) PYR (0.3%)
31413	Domestic	Kuus Inc.	Knock Down Greenhouse Plant & Flower Insect Killer (0.02% Pyrethrins from Chrysanthemum flower Pyrethrum)	Solution	PBU (0.2%) PYR (0.02%)
31606	Domestic	Business Helpers' Depot Inc.	Gotcha™ Outdoor Yard Spray	Pressurized Product	PBU (1.0%) PYR (0.1%)
31635	Domestic	Business Helpers' Depot Inc.	Gotcha Bed Bug Killer	Pressurized Product	PBU (1.0%) PYR (0.1%)
31638	Domestic	UR-Can Inc.	Eco-Guard Complete Insect Treatment	Pressurized Product	PBU (1.0%) PYR (0.1%)
31841	Domestic	Premier Tech Ltd.	Wilson One Shot Mosquito & Flying Insect Spray	Pressurized Product	PBU (1.0%) PYR (0.1%)
31851	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Indoor Lice Killer	Pressurized Product	PBU (1.5%) PYR (0.3%)
31897	Domestic	S.C. Johnson and Son, Limited	Raid Bed Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
31938	Domestic	Neogen Corporation	Prozap Shu-Fly	Pressurized Product	PBU (1.93%) PYR (0.4%)
31975	Domestic	Neogen Corporation	Prozap Defender RTU	Solution	PBU (1.0%) PYR (0.1%)
32095	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Insect Killer for Use on Fruit, Vegetables, Flowers and Ornamental Plants	Solution	PBU (0.2%) PYR (0.02%)
32379	Domestic	Business Helpers' Depot Inc.	Gotcha Flying Insect Killer for Horse & Stable	Pressurized Product	PBU (1.0%) PYR (0.1%)
32434	Domestic	S.C. Johnson and Son, Limited	Raid Ant Roach & Earwig Inset Killer 2	Pressurized Product	PBU (1.01%) PYR (0.25%)
32435	Domestic	S.C. Johnson and Son, Limited	Raid Max Crawling Insect Bug Killer 4	Pressurized Product	PBU (1.01%) PYR (0.25%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
32436	Domestic	S.C. Johnson and Son, Limited	Raid Home Insect Killer 2	Pressurized Product	PBU (1.01%) PYR (0.25%)
32437	Domestic	S.C. Johnson and Son, Limited	Raid Spider Blaster Bug Killer 6	Pressurized Product	PBU (1.01%) PYR (0.25%)
32438	Domestic	S.C. Johnson and Son, Limited	Raid Max Flying Insect Killer 3	Pressurized Product	PBU (1.01%) PYR (0.25%)
32439	Domestic	Business Helpers' Depot Inc.	Gotcha Biting Tick Destroyer	Pressurized Product	PBU (0.84%) PYR (0.087%)
32482	Domestic	Business Helpers' Depot Inc.	Fight Back Original Bed Bug Killer	Pressurized Product	PBU (1.0%) PYR (0.2%)
32507	Domestic	Kuus Inc.	Knock Down Total Home & Indoor Garden Insect Killer	Pressurized Product	PBU (1.25%) PYR (0.25%)
32701	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Deer Tick Killer	Pressurized Product	PBU (0.84%) PYR (0.087%)
32793	Domestic	Empack Spraytech Inc.	EmZone Pyrocide House and Garden Insect Killer	Pressurized Product	PBU (1.0%) PYR (0.2%)
32899	Domestic	PLZ Corp.	K-G Multi-Purpose Insect Killer RTU Spray	Pressurized Product	PBU (1.0%) PYR (0.1%)
32966	Domestic	S.C. Johnson and Son, Limited	Raid Max Bed Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
33123	Domestic	Empack Spraytech Inc.	Emzone Fly Killer Insecticide	Pressurized Product	PBU (5.0%) PYR (0.5%)
33324	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Go Green Indoor Plant Insect Killer	Pressurized Product	PBU (1.25%) PYR (0.25%)
33393	Domestic	PLZ Corp.	K-G Lice and Bed Bug Killer	Pressurized Product	PBU (1.5%) PYR (0.3%)
33823	Domestic	Kuus Inc.	Knock Down® Equine Fly Spray	Solution	PBU (0.5%) PYR (0.05%)
34000	Domestic	Vétoquinol N.-A. Inc.	Enough!	Pressurized Product	PBU (5.0%) PYR (0.5%)
34069	Domestic	S.C. Johnson and Son, Limited	Raid Essentials Ant & Spider Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
34070	Domestic	S.C. Johnson and Son, Limited	Raid Essentials Flying Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)
34071	Domestic	S.C. Johnson and Son, Limited	Raid Essentials Multi-Bug Killer	Pressurized Product	PBU (1.01%) PYR (0.25%)

Registrant number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
34291	Domestic	Premier Tech Ltd.	Wilson Fly Out House & Indoor Garden Insect Killer	Pressurized Product	PBU (1.0%) PYR (0.25%)
34536	Domestic	S.C. Johnson and Son, Limited	Raid® Max Spider Blaster Bug Killer 2	Pressurized Product	PBU (1.01%) PYR (0.25%)

¹As of 1 January 2023, excluding discontinued products or products with a submission for discontinuation.

²PBU – piperonyl butoxide;

³PYR – pyrethrins;

⁴MGK - N-octyl bicycloheptene dicarboximide;

⁵PFL – permethrin;

⁶NEO – tetramethrin;

⁷CXF – cyfluthrin;

⁸PRX – pyriproxyfen;

⁹PHG – D-phenothrin;

¹⁰SIF – silicon dioxide (present as 100% diatomaceous earth) – fresh water fossils

Table 2 Products containing piperonyl butoxide requiring expedited cancellation as a result of re-evaluation (18-month phase-out period)¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
14969	Domestic	Medtech Products Inc.	R&C II Spray Insecticide	Pressurized Product	PBU ² (1.5%) PYR ³ (0.3%)
24196	Domestic	Acuity Holdings, Inc.	Konk 418D Flying Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
24495	Domestic	Acuity Holdings, Inc.	Kong 416D Flying Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
28372	Domestic	Kuus Inc.	Knock Down X-Max Flying Insect Killer (D) (1.8 Pyrethrin from Chrysanthemum flower pyrethrum)	Pressurized Product	PBU (10%) PYR (1.8%)
28612	Domestic	PLZ Corp.	K-G Flying Insect Killer Metered III (1.8% PYR-Domestic)	Pressurized Product	PBU (10%) PYR (1.8%)
28858	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Metered Release Flying Insect Spray	Pressurized Product	PBU (10%) PYR (1.8%)
28912	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Go Green Doktor Doom Total Release Fogger	Pressurized Product	PBU (2.0%) PYR (0.4%)
28972	Domestic	Les Produits de Controle Superieur Inc./Superior Control Products Inc.	Super Mist for Control of Flies and Mosquitoes	Pressurized Product	PBU (10%) PYR (1.8%)
29150	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Metered Release BVT/CSA Flying Insect Spray	Pressurized Product	PBU (10%) PYR (1.8%)
29454	Domestic	PLZ Corp.	K-G Total Release Fumigator	Pressurized Product	PBU (2.0%) PYR (0.4%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
29923	Domestic	Les Produits de Controle Superieur Inc /Superior Control Products Inc.	The Fumigator II	Pressurized Product	PBU (2.0%) PYR (0.4%)
29977	Domestic	Kuus Inc.	Knockdown Total Release Fogger (or Fumigator)(0.4% Pyrethrin from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (2.0%) PYR (0.4%)
30604	Domestic	Auro Pro Solutions, Inc	Zone Guard, Pro Flying Insect Killer-D 1.80%	Pressurized Product	PBU (10%) PYR (1.8%)
30753	Domestic	Kuus Inc.	Knock Down Professional Total Release Fumigator (Fogger)	Pressurized Product	PBU (2.0%) PYR (0.4%)
30774	Domestic	Auro Pro Solutions, Inc.	Zone Guard, Domestic Pro Flying Insect Killer 1.8%	Pressurized Product	PBU (10%) PYR (1.8%)
31161	Domestic	Kuus Inc.	Knock Down Pot-It Plant & Garden Total Release Fumigator (or Fogger) (0.4% Pyrethrins from Chrysanthemum Flower)	Pressurized Product	PBU (2.0%) PYR (0.4%)
31412	Domestic	Kuus Inc.	Knock Down Greenhouse vegetable Insect Killer (0.02% Pyrethrin from Chrysanthemum Flower Pyrethrum)	Solution	PBU (0.20%) PYR (0.02%)
31599	Domestic	Novella Brands Inc.	Kombat Lice Killer for the Home	Pressurized Product	PBU (1.5%) PYR (0.3%)
32676	Domestic	Acuity Holdings Inc.	Konk Complete Release Fogger	Pressurized Product	PBU (2.0%) PYR (0.4%)
33698	Domestic	PLZ Corp.	K-G Total Release Fogger-WB	Pressurized Product	PBU (2.0%) PYR (0.4%)
33707	Domestic	Can-Vet Animal Health Supplies Ltd.	Bugwacker III Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
33939	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Total Release Fogger II	Pressurized Product	PBU (2.0%) PYR (0.4%)
34212	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Formula 420 Hydroponic Fogger	Pressurized Product	PBU (2.0%) PYR (0.4%)
34692	Domestic	Kuss Inc.	Knockdown Total Release Fumigator-Water Based	Pressurized Product	PBU (2.0%) PYR (0.4%)

¹As of 1 January 2023, excluding discontinued products or products with a submission for discontinuation

²PBU – piperonyl butoxide;

³PYR – pyrethrins.

Table 3 Products containing piperonyl butoxide requiring label amendments as a result of re-evaluation (24-month implementation timeline)¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
17400	Domestic	Wellmark International	Vet-Kem Flea & Tick Shampoo for Dogs and Cats	Solution	PBU (0.50%) PYR (0.05%)
19209	Domestic	Wellmark International	Zodiac Flea & Tick Shampoo	Solution	PBU (0.50%) PYR (0.05%)
19981	Domestic	PLZ Corp.	K-G Flea & Tick Shampoo for Dogs and Cats II	Pressurized Product	PBU (0.085%) PYR (0.042%) MGK ⁶ (0.42%)
20034	Domestic	McLaughlin Gormley King Company	Pump Insecticide Spray IV	Solution	PBU (0.194%) PYR (0.100%) MGK (0.322%)
20418	Domestic	McLaughlin Gormley King Company	Flea & Tick Pet Shampoo for Dogs and Cats	Solution	PBU (0.086%) PYR (0.045%) MGK (0.140%)
21078	Domestic	PLZ Corp.	K-G Flea & Tick Quick Breaking Insecticide Foam for Dogs & Cats V	Pressurized Product	PBU (0.2%) PYR (0.1%) MGK (0.36%)
21206	Domestic	Wellmark International	Vet-Kem Ovitrol Plus for Dogs & Cats (with Precor)	Solution	PBU (0.37%) PYR (0.20%) MPR ⁷ (0.27%) MGK (0.62%)
21744	Domestic	Wellmark International	Zodiac Flea & Tick Spray for Dogs & Cats	Solution	PBU (0.37%) PYR (0.20%) MPR (0.27%) MGK (0.62%)
21889	Domestic	PLZ Corp.	K-G Flea & Tick Spray for Dogs & Cats IX	Pressurized Product	PBU (0.2%) PYR (0.1%) MGK (0.336%)
22678	Domestic	Wellmark International	Vet-Kem Ovitrol Mousse	Pressurized Product	PBU (5.0%) PYR (0.4%) MPR (0.5%)
22808	Domestic	PLZ Corp.	Spray-Pak Garden & Patio Fogger	Pressurized Product	PBU (1.0%) PYR (0.2%)
22808.01	Domestic	Kuus Inc.	Mosquito Shield backyard Bug Control Outdoor Fogger	Pressurized Product	PBU (1.0%) PYR (0.2%)
22808.03	Domestic	Canadian Tire Corp. Ltd.	Muskol Patio & Deck Fogger	Pressurized Product	PBU (1.0%) PYR (0.2%)
22916	Domestic	Wellmark International	Zodiac Mousse	Pressurized Product	PBU (5.0%) PYR (0.4%) MPR (0.5%)
23013	Domestic	Rolf C. Hagen Inc.	Sentry Flea Killer & Mosquito Repellent Spray for Dogs	Solution	PBU (0.150%) PYR (0.075%) PFL ⁸ (0.052%) MGK (0.250%)
23067	Domestic	PLZ Corp.	K-G Flea & Tick Shampoo for Dogs & Cats III	Pressurized Product	PBU (2.4%) PYR (0.3%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
23073	Domestic	PLZ Corp.	K-G Flea & Tick Quick Breaking Insecticide Foam for Dogs & Cats VIII	Pressurized Product	PBU (2.4%) PYR (0.3%)
23316	Domestic	Bio-Derm Laboratories Inc.	Bio-Groom Ear Mite Treatment	Solution	PBU (1.20%) PYR (0.15%)
23593	Domestic	Neogen Corporation	Ecto-Soothe Plus Emollient Oatmeal Pesticidal Shampoo	Emulsifiable Concentrate	PBU (1.50%) PYR (0.15%) MGK (0.5%)
23692	Domestic	Wellmark International	Ovex Pump Spray for Dogs and Cats	Solution	PBU (0.37%) PYR (0.20%) MPR (0.10%) MGK (0.61%)
24375	Domestic	Vétoquinol N.-A. Inc.	Veto Equin Water Base Insecticide for Horses	Emulsifiable Concentrate	PBU (1.10%) PYR (0.11%)
24427	Domestic	W.F. Young Inc.	Absorbine Ultrashield EX Insecticide & Repellent	Solution	PBU (1.00%) PYR (0.10%) PFL (0.5%)
25902	Domestic	Rolf C. Hagen Inc.	Sergeant's Skip-Flea & Tick Shampoo for Dogs	Solution	PBU (0.50%) PYR (0.05%)
25903	Domestic	Rolf C. Hagen Inc.	Sergeant's Skip-Flea & Tick Shampoo for Cats	Solution	PBU (0.50%) PYR (0.05%)
26133	Domestic	Hartz Canada Inc.	Hartz Ultraguard Rid Flea & Tick Shampoo for Dogs	Solution	PBU (0.086%) PYR (0.045%) MGK (0.142%)
26413	Domestic	Wellmark International	Zodiac Double Action Flea & Tick Shampoo for Dogs and Cats	Solution	PBU (1.50%) PYR (0.15%) MPR (0.10%)
26608	Domestic	Wellmark International	Vet-Kem Ovitrol Plus Flea & Tick Shampoo	Solution	PBU (1.50%) PYR (0.15%) MPR (0.10%)
27187	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Wasp & Hornet Insecticide	Pressurized Product	PBU (2.4%) PYR (0.3%)
28382	Domestic	Wellmark International	Zodiac Dual Action Flea & Tick Spray for Cats & Kittens	Solution	PBU (0.37%) PYR (0.20%) MPR (0.27%) MGK (0.62%)
28415	Domestic	Can-Vet Animal Health Supplies Ltd.	Can-Vet Mustang Fly Shield	Solution	PBU (0.50%) PYR (0.05%) PFL (0.1%)
28493	Domestic	Can-Vet Animal Health Supplies Ltd.	Can-Vet Kentucky Fly Shield II for Horses	Solution	PBU (1.0%) PYR (0.1%)
28529	Domestic	Can-Vet Animal Health Supplies Ltd.	Extenda Shield	Solution	PBU (1.00%) PYR (0.10%) PFL (0.5%)
28702	Domestic	Can-Vet Animal Health Supplies Ltd.	Can-Vet Power Shield	Solution	PBU (1.00%) PYR (0.10%) PFL (0.5%)
29184	Domestic	Farnam Companies Inc.	Repel-XP	Solution	PBU (0.966%) PYR (0.410%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
29935	Domestic	W.F. Young Inc.	Absorbine Ultrashield Ex Insecticide & Repellent Continuous Spray	Pressurized Product	PBU (1.00%) PYR (0.10%) PFL (0.5%)
29957	Domestic	Pyranha Inc.	Pony XP	Solution	PBU (0.50%) PYR (0.05%) PFL (0.104%)
29988	Domestic	W.F. Young Inc.	Absorbine® Ultrashield® Ex Easy Swipe	Solution	PBU (1.0%) PYR (0.1%) PFL (0.5%)
30637	Domestic	Kuus Inc.	Knock Down Flea & Tick Killer for Dogs & Cat	Solution	PBU (0.194%) PYR (0.100%) MGK (0.336%)
30724	Domestic	Kuus Inc.	Knock Down Hornet & Wasp Killer II (0.05% Pyrethrin from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (0.1%) PYR (0.05%) MGK (0.167%) BAY ⁹ (0.5%)
30837	Domestic	Kuus Inc.	Knock Down Crawling Insect Killer II (0.05% Pyrethrin from Chrysanthemum Flower Pyrethrum)	Pressurized Product	PBU (0.1%) PYR (0.05%) MGK (0.167%) BAY (0.5%)
31144	Domestic	Esprea Animal Products, Inc.	Flea and Tick Dog and Cat Shampoo	Solution	PBU (0.086%) PYR (0.045%) MGK (0.150%)
31149	Domestic	Esprea Animal Products, Inc.	Flea and Tick Pet Shampoo for Dogs and Cats	Solution	PBU (0.086%) PYR (0.045%) MGK (0.150%)
31466	Domestic	Business Helpers' Depot Inc.	Klenze	Pressurized Product	PBU (0.081%) PYR (0.042%) MGK (0.141%)
31476	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Maximum Strength, Premium Quality #1, "No Ticks & Fleas on Us" Dog & cat Tick and Flea Killer Shampoo with Coconut Oil	Pressurized Product	PBU (2.4%) PYR (0.3%)
31477	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Maximum Strength Premium Quality #1 "No Ticks & Fleas on U"	Pressurized Product	PBU (2.485%) PYR (0.3%)
31605	Domestic	Business Helpers' Depot Inc.	Sure Spray Flea & Tick Spray for Dogs & Cats	Pressurized Product	PBU (1.0%) PYR (0.1%)
31616	Domestic	Rolf C. Hagen Inc.	Sentry Flea & Tick Shampoo for Dogs	Solution	PBU (0.086%) PYR (0.045%) MGK (0.150%)
31617	Domestic	Rolf C. Hagen Inc.	Sentry Flea & Tick Shampoo for Cats	Solution	PBU (0.086%) PYR (0.045%) MGK (0.140%)
31630	Domestic	Business Helpers' Depot Inc.	Gotcha Hornet & Wasp Killer	Pressurized Product	PBU (1.0%) PYR (0.1%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
31939	Domestic	Neogen Corporation	Prozap Pet Guard	Solution	PBU (0.194%) PYR (0.100%) MGK (0.336%)
31940	Domestic	Neogen Corporation	Prozap Pet Guard Flea & Tick Shampoo	Solution	PBU (0.086%) PYR (0.045%) MGK (0.150%)
32480	Domestic	Business Helpers' Depot Inc.	Fight Back Hornet & Wasp Killer double Shot Jet & Fogger Sprays	Pressurized Product	PBU (1.0%) PYR (0.2%)
32481	Domestic	Business Helpers' Depot Inc.	Fight Back Patio & Yard Fogger	Pressurized Product	PBU (1.0%) PYR (0.2%)
32697	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Tick & Flea Killer Spray for Cats & Dogs	Pressurized Product	PBU (1.0%) PYR (0.1%)
32705	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Yard & Patio Fogging Insect Killer	Pressurized Product	PBU (1.0%) PYR (0.2%)
33034	Domestic	Scotts Canada Ltd.	Ortho® Mosquito B Gon Max Flying Insect Killer Area Spray	Pressurized Product	PBU (1.0%) PYR (0.2%)
33674	Domestic	Can-Vet Animal Health Supplies Ltd	Tick End for Horses	Solution	PBU (0.77%) PYR (0.335%)
33682	Domestic	Can-Vet Animal Health Supplies Ltd.	Power Shield Fly and Tick Spray for Horses	Solution	PBU (0.77%) PYR (0.33%) PFL (0.5%)
33683	Domestic	Can-Vet Animal Health Supplies Ltd.	Extenda Shield Fly and Tick Spray for Horses	Solution	PBU (0.77%) PYR (0.33%) PFL (0.5%)
33749	Domestic	Scotts Canada Ltd.	Ortho® Mosquito B Gon Max Flying Insect Killer Area Spray I	Pressurized Product	PBU (1.0%) PYR (0.2%)
33992	Domestic	Eco-Cop Inc.	Klenze 15 Insecticide for Horses	Solution	PBU (1.00%) PYR (0.10%) PFL (0.5%)
34523	Domestic	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Premium Insect Killer for Use on Horses	Solution	PBU (1.00%) PYR (0.10%) PFL (0.5%)
6109	Commercial	Gardex Chemicals Ltd.	Gardex Industrial Insecticide 50-7	Solution	PBU (1.27%) PYR (0.13%)
9371	Commercial	Gardex Chemicals Ltd.	Gardex Pyrethrin Spray 5-25	Emulsifiable Concentrate	PBU (2.0%) PYR (0.5%)
11540	Commercial	Premier Tech Brighton Ltd.	Pro Professional 3610 Ultra-Low Volume Insecticide	Solution	PBU (4.8%) PYR (3.0%) MGK (10.0%)
11684	Commercial	Gardex Chemicals Ltd.	Gardex Pyrethrin Emulsifiable Concentrate 1%	Emulsifiable Concentrate	PBU (8.0%) PYR (1.0%)
11855	Commercial	Gardex Chemicals Ltd.	Gardex Industrial Micro Spray Concentrate	Emulsifiable Concentrate	PBU (6.0%) PYR (3.0%) MGK (10.0%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
13378	Commercial	McLaughlin Gormley King Company	Pyroicide Fogging Formula 7067 for ULV Mosquito Adulticiding	Solution	PBU (24.0%) PYR (5.0%)
13779	Commercial	McLaughlin Gormley King Company	Pyroicide 300	Solution	PBU (5.76%) PYR (3.0%) MGK (9.57%)
14399	Commercial	Poulin's Pest Control	Poulin's C Plus C Insecticide	Solution	PBU (1.53%) PYR (0.16%)
15162	Commercial	McLaughlin Gormley King Company	Multi-Purpose Pyroicide Commercial Insecticide	Emulsifiable Concentrate	PBU (10.0%) PYR (1.0%)
15255	Commercial	Bayer CropScience Inc.	Drione Insecticide Dust	Dust	PBU (9.7%) PYR (1.0%) SIL ¹⁵ (40.0%)
15330	Commercial	Premier Tech Brighton Ltd.	Pro Professional 110 Ultra Low Volume Insecticide	Solution	PBU (8.0%) PYR (1.0%)
18201	Commercial	Gardex Chemicals Ltd.	Gardex Bugkill Pressurized Spray	Pressurized Product	PBU (4.0%) PYR (0.5%)
18840	Commercial	PLZ Corp.	K-G Hi-Pressure Fumigator	Pressurized Product	PBU (2.0%) PYR (0.4%)
20094	Commercial	PLZ Corp.	K-G Milk Room & Cattle Spray II	Pressurized Product	PBU (5.0%) PYR (0.5%)
20098	Commercial	PLZ Corp.	K-G Milk Room & Cattle Spray I	Pressurized Product	PBU (4.8%) PYR (0.5%)
20384	Commercial	McLaughlin Gormley King Company	Flying & Crawling Insect Killer I	Pressurized Product	PBU (3.84%) PYR (0.5%)
20385	Commercial	McLaughlin Gormley King Company	Flying & Crawling Insect Killer II	Pressurized Product	PBU (4.0%) PYR (0.5%)
20424	Commercial	Vétoquinol N.-A. Inc.	Disvap IV Insecticide Solution	Solution	PBU (1.0%) PYR (0.10%)
20463	Commercial	Acuity Holdings, Inc.	Konk 409 Flying Insect Killer	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)
20499	Commercial	Acuity Holdings, Inc.	Konk 408 Flying Insect Killer	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)
21004	Commercial	McLaughlin Gormley King Company	Pyroicide Concentrate 7369	Solution	PBU (28.8%) PYR (3.0%)
22563	Commercial	Can-Vet Animal Health Supplies Ltd.	Bugwacker fogging Solution Insecticide	Solution	PBU (1.5%) PYR (0.15%)
22661	Commercial	PLZ Corp.	Terand Wasp & Hornet Killer	Pressurized Product	PBU (0.1%) PYR (0.05%) MGK (0.166%) BAY (0.5%)
22846	Commercial	PLZ Corp.	K-G Flying Insect Killer X	Pressurized Product	PBU (5.0%) PYR (0.5%)
23433	Commercial	Can-Vet Animal Health Supplies Ltd.	Bugwacker Tall Insecticide	Pressurized Product	PBU (4.0%) PYR (0.5%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
23884	Commercial	PLZ Corp.	Spray-Pak Industrial & Dairy Insecticide Pressurized Spray	Pressurized Product	PBU (3.84%) PYR (0.5%)
24082	Commercial	PLZ Corp.	K-G Insecticide III	Pressurized Product	PBU (8.0%) BAY (2.0%)
24159	Commercial	Can-Vet Animal Health Supplies Ltd.	Can Vet Barn & Dairy Fly Shield	Solution	PBU (1.0%) PYR (0.10%)
24244	Commercial	PLZ Corp.	K-G Milk Room & Cattle Spray III	Pressurized Product	PBU (2.4%) PYR (0.3%)
24249	Commercial	PLZ Corp.	K-G Flying Insect Killer XII	Pressurized Product	PBU (2.4%) PYR (0.3%)
24251	Commercial	PLZ Corp.	K-G Flying Insect Killer XI	Pressurized Product	PBU (5.0%) PYR (0.5%)
24254	Commercial	PLZ Corp.	K-G Flying Insect Killer XIII	Pressurized Product	PBU (2.4%) PYR (0.3%)
24435	Commercial	Acuity Holdings Inc.	Konker Commercial & Farm Insect Killer	Pressurized Product	PBU (2.4%) PYR (0.3%)
24436	Commercial	Acuity Holdings Inc.	Konk Too Farm & Livestock Insect Killer	Pressurized Product	PBU (4.0%) PYR (0.5%)
24437	Commercial	Acuity Holdings Inc.	Konk Pro Commercial & Farm Insect Killer	Pressurized Product	PBU (5.0%) PYR (0.5%)
24711	Commercial	PLZ Corp.	K-G Insecticide II	Pressurized Product	PBU (2.0%) PYR (1.0%) MGK (3.33%)
24729	Commercial	McLaughlin Gormley King Company	Pyrocide Pressurized Multi-Purpose Spray 7416	Pressurized Product	PBU (4.8%) PYR (0.5%)
24875	Commercial	Acuity Holdings, Inc.	Konk 407 Insecticide Spray with Pyrethrin	Pressurized Product	PBU (2.0%) PYR (1.0%) MGK (3.33%)
24927	Commercial	McLaughlin Gormley King Company	Evergreen Emulsifiable 60-6	Emulsifiable Concentrate	PBU (60.0%) PYR (6.0%)
25364	Commercial	Poulin's Pest Control	Poulin's Liquid Insecticide	Solution	PBU (4.10%) PYR (0.43%)
25936	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom "Mini" Fumigator Total Release	Pressurized Product	PBU (2.0%) PYR (0.4%)
26261	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Hi-Pressure Fumigator	Pressurized Product	PBU (2.0%) PYR (0.4%)
26460	Commercial	Neogen Corporation	Turbocide Gold with Pyrocide	Solution	PBU (30.97%) PYR (4.03%)
27220	Commercial	BASF Canada Inc.	Prescription Treatment Brand P.I. Contact Insecticide	Pressurized Product	PBU (4.0%) PYR (0.5%)
27678	Commercial	Acuity Holdings Inc.	Konk 403 Total Release Fumigator	Pressurized Product	PBU (2.0%) PYR (0.4%)
28244	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Professional 3% Pyrethrin Knockdown Farm Buildings Insect Killer	Emulsifiable Concentrate	PBU (28.8%) PYR (3.0%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
28248	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom “Commercial Grade Knockdown Concentrate” Mosquito Adulticiding for ULV Fogging Systems	Solution	PBU (24.0%) PYR (5.0%)
28371	Commercial	Kuus Inc.	Knock Down X-Max Farm and Livestock Insect Killer (0.6 Pyrethrin from Chrysanthemum flower)	Pressurized Product	PBU (4.0%) PYR (0.6%)
28402	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom 6% Pyrethrin Knockdown Insect Killer	Emulsifiable Concentrate	PBU (60.0%) PYR (6.0%)
28462	Commercial	Kuus Inc.	Knock Down Max Farm and Livestock Insect Killer (0.3 Pyrethrin from Chrysanthemum flower)	Pressurized Product	PBU (2.4%) PYR (0.3%)
28584	Commercial	Kuus Inc.	Knock Down Max Flying Insect Killer (1.0 Pyrethrin from Chrysanthemum)	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)
28792	Commercial	PLZ Corp.	K-G Flying Insect Killer Metered II (0.975% PYR- Commercial)	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)
29042	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Maximum Strength Livestock & Buildings Insect Eliminator	Pressurized Product	PBU (5.0%) PYR (0.5%)
29044	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Extra Strength Farm & Livestock Insect Eliminator	Pressurized Product	PBU (4.0%) PYR (0.6%)
29687	Commercial	Kuus Inc.	Knock Down Max Bed Bug & Flea Killer	Pressurized Product	PBU (4.0%) PYR (0.6%)
29728	Commercial	Kuus Inc.	Knockdown Total Release Fumigator-C	Pressurized Product	PBU (2.0%) PYR (0.4%)
30031	Commercial	Kuus Inc.	Knock Down Professional KD241P Food Processing Plants & Institutional Insect Killer (0.6 Pyrethrin from Chrysanthemum flower)	Pressurized Product	PBU (4.0%) PYR (0.6%)
30421	Commercial	UR-Can Inc.	Onguard PC5	Pressurized Product	PBU (5.0%) PYR (0.5%)
30749	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom 4 Zero Nine C	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)
30752	Commercial	Kuus Inc.	Knock Down Farm and Livestock Insect Killer (0.5% pyrethrins from chrysanthemum flower pyrethrum)	Pressurized Product	PBU (4.8%) PYR (0.5%)
30766	Commercial	Aura Pro Solutions, Inc.	Zone Guard, Commercial Flying Insect Killer 1-C	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK (3.21%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
30805	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Professional Quality Insecticide 1% Pyrethrin Spray	Pressurized Product	PBU (2.0%) PYR (1.0%) MGK (3.33%)
30806	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Protech Premier 3610 Insect Killer	Solution	PBU (5.76%) PYR (3.0%) MGK (10.0%)
31036	Commercial	UR-Can Inc.	On Guard PC-5/2	Solution	PBU (2.0%) PYR (0.5%)
31059	Commercial	Kuus Inc.	Knock Down Pro-154 RTU Farm & Barn Flying Insect Killer	Solution	PBU (1.0%) PYR (0.10%)
31060	Commercial	Business Helpers' Depot Inc.	Surespray Pyrethrum Multi-Purpose Insect Spray	Emulsifiable Concentrate	PBU (60.0%) PYR (6.0%)
31111	Commercial	Acuity Holdings Inc.	Konk Commercial Bed Bug Killer	Pressurized Product	PBU (5.0%) PYR (0.5%)
31121	Commercial	Business Helpers' Depot Inc.	Surespray Pyrethrin Insect Spray	Pressurized Product	PBU (5.0%) PYR (0.5%)
31338	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Premium Quality #1 No Flies on Us Beef & Dairy Cattle-Farm, Industrial & Commercial Building Insect Killer	Pressurized Product	PBU (5.0%) PYR (0.5%)
31943	Commercial	Neogen Corporation	Prozap Annihilator-XP	Emulsifiable Concentrate	PBU (60.0%) PYR (6.0%)
31960	Commercial	Neogen Corporation	Prozap LD 44Z Dairy Bomb Aerosol Insecticide	Pressurized Product	PBU (4.8%) PYR (0.5%)
32339	Commercial	Kuus Inc.	Knock Down Pro 155 Farm, Barn & Livestock Insect Killer	Solution	PBU (1.0%) PYR (0.10%)
32865	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Lice Killer for Poultry Plus+	Pressurized Product	PBU (4.8%) PYR (0.5%)
33946	Commercial	Eco-Cop Inc.	Klenze 7 Insecticide	Solution	PBU (5.0%) PYR (0.5%)
34005	Commercial	Vétoquinol N.-A. Inc.	Disvap Gold	Pressurized Product	PBU (5.0%) PYR (0.5%)
34029	Commercial	Eco-Cop Inc.	Klenze 5 Insecticide	Solution	PBU (2.0%) PYR (0.5%)
34144	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Protech Commercial Insect Killer	Solution	PBU (2.0%) PYR (0.5%)
34524	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom Lice Killer for Livestock Plus (+)	Solution	PBU (0.5%) PYR (5.0%)

¹As of 1 January 2023, excluding discontinued products or products with a submission for discontinuation

²PBU – piperonyl butoxide;

³PYR – pyrethrins;

⁴BPG – butoxypolypropylene glycol;

⁵MGD – di-n-propyl isocinchomeronate;

⁶MGK – N-octyl bicycloheptene dicarboximide;

⁷MPR – s-methoprene;

⁸PFL – permethrin;

⁹BAY – propoxur.**Table 4 Products containing piperonyl butoxide cancelled as a result of re-evaluation (36-month phase-out period)**

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
19829	Domestic	Woodstream Canada Corporation	Safer's Tomato & Vegetable Insecticide RTU	Solution	PBU ² (0.20%) PYR ³ (0.02%)
17591	Commercial	Acuity Holdings, Inc.	KO 14 Flying Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
17592	Commercial	Acuity Holdings, Inc.	Konk 418 Flying Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
18348	Commercial	Gardex Chemicals Ltd.	Guard Mist Insecticide	Pressurized Product	PBU 10% PYR 1.8%
19685	Commercial	Gardex Chemicals Ltd.	Guard Mist 1 Pyrethrins Insecticide	Pressurized Product	PBU 10% PYR 1.8%
20390	Commercial	McLaughlin Gormley King Company	Flying Insect Killer II (Metered Pressurized Spray)	Pressurized Product	PBU (9.6%) PYR (1.8%)
23029	Commercial	Vétoquinol N.-A. Inc.	Disvap V Barn Insecticide	Emulsifiable Concentrate	PBU (1.0%) PYR (0.1%) PFL ⁴ (0.1%)
24151	Commercial	Acuity Holdings, Inc.	Konk 416 Flying Insect Killer	Pressurized Product	PBU (10%) PYR (1.8%)
28373	Commercial	Kuus Inc.	Knock Down X-Max Flying Insect Killer (1.8 Pyrethrin from Chrysanthemum flower Pyrethrum)	Pressurized Product	PBU (10%) PYR (1.8%)
28691	Commercial	PLZ Corp.	Flying Insect Killer Metered I (1.8% PYR-commercial)	Pressurized Product	PBU (10%) PYR (1.8%)
30605	Commercial	Aura Pro Solutions, Inc.	Zone Guard, Pro Flying Insect Killer 1.80%	Pressurized Product	PBU (10%) PYR (1.8%)
30616	Commercial	FMC Corporation	Purge III Insecticide	Pressurized Product	PBU (1.95%) PYR (0.975%) MGK ⁵ (3.050%)
30772	Commercial	Aura Pro Solutions, Inc.	Zone Guard, Commercial Pro Flying Insect Killer 1.80%	Pressurized Product	PBU (10%) PYR (1.8%)
31056	Commercial	753146 Alberta Ltd. O/A Ultrasol Industries	Doktor Doom BVT 4 Eighteen Flying Insect Killer – Commercial	Pressurized Product	PBU (10%) PYR (1.8%)
19985	Restricted	Wellmark International	Prentox Nusyn-Noxfish Fish Toxicant	Emulsifiable Concentrate	PBU (2.5%) ROT ⁶ (2.5%)

¹As of 1 January 2023, excluding discontinued products or products with a submission for discontinuation.²PBU – piperonyl butoxide;³PYR – pyrethrins;⁴PFL – permethrin;⁵MGK – N-octyl bicycloheptene dicarboximide;⁶ROT – rotenone.

Table 5 Products containing piperonyl butoxide that do not require label amendments as a result of re-evaluation

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
27451	Technical Grade Active Ingredient	Endura S.P.A.	Endura Piperonyl Butoxide Technical Grade	Liquid	PBU ² (96.57%)
30351	Technical Grade Active Ingredient	McLaughlin Gormley King Company	MGK Technical Piperonyl Butoxide	Liquid	PBU (96.57%)
31822	Technical Grade Active Ingredient	Wellmark International D.B.A.	Wellmark Piperonyl Butoxide Technical	Liquid	PBU (96.57%)
18528	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide 30-3 S.E. Insecticide Concentrate	Emulsifiable Concentrate	PBU (30.0%) PYR ³ (3.0%)
19615	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Intermediate 5192	Solution	PBU (17.28%) PYR (9.00%) MGK ⁴ (28.72%)
19616	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Intermediate 75-OF	Solution	PBU (72.43%) PYR (7.50%)
19632	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Intermediate 54	Solution	PBU (38.63%) PYR (5.00%)
19641	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Intermediate 57	Solution	PBU (48.29%) PYR (10.00%)
19833	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Concentrate 7352	Emulsifiable Concentrate	PBU (28.8%) PYR (3.00%)
19889	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide Booster Concentrate K	Solution	PBU (48.00%) PYR (5.00%)
21314	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide (5.0-0.5) E.C. Insecticide	Emulsifiable Concentrate	PBU (5.00%) PYR (0.50%)
22165	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide W-B 20-4 Insecticide	Solution	PBU (20.00%) PYR (4.00%)
22419	Manufacturing Concentrate	McLaughlin Gormley King Company	Pyrocide & Dri-Die Dust Base Insecticide	Dust	PBU (20.00%) PYR (2.00%) SIL ⁵ (40.0%)

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (g/L)
23906	Manufacturing Concentrate	Wellmark International D.B.A.	Pyrocide Intermediate 7045	Solution	PBU (1.18%) PYR (0.58%) MGK (1.97%) BAY ⁶ (5.89%)
24382	Manufacturing Concentrate	Wellmark International D.B.A.	Pyrocide Intermediate 7415	Emulsifiable Concentrate	PBU (48.00%) PYR (5.00%)
30020	Manufacturing Concentrate	Wellmark International D.B.A.	Pyrocide Concentrate 7440	Emulsifiable Concentrate	PBU (28.80%) PYR (3.00%)

¹As of 1 January 2023, excluding discontinued products or products with a submission for discontinuation.

²PBU – piperonyl butoxide;

³PYR – pyrethrins;

⁴MGK – n-octyl bicycloheptene dicarboximide;

⁵SIL – silica aerogel;

⁶BAY – propoxur.

Appendix II List of commenters to PRVD2020-09

List of commenters' affiliations for comments submitted in response to PRVD2020-09.

Category	Commenter
Registrant	PLZ Corp.
	KUUS Inc.
	Maheu & Maheu Inc.
	McLaughlin Gormley King Co., Inc. (MGK)
	Premier Tech Ltd.
	Premier Tech Brighton Ltd.
	SC Johnson
	Scotts Canada
Stakeholder	Canadian Pest Management Association (CPMA)
	Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec (MAPAQ)
Task force	Piperonyl Butoxide Task Force II (PBTFII)
Trade association	Canadian Consumer Specialty Products Association (CCSPA)

Appendix III Comments and responses

Health Canada received 18 written comments during the public consultation for the piperonyl butoxide 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 the health risk assessment

1.1 Comments related to toxicology

1.1.1 Comments related to the oral reference doses

1.1.1.1 Comment

One registrant suggested that the no observed adverse effect level (NOAEL) of 2.9 mg/kg bw/day from the 12-month dog toxicity study¹¹ selected by Health Canada for the derivation of the acceptable daily intake (ADI) for piperonyl butoxide is not appropriate, and that a NOAEL of 15.5 mg/kg bw/day in male dogs (the mid-dose level in the 12-month dog study) should be considered as the point of departure for derivation of the ADI and "other long-term reference doses" for the reasons outlined below.

The registrant stated that any apparent decreases in body weight at the mid-dose level of 15.5/16.3 mg/kg bw/day in males/females in the 12-month dog study, which was identified by Health Canada as the lowest observed adverse effect level (LOAEL), were incidental and unrelated to treatment with piperonyl butoxide. The registrant noted that dog studies have an inherently low statistical power for discerning biological effects, that the differences in the female values at the end of the study were marginal, and that higher body weights in the male control group (which exceeded the historical control range) confounded the interpretation of the results.

The registrant contended that there were no treatment-related effects on liver weight. They noted that the changes in relative liver weights in the mid-dose groups were not statistically significant and seemed to be caused by one dog each in the male and female control groups with low relative liver weights. Further, when liver weights relative to brain weights are compared, the difference between group means is lower, and the liver histopathology and clinical chemistry measurements pertaining to liver function did not show relevant or statistically significant changes. Although Health Canada included increased serum alkaline phosphatase as an effect at the LOAEL, the registrant noted that the differences between the mid-dose and control groups were not statistically significant and reflected the higher pre-test values in the mid-dose group and were thus unlikely to be treatment related.

¹¹ 1993. *Evaluation of piperonyl butoxide in a one-year chronic dietary toxicity study in dogs. DACO 4.4.5. (PRVD2020-09; PMRA# 2132143).*

The testis findings considered by Health Canada to be relevant for the derivation of the LOAEL were singular findings in one dog each at the mid- and high-dose levels, and there was no increase in the incidence or severity of testicular atrophy with progression from the mid- to the high-dose level. The registrant asserted that these effects were incidental and unrelated to treatment.

Health Canada response:

Health Canada conducted a critical review of the comments received concerning the 12-month dietary toxicity study in dogs. The individual body weight and body weight gain data from this study were examined in detail along with historical control data that were newly submitted by the registrant. While it was apparent that there was variability in the body weights of control animals during both the pre-test and dosing periods, the historical control data did not aid in the interpretation of the results. In the study conducted with piperonyl butoxide, the majority of dogs from all of the groups, including the controls, weighed more than the historical control ranges provided. In one of the historical control studies, animals displayed higher body weights at the pre-test and terminal sacrifice time-points but actually gained the least amount of weight out of all of the historical control studies provided. It was also unclear as to how the animals were allocated to the different test groups in the 12-month piperonyl butoxide study since the high-dose female group had a mean body weight that was 6.6% lower than the control females at the pre-test time-point. Given the wide range of body weight values noted at pre-test, statistical significance cannot be solely relied upon to determine the toxicological significance of the alterations noted in body weight. Health Canada considers a decrease in body weight of at least 5% to be toxicologically significant and adverse, and despite the variability, the magnitude of the decreases noted in the body weight of the animals at 15.5 mg/kg bw/day relative to control animals were clearly greater than 5% at 13 weeks and at various points throughout the study, including at study termination. Therefore, these alterations were still considered sufficient to form the basis of the LOAEL for this 12-month toxicity study.

Throughout the piperonyl butoxide database, the liver was a consistent target organ of toxicity in short- and long-term repeat-dose oral toxicity studies in mice, rats and dogs. In the 12-month dog study, the effects on liver weight noted at the mid-dose level progressed in magnitude in both sexes at the high-dose level. Additional liver effects noted at the high-dose level included an increase in alkaline phosphatase activity and diffuse hepatocellular hypertrophy in both sexes and a decrease in cholesterol in females, indicating a progression in the liver effects. Therefore, the increased liver weights at the mid-dose level cannot be dismissed and will be retained as treatment-related effects at the LOAEL in the 12-month dog study. It should be noted that the registrant's comment regarding the effect level reported by Health Canada for alkaline phosphatase is inaccurate, as PRVD2020-09 only reported a treatment-related effect on alkaline phosphatase at the high-dose level in the 12-month dog study.

Upon re-examination of the histopathological findings in the testes, Health Canada remains of the opinion that the bilateral atrophy of the testes noted in one male dog from each of the mid- and high-dose groups may be treatment-related, but notes that it is possible that this finding may not be toxicologically significant as the incidence did not increase in frequency or severity when the dose progressed from the mid- to the high-dose level. Therefore, this finding will be re-classified as equivocal and the toxicology study summary for the 12-month dog study presented in PRVD2020-09 will be updated to reflect this change (Table 1).

Table 1 Updated toxicology study summary for the 12-month dietary toxicity study in dogs exposed to piperonyl butoxide

Study Type/Animal/ PMRA#	Study results
12-month Dietary Study Beagle dogs PMRA# 2132143	NOAEL = 2.9/2.7 mg/kg bw/day ≥15.5/16.3 mg/kg bw/day: ↓ bw and bwg, ↑ relative liver wt (♂/♀); ↓ fc, mild atrophy of the testis (equivocal) (♂); ↑ absolute liver wt (♀). 52.8/71.0 mg/kg bw/day: ↑ ALP, diffuse hepatocellular hypertrophy (♂/♀); ↓ RBC, ↑ absolute liver wt, cyst in the gall bladder (♂); ↓ cholesterol, ↑ thyroid/parathyroid wt (♀).

1.1.1.2 Comment

One registrant stated that a benchmark dose analysis using a 10% response level for the body weight effects in dogs in the 12-month dietary study should be conducted to provide a more accurate estimate of the point of departure for the assessment of intermediate- and long-term non-dietary oral ingestion.

Health Canada response:

The 12-month dietary toxicity study in the dog was selected by Health Canada for the assessment of intermediate- and long-term non-dietary oral ingestion risk. The NOAEL of 2.9 mg/kg bw/day was selected for each of these exposure scenarios based on decreased body weight and body weight gain observed by week 13 in dogs treated with 15.5 mg/kg bw/day piperonyl butoxide for the intermediate-term oral scenario, and decreased body weight, decreased body weight gain and increased liver weight noted at study termination in dogs treated with 15.5 mg/kg bw/day piperonyl butoxide for the long-term scenario. Health Canada considers decreases in body weight of 5% or more, relative to controls, to be biologically adverse. In this 12-month toxicity study, given that the magnitude of the decrease in body weight at 15.5 mg/kg bw/day was greater than 5% at 13 weeks and at study termination, and that a clear NOAEL was established in this study, Health Canada considers that the NOAEL of 2.9 mg/kg bw/day from this study remains an appropriate point of departure for the assessment of intermediate- and long-term non-dietary oral ingestion; therefore, no further refinements were necessary.

1.1.2 Comments related to the dermal reference values

One registrant stated that a dermal risk assessment is not required for piperonyl butoxide given that adverse toxicological effects were not observed at the limit dose of 1000 mg/kg bw/day in a 21-day rabbit dermal toxicity study¹² and the USEPA did not require a dermal risk assessment for this compound. The registrant further indicated that the liver, a target organ, was adequately assessed in the dermal toxicity study, the dermal margins of exposure (MOEs) exceeded the target MOE for all indoor, outdoor and pet postapplication scenarios and risks were found to be

¹² 1992. 21-day repeated dose dermal toxicity study with piperonyl butoxide in rabbits. DACO 4.3.5. (PRVD2020-09; PMRA# 2423238).

acceptable for all life stages. The registrant considered Health Canada's use of the dermal NOAEL of 1000 mg/kg bw/day for the purposes of MOE derivation to be misleading and inappropriate.

Health Canada response

Health Canada uses contemporary risk assessment methodologies that are based on sound science, agency policies and practices, and are recognized globally by our pesticide regulatory partners. Notwithstanding the similarities in approach, it is not uncommon for regulatory bodies to differ with regards to study selection or requirements to refine assessments, or for them to have unique regulatory policies. When repeat-dose dermal toxicity studies demonstrate the absence of systemic toxicity at the limit dose of 1000 mg/kg bw/day, it is standard practice for Health Canada to use this limit dose as a point of departure for dermal risk assessment provided that there is no concern for other endpoints in the toxicology database, such as developmental or reproductive effects, that were not assessed in the dermal toxicity study. In rare circumstances, the selection of a reference value for assessing risks from dermal exposure may not be warranted, but only if minimal to no toxicity is demonstrated at or near the limit dose of testing in the suite of studies that make up a robust toxicology database. However, this is not the case for piperonyl butoxide. Therefore, the dermal NOAEL of 1000 mg/kg bw/day derived from the 21-day rabbit dermal toxicity study will be retained as the point of departure for the assessment of short-, intermediate- and long-term risk from dermal exposure to piperonyl butoxide.

1.1.3 Comments related to the inhalation reference values

One registrant stated that the severity of the clinical signs and microscopic effects observed in the larynx of rats in the critical 90-day inhalation toxicity study selected for all durations of inhalation risk assessment were increased at the highest concentration only where they were associated with inflammatory injury. Since inflammation was not observed at lower concentrations in the critical study, the registrant asserted that the microscopic changes in the larynx noted at lower dose levels are adaptive and non-adverse. Therefore, the registrant stated that the relevance of these effects for human health risk assessment, particularly in the case of intermittent, low-level occupational and consumer inhalation exposure scenarios,¹³ should be reconsidered under USEPA guidelines for Data Derived Extrapolation Factors.

Health Canada response:

As indicated in PRVD2020-09, for the assessment of short-, intermediate- and long-term inhalation risk, the LOAEL of approximately 3.9 mg/kg bw/day (LOAEC = 0.015 mg/L) from the 90-day inhalation toxicity study in rats¹⁴ was selected as the point of departure by Health Canada. This LOAEC was established based on an increase in the incidence and severity of histopathological lesions in the ventral seromucous glands of the larynx and respiratory signs of toxicity in both sexes at the lowest concentration tested.

¹³ Mowat V., Alexander D.J. and Pilling A.M. 2017. *A Comparison of Rodent and Nonrodent Laryngeal and Tracheal Bifurcation Sensitivities in Inhalation Toxicity Studies and Their Relevance for Human Exposure. Toxicologic Pathology, 45(1): 216-222.*

¹⁴ 1994. *United States Environmental Protection Agency Data Evaluation Record, Piperonyl butoxide, review of a subchronic inhalation toxicity study in rats. DACO 12.5.4 (PRVD2020-09; PMRA# 2132115).*

Health Canada re-visited the rat 90-day inhalation toxicity study in the context of the weight of evidence for these findings and still considers the lesions in the ventral seromucous glands and clinical signs at the LOAEC of 0.015 mg/L and above to be treatment-related and adverse based on the following weight of evidence:

- Starting from week one of exposure, both sexes exposed to the lowest concentration of piperonyl butoxide demonstrated respiratory signs of toxicity (dried red nasal discharge and brown material on the facial area) that were not observed in control animals. As the animals were exposed to greater concentrations of piperonyl butoxide, additional effects on the respiratory system were noted in both sexes, including an increased incidence of secretory activity, nasal discharge and dried material on the tail and extremities compared to controls.
- At the lowest concentration tested, microscopic lesions were observed in the ventral seromucosal glands of the laryngeal submucosa, consisting of minimal squamous/squamoid metaplasia/hyperplasia of the pseudostratified ciliated/nonciliated columnar epithelium. These microscopic lesions were concentration-related in incidence and severity, observed in both sexes and in the majority of treated animals, but were rarely observed in untreated controls.
- With exposure to increasing concentrations of piperonyl butoxide, there was progression to additional microscopic changes in the epithelium of ventral the laryngeal seromucosal glands and the ventral laryngeal diverticulum in both sexes of treated animals. Additional findings in the seromucosal glands included an increase in the incidence and severity of granulomatous inflammation/granuloma in females at the mid- and high-concentrations, an increase in the incidences of hyperplasia and hyperkeratosis of the stratified squamous epithelium in both sexes at the highest concentration and an increase in the severity of subacute/chronic inflammation in both sexes, indicative of irritation, at the highest concentration tested. In the ventral diverticulum, there was an increased incidence of squamous/squamoid metaplasia/hyperplasia of the columnar epithelium in both sexes at the highest concentration tested. These additional lesions ranged in severity from minimal to moderate.
- The commenter suggested that the histopathological lesions observed at the LOAEC (squamous metaplasia/hyperplasia) were adaptive and not adverse since they were not accompanied by inflammation. At a workshop organized by the European Society of Toxicologic Pathology to evaluate and discuss laryngeal lesions, it was agreed that minimal to slight focal squamous metaplasia in the larynx on its own is not adverse. However, there was consensus that when the metaplasia is accompanied by squamous hyperplasia, it is considered to be adverse (PMRA# 3279521), and may progress to laryngeal dysfunction, with hypersecretion of mucous and alterations to mucocilliary clearance (PMRA# 3279521; PMRA# 3242169). This combination of lesions, which were observed at the LOAEC in the piperonyl butoxide inhalation study, are thus considered to be treatment-related and adverse.

It was suggested by the commenter that the microscopic changes noted in the larynx at the lower concentration levels were of limited relevance to the human health inhalation risk assessment for piperonyl butoxide. To support this conclusion, a publication summarizing 52 inhalation toxicity

studies, organized as 26 cases with each case comprising a pair of studies where the same test material was administered to a rodent and non-rodent species, was cited.¹⁵ In the 26 pairs of studies, laryngeal changes were present with much higher frequency in the rodent (rats and mice) than non-rodent (dogs and monkeys) species, leading the study authors to suggest that, with all other factors remaining similar, the larynx of the rodent may be more sensitive than that of the non-rodent to irritant exposure. Although the study authors reported that study methods were similar across the paired studies regarding exposure parameters (dose level, daily length of exposure and study duration), it was noted that a greater number of sections for the larynx were examined in rodents (five to seven) compared to non-rodents (two) in the summarized studies, potentially biasing towards higher detection of laryngeal findings in the rodent species included in this study. The study authors stated that anatomically and histologically, the human larynx resembles that of the non-rodent more closely than the rodent and therefore, more emphasis should be placed on findings in non-rodent animal models than in rodent models when assessing potential health effects of inhaled chemicals. However, given the above-noted limitation with this study, and that repeat-dose inhalation toxicity data for piperonyl butoxide are only available in the rodent, the effects observed in the rat 90-day inhalation toxicity study conducted with piperonyl butoxide cannot be dismissed.

Overall, given that the histopathological lesions (hyperplasia, metaplasia) in the rat laryngeal seromucosal glands at the LOAEC of 0.015 mg/L have the potential to cause adverse effects on respiration and laryngeal function, and may progress to more severe lesions, Health Canada remains of the opinion that they are treatment-related and adverse. Therefore, Health Canada will retain the LOAEC of 0.015 mg/L for the assessment of all inhalation exposure scenarios for piperonyl butoxide and no changes to the inhalation reference values are warranted at this time.

1.1.4 Comment related to research conducted by the Pyrethrins Joint Venture and Piperonyl Butoxide Task Force II

It was suggested that Health Canada consider the ongoing research by the Pyrethrins Joint Venture (PJV) and Piperonyl Butoxide Task Force II to refine the inhalation point of departure and reference concentration, and that risk mitigation measures related to potential inhalation exposures and health risks be based on the outcome of this data development effort.

Health Canada response:

During the public consultation period the PJV and Piperonyl Butoxide Task Force II indicated to Health Canada that there were new studies close to completion that address the inhalation toxicity of piperonyl butoxide and requested that Health Canada incorporate these new studies into the re-evaluation decision for piperonyl butoxide. Health Canada agreed to accept the submission of the new studies if provided by an agreed upon deadline. Despite providing deadline extensions, the studies were not provided by the final deadline to be reviewed and incorporated into this final re-evaluation decision. Therefore, the new studies generated jointly by the PJV and Piperonyl Butoxide Task Force II will be reviewed through a pre-market submission. The outcome of the pre-market review will be applied to relevant products.

¹⁵ Mowat V., Alexander D.J. and Pilling A.M. 2017. *A Comparison of Rodent and Nonrodent Laryngeal and Tracheal Bifurcation Sensitivities in Inhalation Toxicity Studies and Their Relevance for Human Exposure. Toxicologic Pathology*, 45(1): 216-222.

In conclusion, there are no changes to Health Canada's human health risk assessment of piperonyl butoxide at this time with regards to the PJV and Piperonyl Butoxide Task Force II data.

1.2 Comments related to occupational/non-occupational exposure

1.2.1 Comment concerning the use of handheld equipment

Concern was noted by some user groups and registrants that the use of mechanically-pressurized handheld ultra-low volume (ULV) and mechanically-pressurized handheld sprayer application equipment were proposed for cancellation in PRVD2020-09. These user groups indicated that prohibiting this equipment limits the available alternatives for effective pest control in warehouses and food processing facilities.

Health Canada response:

No commercial hand-held equipment was proposed for cancellation in PRVD2020-09. This includes mechanically- and manually-pressurized equipment used for ULV, mist, aerosol and fogging applications. Risks were shown to be acceptable with mitigation measures such as PPE and limiting the amount handled. In the revised risk assessment, as summarized in Appendix V, risks continue to be acceptable for applicators using these types of equipment and they will not be prohibited, provided the mitigation measures in Appendix IV are implemented.

1.2.2 Comment noting the registration of drug products containing piperonyl butoxide

Comments were received from user groups and registrants noting that there are Health Canada approved lice shampoos. The commenters noted that it was unclear why Health Canada judges these products to be safe while some surface and space sprays were not safe even when PPE were used and treated rooms were empty.

Health Canada response:

Health Canada assesses drug and pesticide products registered for sale in Canada to ensure that they can be used safely by Canadians. Exposure and risk for a person applying a shampoo for the treatment of a parasite are different than the exposure and risks for a person applying a pesticide daily to large warehouses to treat insects. In the assessment for pesticides, Health Canada also considers the risk for persons entering treated areas who may not be aware they were recently treated or have access to the pesticide product label. As exposure scenarios for these products differ, as does the legislation under which they are regulated, it is not appropriate to directly compare them.

As summarized in Appendix IV, this updated assessment has demonstrated that most currently registered products and uses for piperonyl butoxide are acceptable for continued registration including dust and pressurized product space sprays, provided that the mitigation measures in Appendix IV are followed.

1.2.3 Comment regarding prohibiting or limiting domestic-class products

The commenters expressed concern that many products, particularly domestic-class products were proposed for cancellation or required limitations around their continued registration in PRVD2020-09. These product types include dust products, indoor aerosol space sprays, outdoor/backyard sprays, and total release foggers. The commenters requested that Health Canada revisit these decisions and provided proposed mitigation measures which include limiting container sizes and net contents, adjusting valve apertures to reduce volume sprayed per time, and providing more detailed description of the application process to reduce applicator exposure.

Health Canada response:

Health Canada updated the risk assessments for most products and scenarios to incorporate the use pattern information and data submitted to Health Canada during the comment period, as summarized in Appendices V and VI. As a result, most domestic-class product cancellations proposed in PRVD2020-09 are no longer required. Domestic-class dust products, as well as indoor and outdoor space sprays using pressurized products are now acceptable for continued registration, provided the mitigation measures in Appendix IV are implemented.

For pressurized products used as total release foggers and liquid products applied as a space spray, the risk assessments were refined to the extent possible using the data available to Health Canada. However, inhalation risks from exposure to aerosols (droplets) present in the air after application continue to not be acceptable, even for the lowest registered application rates. As discussed in PRVD2020-09, Health Canada does not establish risk-based re-entry intervals for domestic-class products. Therefore, all domestic-class total release fogger pressurized products will be cancelled. In addition, space spray uses for liquid domestic-class products will be cancelled. Refer to Appendix IV for more information.

1.2.4 Comment regarding the incidental oral risk assessment

Registrants noted that higher risks were calculated for the object-to-mouth assessment compared to the hand-to-mouth assessment for a given scenario. When following the USEPA residential SOPs (2012), the object-to-mouth exposure estimate should be lower. It was also noted that standard ‘transferrable fraction’ values were not used.

Health Canada response:

Health Canada uses the models and approaches outlined in the USEPA Residential Standard Operating Procedures (SOPs) (2012) for most residential applicator and postapplication exposure assessments.

As indicated in PRVD2020-09, chemical-specific “transferrable fraction” values from the Residential SOPs (2012) were used (2% for soft surfaces; 5% or 2% for hard surfaces for the short/intermediate-term and long-term assessments, respectively). These values were used in the dermal and object-to-mouth assessments, as outlined in chapter 7 of the Residential SOPs.

For hand-to-mouth exposure, Health Canada has updated the equation outlined in the USEPA Residential SOPs (2012) to account for double counting of time in the equation. In the equation, the hand residue value is based on dermal exposure calculated from the corresponding dermal assessment for each scenario. As dermal exposure is already normalized to a full day (mg/day), it needs to be multiplied by the corresponding scenario exposure time so that time is not double counted and the resulting hand-to-mouth exposure results in the appropriate units (mg/kg bw/day). This modification of the original equation has been communicated to the USEPA.

1.2.5 Comment regarding indoor space spray postapplication assessments

The commenter expressed concern over the proposed cancellation of domestic-class indoor aerosol space sprays applied using pressurized products (including total release foggers) as well as the mitigation required for commercial-class indoor space sprays. The following comments were made regarding inputs in the postapplication inhalation assessment:

- a) The highest 8-hour time-weighted average air concentration following space spray use or spraying animal quarters from an indoor air monitoring study for an aerosol product (Selim, 2002) could be used.
- b) The air exchange rate (ACH) could be increased to 10 per hour for animal barns.
- c) The re-entry intervals currently on domestic-class products in the exposure assessment (for example, 10–15 minutes for animal quarters) could be considered.

A list of studies conducted by the Non-Dietary Exposure Task Force (NDETF) that are relevant to the consumer and occupational exposure assessment of piperonyl butoxide was also submitted.

Health Canada response:

As discussed in Appendix V, the postapplication assessments for all indoor space sprays were updated to reflect the submitted use pattern information and available data. The suggested inputs above were considered by Health Canada for the updated assessment. This is discussed in greater detail below.

As noted in PRVD2020-09, Health Canada used the maximum measured air concentration and normalized it to registered application rates in order to estimate inhalation postapplication exposure. A time-weighted average (TWA) approach was not considered appropriate to assess postapplication inhalation exposure to aerosols, based on the current use pattern of piperonyl butoxide and the study data. TWA values are typically used for longer-term exposure durations, and they are conducted in conjunction with a short-term assessment to ensure that the maximum air concentration is considered. The available studies (Selim, 2002; Acedo, 2016) monitored air concentrations over 2 hours, which is consistent with the expected duration that aerosols may be suspended in the air after an application and available for exposure. Using these data to calculate an average air concentration over 8 hours would include 6 hours of time when aerosols are not expected to be available for exposure.

Averaging air concentrations over 8 hours would result in a lower air concentration to estimate postapplication exposure and would not address the peak air concentration which is relevant to the adverse toxicological effects (portal of entry) noted in the 90-day rat inhalation toxicity study used to derive the point of departure for the inhalation risk assessments.

In PRVD2020-09, Health Canada used standard air exchange rates from the USEPA Residential SOPs (2012). To use different values, as proposed by the commenter, science-based information or a rationale would be required (for example, nationally representative data reflective of air changes in these buildings). The commenter did not provide such a rationale. For piperonyl butoxide, the postapplication exposure assessments for indoor space sprays with pressurized products were conducted with data from the Acedo (2016) air concentration study, which was considered to be representative of application in residential areas and the air concentrations from this study could not be modified to reflect animal barns.

Re-entry intervals less than 2 hours were considered for the postapplication assessment for commercial-class products. For pressurized products (except metered release products), risks were not shown to be acceptable at shorter re-entry intervals for the highest registered rates. Therefore, the 2-hour re-entry interval was maintained in this updated assessment. For domestic application of a space spray using a pressurized product, risks were not shown to be acceptable immediately following application. Health Canada does not establish risk-based re-entry intervals for domestic-class products. Therefore, this use is to be cancelled for domestic-class products. Refer to Appendix IV for more information.

Health Canada examined the list of the submitted NDETF studies. These studies are incorporated into the USEPA Residential SOPs (2012) which were used to assess residential exposure to piperonyl butoxide. Chemical-specific study data were also considered to refine the piperonyl butoxide assessments, where applicable.

2.0 Comments related to the value assessment

2.1 Comments regarding the importance of piperonyl butoxide in agriculture and public health

Several stakeholders commented on the vital role professional pest control plays in protecting our food supply and public health. Professional pest control officers require pyrethrins and piperonyl butoxide products to target flies, cockroaches and stored product pests that spread food borne pathogens, impact public health and adulterate the food supply. Due to a lack of available alternatives, Health Canada's proposed cancellation of the application of pyrethrins via mechanically pressurized handheld ultra-low volume (ULV) foggers in food factories and warehouses will result in the use of fumigation, which is considered a more drastic approach to fogging. Pyrethrins products are applied using handheld ULV foggers, which allow applicators to target applications to where pests hide, so to have a flushing effect, therefore helping to pinpoint pest infestations. As a result, handheld ULV foggers are an effective application tool in integrated pest management, resulting in more targeted applications, and a reduction in the use of additional general surface and broadcast applications. In addition, pyrethrins are one of the few pest control products that are approved for use in organic facilities.

Health Canada response:

Health Canada acknowledges the role professional pest control plays in protecting our food supply and public health. Note that all commercial-class pyrethrins products are co-formulated with conventional active ingredients. Health Canada recognizes the need for effective pest control products, and the importance of equipment such as ULV foggers, which allows for targeted applications, resulting in a flushing effect to help pinpoint pests. To clarify, the proposed re-evaluation decisions for pyrethrins and piperonyl butoxide (PRVD2020-08 and PRVD2020-09, respectively), indicated that the use of mechanically pressurized handheld sprayers for mists, aerosols, and fogs were proposed for cancellation for domestic products. In the case of commercial products, this type of equipment was not proposed for cancellation. Rather, the addition of a two-hour re-entry interval, new requirements for personal protective equipment and engineering controls and limits on the amount of pyrethrins and piperonyl butoxide handled per day (0.05 kg of active ingredient per person/day and 0.27 kg of active ingredient per person/day, respectively) were proposed. The comments received during consultation did not change the outcome of the proposed decision (in other words, continued registration of commercial products using mechanically pressurized handheld ULV foggers for indoor space sprays with the above risk mitigation measures; cancellation of domestic products using mechanically pressurized handheld sprayers for mists, aerosols, and fogs).

2.2 Comment regarding the importance of piperonyl butoxide for stored grains

A stakeholder commented on the importance of pyrethrins and piperonyl butoxide as a direct application to stored grains, and for use in grain facilities or empty storage areas. The importance of these products lies in the rapid breakdown of pyrethrins, which makes it a major tool for pest management in food and feed facilities.

Health Canada response:

Health Canada acknowledges the value of pyrethrins and piperonyl butoxide as important pest management tools for use in food and feed handling facilities and users will continue to have access to products containing these active ingredients for structural applications in these locations of use. However, risks of concern remain for direct application to stored grains, and therefore this specific use of pyrethrins and piperonyl butoxide is cancelled. Alternatives such as malathion and silicon dioxide are registered for direct applications to stored grains.

2.3 Comments regarding the importance of piperonyl butoxide for domestic use

Several stakeholders commented on the importance of domestic products for use by the public to target household pests when applied indoors as dusts and space sprays. Space sprays are important for use in unoccupied garages and sheds that are open to the outside; therefore, subject to house fly and mosquito incursions. Stakeholders also commented on the importance of domestic pyrethrins and piperonyl butoxide products for use in and around homes to kill household pests that can transmit disease including ticks and mosquitoes. Comments indicated that the cancellation of uses could result in fewer products being available for Canadians who require these products to control pests such as cockroaches and bed bugs, in homes and apartments, as there are limited alternative active ingredients registered. Alternative products that contain other registered active ingredients include baits, attractants, pheromones, insecticide powders and dusts, however, these are not suitable alternatives to products containing pyrethrins

and piperonyl butoxide. The reduction in available products may also encourage Canadians to do more cross-border shopping and/or mix homemade pesticides, both of which pose their own risk. Further, e-commerce companies have allowed shipping of United States products into Canada “for personal use”; therefore, it is likely that there will be an increase in this activity by consumers if they are unable to find products in Canada to meet their pest control needs.

Health Canada response:

Health Canada acknowledges the importance of domestic products to control household and disease vector pests. Health Canada agrees there is value to the use of pyrethrins and piperonyl butoxide products for personal use in and around homes when applied as dusts and space sprays. Based on the additional information received during consultation, Health Canada updated the risk assessment, and indoor use of dust products, and all domestic outdoor space spray applications are retained. Indoor space sprays using aerosol cans are retained with mitigation (rate reduction). However, the risk was not acceptable for space spray applications using products formulated as liquids, total release foggers and metered-release devices, and these uses are cancelled.

Following the re-evaluation of pyrethrins and piperonyl butoxide, consumers will continue to have pyrethrins and piperonyl butoxide products to meet their pest control needs. If consumers do purchase products online, they need to ensure that they are purchasing a product that is registered in Canada. Further information can be found on the [Buying pest control products online](#) page on Canada.ca. A list of the registered products containing piperonyl butoxide in Canada can be accessed through the PMRA’s Pesticide Product Information Database (PPID).

3.0 Comments related to other considerations

3.1 Comment on proposed cancellation of domestic-class uses in PRVD2020-09

The registrant commented that dust and indoor space spray applications are proposed for cancellation for domestic-class products but not for commercial-class products. Should the proposal be maintained at final decision the registrant would like to convert the domestic-class products to commercial-class products.

Health Canada response:

As outlined in this re-evaluation decision, domestic-class dust products and domestic-class aerosol space spray products are acceptable for continued registration provided that the required risk mitigation measures presented in this re-evaluation decision are implemented (Appendix IV).

3.2 Comments on the timeline to implement required label amendments

Registrants and stakeholders commented for PMRA to be clear to whom the 24-month label amendment timeline applies to (registrants, retailers, distributors and/or users). In addition, registrants requested more than 24 months to implement required label amendments.

Health Canada response:

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides the general framework for amendments to pesticide product uses following a re-evaluation or special review decision. The policy outlines the process and how the associated timelines for amendment of pesticide products are established.

The main consideration for the implementation timeline for label amendments is based on the risks of concern to human health or the environment. Following a re-evaluation, regulatory changes are to be implemented as soon as possible to manage identified risks. The timelines provided by the policy are intended to facilitate the timely and orderly implementation of the decision.

The piperonyl butoxide re-evaluation decision requires different implementation timelines to manage risks to human health for domestic-class products with indoor uses. The implementation timelines outlined in the “Next steps” Section are applicable to registrants, retailers/distributors, and users.

Appendix IV Label amendments for products containing piperonyl butoxide

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements given below.

Piperonyl butoxide is co-formulated with other active ingredients. When updating the label statements, follow the more stringent label directions of all the actives with which a given product is co-formulated.

For acceptable uses, differentiate on labels between residential and non-residential sites and include the definitions as noted below.

In addition, label statements are required to be updated as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates* and as per DIR2002-01 Regulatory Directive: *Canadian Label Improvement Program for Pesticides Used on Companion Animals*.

Label amendments relating to the human health risk assessments

1.0 Label amendments for restricted-class end-use products containing piperonyl butoxide

1.1 Products/Uses cancelled

The following uses and any references to these uses must be removed from product labels:

- Direct application to lakes, ponds, and reservoirs for the eradication of fish.

2.0 Label amendments for commercial-class end-use products containing piperonyl butoxide

2.1 Products/Uses cancelled

The following uses and any references to these uses are cancelled and must be removed from product labels:

- Indoor structural broadcast applications to control flies and mosquitoes in livestock and poultry housing and facilities.
- Fogging applications to control adult mosquitoes in pastures.
- Direct application to bulk or bagged stored grain.
- Space spray application while livestock, other than poultry, are present.

2.2 Label amendments

Pressurized products with indoor metered release space spray applications

Limit the maximum application rate of piperonyl butoxide to 1.07 mg of piperonyl butoxide released every 15 minutes. The active ingredient amount (in other words 1.07 mg a.i.) is to be converted into the corresponding amount of product by the registrant for each applicable product.

Products with indoor surface spray applications

For indoor surface-directed applications the maximum application rate of piperonyl butoxide for each treatment type is outlined in Table 1 below. The definitions of each treatment type are required to be added to labels where the current label instructions are absent or ambiguous (Table 2). For liquid products that have the higher application rate for non-residential areas, the definition of residential areas must be added to labels.

All products formulated as dusts

Application of dust products is to be limited to areas that do not impact food, feed, or livestock that are used to produce food commodities (for example, voids, non-food areas).

Space spray applications while poultry are present

The application rate of space spray applications while poultry are present is to be limited to 0.12 g a.i./m³ or less. The active ingredient amount (in other words 0.12 g a.i./m³) is to be converted into the corresponding amount of product by the registrant for each applicable product.

Products with outdoor uses

Products formulated as emulsifiable concentrates or solutions that are applied to the ground, to ornamentals or for mosquito abatement (fogging) the number of applications for outdoor uses are to be limited such that the yearly cumulative rate is less than 1100 g a.i./ha. The active ingredient amount (in other words 1100 g a.i./ha) is to be converted into the corresponding amount of product by the registrant for each applicable product.

All labels with structural application uses are to be updated as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates*.

It is the responsibility of the registrant to ensure that application rate restrictions can be met based on how the product is packaged and sold.

Table 1 Maximum rates for indoor surface-directed applications for commercial-class products

Formulation	Treatment type ^a	Overall rate limit ^b
Application to Non-Residential Areas ONLY^c		
Liquid	All currently registered surface treatments	2.76 g a.i./m ²
Application to Residential ^c and Non-Residential Areas^c		
Liquid	Indoor broadcast	0.813 g a.i./m ²
	All other registered surface treatments	1.10 g a.i./m ²
Pressurized product	All currently registered surface treatments	0.55 g a.i./m ²
Dust	All currently registered surface treatments	0.582 g a.i./m ²

^a Definition of these treatment types are as follows:

Indoor Broadcast: Indoor broadcast application is to broad expanses of indoor structural surfaces such as walls, floors, ceilings, and indoor foundation walls/crawlspaces. Indoor Perimeter: Indoor perimeter application is less than 0.1 m wide along the edges of a room to baseboards, wall-floor and ceiling-wall joints, and around doorways or windows. Spot: Spot application is localized to a surface area not more than 0.2 m². Spots are not to be adjoining. The combined area of spots is not to exceed 10% of the total surface area of a room. Crack and Crevice: Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings. Void: Void application applies to inaccessible, enclosed empty spaces of a structure. For example, hollow walls and suspended ceilings.

^b Overall rate limit: Registered rates above this limit are prohibited; registered rates below this limit are maintained. The registrant is required to convert the specified rates into the corresponding amount of product for each end-use product label.

^c **Residential areas** are defined as any use-site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed.

Non-residential areas include but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock and poultry housing, and pet kennels).

Label statements for commercial-class products are outlined in Table 2. Note that all currently registered uses of piperonyl butoxide should fit into one or more of these scenarios and the proposed label statements in Table 2 should be added **where necessary, based on the use scenario**. Some product labels may include more than one scenario. In these situations, it is important that the statements required for each use scenario be included on the label, with the exception of statements that are identical. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.

Table 2 Label statements for piperonyl butoxide commercial-class product by use scenario

Scenario	Registered use	Form ^a	Proposed label statements
Indoor surface ^b application, indoor nest application	All	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply to overhead areas or in confined spaces without appropriate respiratory and eye protection.” • “Ventilate treated areas after application either by opening windows and doors or using fans, where required, to aid in the circulation of air. Air exchange/ventilation systems confirmed to be operational may also be used.” • “DO NOT apply when people or pets [or livestock]^c are present, unless otherwise specified.” • “DO NOT apply to surfaces that may come into contact with food/feed.”
	All	Liquid	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.” • For broadcast, perimeter, and spot spray applications, add “Use a coarse droplet size and low pressure spray not exceeding 345 kPa (50 psi) to avoid splashing onto non-target surfaces.”
	All	Liquid, PP	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^c to enter treated areas until sprays have dried, unless otherwise specified.” • “DO NOT allow spray to drip or allow drift onto non-target surfaces.” <p>If the product is registered as a surface spray and does not also have application instructions for use as a space spray, then the following statement are required to be added under PRECAUTIONS:</p>

Scenario	Registered use	Form ^a	Proposed label statements
			<ul style="list-style-type: none"> • “DO NOT apply as a space spray treatment.”
	All	Dust	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during loading, application, clean-up and repair (unless otherwise specified below).” • “For shaker can application, also wear a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.”
			<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^c to enter treated areas until dusts have settled.” • “DO NOT allow dust to deposit onto non-target surfaces.”
Indoor surface ^b application, indoor nest application	Food/feed processing facilities	All	<p>For products registered for use in food/feed processing facilities, the following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply when a food/feed processing facility is in operation.”
Indoor surface ^b application, indoor nest application	Not registered for use on stored food and feed	All	<p>For products not registered for use on stored food and feed, the following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply to surfaces that may come into contact with food/feed.” • “Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment, and utensils or thoroughly wash following treatment.” <p>For products not registered for use on stored food and feed, but registered for use in milking parlours, milk houses or milk rooms, add:</p> <ul style="list-style-type: none"> • “DO NOT apply to surfaces that may come into contact with food/feed. Cover or remove all food/feed (including bulk tanks

Scenario	Registered use	Form ^a	Proposed label statements
			<p>that contain milk). Any milk accidentally contaminated with spray solution must be discarded.</p> <p>For products that can be applied in milking parlours, add the following statement: “Cover or remove all milking equipment and thoroughly wash before use.”</p> <p>For products that can be applied in milking parlours, add the following statement:</p> <ul style="list-style-type: none"> • “Cover or remove all milking equipment and thoroughly wash before use.”
Indoor surface ^b application, indoor nest application	Void application	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <p>“Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non-target surfaces must be removed by the applicator.”</p>
Indoor surface ^b application	All	PP	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <p>“Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application, clean-up and repair.”</p>
	All	All	<p>The maximum application rates for each treatment type must not exceed the rates specified in Table 1 (above) for residential and non-residential sites.^f</p>
	All	Liquid	<p>If the maximum application rate is greater than 1.10 g a.i./m², then the following statement is required to be added under DIRECTIONS OF USE for the uses with the higher rates:</p> <ul style="list-style-type: none"> • “DO NOT use in residential areas. Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed. Non-residential areas include but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers

Scenario	Registered use	Form ^a	Proposed label statements
			are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock and poultry housing, and pet kennels).”
Indoor surface ^b application	All	All	<p>The definitions of each treatment type, as applicable, are required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. These definitions may have to be tailored/adjusted for non liquid formulations (dusts, aerosols, etc.). Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “Indoor Broadcast: Indoor broadcast application is to broad expanses of indoor structural surfaces such as walls, floors, ceilings and indoor foundation walls/crawlspace.” • “Indoor Perimeter: Indoor perimeter application is less than 0.1 m wide along the edges of a room to baseboards, wall-floor and ceiling-wall joints, and around doorways or windows.” • “Spot: Spot application is localized to a surface area not more than 0.2 m². Spots are not to be adjoining. The combined area of spots is not to exceed 10% of the total surface area of a room.” • “Crack and Crevice: Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings.” • “Void: Void application applies to inaccessible, enclosed empty spaces of a structure. For example, hollow walls and suspended ceilings.”
Indoor surface ^b application	Clothing treatment	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Only apply to clothing which can be laundered. Treated clothing must be laundered prior to wearing.”

Scenario	Registered use	Form ^a	Proposed label statements
Indoor surface ^b application	Mattress and furniture treatment (including but not limited to upholstered furniture, hard surface furniture, mattresses, box spring, pet bedding, bed frames, dressers, curtains, picture frames, wall coverings, hollow furniture legs, etc.)	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT use on items which can be laundered (e.g., pillows, bedding, toys, etc.), unless otherwise specified.” • “Remove all objects before treatment of furniture, luggage, closets or other areas where clothing, toys, towels, and other items are stored. Treated furniture must be dry before replacing stored items.” <p>When approved for application to voids, add:</p> <ul style="list-style-type: none"> • “Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non-target surfaces must be removed by the applicator.”
		All	<p>The definitions of each treatment type, as applicable, are required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. These definitions may have to be tailored/adjusted for non liquid formulations (dusts, aerosols, etc.). Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “<u>Broadcast</u> – Broadcast furniture application covers large areas or the entire surface of listed items.” • “<u>Spot</u> – Spot furniture application is up to 10% of the surface of the treated item.” • “<u>Crack and crevice</u> – Crack and crevice furniture treatments are applications to junction points on items.” • “<u>Tufts and seams (mattresses and upholstered furniture only)</u> – Tufts and seam treatment is to the junction of two or more pieces of fabric and any decorative trim (for example buttons).” • “<u>Void</u> – Void furniture treatment targets inaccessible empty spaces of items. For example, inside the dust cover on the underside of furniture or hollow table legs.”

Scenario	Registered use	Form ^a	Proposed label statements
Indoor surface ^b application	Mattress treatment	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Remove bedding before treating mattresses. Treated mattress must be dry before replacing laundered bedding.” <p>When approved for tuft and/or seam application only, add:</p> <ul style="list-style-type: none"> • “DO NOT apply to the entire mattress or piece of furniture. Apply to tufts [and/or] seams only.”
Indoor surface ^b application	<u>Not</u> registered for use on mattress, clothing or furniture	All	<p>For products not registered for use on mattresses, clothing, or furniture, the following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply to [furniture, mattresses]^d, linens, pet bedding, toys or clothing.”
Indoor Space Spray ^e Application	Food/feed processing facilities	All (not metered release)	<p>For products registered for use in food/feed processing facilities, the following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply when a food/feed processing facility is in operation.”
Indoor Space Spray ^e Application	All	All (not metered release)	<p>The following statement is required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^e to enter treated area until 2 hours after application. The commercial applicator is responsible for notifying workers, the homeowner, and others of the re-entry period requirement.” <p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p>

Scenario	Registered use	Form ^a	Proposed label statements
			<ul style="list-style-type: none"> • “When applying to overhead areas or in confined spaces, wear appropriate respiratory and eye protection.” • “Ventilate treated areas after application either by opening windows and doors or using fans, where required, to aid in the circulation of air. Air exchange/ventilation systems confirmed to be operational may also be used.” • “DO NOT apply when people or pets [or livestock]^c are present.” • “DO NOT remain in treated areas after application.” • “Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash following treatment.” <p>If also registered for milking parlours, milk houses or milk rooms, add the following statement:</p> <ul style="list-style-type: none"> • “Cover or remove all food/feed (including bulk tanks that contain milk). Any milk accidentally contaminated with spray solution must be discarded. Cover or remove all milking equipment and thoroughly wash before use. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment.”
	All	Liquid	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair (unless otherwise specified below).” • “In addition, for applications using mechanically-pressurized handguns, wear a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides during mixing, loading, and application.” • “When using mechanically-pressurized handheld application equipment for space spray application of mists, aerosols, and fogs (droplet sizes 0.1-100 µm) wear chemical-resistant coveralls with a chemical-resistant hood over a long-sleeved

Scenario	Registered use	Form ^a	Proposed label statements
			<p>shirt and long pants, 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.”</p> <ul style="list-style-type: none"> • “If entering treated indoor areas prior to venting or before the 2-hour re-entry interval, wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant footwear, socks, chemical-resistant gloves, 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.” <p>The definition of a space spray application method is required to be added to product labels where space spray application is currently specified:</p> <ul style="list-style-type: none"> • “Space spray: Space application is a suspension of fine droplets (0.1 to 100 µm) in the air within an indoor space.”
Indoor Space Spray ^e Application	All	PP (not metered release)	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application, clean-up and repair.” <p>The definition of a space spray application method is required to be added to product labels where space spray application is currently specified:</p> <ul style="list-style-type: none"> • “Space spray: Space application is a suspension of fine droplets (0.1 to 100 µm) in the air within an indoor space.”
Indoor Space Spray ^e Application	All	PP that is a TRF	<p>The following personal protective equipment statements are required to be added to pressurized products that can be used as a total release fogger (TRF) under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “After total release fogger application, if entering treated indoor areas prior to venting or before the 2-hour re-entry interval, wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant footwear, socks, chemical-resistant gloves, and a respirator with a NIOSH-approved organic-vapour-removing cartridge

Scenario	Registered use	Form ^a	Proposed label statements
			with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.”
Indoor Space Spray [°] Application	All	MR	The maximum amount released by the pressurized product should not exceed 1.07 mg a.i. every 15 minutes, as specified in Section 8.3.1.
Outdoor structural, surface application (including buildings, porches, patios, barns, garages, under eaves, around doors and windows, etc.) Outdoor nest application (including stinging insect nests, ant nests)	All	All	The following statements are required to be added under PRECAUTIONS . Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “DO NOT apply to overhead areas or in confined spaces without appropriate respiratory and eye protection.” • • “DO NOT apply when people or pets [or livestock] [°] are present.”
	All	Liquid, PP	The following statements are required to be added under PRECAUTIONS . Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock][°] to enter treated areas until sprays have dried.” • “DO NOT allow spray to drip or allow drift onto non-target surfaces.”
	All	Liquid	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.” The following statements must be added under PRECAUTIONS . Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”
	All	PP	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and

Scenario	Registered use	Form ^a	Proposed label statements
	All	Dusts	<p>shoes during application, clean-up and repair.”</p> <p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^c to enter treated areas until dusts have settled.” • “DO NOT allow dust to deposit onto non-target surfaces.” <p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during loading, application, clean-up and repair (unless otherwise specified below).” • “For shaker can application, also wear a NIOSH-approved N95 (minimum) filtering facepiece respirator (dust mask) that is properly fit tested.”
Outdoor structural, surface application (including buildings, porches, patios, barns, garages, under eaves, around doors and windows, etc.)	All	All	<p>The definition of the treatment type, as applicable, is required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “Outdoor Structural Broadcast: Outdoor broadcast application is to large outdoor structural surfaces (in other words, roofs, walls, doors, windows and foundations).^g”
Outdoor Application for flying insects (including mosquito abatement)	All	Liquid	<p>The following personal protective equipment statements are required to be added under PRECAUTIONS:</p> <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.” • “When using handheld airblast/mistblower application equipment wear chemical-resistant coveralls with a chemical-resistant hood over a long-sleeved shirt and long pants, chemical-resistant footwear, and a respirator with a NIOSH-approved organic-vapour removing cartridge with a prefilter approved for pesticides OR a NIOSH-

Scenario	Registered use	Form ^a	Proposed label statements
Outdoor Application for flying insects (including mosquito abatement)	All	PP	approved canister approved for pesticides.” The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application, clean-up and repair.”
	All	All	The following statements are required be added under PRECAUTIONS . Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^c to enter treated areas until sprays have dried.” • “Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”
Outdoor Ornamentals and foliar applications to outdoor plants (including vegetation around buildings and premises)	All	All	The following statements must be added under PRECAUTIONS Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “DO NOT enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.” • “Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”
	All	Liquid	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.” • “When using handheld airblast/mistblower application equipment wear chemical-resistant coveralls with a chemical-resistant hood over a long-sleeved shirt and long pants, chemical-resistant footwear, and a respirator with a NIOSH-approved organic-vapour

Scenario	Registered use	Form ^a	Proposed label statements
			removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides. DO NOT handle more than [0.27 kg a.i. to be reported as a product equivalent value] per person, per day when using a handheld airblast/mistblower (droplet sizes 0.1-100 µm). These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators.”
Outdoor Ornamentals	All	PP	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.”
	All	All	The following statement is required to be added under DIRECTIONS OF USE : <ul style="list-style-type: none"> • “DO NOT apply in greenhouses or to greenhouse crops.”
Direct Application to animals (including pets and livestock)	All	All	The following statements are required to be added under PRECAUTIONS . Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable. <ul style="list-style-type: none"> • “Avoid contact with treated animals until dried.” • “DO NOT allow product to contact non-target surfaces.”
	All	Liquid	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair.” • “When using handheld airblast/mistblower application equipment wear chemical-resistant coveralls with a chemical-resistant hood over a long-sleeved shirt and long pants, 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. DO NOT handle more than [0.27 kg a.i. to be reported as a

Scenario	Registered use	Form ^a	Proposed label statements
			product equivalent value] per person, per day when using a handheld airblast/mistblower (droplet sizes 0.1-100 µm). These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators.” As indicated by the square brackets above, the active ingredient amount in this statement (in other words 0.27 kg a.i.) is to be converted into the corresponding amount of product by the registrant for each product.”
	All	PP	The following personal protective equipment statements are required to be added under PRECAUTIONS : <ul style="list-style-type: none"> • “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during application, clean-up and repair.”

^a Form = formulation. Liquid = emulsifiable concentrate, solution; PP = pressurized product; MR= metered-release pressurized product; TRF = pressurized products that can be use as a total release fogger

^b A surface application is a directed application to a surface (floor, wall, foundation, ceiling, mattress, furniture, etc.). This includes but is not limited to broadcast, perimeter, spot, crack and crevice and void applications. It includes all indoor sites currently registered on commercial-class product labels, such as homes, commercial/industrial/institutional site, vehicles, agricultural premises, pet premises, horse stables and barns, etc.

^c Statement to be modified, as applicable, based on uses registered on product labels.

^d Modify to remove applications (furniture and/or mattresses) that are currently registered on the label.

^e A space spray application is an application of a pesticide as a suspension of fine droplets in air within an indoor space. This definition does not include fumigants, outdoor fogging and outdoor misting systems. This term may not be specifically included on the current product label.

^f “Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. For structural uses, in residential sites, this includes homes, schools, restaurants, public buildings or any other areas where the general public including children may potentially be exposed.

Non-residential areas include but are not limited to: industrial/commercial indoor sites (for example, laboratories, warehouses, food granaries); modes of transport in areas where passengers are not present (for example, buses, railcars, trailers); and animal housing (for example, livestock and poultry housing, and pet kennels).”

^g Other locations can be included in a case-by-case basis (for example, porches, patios) depending on the uses registered on product labels.

3.0 Label amendments for domestic-class end-use products containing piperonyl butoxide

It is the responsibility of the registrant to ensure that application rate restrictions can be met based on how the product is packaged and sold.

3.1 Products/Uses cancelled

The following domestic-class product labels are to be cancelled:

- Products that are registered as a total release fogger (including lock-valve mechanism).
- Metered-release pressurized products.

The following uses and any references to these uses must be removed from domestic-class product labels:

- Space spray use on liquid product labels.
- Garden and greenhouse food uses.

3.2 Label amendments

Pressurized products with indoor space spray applications (not metered release)

Limit the maximum application rate of piperonyl butoxide to 0.005 g a.i./m³. The active ingredient amount (in other words, 0.005 g a.i.) is to be converted into the corresponding amount of applied product by the registrant for each applicable product.

Indoor surface-directed applications

For indoor surface-directed applications specified on domestic-class product labels, the maximum application rate of piperonyl butoxide for each treatment type is outlined in Table 3 below. The definitions of each treatment type are required to be added to labels where the current label instructions are absent or ambiguous (Table 3).

All products formulated as dusts

Application of dust products is to be limited to areas that do not impact food, feed, or livestock that are used to produce food commodities (for example, voids, non-food areas).

Companion animal products

All companion animal spray and shampoo products containing piperonyl butoxide products co-formulated with pyrethrins and synthetic pyrethroids must reflect the statements outlined in DIR2002-01, *Canadian Label Improvements for Pesticides used on Companion Animals*.

In addition, the following label improvements must be included for companion animal products, in other words, piperonyl butoxide shampoos and sprays co-formulated with pyrethrins or synthetic pyrethroids:

Add label language to restrict the use of other companion animal products with the same active ingredient(s) as that in the spray/shampoo product (for example, “This product contains [name of active ingredient(s)]. Do not apply another pest control product such as a shampoo, spot-on, spray, collar, or powder that contains [name of active ingredient(s)] to the treated animal after applying [name of spray/shampoo product]”).

Label language that allows the re-application of the product before the end of the effective control period must be removed.

Additionally, the general term “pet” or “animal,” as currently noted in the use directions, must be replaced by the type of companion animal, in other words, “cat,” “dog” or “cats and dogs,” on which the specific product is registered for use.

Additional label statements for specific uses (in other words, direct application to pets (dogs, cats) and use in enclosed areas) are included in Table 4. All labels with structural application uses are to be updated as per the 2020 PMRA Guidance Document, *Structural Pest Control Products: Label Updates*.

It is the responsibility of the registrant to ensure that application rate restrictions can be met the way the product is packaged and sold.

Table 3 Maximum rates for indoor surface-directed applications for domestic-class products

Formulation	Treatment type ^a	Overall rate limit ^b
Liquid	All currently registered surface treatments	0.813 g a.i./m ²
Pressurized product	Indoor broadcast	0.813 g a.i./m ²
	All other registered surface treatments	1.10 g a.i./m ²
Dust	All currently registered surface treatments	0.40 g a.i./m ²

^a Definitions of these treatment types are as follows:

Indoor Broadcast: Indoor broadcast application is to broad expanses of indoor structural surfaces such as walls, floors, ceilings and indoor foundation walls/crawlspaces. Indoor Perimeter: Indoor perimeter application is less than 0.1 m wide along the edges of a room to baseboards, wall-floor and ceiling-wall joints, and around doorways or windows. Spot: Spot application is localized to a surface area not more than 0.2 m². Spots are not to be adjoining. The combined area of spots is not to exceed 10% of the total surface area of a room. Crack and Crevice: Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings. Void: Void application applies to inaccessible, enclosed empty spaces of a structure. For example, hollow walls and suspended ceilings.

^b Overall rate limit: Registered rates above this limit are prohibited; registered rates below this limit are maintained. The registrant is required to convert the specified rates into the corresponding amount of product for each end-use product label.

Specific label statements for domestic-class products are outlined in Table 4 below. Note that all currently registered uses of piperonyl butoxide should fit into one or more of these scenarios; some product labels may include more than one scenario. In these situations, it is important that the statements required for each use scenario be included on the label, with the exception of statements that are identical.

Table 4 Label statements for piperonyl butoxide domestic-class product by use scenario

Scenario	Registered use	Form ^a	Proposed label statements
All	Enclosed indoor areas (for example, indoor space spray, indoor surface application, dusts, etc.)	All	The following statements ^b are required to be added under TOXICOLOGICAL INFORMATION . <ul style="list-style-type: none"> “Skin exposure may cause transient sensations (tingling, burning, itching, numbness).” “Other symptoms of exposure could include respiratory effects (such as cough, respiratory irritation, or shortness of breath), nausea, headache or dizziness.”

Scenario	Registered use	Form ^a	Proposed label statements
All (except nest treatment, direct application to animals)	All	Liquid	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply using handheld or stationary fogging or misting equipment.” • “DO NOT apply as a space spray. Space spray: Space application is a suspension of fine droplets (0.1 to 100 µm) in the air.”
Indoor surface ^c application, indoor nest application	All	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply to overhead areas or in confined spaces (for example, attics, crawlspaces, small storage rooms, closets)” • “Ventilate treated indoor areas after application by opening windows and doors or using fans, where required, to aid in the circulation of air.” • “DO NOT apply when people or pets [or livestock]^d are present, unless otherwise specified.” • “DO NOT apply to surfaces that may come into contact with food/feed.” • “Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment.” <p>If also registered for milking parlours, milk houses or milk rooms, add the following statement:</p> <ul style="list-style-type: none"> • “Cover or remove all food/feed (including bulk tanks that contain milk). Any milk accidentally contaminated with spray solution must be discarded. Cover or remove all milking equipment and thoroughly wash before use. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment.”
Indoor surface ^c application	All	Liquid and PP	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^d to enter treated areas until sprays have dried.” • “DO NOT allow spray to drip or allow drift onto non-target surfaces.”
	All	Dust	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p>

Scenario	Registered use	Form ^a	Proposed label statements
			<ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^d to enter treated areas until dusts have settled.” • “DO NOT allow dust to deposit onto non-target surfaces.”
	All	All	The maximum application rates for each treatment type must not exceed the rates specified in Table 3 (above).
	All	All	<p>The definitions of each treatment type, as applicable, are required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. These definitions may have to be tailored/adjusted for non liquid formulations (dusts, aerosols, etc.). Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “Indoor Broadcast: Indoor broadcast application is to broad expanses of indoor structural surfaces such as walls, floors, ceilings and indoor foundation walls/crawlspaces.” • “Indoor Perimeter: Indoor perimeter application is less than 0.3 m wide along the edges of a room to baseboards, wall-floor and ceiling-wall joints, and around doorways or windows.” • “Spot: Spot application is localized to a surface area not more than 0.2 m². Spots are not to be adjoining. The combined area of spots is not to exceed 10% of the total surface area of a room.” • “Crack and Crevice: Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings.” • “Void: Void application applies to inaccessible, enclosed empty spaces of a structure. For example, hollow walls and suspended ceilings.”
Indoor surface ^c application	Void application	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non-target surfaces must be removed by the applicator.”
Indoor surface ^c application	Clothing treatment	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Only apply to clothing which can be laundered. Treated clothing must be laundered prior to wearing.”

Scenario	Registered use	Form ^a	Proposed label statements
Indoor surface ^c application	Mattress and furniture treatment (including but not limited to upholstered furniture, hard surface furniture, mattresses, box spring, pet bedding, bed frames, dressers, curtains, picture frames, wall coverings, hollow furniture legs)	All	<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT use on items which can be laundered (e.g., pillows, bedding, toys).” • “Remove all objects before treatment of furniture, luggage, closets or other areas where clothing, toys, towels, and other items are stored. Treated furniture must be dry before replacing stored items.” <p>When approved for application to furniture voids, add:</p> <ul style="list-style-type: none"> • “Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non-target surfaces must be removed by the applicator.” <p>The definitions of each treatment type, as applicable, are required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. These definitions may have to be tailored/adjusted for non liquid formulations (dusts, aerosols, etc.). Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “<u>Broadcast</u> – Broadcast furniture application covers large areas or the entire surface of listed items.” • “<u>Spot</u> – Spot furniture application is up to 10% of the surface of the treated item.” • “<u>Crack and crevice</u> – Crack and crevice furniture treatments are applications to junction points on items.” • “<u>Tufts and seams (mattresses and upholstered furniture only)</u> – Tufts and seam treatment is to the junction of two or more pieces of fabric and any decorative trim (for example buttons). • “<u>Void</u> – Void furniture treatment targets inaccessible empty spaces of items. For example, inside the dust cover on the underside of furniture or hollow table legs.”
Indoor surface ^c application	Mattress treatment		<p>The following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Remove bedding before treating mattresses. Treated mattress must be dry before replacing laundered bedding.” <p>When approved for tuft and/or seam application only, add:</p> <ul style="list-style-type: none"> • “DO NOT apply to the entire mattress or piece of furniture. Apply to tufts [and/or] seams only.”

Scenario	Registered use	Form ^a	Proposed label statements
Indoor surface ^c application	Not registered for use on mattress, clothing or furniture		<p>For products not registered for use on mattresses, clothing, or furniture, the following statements are required to be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply to [furniture, mattresses]^c linens, pet bedding, toys or clothing.”
Indoor Space Spray ^f Application	All	PP (not metered release)	<p>The following statements must be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT remain in treated areas after application.” • “DO NOT allow people, pets, or livestock ^d to enter treated areas until sprays have settled.” • “Ventilate treated indoor areas after application either by opening windows and doors or using fans, where required, to aid in the circulation of air.” • “DO NOT apply when people or pets [or livestock]^d are present.” • “Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash following treatment.” <p>If also registered for milking parlours, milk houses or milk rooms, add the following statements:</p> <ul style="list-style-type: none"> • “Do NOT apply to surfaces that may come into contact with food/feed. Cover or remove all food/feed (including bulk tanks that contain milk). Any milk accidentally contaminated with spray solution must be discarded. Cover or remove all milking equipment and thoroughly wash before use.” • “Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment.” <p>The definition of a space spray application method is required to be added to product labels where space spray application is currently specified:</p> <ul style="list-style-type: none"> • “Space spray: Space application is a suspension of fine droplets (0.1 to 100 µm) in the air within an indoor space.” <p>The maximum application rates must not exceed the maximum application rate of 0.005 g a.i./m³, as specified in Section 3.2.</p>
Outdoor structural, surface application (including buildings, porches, patios, barns, garages, under eaves, around	All	Liquid, PP	<p>The following statements must be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply when people or pets [or livestock]^d are present.”

Scenario	Registered use	Form ^a	Proposed label statements
<p>doors and windows, etc.);</p> <p>Outdoor Application for flying insects (including mosquito abatement);</p> <p>Outdoor nest application (including stinging insect nests, ant nests);</p> <p>Outdoor and indoor (non-commercial greenhouse) ornamentals</p>	All	Dust	<ul style="list-style-type: none"> • “DO NOT allow people or pets [or livestock]^d to enter treated areas until sprays have dried.” • “DO NOT allow spray to drip or allow drift onto non-target surfaces.” <p>The following statements must be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “DO NOT apply when people or pets [or livestock]^d are present.” • “DO NOT allow people or pets [or livestock]^d to enter treated areas until dusts have settled.” • “DO NOT allow dust to deposit onto non-target surfaces.”
Outdoor structural surface application (including buildings, porches, patios, barns, garages, under eaves, around doors and windows, etc.);	All (except nest application)	All	<p>The definition of the treatment type, as applicable, is required to be added to the label under DIRECTIONS OF USE where the current label instructions are absent or ambiguous. Only add definitions that reflect the current use instructions. Do not add these statements to product labels if more restrictive application instructions are already present:</p> <ul style="list-style-type: none"> • “Outdoor Structural Broadcast: Outdoor broadcast application is to large outdoor structural surfaces (in other words, roofs, walls, doors, windows and foundations).^g”
Indoor (including non-commercial greenhouse) houseplants (ornamentals)	Foliar applications	All	<p>The following statement is required to be added under DIRECTIONS FOR USE:</p> <ul style="list-style-type: none"> • “DO NOT apply in commercial greenhouses.”
Direct application to animals (for example, pets)	All	All	<p>The following statements must be added under PRECAUTIONS. Replace similar wording on the label with these statements. If more stringent mitigation is currently specified on the label, integrate it in the statements below, as applicable.</p> <ul style="list-style-type: none"> • “Avoid contact with treated animals until dried.” “DO NOT allow product to contact non-target surfaces.”
	Dogs	All	<p>The following statements ^h must be added under DIRECTIONS OF USE:</p> <ul style="list-style-type: none"> • “Monitor your dog after application. Side effects may include: skin irritation such as redness or scratching; changes in behaviour such as agitation or lethargy; or gastrointestinal effects such as vomiting or loss of appetite. If these or other side effects occur consult your veterinarian or [Registrant at 1-800-number].”
	Cats	All	<p>The following statements ^h must be added under DIRECTIONS OF USE:</p>

Scenario	Registered use	Form ^a	Proposed label statements
			<ul style="list-style-type: none"> “Monitor your cat after application. Side effects may include: skin irritation such as scratching or hair loss at the application site, or changes in behaviour such as agitation or lethargy. Gastrointestinal effects such as drooling, vomiting, or loss of appetite may also occur. If these or other side effects occur consult your veterinarian or [Registrant at 1-800-number].”

^a Form = formulation. Liquid = emulsifiable concentrate, solution; PP = pressurized product; MR= metered-release pressurized product

^b Include label statements to inform the consumer of the potential effects that can be expected following the use of piperonyl butoxide products co-formulated with pyrethrins or synthetic pyrethroids.

^c A surface application is a directed application to a surface (floor, wall, foundation, ceiling, mattress, furniture, etc.). This includes but is not limited to broadcast, perimeter, spot, crack and crevice and void applications etc.

^d Statement to be modified, as applicable, based on uses registered on product labels.

^e Modify to remove applications (furniture and/or mattresses) that are currently registered on the label.

^f A space spray application is an application of a pesticide as a suspension of fine droplets in air within an indoor space. This definition does not include fumigants, outdoor fogging and outdoor misting systems. This term may not be specifically included on the current product label.

^g Other locations can be included in a case-by-case basis (for example, porches, patios) depending on the uses registered on product labels.

^h Include label statements to inform the consumer as to the possible side effects that may be expected in their pets following use of piperonyl butoxide sprays or shampoo products co-formulated with pyrethrins or synthetic pyrethroids. For piperonyl butoxide spray and shampoo products co-formulated with pyrethrins or synthetic pyrethroids and registered for use on both cats **and** dogs, the labels must contain statements relating to the possible effects on both animal types.

4.0 Label amendments relating to the value assessment

Any reference to the use to control lice on mattresses, bedding, furniture, and garments are to be removed from all domestic-class products.

Appendix V Revised occupational and non-occupational exposure and risk assessments for piperonyl butoxide

Details for the revised risk assessment are included in this appendix. Please refer to PRVD2020-09 for additional information.

Use pattern

As outlined in PRVD2020-09, additional data were required under section 19 of the *Pest Control Products Act* to confirm that application rates and use directions on product labels are consistent with the rates used in the health risk assessments. As a result of the information received from registrants in response to this data call-in, the occupational and non-occupational risk assessment of piperonyl butoxide for most uses was revised to reflect the clarifications to the currently registered use pattern, such as changes to application rates, application equipment, concentration of piperonyl butoxide in containers, application intervals, and registered formulations for some sites. The revised use pattern formed the basis of the revised occupational and non-occupational risk assessment for piperonyl butoxide and reflect the information available. Golf courses and suspension formulations are no longer part of the registered use pattern and were not included in the updated assessment.

Piscicide uses

An updated assessment was not required for the restricted-class piscicide product as the use pattern and exposure models were not updated from the PRVD and no comments were received during the PRVD consultation period.

Outdoor air concentrations

The postapplication inhalation risk assessment for outdoor space spray applications in residential areas using pressurized products was refined using air concentration data from a study submitted through a clarification with the registrant (Boatwright, 2009). The product used in this study did not contain piperonyl butoxide but was considered to be representative of registered piperonyl butoxide pressurized products, based on the fact that the resulting air concentrations were primarily due to behaviour of the aerosols following application of a pressurized product in an outdoor environment, rather than to chemical-specific properties. To estimate piperonyl butoxide air concentrations, study air concentrations were normalized by the concentration of active ingredient in the study product and extrapolated to piperonyl butoxide concentrations in registered products. This approach is conservative (that is, it represents an upper bound estimate of exposure) as it assumed the largest registered piperonyl butoxide aerosol product (twice the size of the can used in the study) was applied to the treated area.

Indoor air concentrations

The indoor air concentration studies considered for the postapplication inhalation risk assessment for pressurized space spray products were revisited based on comments received during the PRVD consultation period. For the assessment summarized in PRVD2020-09, both the Selim (2002) and Acedo (2016) studies were considered in the assessment. For the updated assessment, the Selim (2002) study was not used as the ventilation system was turned off in the study for the duration of the sampling, which is not reflective of typical practice in commercial and residential

buildings. The Acedo (2016) study was considered to be more representative, as the ventilation system was turned off for 15 minutes after application and then re-started. These conditions are representative of typical uses in commercial sites and conservative for residential sites, where ventilation is unlikely to be turned off. Air concentrations in the study were normalized by the study application rate and extrapolated to the registered Canadian application rates. The data from these studies were not considered appropriate to characterize air concentrations for liquid or total release fogger pressurized products, as the application rates and droplet sizes are different.

Occupational exposure and risk assessment

The occupational mixer/loader/applicator and postapplication assessments were revised to incorporate the use pattern information submitted to Health Canada. Results are summarized in Tables 2 and 3. The occupational non-agricultural/structural postapplication exposure assessment is addressed by the residential postapplication exposure and risk assessment, as discussed in PRVD2020-09. Refer to Table 1 for a summary of mitigation required as a result of the updated risk assessment. The mitigation required for mixers/loaders/applicators and postapplication workers is comparable to that proposed in PRVD2020-09, except for the application rate limit for indoor broadcast surface sprays and outdoor space spray applications for flying insects (for example, mosquito abatement) using liquid commercial-class products. Rates were limited for these uses as handler and residential postapplication risks were not shown to be acceptable for these rates. Therefore, products for which only one rate was available, and which is the highest rate for each use will be cancelled.

Non-occupational handler exposure and risk assessment

The residential mixer/loader/applicator assessments were revised to incorporate the use pattern information submitted to Health Canada. Results are summarized in Tables 4. See Table 1 for a summary of mitigation required as a result of the updated risk assessment. Risks were shown to be acceptable for all assessed application equipment. The clarified use information for piperonyl butoxide indicated that liquid domestic-class products could be applied as a space spray. Trigger spray bottles were included in the assessment assuming an area treated per day of 369 m³ based on the average volume of a residential home (USEPA, Exposure Factors Handbook, 2011). No data were available to assess residential handler risks when using handheld or stationary fogging (space spray) equipment. As postapplication risks for liquid product space sprays were not shown to be acceptable, discussed below, all space spray uses on liquid domestic-class products are to be cancelled. A label statement will also be added to domestic-class liquid products to prohibit the use of fogging and misting application equipment.

Non-occupational postapplication exposure and risk assessment

The residential postapplication assessments were updated to reflect the clarified use pattern and to incorporate the air concentration data for indoor and outdoor space sprays using pressurized products. For treated pets, postapplication risks were shown to be acceptable in PRVD2020-09. As there were no changes to the assessed use pattern and no comments were received, the postapplication assessments for treated pets were not updated; refer to the PRVD for result tables.

The results of the updated assessments are summarized in Tables 5 to 14.

For all products, further label revisions as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* are required. These include ventilation and other best practice statements aimed at reducing postapplication exposure.

Outdoor uses and indoor plants

For all outdoor uses (for example, outdoor ornamentals, outdoor areas), risks were shown to be acceptable provided that the rate for outdoor space sprays for flying insects (for example, mosquito abatement) for commercial-class liquid products are limited, as summarized in Table 1. For nest application, postapplication risks were assessed qualitatively and considered to be addressed by the other outdoor uses. For indoor/non-commercial greenhouse plants (ornamentals), risks were shown to be acceptable at the currently registered maximum rates.

Indoor uses - surface sprays

For surface sprays in indoor environments, risks are shown to be acceptable for non-residential areas, provided that the rate for commercial-class liquid products is limited, as summarized in Table 1. For residential areas, further rate limitations are required for risks to be acceptable for all sub-populations. Risks were shown to be acceptable for all treatment types at the rate of 1.10 g a.i./m², except for broadcast applications, which required a rate limit of 0.813 g a.i./m² for incidental oral (object-to-mouth) risks to be acceptable. These rates are higher than the maximum registered application rate for most formulations, depending on the product class. Maximum rates for surface-directed sprays for commercial-class products are summarized in Table 1 and Table 3 for domestic-class products, in Appendix IV.

For clothing application, postapplication risks were assessed qualitatively and considered to be addressed by surface spray applications, as registered rates are lower than the assessed surface spray application rates and treated clothing is laundered prior to wearing. Label statements are required for treated clothing, such as laundering prior to wearing.

Indoor uses - space sprays

For space sprays in indoor environments (liquid and pressurized products, except metered release), inhalation risks were not shown to be acceptable for aerosols following application of products at the maximum registered rates. This includes indoor space sprays when the air concentrations from the Acedo (2016) study were used. However, as aerosols settle within 2 hours, risks are considered to be acceptable provided that a 2-hour re-entry interval is implemented. For commercial-class products, a re-entry interval of 2 hours is required for all indoor space spray uses (except metered release). The commercial applicator is responsible for notifying workers, the homeowner, and others of the re-entry period requirement. This mitigation is the same as what was proposed in PRVD2020-09 and considered feasible based on comments from a user group submitted during the consultation period. Health Canada does not establish risk-based re-entry intervals for domestic-class products. Therefore, this use on domestic-class products is to be cancelled. All liquid and total release pressurized products are to be cancelled, as inhalation risks were not shown to be acceptable for any currently registered application rate. This mitigation is the same as what was proposed in PRVD2020-09, as the assessment could not be further refined with the data available.

For pressurized products (excluding total release fogger), the rate will be limited to 0.005 g a.i./m³, which is the highest registered rate at which risks were shown to be acceptable. This an update from the PRVD, where all pressurized products were proposed for cancellation as information on the registered rates were not available. Mitigation is summarized in Table 1.

For metered-release devices, risks in PRVD2020-09 and in the updated assessment were shown to be acceptable under the conditions in the chemical-specific study (Selim, 2008). The steady-state air concentration from the study could not be extrapolated to the registered metered release product rates as it was an average value measured after many applications over multiple days. Therefore, as proposed in PRVD2020-09, the application rate for all metered release sprays in indoor areas will be limited to the application rate from the study (maximum of 1.07 mg a.i. released every 15 minutes). However, as all currently registered domestic-class products are registered at application rates higher than the rate in the study, these products will be cancelled. The rate limit was proposed in PRVD2020-09; however, as rate information for all domestic-class metered release products were not available at the time, it was not possible to determine the extent of the impact of this mitigation. Mitigation is summarized in Table 1.

Table 1 Summary of mitigation required based on the revised assessment

Product class	Scenario	Mitigation^a
Commercial	Shaker can dust application (indoor, outdoor)	Filtering facepiece respirator (dust mask).
	Handheld airblast/mistblower	Chemical-resistant coveralls over long pants and long-sleeved shirt, chemical-resistant hood, chemical-resistant gloves, and a respirator. For outdoor ornamentals and direct animal treatment, also restrict the amount handled per day to 0.27 kg a.i. per day.
	Outdoor space sprays for flying insects (for example, mosquito abatement) with liquid products	Do not exceed an outdoor fogging application rate of 18.05 g a.i./ha for mosquito abatement.
	Workers entering indoor areas following space spray application with a liquid product or a total release fogger pressurized product	Maximum PPE when entering treated sites prior to ventilation or 2-hour re-entry interval (chemical-resistant coveralls over long pants and long-sleeved shirt, chemical-resistant hood, chemical-resistant gloves, and a respirator).
	Occupational agricultural postapplication for outdoor ornamentals	Restricted-entry intervals (REIs) of 12 hours.
	Indoor surface spray application with liquid products	Application rates for commercial-class products limited as per Appendix IV, Table 1 (non-residential areas limited to 2.76 g a.i./m ² residential areas limited to 0.813 g a.i./m ² for broadcast and 1.10 g a.i./m ² for all other registered treatment types).
	Space spray applications	Re-entry interval of 2-hours.

Product class	Scenario	Mitigation ^a
	with liquid and pressurized products (not metered release)	
	Metered release products	Limited application rate to 1.07 mg a.i. released every 15 minutes.
Domestic	Indoor surface spray applications with pressurized products	Application rates for domestic-class products limited as per Table 3, Appendix IV (broadcast application limited to 0.813 g a.i./m ² and 1.10 g a.i./m ² for all other registered treatment types).
	Pressurized products used as total release foggers	Total release fogger application uses prohibited on all products.
	Space spray application of liquid products	Use prohibited.
	Space spray application (manual spray) of pressurized products (not metered release or total release foggers)	Limit application rate to 0.005 g a.i./m ³ .
	Metered release products	Use prohibited.
All	Indoor and outdoor uses. All formulations and products with structural uses	Relevant types of application and associated definitions outlined in Appendix II of the PMRA Guidance Document, <i>Structural Pest Control Products: Label Updates</i> must be included in the DIRECTIONS FOR USE section under the header “How to Apply”.

^a Mitigation in this table for mixers/loaders/applicators is based on a single layer of personal protective equipment (long pants and long-sleeved shirt with chemical-resistant gloves) unless otherwise specified.

Table 2 Occupational mixer/loader/appliator exposure and risk assessment

Form.	Site(s)	Application method ^l	Application equipment	Max. application rate ^a	ATPD /AHPD	Dermal exposure ^b (mg/kg bw/day)	Inhalation exposure ^b (mg/kg bw/day)	Dermal MOE ^c (T=100)	Inhalation MOE ^d (T=300)
PPE (M/L/A): Single layer (long pants, long-sleeved shirt) + CR gloves									
PP	All	Indoor/outdoor space and surface applications; total release fogger applications, direct application to livestock and poultry	RTU aerosol Can (including total release fogger)	0.045 kg a.i./can ^k	14 cans/day	1.15E+00	1.30E-02	870	300
		Indoor space spray (metered release)	Automatic metered release dispenser	Applicator exposure from loading automatic dispensers is expected to be low compared to other scenarios. ⁱ					
	Direct application to animals	Direct application to livestock	Spray, wipe +cloth ^h	0.0022 kg a.i./animal	120 animals	1.80E+00	7.9E-03	550	490
Liquid	Direct application to animals	Direct application to livestock	MPHG	0.0004716 kg a.i./animal	6440 animals	2.12E-01	5.73E-03	4700	680
			MPHW			3.58E-02	1.72E-03	28 000	2300
			Backpack			2.07E-01	2.36E-03	4800	1700
			Spray + Brush ^h			0.00036 kg a.i./animal	120 animals	2.16E-01	4.01E-04
	Indoor environments	Indoor space spray	Stationary equipment (ML only)	0.0000775 kg a.i./m ³ ^r	28 300 m ³	1.60E-03	1.73E-05	620 000	230 000
	Indoor environments (specifically agricultural premises and equipment)	Indoor surface spray: broadcast	MPHW PCO / MechPH-ULV	0.0402 kg a.i./m ²	1040 m ²	4.49E+01	1.72E-01	22	23
	Indoor environments	Indoor surface spray: broadcast, perimeter, spot, crack and crevice; nest		0.00276 kg a.i./m ²		3.08E+00	1.18E-02	320	330
Outdoor plants and outdoor areas (structures and	Outdoor broadcast (foliar),	MPHG	0.00077 kg a.i./L ^f	3800 L	2.04E-01	5.52E-03	4,900	710	
		MPHW			150	1.36E-03	6.53E-05	730 000	60 000

Form.	Site(s)	Application method ^l	Application equipment	Max. application rate ^a	ATPD /AHPD	Dermal exposure ^b (mg/kg bw/day)	Inhalation exposure ^b (mg/kg bw/day)	Dermal MOE ^c (T=100)	Inhalation MOE ^d (T=300)
	surrounding areas)		Backpack		L				
					150 L	7.86E-03	8.97E-05	130 000	43 000
		Outdoor space spray (mosquito abatement)	Truck-mounted spray equipment ^g	1.68 kg a.i./ha ^o 0.01805 kg a.i./ha ^o	1,200 ha	9.65E+01	2.45E-01	10	16
						1.04E+00	2.63E-03	960	1500
Dust	Outdoor areas, Indoor Environments	Surface spray: Broadcast, perimeter, spot, crack and crevice; void; furniture treatment	Bulbous/Plunger Duster; Hand-crank Duster; Electric/Power Duster ^m	0.000582 kg a.i./m ²	111 m ²	1.26E-01	2.19E-03	8000	1800
						1.96E-01	3.12E-02	5100	130
	Indoor Environments	Nests	Bulb duster ^m Shaker can ⁿ	0.000194 kg a.i./nest (large nest)	100 nests ^p	3.78E-02	6.57E-04	26 000	5900
						5.88E-02	9.36E-03	17 000	420
PPE (M/L): Single layer (long pants, long-sleeved shirt) + CR gloves; (A): CR coveralls, CR hood, CR gloves, CR footwear, socks + Respirator^e									
Liquid	Indoor environments	Indoor space spray	MPHS	0.0000775 kg a.i./m ³	2540 m ³	8.03E-02	9.70E-03	12 000	400
	Direct application to animals	Direct application to livestock	HH AB/MB	0.0004716 kg a.i./animal	6440 animals	1.24E+00	1.50E-01	810	26
	Outdoor plants and outdoor areas	Outdoor broadcast (foliar)	HH AB/MB	0.7322 kg a.i./ha	0.81 ha	2.42E-01	2.92E-02	4100	130
	Outdoor plants and outdoor areas	Outdoor space spray (mosquito abatement)	HH AB/MB	1.68 kg a.i./ha ^o 0.01805 kg a.i./ha ^o	0.81 ha	5.55E-01	6.70E-02	1800	58
5.96E-03						7.20E-04	170 000	5400	
Mitigation									
For HH AB/MB: Limit a.i. handled/day^j									
Liquid	Outdoor plants and outdoor areas	Outdoor broadcast (foliar)	HH AB/MB,	0.27 kg a.i./day		1.08E-01	1.31E-02	9300	300
	Direct application to animals	Direct application to livestock	HH AB/MB						

Form.	Site(s)	Application method ^l	Application equipment	Max. application rate ^a	ATPD /AHPD	Dermal exposure ^b (mg/kg bw/day)	Inhalation exposure ^b (mg/kg bw/day)	Dermal MOE ^c (T=100)	Inhalation MOE ^d (T=300)
For shaker can: Single layer (long pants, long-sleeved shirt) + CR gloves + Filtering facepiece respirator (Dust Mask) ^q									
Dust	Outdoor areas, indoor environments	Surface spray: Broadcast, perimeter, spot, crack and crevice; void; furniture treatment	Shaker can ⁿ	0.000582 kg a.i./m ²	111 m ²	1.96E-01	6.23E-03	5100	630

Form. = formulation; PP = pressurized product; Max = maximum; ATPD / AHPD = area treated per day or amount handled per day; MOE = margin of exposure; T = target MOE; M/L/A = mixer/loader/applicator; CR = chemical resistant; MPHG = mechanically-pressurized handgun; MPHW = manually-pressurized handwand; MechPH-ULV = Mechanically-pressurized handheld ULV equipment; PCO = pest control operator; HH AB/MB = handheld airblast/mistblower; MPHS = mechanically-pressurized handheld sprayer for mists, aerosols, and fogs; PPE = personal protective equipment

Bolded values indicate that the target MOE was not met, and further mitigation is required.

^a Highest available rate for all listed scenario/application equipment are presented. Pressurized product (aerosol can) application rate is based on net contents, maximum concentration of piperonyl butoxide and density.

^b Where exposure (mg/kg bw/day) = (unit exposure × area treated per day × application rate)/80 kg.

^c Dermal MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 100.

^d Inhalation MOEs for short- to intermediate-term exposure durations are based on a LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target MOE of 300

^e NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides.

^f Maximum application rate was calculated based on a spray volume of 380 L/0.4 ha and the application rate for outdoor ornamentals and outdoor (non-structural) applications (732.2 g a.i./ha).

^g Airblast application equipment was used as surrogate for truck-mounted ULV sprayer application equipment.

^h For PP, this was assessed using unit exposures for PHED aerosol (MLA) + PHED paintbrush (A). For liquids, this was assessed using unit exposures for AHETF liquid (M/L) + PHED paintbrush (A). The same inputs and approach was used from the 2020 monograph.

ⁱ Exposure data was not available for loading aerosol cans into a metered release dispenser; however, exposure is considered to be less than aerosol can application. As MOEs for all aerosol can application scenarios were greater than the target MOE, exposure from loading a metered release device is considered to be acceptable.

^j Limit on amount handled for HH AB/MB equipment is required to reach target MOEs for all scenarios.

^k Based on product with largest amount of piperonyl butoxide (900g, 5% piperonyl butoxide) across all use sites. This was determined when looking at all commercial-class pressurized products.

^l Not all application methods are registered for all sites. This is a summary of all application methods across all sites.

^m Not all of this equipment is registered for all products. Furthermore, the unit exposure values used are from the USEPA 2012 Residential SOP which does not assume applicators wear gloves. This may result in an overestimate of exposure for commercial applicators.

ⁿ The unit exposure values used for shaker can are from the USEPA Occupational Pesticide Handler Unit Exposure Surrogate Reference table (2018) and are representative for commercial applicators (including appropriate PPE).

^o Highest application rate (1.68 kg a.i./ha) for outdoor mosquito abatement. 2nd highest rate was 0.01805 kg a.i./ha.

^p Value (100 nests) was used as a tier-1 input based on the approach followed by the USEPA in its Proposed Interim Registration Review Decision for cyfluthrin (USEPA, 2020).

^q NIOSH approved N95 (minimum) filtering facepiece respirator (dust mask).

^r As part of a Tier 1 assessment, the highest indoor fogging rate was assumed for this equipment.

Table 3 Postapplication worker exposure and risk assessment

Site	Activity	TC (cm ² /hr) ^a	DFR (µg/cm ²) ^b	Rate (kg a.i./ha) ^c	Max. # of apps per year	Min. Interval between apps (days)	Dermal exposure (mg/kg bw/day) ^d	MOE (day 0) (T=100) ^e	REI
Outdoor areas following outdoor space spray (for example, mosquito abatement) including pastures ^f	Scouting	1100	8.05	1.68 ^g	24	7	0.89	1100	Until sprays have dried
Outdoor ornamentals	Cut flower, hand harvesting, disbudding, and pruning (full foliage)	4000	3.51	0.732 ^h	30	7	1.40	710	12 Hrs
	Hand set/hand line irrigation related activities involving workers contacting foliage	1750					0.614	1600	
	Container Moving, Pinching, Plant support/staking, Pruning (Hand), Scouting, Transplanting, Weeding (Hand)	230					0.081	12 000	

TC = transfer coefficient; DFR = dislodgeable foliar; MOE = margin of exposure; T = target MOE; REI = restricted entry interval; hrs = hours; max = maximum; min = minimum; apps = applications; # = number

^a Standard transfer coefficient values were used unless otherwise noted.

^b No chemical specific DFR studies were available. The standard peak DFR value of 25% of the application rate and a 10% dissipation rate per day was used for all scenarios.

^c Highest available application rates for each site were assessed.

^d Dermal exposure (mg/kg bw/day) = DFR × TC × Exposure Time (8 hrs)/Body Weight (80 kg).

^e Dermal MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 100.

^f TCs for forage crop activities were used as surrogate for outdoor areas.

^g Maximum rate from mosquito abatement in outdoor areas (1680 g a.i./ha, 24 applications/year, 7-day interval between applications) was used as part of a Tier 1 approach. This rate was used to address all other registered space and surface applications to outdoor areas where workers may enter.

^h Maximum rate for broadcast applications to outdoor ornamentals (732.2 g a.i./ha, 30 applications/year, 7-day interval between applications).

Table 4 Residential applicator exposure and risk assessment

Scenarios	Form.	Application equipment	Treatment type	Maximum application rate ^a	ATPD ^b	Exposure (mg/kg bw/day) ^c		MOE		
						Dermal	Inhalation	Dermal ^d (T = 100)	Inhalation ^e (T = 300)	
Outdoor stinging insect nests	PP	Aerosol RTU can ⁿ	Outdoor – stinging insect nest)	0.0325 kg a.i./can	2 cans	6.63E-01	5.37E-03	1500	730	
Outdoor plants (for example, Ornamentals)	Liquid (Concentrate)	MPHW Backpack ^f	Foliar application (Broadcast)	0.002 kg a.i./L	18.927 L	6.57E-02	1.89E-05	15 000	210 000	
		Trigger spray Bottle			2 bottles	1.36E-01	1.47E-04	7400	27 000	
	RTU Liquid	Plunger Duster, Bulb Duster		0.0097 kg a.i./bottle	2 bottles	4.55E-02	3.15E-05	22 000	120 000	
	Dust	0.0004 kg a.i./m ²		111.48 m ²	3.07E-01	2.09E-03	3300	1900		
Indoor/ greenhouse plants (for example, ornamentals)	Liquid (Concentrate)	MPHW	0.002 kg a.i./L	18.927 L	6.57E-02	1.89E-05	15 000	210 000		
	PP	Aerosol RTU can	0.0325 kg a.i./can	2 cans	6.63E-01	5.37E-03	1500	730		
	RTU Liquid	Trigger spray bottle	0.002 kg a.i./bottle	2 bottles	9.38E-03	6.50E-06	110 000	600 000		
Outdoor areas (for example, backyard, porches, domestic kennels and stables, barns, surrounding bushes or grass)	PP	Aerosol RTU can ^o	Space Spray	0.0325 kg a.i./can	1 can	3.31E-01	2.69E-03	3000	1500	
			Surface application		2 cans	6.63E-01	5.37E-03	1500	730	
	RTU liquid	Trigger spray bottle	Surface application ⁱ	0.0189 kg a.i./bottle	2 bottles	8.86E-02	6.14E-05	11 000	63 000	
Outdoor areas (for example, backyard, porches, domestic kennels and stables, barns, surrounding bushes or grass)	Dust	Shaker Can ^{f, n}	Surface application (Broadcast)	0.00004 kg a.i./m ²	111.48 m ²	5.28E-01	2.21E-03	1900	1800	
	Indoor Environments: Agricultural Premises (including animal barns)	RTU Liquid	Trigger Spray Bottle	Surface spray (Broadcast) ⁱ	0.0189 kg a.i./bottle	1 bottle	8.86E-02	6.14E-05	23 000	130 000

Scenarios	Form.	Application equipment	Treatment type	Maximum application rate ^a	ATPD ^b	Exposure (mg/kg bw/day) ^c		MOE	
						Dermal	Inhalation	Dermal ^d (T = 100)	Inhalation ^e (T = 300)
Indoor Environments: Dwellings and Indoor Sites (including bed bug treatment); Pet Premises (in homes); and/or Clothing Treatment ^h	Liquid (Concentrate)	MPHW	Surface spray (Broadcast)	0.020 kg a.i./L	1.89 L	7.19E-02	1.15E-03	14 000	3400
		Backpack ^q	Space spray	0.00003 kg a.i./m ³	369 m ³	3.97E-02	4.29E-05	25 000	91 000
	PP	Aerosol RTU Can	Surface spray (Broadcast)	0.0325 kg a.i./can	1 can	3.31E-01	2.69E-03	3000	1500
		Aerosol RTU Can (including total release foggers)	Space spray		0.25 cans	8.28E-02	6.71E-04	12 000	5800
	RTU Liquid	Trigger Spray Bottle ^p	Surface spray (Broadcast) ⁱ	0.012 kg a.i./bottle	1 bottle	2.81E-02	1.95E-05	36 000	200 000
			Space Spray ^l	0.000014 kg a.i./m ³	369 m ³	1.21E-03	8.39E-07	830 000	4 600 000
	Dust	Bulb Duster	Surface application (broadcast)	0.0004 kg a.i./m ²	111.48 m ²	3.07E-01	2.09E-03	3300	1900
			Surface application (Perimeter, spot)	0.01 kg a.i./kg dust	0.113 kg dust	7.79E-03	5.30E-05	130 000	74 000
		Plunger Duster	Surface application (Broadcast)		0.227 kg dust	1.56E-02	1.06E-04	64 000	37 000
		Shaker Can ^f	Surface application (Broadcast)	0.026 kg a.i./can ^g	1 can	3.08E00	1.29E-24	320	300
Indoor Environments: Agricultural Premises (for example, livestock housing, animal barns/quarters)	RTU Liquid	Trigger Spray Bottle	Surface spray (Broadcast) ⁱ	0.0189 kg a.i./bottle	1 bottle	8.86E-02	6.14E-05	23 000	130 000
All indoor environments	PP	Automatic dispensers	Space spray: Metered release	Applicator exposure from loading automatic dispensers is expected to be low compared to other scenarios.					

Scenarios	Form.	Application equipment	Treatment type	Maximum application rate ^a	ATPD ^b	Exposure (mg/kg bw/day) ^c		MOE	
						Dermal	Inhalation	Dermal ^d (T = 100)	Inhalation ^e (T = 300)
Direct application to Livestock (Horses, ponies)	Liquid (Concentrate)	MPHW	Livestock, direct animal treatment	0.000402 kg a.i./animal	24 animals	1.67E-02	4.82E-06	60 000	810 000
	RTU Liquid	Trigger spray Bottle		0.002 kg a.i./animal		1.08E+00	4.37E-03	920	890
		Wipe-on (paste) ^j		0.002 kg a.i./animal		2.65E00	3.84E-04	380	10 000
	PP	Aerosol RTU Can		0.00088 kg a.i./animal		4.77E-01	1.92E-03	2100	2000
		Aerosol RTU Can, wipe ^j		0.00006 kg a.i./animal		7.94E-02	1.15E-05	13 000	340 000
	Direct application to Livestock (Cattle)	Liquid (Concentrate)		MPHW		0.0012 kg a.i./animal	5.00E-02	1.44E-05	20 000
RTU Liquid		Trigger spray Bottle	6.51E-01	2.62E-03	1500		1500		
		Wipe-on (liquid) ^j	1.59E00	2.30E-04	630		17 000		
Direct application to Pets (Dogs, cats, birds, rabbits, etc.)	RTU Liquid	Shampoo	Pets, direct animal treatment	0.0128 kg a.i./animal ^k	2 animals	1.41E+00	2.05E-04	710	19 000
		Ear dropper ^j		0.0000157 kg a.i./animal		1.73E-03	2.51E-07	580 000	16 000 000
		Trigger Spray Bottle,		0.0031 kg a.i./animal ^k		1.41E-01	5.66E-04	7100	6900
		Rollerball ^m		0.000516 kg a.i./animal		2.33E-02	9.39E-05	43 000	42 000
	PP	Aerosol RTU Can		0.0208 kg a.i./animal ^k		9.40E-01	3.79E-03	1100	1000

Form = formulation; max = maximum; ATPD = area treated per day; MOE = margin of exposure; RTU = ready-to-use; MPHW = manually-pressurized handwand; T = target MOE; concentrate = product that is not RTU and will need to be mixed and/or loaded prior to application.

^a Highest available rates for each scenario/application equipment (unless noted otherwise). Except for treated pets and livestock, trigger sprayer, aerosol can, and space spray application rates were based on net contents, maximum concentration of piperonyl butoxide, and density.

^b Based on USEPA Residential SOP inputs (USEPA, 2012), except the value for livestock which was based on data from Statistics Canada (2016).

^c Where exposure (mg/kg bw/day) = (unit exposure × area treated per day × application rate)/80 kg.

^d Dermal MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 100.

^e Inhalation MOEs for short- to intermediate-term exposure durations are based on a LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target MOE of 300.

^f The unit exposure values are representative of persons wearing gloves in addition to short sleeves and short pants. As gloves are not assumed to be worn for domestic-class products, this may result in an underestimate of exposure.

^g The amount of dust that could be applied per day where risks are acceptable. The application rate of 0.026 kg a.i./can is representative of 2.6 kg of dust with the highest registered concentration of piperonyl butoxide (1%). Based on the registered application rate (0.4 g a.i./m²), this could treat 65 m², which is representative of almost 9 standard rooms (12 ft × 12 ft (7.3 m²)), which is considered to be high-end.

^h Exposure from clothing treatment is not expected to be greater than exposure from other surface applications in dwellings and indoor sites.

ⁱ The application rate for RTU liquid using trigger pump sprayer was based on product size (0.5% piperonyl butoxide, 3.785L).

^j Exposure from shampoo will address exposure from dropper bottle and wipe-on applications, including paste wipe on to wounds.

^k Application rates for liquid and pressurized products (0.03–0.12 g a.i./kg bw pet and 0.2 g a.i./kg bw pet, respectively) calculated based on assumption of 230 lbs (104 kg) for a large dog (mastiff).

^l There are domestic-class liquid products registered to be applied as a “fine mist” space spray (using trigger spray bottle).

^m Exposure from rollerball application is not expected to be greater than exposure from trigger spray bottle. This is consistent with the 2012 USEPA Residential SOP.

ⁿ Unit exposures from the Res SOP Gardens and Trees scenario were used for the applicable application equipment.

^o Unit exposures from the Res SOP Outdoor Fogging/Misting System scenario were used for the applicable application equipment.

^p Unit exposures from the Res SOP Indoor Environment scenario were used for the applicable application equipment.

^q Backpack application equipment is unlikely to be used indoors but was included in the assessment based on information from the registered use pattern. An outdoor scenario was used as surrogate, which may underestimate inhalation exposure, MOEs exceed the target MOE by a sufficient margin and risk are considered to be acceptable.

Table 5 Residential postapplication dermal exposure and risk assessment – outdoor areas and outdoor and indoor/non-commercial greenhouse plants

Exposure scenario			Life stage	DFR or TTR (µg/cm ²)	TC ^a (cm ² /hr)	ET ^b (hr/day)	Dermal Exposure ^c (mg/kg bw/day)	MOE ^d (T = 100)
Outdoor and indoor/greenhouse plants (for example, ornamentals, vegetation around buildings)	Liquid, PP	Gardens	Adult	16.6 ^e	8400	2.2	3.83	260
			Child (6 to <11 years)		4600	1.1	2.62	380
		Trees	Adult		1700	1	0.352	2800
			Child (6 to <11 years)		930	0.5	0.241	4200
		Indoor Plants / Greenhouses	Adult		220	1	0.0577	17 000
			Child (6 to <11 years)		120	0.5	0.0393	25 000
	Dust	Gardens	Adult	17.1 ^g	8400	2.2	3.94	250
			Child (6 to <11 years)		4600	1.1	2.70	370
		Trees	Adult		1700	1	0.363	2800
			Child (6 to <11 years)		930	0.5	0.248	4000

Exposure scenario		Life stage	DFR or TTR ($\mu\text{g}/\text{cm}^2$)	TC ^a (cm^2/hr)	ET ^b (hr/day)	Dermal Exposure ^c (mg/kg bw/day)	MOE ^d (T = 100)
Outdoor areas (structures and surrounding areas) after space spray for flying insects (for example, mosquito abatement)	PP	Adult	1.55 (peak) ^h	180 000	1.5	5.23	190
		Children (1 to <2 years)				10.4	100
			0.944 (TWA) ⁱ	49 000	1.5	6.31	160
	Commercial Liquid (Max rate-0.1680 g a.i./m ²)	Adult	0.322 ^j	180 000	1.5	1.09	920
		Children (1 to <2 years)				49 000	1.5
	Commercial Liquid (2 nd highest rate 0.001805 g a.i./m ²)	Adult	0.00346 ^k	180 000	1.5	0.0117	86 000
		Children (1 to <2 years)				49 000	1.5

DFR or TTR = dislodgeable foliar or turf transferable residue; TC = transfer coefficient; ET = exposure time; MOE = margin of exposure; T = target MOE; PP = pressurized product; TWA = time-weighted average; max = maximum; 2nd = second

^a Transfer coefficient values from USEPA Residential SOPs (2012) were used.

^b Exposure time values from USEPA Residential SOPs (2012) were used.

^c Dermal exposure (mg/kg bw/day) = DFR or TTR \times TC \times ET/body weight (kg). Body weights of 80, 32 and 11 kg were used for adults, children (6 to <11 years), and children (1 to <2 years), respectively, as stated in the USEPA Residential SOPs (2012).

^d Dermal MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 100.

^e Based on maximum domestic-class liquid application rate of 0.388 g a.i./m². Addresses all other rates for domestic and commercial-class liquid and pressurized products registered for this use. DFR is based on 3 applications per year: 7-day interval and standard peak DFR 25% of application rate and 10%/day dissipation outdoors.

^f Based on maximum domestic-class liquid application rate of 0.32 g a.i./m² for indoor ornamentals scenario. Addresses all other rates for domestic-class products registered for this use. No commercial-class products registered for this used. DFR is based on 15 applications per year; 7-day interval and standard peak DFR 25% of application rate and 2%/day dissipation indoors.

^g Based on maximum domestic-class outdoor ornamental dust rate of 0.40 g a.i./m². Addresses all other rates for domestic-class dust products registered for this use. DFR is based on 3 applications per year, 7-day interval and standard peak DFR 25% of application rate and 10%/day dissipation outdoors.

^h Based on maximum amount of piperonyl butoxide in a commercial-class pressurized product (33.6 g a.i./can) used for outdoor space sprays. This addresses all domestic-class products registered for this use. TTR is based on 3 applications per year: 7-day interval and standard peak TTR 1% of application rate and 10%/day dissipation outdoors.

ⁱ Same inputs as for footnote h; however, the TTR is an average of residues after the first application (day 0) to 7 days after the 3rd application (21 days). The value was calculated to support the hand-to-mouth incidental oral assessment (Appendix V, Table 11).

^j Based on maximum commercial-class liquid rate of 0.1680 g a.i./m² for outdoor space sprays for mosquito abatement TTR is based on 24 applications per year: 7-day interval and standard peak TTR 1% of application rate and 10%/day dissipation outdoors. This TTR value addresses the maximum rate for application to vegetation around buildings (0.0732 g a.i./ m²).

^k Based on second highest commercial-class liquid rate of 0.001805 g a.i./m² outdoor space sprays for mosquito abatement TTR is based on (30 applications per year; 7-day interval and standard peak TTR 1% of application rate and 10%/day dissipation outdoors).

Table 6 Residential postapplication dermal exposure and risk assessment – indoor environments (short- to intermediate-term)

Exposure scenario		Life stage	TR ^a ($\mu\text{g}/\text{cm}^2$)	TC ^b (cm^2/hr)	ET ^c (hr/day)	Dermal Exposure ^d (mg/kg bw/day)	MOE ^e ($T = 100$)	
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	Broadcast ^f (Max rate - 40.2 g a.i./m ²)	Soft Surface	Adults	80.4	6800	8	5.47E+01	18
			Children (1 to <2 years)		1800	4	5.26 E+01	19
		Hard Surface	Adults	201	6800	2	3.42E+01	29
			Children (1 to <2 years)		1800	2	6.58E+01	15
	Broadcast ^g (2 nd highest non-res rate: 2.76 g a.i./m ²)	Soft Surface	Adults	5.52	6800	8	3.75E+00	270
			Children (1 to <2 years)		1800	4	3.61E+00	280
		Hard Surface	Adults	13.8	6800	2	2.35E+00	430
			Children (1 to <2 years)		1800	2	4.52E+00	220
	Perimeter/ Spot/Bed bug (Coarse and Pin Stream) ^g (2.76 g a.i./m ²)	Soft Surface	Adults	2.76	6800	8	1.88E+00	530
			Children (1 to <2 years)		1800	4	1.81E+00	550
		Hard Surface	Adults	6.9	6800	2	1.17E+00	850
			Children (1 to <2 years)		1800	2	2.26E+00	440
	Bed bug crack and crevice ^h (Commercial application only) (Max com BB rate - 0.813 g a.i./m ²)	Soft Surface	Adults	0.407	6800	8	2.76E-01	3,600
			Children (1 to <2 years)		1800	4	2.66E-01	3,800
		Hard Surface	Adults	1.02	6800	2	1.73E-01	5,800
			Children (1 to <2 years)		1800	2	3.33E-01	3,000
	Crack and Crevice (Commercial application only) ^g (2.76 g a.i./m ²)	Soft Surface	Adults	0.552	6800	8	3.75E-01	2,700
			Children (1 to <2 years)		1800	4	3.61E-01	2,800
Hard Surface		Adults	1.38	6800	2	2.35E-01	4,300	
		Children (1 to <2 years)		1800	2	4.52E-01	2,200	
Space Spray (liquid) ⁱ	Soft Surface	Adults	0.378	6800	8	2.57E-01	3,900	
		Children (1 to <2 years)		1800	4	2.47E-01	4,000	

Exposure scenario		Life stage	TR ^a ($\mu\text{g}/\text{cm}^2$)	TC ^b (cm^2/hr)	ET ^c (hr/day)	Dermal Exposure ^d (mg/kg bw/day)	MOE ^e (T = 100)	
			to <2 years)					
		Hard Surface	Adults	0.945	6800	2	1.61E-01	6,200
	Children (1 to <2 years)		1800		2	3.09E-01	3,200	
	Space Spray (PP, including total release fogger) ^j	Soft Surface	Adults	0.702	6800	8	4.78E-01	2,100
			Children (1 to <2 years)		1800	4	4.60E-01	2,200
		Hard Surface	Adults	1.76	6800	2	2.98E-01	3,400
			Children (1 to <2 years)		1800	2	5.75E-01	1,700
	Space Spray (PP) - Metered Release automatic dispenser ^k	Soft Surface	Adults	0.0165	6800	8	1.12E-02	89,000
			Children (1 to <2 years)		1800	4	1.08E-02	92,000
		Hard Surface	Adults	0.0413	6800	2	7.02E-03	140,000
			Children (1 to <2 years)		1800	2	1.35E-02	74,000

TR = transferable residue; TC = transfer coefficient; ET = exposure time; MOE = margin of exposure; T = target MOE; PP = pressurized product; Max = maximum; 2nd = second

^a Transferable residue calculated based on the amount of residue deposited on surfaces, depending on the application rate and the exposure scenario, and the chemical-specific fraction transferred values of 2% for soft surfaces and 5% for hard surfaces for indoor scenarios.

^b Transfer coefficient values from USEPA Residential SOPs (2012) were used.

^c Exposure time values from USEPA Residential SOPs (2012) were used.

^d Dermal exposure (mg/kg bw/day) = TR × TC × ET/BW (kg). Body weights of 80, and 11 kg were used for adults and children (1 to <2 years), respectively, as stated in the USEPA Residential SOPs (2012).

^e Dermal MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 100.

^f Based on the maximum commercial-class liquid product rate of 40.2 g a.i./m² for surface spray broadcast applications. No other application methods were registered for this rate. Deposited residues used to calculate the TR are calculated as fractions of the label rate: 100% for broadcast.

^g Based on the second highest commercial-class liquid product rate of 2.76 g a.i./m² for surface spray applications. This rate was used to address exposure for all other liquid/pressurized products and surface spray application methods, except those specific to bedbug. Deposited residues used to calculate the TR are calculated as fractions of the label rate: 100% for broadcast, 50% for perimeter/spot/bed bug, 25% for commercial applicator-only bed bug crack and crevice, and 10% for standard crack and crevice treatment.

^h Based on the maximum commercial-class liquid product rate of 0.813 g a.i./m² for surface spray broadcast applications for bedbugs. Deposited residues used to calculate the TR are calculated as fractions of the label rate: 25% for commercial applicator-only bed bug crack and crevice: Addresses all other commercial-class product rates. The rate for the domestic-class product is higher, but bed bug crack and crevice is only assumed for pest control operators (PCO), as it assumes that PCOs will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture. This results in greater exposure than the standard crack and crevice method, but less than the perimeter/spot method.

ⁱ Based on maximum commercial-class liquid product rate of 0.0775 g a.i./m³. Rate addresses domestic-class liquid products applied by trigger spray bottle. Deposited residues used to calculate the TR were estimated by assuming all residues in the air were deposited evenly on the room surface.

^j Based on commercial-class pressurized product rate of 0.144 g a.i./m³. This rate addresses the domestic-class rate of 0.125 g a.i./m³. Deposited residues used to calculate the TR were estimated by assuming all residues in the air were deposited evenly on the room surface.

^k Deposited residue calculation was updated to be based on application rate per spray event and room volume, which is consistent with the space spray scenario. In addition, the residues were extrapolated to estimate what could be deposited in a day (24 hours).

Table 7 Residential postapplication dermal exposure and risk assessment – indoor environments (long-term, for bed bugs)

Exposure scenario		Life stage	TR ^a ($\mu\text{g}/\text{cm}^2$)	TC ^b (cm^2/hr)	ET ^c (hr/day)	Dermal exposure ^d (mg/kg bw/day)	MOE (T = 300) ^e	
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	Broadcast (Highest domestic-class BB rate: 1.1 g a.i./m ²)	Soft surface	Adults	2.20	4700	8	1.03E+00	970
			Children (1 to <2 years)		1300	4	1.04E+00	960
		Hard surface	Adults		4700	2	2.59E-01	3,900
			Children (1 to <2 years)		1300	2	5.20E-01	1,900
	Perimeter/Spot/Bed bug (Coarse and Pin Stream) (1.1 g a.i./m ²)	Soft surface	Adults	1.10	4700	8	5.17E-01	1,900
			Children (1 to <2 years)		1300	4	5.20E-01	1,900
		Hard surface	Adults		4700	2	1.29E-01	7,700
			Children (1 to <2 years)		1300	2	2.60E-01	3,800
	Bed bug crack and crevice ^f (Commercial application only) (Highest commercial BB rate: 0.813 g a.i./m ²)	Soft surface	Adults	0.407	4700	8	1.91E-01	5,200
			Children (1 to <2 years)		1300	4	1.92E-01	5,200
		Hard surface	Adults		4700	2	4.78E-02	21,000
			Children (1 to <2 years)		1300	2	9.61E-02	10,000
	Space Spray (PP, including total release fogger) (Highest BB rate: 0.0915 g a.i./m ³) ^g	Soft surface	Adults	0.446	4700	8	2.10E-01	4,800
			Children (1 to <2 years)		1300	4	2.11E-01	4,700
		Hard surface	Adults		4700	2	5.24E-02	19,000
			Children (1 to <2 years)		1300	2	1.05E-01	9,500

TR = transferable residue; TC = transfer coefficient; ET = exposure time; MOE = margin of exposure; T = target MOE; PP = pressurized product; BB = bed bug

^a Transferable residue for surface sprays calculated based on the application rate and the exposure scenario using (50th percentile) chemical-specific fraction transferred values of 2% for both soft and hard surfaces. Application rate is based on maximum indoor surface rate for domestic-class PP product with bed bug uses (1.10 g a.i./m²). It addresses other domestic-class products with this use and the highest rate for commercial-class liquid products with bed bug uses (0.813 g a.i./m²). Deposited residues are calculated as fractions of the label rate: 100% for broadcast, 50% for perimeter/spot/bed bug, and 25% for commercial applicator-only bed bug crack and crevice. Space spray deposited residues assume everything sprayed into the air is evenly deposited on the ground.

^b Transfer coefficient values from USEPA Residential SOPs (2012) were used. 50th percentile values were used for long-term exposure durations.

^c Exposure time values from USEPA Residential SOPs (2012) were used.

^d Dermal exposure (mg/kg bw/day) = TR × TC × ET/BW (kg). Body weights of 80 and 11 kg were used for adults and children (1 to <2 years), respectively, as per the USEPA Residential SOPs (2012).

^e Dermal MOEs for the long-term exposure duration are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 300.

^f Bed bug crack and crevice: Assumes pest control operators (PCO) will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture. This results in greater exposure than the standard crack and crevice method, but less than the perimeter/spot method. This application method is only assumed for commercial-class products.

^g Highest space spray application rate for bed bugs (commercial-class pressurized product). Addresses other space sprays registered for use on bed bugs.

Table 8 Residential postapplication dermal exposure and risk assessment – mattresses (long-term, for bed bugs)

Exposure scenario	Life stage	Deposited residue (µg/cm ²) ^a	Surface area/Body weight ratio (cm ² /kg) ^b	Dermal exposure (mg/kg bw/day) ^c	MOE ^d (T = 300)
Bed bugs (highest available domestic-class application rate of 1.10 g a.i./m²)					
Application to mattress	Adults	55.0	280	0.077	13,000
	Children (1 to <2 years)		640	0.176	5,700
Bed bugs (highest available commercial-class application rate of 0.813 g a.i./m²)					
Application to mattress	Adults	40.65	280	0.0569	18,000
	Children (1 to <2 years)		640	0.130	7,700

MOE = margin of exposure; T = target MOE

^a Deposited residue for mattresses is based on the maximum indoor surface rate for domestic-class and liquid products with bed bug uses. Deposited residues are calculated as fractions of the label rate (50%). See Section 3.14.2 for more information,

^b Values were obtained from the USEPA Residential SOPs (2012) for adults and children (1 to <2 years).

^c Dermal exposure (mg/kg bw/day) = (Deposited Residue (µg/cm²) × 0.001 mg/µg × Surface Area/Body Weight Ratio (cm²/kg) × Fraction of skin in contact with mattress (0.5) × Fraction transferred (0.02) × Protection Factor (0.5). The fraction transferred value is chemical-specific and the same for all exposure durations for soft surfaces such as mattresses.

^d Dermal MOEs for the long-term exposure duration are based on a NOAEL of 1000 mg/kg bw/day from a 21-day rabbit dermal toxicity study and a target MOE of 300.

Table 9.1 Residential postapplication inhalation exposure and risk assessment for outdoor space sprays (liquid) and indoor space sprays (liquid and total release foggers)

Exposure scenario	Life stage	C ₀ or AR ^a	ET ^b (hr/day)	Inhalation Exposure ^c (mg/kg bw/day)	MOE ^d (T = 300)
Highest available application rates for space sprays					
Outdoor areas (structures and surrounding areas) after space spray application for flying insects (for example, mosquito abatement)	Commercial liquid – max rate (0.1680 g a.i./m ²) ^e	Adult	1.5	4.03E-02	97
		Children (1 to <2 years)		1.51E-01	26
	Commercial liquid- 2 nd highest rate (0.001805 g a.i./m ²) ^f	Adult	1.5	4.33E-04	9,000
		Children (1 to		1.62E-03	2,400

Exposure scenario		Life stage	C ₀ or AR ^a	ET ^b (hr/day)	Inhalation Exposure ^c (mg/kg bw/day)	MOE ^d (T = 300)
		<2 years)				
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	PP- total release fogger; max rate (0.0266 g a.i./m ³) ^g	Adult	26.6 mg a.i./m ³	2	2.81E-01	14
		Children (1 to <2 years)		2	1.05E+00	4
	PP- total release fogger; lowest rate (0.0034 g a.i./m ³) ^g	Adult	3.4 mg a.i./m ³	2	3.59E-02	110
		Children (1 to <2 years)		2	1.35E-01	29
	Commercial liquid- max rate (0.0775 g a.i./m ³) ^h	Adult	77.5 mg a.i./m ³	2	8.18E-01	4.8
	Liquid- lowest rate (0.0016 g a.i./m ³) ⁱ	Adults	1.60 mg a.i./m ³	2	1.69E-02	230
		Children (1 to <2 years)		2	6.33E-02	62

Bolded cells indicate that the target MOE was not met, and risks were not shown to be acceptable.

ET = exposure time; MOE = margin of exposure; T = target MOE; max = maximum; 2nd = second

^a Application rate (AR) or C₀ = initial air concentration (mg/m³) following a space spray determined from the label application rate if available, or from the maximum product size and highest concentration of piperonyl butoxide.

^b Exposure time values from USEPA Residential SOPs (2012) were used.

^c For outdoor areas, inhalation exposure (mg/kg bw/day) = AR (Application rate (g a.i./m²) × treated area (1 m²)/0.5 m × 1000 mg/g) × fraction of chemical available in outdoor air (1%) × inhalation rate × ET (hr) / BW (kg). Body weights of 80 and 11 kg were used for adults and children (1 to <2 years), respectively, as stated in the USEPA Residential SOPs (2012). Inhalation rates are 0.64 m³/h and 0.33 m³/h for adults and children, respectively.

For indoor environments, inhalation exposure (mg/kg bw/day) = [(C₀ × IR) / (ACH × BW)] × [1 - e^(-ACH × ET)]. Where C₀ = application rate (g a.i./m³) × 1000 mg/g; IR = inhalation rate (m³/hr); ACH = air exchanges per hour (0.45 hr⁻¹); values from USEPA Residential SOPs (2012).

^d Inhalation MOEs for short- to intermediate-term exposure durations are based on a LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target MOE of 300.

^e Based on maximum commercial-class liquid rate of 0.1680 g a.i./m². Exposure (mg/day) = AR × F × IR. Where AR = application rate, calculated as the amount applied to 1 m × 1 m × 0.5 m space (mg/m³); F = fraction of chemical available in outdoor air for exposure (0.01); IR = inhalation rate (m³/hr), values from USEPA Residential SOPs (2012).

^f Based on the next highest commercial-class liquid product rate of 0.001805 g a.i./m².

^g Based on maximum commercial- and domestic-class pressurized product rate of 0.0266 g a.i./m³ for products that can be used as a total release fogger. The lowest registered rate is 0.0034 g a.i./m³ from a domestic-class product.

^h Based on maximum commercial-class liquid space spray product rate of 0.0775 g a.i./m³. This rate is specifically for commercial sites with no residential uses ("Dried Fruit products being processed and in storage") therefore children were not included in the assessment.

ⁱ Based on the lowest commercial-class liquid space spray product rate of 0.0016 g a.i./m³. This addresses the lowest liquid domestic-class product rate (0.011 g a.i./m³) for trigger pump sprayer application.

Table 9.2 Residential postapplication short-term inhalation exposure from aerosols – refined using air concentration estimates for pressurized product (outdoor)

Sampling Interval	Air Concentration (mg/m ³)		Exposure Time (hrs) ^b	Exposure (mg/kg bw/day) ^c	
	Cyfluthrin (Boatwright, 2009)	Piperonyl Butoxide (estimated) ^a		Adults	Children (1 to <2 years)
0–5 min	2.33 ^d	670	0.0833	4.47E-04	1.68E-03
5–10 min	1.00	288	0.0833	1.92E-04	7.20E-04
10–20 min	0.500	141	0.167	1.92E-04	7.20E-04
20–40 min	0.250	72.0	0.333	1.92E-04	7.20E-04
40–80 min	0.125	36.0	0.667	1.92E-04	7.20E-04
80–120 min ^e	0.0227	36.0	0.667	1.92E-04	7.20E-04
Total Exposure			2	1.41E-03	5.27E-03
Inhalation MOE (target = 300)^f				2800	740

Bolded indicate when residues were <LOQ and air concentration was calculated based on ½ LOQ (5 ng/L); Min = minutes; max = maximum; MOE = margin of exposure

^a Estimated piperonyl butoxide air concentration (µg/m³) = piperonyl butoxide: cyfluthrin fold difference (283) × cyfluthrin air concentration, where piperonyl butoxide: cyfluthrin fold difference = piperonyl butoxide amount dispensed (= max of 33.6 g a.i./can for this use (700 g × 4.8% piperonyl butoxide)) / cyfluthrin amount dispensed in study (0.117 g). Estimated piperonyl butoxide air concentrations are representative of a person applying the entire 700 g can to the area in the study that was treated with a 454 g can.

^b Exposure time is the length of the duration of sampling, unless otherwise indicated.

^c Exposure = piperonyl butoxide estimated air concentration (mg/m³) × inhalation rate (m³/hr) × exposure time (hr)/body weight. Inhalation rates are 0.64 and 0.33 m³/hr for adults and children, respectively. Body weights are 80 and 11 kg for adults and children, respectively.

^d The data (greater than LOQ) were adjusted by field fortification recoveries because the corresponding average recoveries were less than 95% (93.4% for cyfluthrin, 90.1% for prallethrin)

^e The sampling interval of 80-120 minutes was extrapolated using ½ LOQ (5 ng/tube) and air volume for 40 minutes (0.04 m³); the 80-300 minute time interval resulted in residues <LOQ (10 ng/tube).

^f MOE = LOAEL/exposure, based on LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target of 300 for the short- to intermediate-term exposure duration.

Table 9.3 Residential postapplication short-term inhalation exposure from aerosols – refined using air concentration estimates for pressurized product (indoor)

Sampling interval	Air concentration (mg/m ³) ^a		Exposure time (hrs) ^b	Exposure (mg/kg bw/day) ^c			
	1 ft height	5 ft height		Adults		Children (1 to <2 years)	
				1 ft height	5 ft height	1 ft height	5 ft height
Acedo, 2016 (Study rate of 0.0027 g a.i./m³ normalized to max rate: 0.144 g a.i./m³)^f							
0–15 min	0.491	0.103	0.25	5.17E-02	1.08E-02	1.94E-01	4.06E-02
15–30 min	0.103	0.095	0.25	1.08E-02	1.00E-02	4.06E-02	3.75E-02
30–60 min	0.064	0.054	0.5	1.34E-02	1.13E-02	5.02E-02	4.25E-02
60–120 min	0.026	0.022	1	1.10E-02	9.22E-03	4.13E-02	3.46E-02
Total exposure^d			2	8.69E-02	4.14E-02	3.26E-01	1.55E-01

Air concentration (mg/m ³) ^a			Exposure time (hrs) ^b	Exposure (mg/kg bw/day) ^c			
Sampling interval	1 ft height	5 ft height		Adults		Children (1 to <2 years)	
				1 ft height	5 ft height	1 ft height	5 ft height
Inhalation MOE (target = 300)^e			45	94	12	25	
Acedo, 2016 (Study rate of 0.0027 g a.i./m³ normalized to max rate: 0.144 g a.i./m³)^e 1 hour re-entry interval^g							
60–120 min	0.026	0.022	1	1.10E-02	9.22E-03	4.13E-02	3.46E-02
Total exposure^d			1	1.10E-02	9.22E-03	4.13E-02	3.46E-02
Inhalation MOE (target = 300)^e				354	423	94	113
Acedo, 2016 (Study rate of 0.0027 g a.i./m³ normalized to rate limit: 0.0050 g a.i./m³)^b							
0–15 min	0.491	0.103	0.25	1.79E-03	3.76E-04	6.73E-03	1.41E-03
15–30 min	0.103	0.095	0.25	3.76E-04	3.47E-04	1.41E-03	1.30E-03
30–60 min	0.064	0.054	0.5	4.65E-04	3.93E-04	1.74E-03	1.47E-03
60–120 min	0.026	0.022	1	3.82E-04	3.20E-04	1.43E-03	1.20E-03
Total exposure^d			2	3.02E-03	1.44E-03	1.13E-02	5.39E-03
Inhalation MOE (target = 300)^e				1300	2700	340	720

Min = minutes; max = maximum; MOE = margin of exposure; ft = foot

Bolded values indicate that the target MOE was not met, and risks were not shown to be acceptable.

^a Estimated from chemical-specific studies (Acedo, 2016).

^b Exposure time is the length of the duration of sampling.

^c Exposure = air concentration (mg/m³) × (maximum Canadian application rate (mg a.i./m³)/study application rate (mg a.i./m³)) × inhalation rate (m³/hr) × exposure time (hr)/body weight. Inhalation rates are 0.64 and 0.33 m³/hr for adults and children, respectively. Body weights are 80 and 11 kg for adults and children, respectively.

^d Total exposure = Sum of exposures over 2-hour sampling period.

^e MOE = LOAEL/exposure, based on LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target of 300 for the short- to intermediate-term exposure duration.

^f The maximum registered pressurized product space spray application rate of 0.144 g a.i./m from commercial-class products addresses the maximum rate for domestic-class products (0.1250 g a.i./m).

^g Inhalation exposure assuming a 1-hour re-entry interval was assessed. Only air concentrations after 60 minutes were included in the assessment. Longer re-entry intervals could not be assumed given the sampling intervals used in the study.

^h The highest registered pressurized product space spray application rate where risks are shown to be acceptable.

Table 10 Residential postapplication inhalation exposure and risk assessment (metered release applications)

Exposure Scenario		Life stage	Air Concentration ($\mu\text{g}/\text{m}^3$) ^a	Exposure Time (hr/day) ^b	Inhalation Exposure (mg/kg bw/day) ^c	MOE ^d (T = 300)
Indoor environments (e.g., residential and commercial/ industrial/ institutional sites, agricultural premises)	Metered Release Automatic Dispensers	Adult	18.74	16	2.40E-03	1,600
		Children (1 to <2 years)		18	1.01E-02	390

MOE = margin of exposure; T = target MOE

^a Average steady-state air concentration from chemical-specific study (peak air concentration to end of the study monitoring period) after metered release spray at 1.8 metres away from the device.

^b Exposure Time (hr/day) values obtained from the USEPA Residential SOPs (2012) for vapours for indoor residential environments.

^c Inhalation exposure (mg/kg bw/day) = AC \times IR \times ET/BW. Where AC = air concentration obtained from study (following release of 55 mg insecticide every 15 minutes); IR = Inhalation Rate (m^3/hour) 0.64 and 0.33 m^3/hr for adult and children (1 to <2 years old), respectively. Body Weight values were 80 kg for adults and 11 kg for children (1 to <2 years old). Values from USEPA Residential SOPs (2012).

^d Inhalation MOEs for short- to intermediate-term exposure durations are based on a LOAEL of 3.9 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target MOE of 300.

Table 11 Residential postapplication hand-to-mouth incidental oral exposure and risk assessment

Exposure scenario			Hand residue (mg/hour) ^a	ET (hr/day) ^b	Oral exposure (mg/kg bw/day) ^c	Oral MOE ^d (T = 100)
Hand-to-mouth exposure (indoors/outdoors) – Children (1 to <2 years)						
Outdoor areas (structures and surrounding areas) after space spray application for flying insects (for example, mosquito abatement)	PP ^e	Residues deposited on lawns/turf	2.20 (peak)	1.5	3.51E-02	430
			1.34 (TWA)	1.5	2.14E-02	140
	Commercial- Liquid ^f - max rate (0.1680 g a.i./m ²)		0.473	1.5	7.54E-03	380
	Commercial- Liquid ^f - 2 nd highest rate (0.001805 g a.i./m ²)		0.0051	1.5	8.10E-05	36,000
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	Broadcast (Max rate 40.2 g a.i./m ²) ^g	Soft surface	10.8	4	4.94E-01	6
		Hard surface	27.1	2	6.17E-01	5
	Broadcast (2 nd highest residential rate 1.10 g a.i./m ²) ^h	Soft surface	0.297	4	1.35E-02	210
		Hard surface	0.743	2	1.69E-02	170
	Perimeter/Spot/Bed bug (Coarse and Pin Stream) (1.10 g a.i./m ²) ^h	Soft surface	0.149	4	6.75E-03	430
		Hard surface	0.371	2	8.44E-03	340

Exposure scenario		Hand residue (mg/hour) ^a	ET (hr/day) ^b	Oral exposure (mg/kg bw/day) ^c	Oral MOE ^d (T = 100)	
Hand-to-mouth exposure (indoors/outdoors) – Children (1 to <2 years)						
	Bed bug crack and crevice (Commercial application only) (Max Com BB rate- 0.813 g a.i./m ²) ⁱ	Soft surface	0.055	4	2.50E-03	1200
		Hard surface	0.137	2	3.12E-03	930
	Crack and Crevice (Commercial application only) (1.10 g a.i./m ²) ^h	Soft surface	0.0297	4	1.35E-03	2100
		Hard surface	0.0743	2	1.69E-03	1700
	Space spray (commercial liquid) ^j	Soft surface	0.0510	4	2.32E-03	1200
		Hard surface	0.128	2	2.90E-03	1000
	Space Spray (PP, including total release fogger) ^k	Soft surface	0.0948	4	4.31E-03	670
		Hard surface	0.237	2	5.39E-03	540
	Space Spray (PP) - Metered Release automatic dispenser ^l	Soft surface	0.0022	4	1.01E-04	29 000
		Hard surface	0.0056	2	1.27E-04	23 000

Bolded values indicate that the target MOE was not met, and risks were not shown to be acceptable.

HtM = hand-to-mouth; MOE = margin of exposure; ET = exposure time; PP = pressurized product; RTU = ready-to-use; T = target MOE; TWA = time-weighted average; N/A = Not applicable; TWA = time-weighted average; max = maximum; com = commercial; BB = bed bug; 2nd = second

^a For outdoor areas and indoor environments: Hand residue is based on the dermal postapplication exposure (dermal exposure value from Appendix V, Table 5 or Appendix V, Table 6, divided by the exposure time from the corresponding scenario) × fraction of a.i. on hands compared to body (0.06 for lawns/turf, 0.15 for indoor sites)/ 2 hands. For domestic-class PP, “peak” and “TWA” values were calculated from the dermal postapplication scenarios (Appendix V, Table 5 based on the peak turf transferable residue following 3 applications and 7-day interval and a TWA of residues from Day 0 of the first application to 7 days after the 3rd application (21 days).

^b Exposure time based on values from the USEPA Residential SOPs (2012).

^c For all scenarios: Oral Exposure (mg/kg bw/day) = [Hand Residue loading (mg/hr) × Fraction of hand mouthed (0.13)] × Exposure Time × (1 – (1 – Saliva Extraction Factor (0.48)) Number events per hour)/Replenishment Intervals (4/hr)]/ Body Weight (11 kg). Number of events per hour is 14 for outdoor areas (lawn/turf) and 20 for indoor environments (hard and soft surfaces). Body weights of 11 kg for children (1 to <2 years), as stated in the USEPA Residential SOPs (2012).

^d For all scenarios except domestic-class outdoor PP using the peak hand residue value: Oral MOEs for the intermediate-term exposure duration are based on a NOAEL of 2.9 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100. For domestic-class outdoor PP using the peak hand residue value: Oral MOEs for the short-term exposure duration are based on a NOAEL of 15.5 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100.

^e Based on maximum commercial-class product (33.6 g a.i./can- based on a can size of 700 g with 4.8% piperonyl butoxide). This addresses all other commercial and domestic-class PP registered for this use.

^f Both the maximum and second highest-rates for commercial-class liquid products were included in the assessment. The outcome is considered in the aggregate risk assessment. The maximum rate addresses the maximum rate for application to vegetation around buildings (0.0732 g a.i./m²).

^g Based on the maximum commercial-class liquid product rate of 40.2 g a.i./m² for surface spray broadcast applications in residential areas. No other application methods were registered for this rate. Although this rate is registered for agricultural areas, the inputs were not refined to reflect “barns” (for example, older children, shorter exposure time) as it would not significantly impact the risk outcome.

^h Based on the second highest domestic-class pressurized product application rate of 1.10 g a.i./m² for residential areas. The commercial-class liquid rate of 2.76 g a.i./m² assessed for dermal exposure is not registered for use in residential areas; children are not expected to be present during or after application, so a quantitative incidental oral risk assessment was not conducted.

ⁱ Based on the maximum commercial-class liquid product rate of 0.813 g a.i./m² for surface spray broadcast applications for bedbugs. Bed bug crack and crevice: Assumes pest control operators (PCO) will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture. This results in greater exposure than the standard crack and crevice method, but less than the perimeter/spot method.

^j Based on maximum commercial-class liquid product rate of 0.0775 g a.i./m³. This rate addresses the highest domestic-class liquid products that is applied using a trigger spray bottle.

^k Based on maximum commercial-class pressurized product rate of 0.144 g a.i./m³. This rate addresses the domestic-class rate of 0.125 g a.i./m³.

^l As discussed in Appendix V, Table 6, the approach for dermal exposure was updated. In this assessment, the rate of 0.0176 mg a.i./m³/spray event was used, and residues were assumed to be cumulative over 24 hours. See Appendix V, Table 6 for more information.

Table 12 Postapplication incidental soil ingestion exposure and risk assessment for children (1 to <2 years)

Exposure scenario	Application rate	Ingestion rate (mg/day)	Soil volume to weight conversion factor (cm ³ /g soil)	Oral exposure (mg/kg bw/day) ^a	MOE ^b
Outdoor areas (structures and surrounding areas) after space spray application for flying insects (for example, mosquito abatement)	0.1680 g a.i./m ^{2c}	50	0.67	5.1E-05	57 000

^a Where Oral Exposure (mg/kg bw/day) = Application rate × fraction available in the top cm of soil (1) × soil volume to weight conversion factor (0.67) × soil ingestion rate (50 mg/day)/BW (11 kg). Application rate is based on maximum commercial-class product rate for this scenario (1680 g a.i./ha); this rate addresses all other registered space spray rates for commercial- and domestic-class products. Other inputs from the USEPA Residential SOPs (2012).

^b Oral MOE for the intermediate-term exposure duration is based on a NOAEL of 2.9 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100.

^c The maximum rate for commercial-class liquid products used as a space spray in outdoor areas was included in the assessment. This rate addresses all other outdoor rates for all other products.

Table 13 Short- to intermediate-term residential postapplication object-to-mouth exposure and risk assessment for children (1 to <2 years)

Exposure Scenario		Object Residue (µg/cm ²) ^a	ET (hr/day) ^b	Oral exposure (mg/kg bw/day) ^c	OtM MOE ^d (T = 100)
Outdoor areas (structures and surrounding areas) after space spray application for flying insects (for example, mosquito abatement)	PP ^e	1.55 (peak)	1.5	6.30E-03	460
	Liquid (max: 0.1680 g a.i./m ²) ^f	0.322		7.06E-04	4100
	Liquid (2 nd highest: 0.001805 g a.i./m ²) ^f	0.00346		1.45E-05	200 000
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	Broadcast (Max rate: 40.2 g a.i./m ²) ^g	Soft surface	4	1.05E+00	3
		Hard surface	2	1.31E+00	2
	Broadcast (2 nd highest res rate: 1.10 g a.i./m ²) ^h	Soft surface	4	2.88E-02	100
		Hard surface	2	3.59E-02	81

Exposure Scenario		Object Residue ($\mu\text{g}/\text{cm}^2$) ^a	ET (hr/day) ^b	Oral exposure (mg/kg bw/day) ^c	OtM MOE ^d (T = 100)	
	Broadcast (3 rd highest res rate: 0.813 g a.i./m ²) ⁱ	Soft surface	1.63	4	2.13E-02	140
		Hard surface	4.07	2	2.66E-02	110
	Perimeter/Spot/Bed bug (Coarse and Pin Stream) (1.10 g a.i./m ²) ^h	Soft surface	1.10	4	1.44E-02	200
		Hard surface	2.75	2	1.80E-02	160
	Bed bug crack and crevice (Commercial application only) (max com BB rate: 0.813 g a.i./m ²) ⁱ	Soft surface	0.407	4	5.31E-03	550
		Hard surface	2.03	2	6.64E-03	440
	Crack and Crevice (Commercial application only) (1.10 g a.i./m ²) ^h	Soft surface	0.220	4	2.88E-03	1,000
		Hard surface	0.550	2	3.59E-03	810
	Space spray (liquid) ^j	Soft surface	0.378	4	4.94E-03	590
		Hard surface	0.945	2	6.18E-03	470
	Space Spray (PP, including total release fogger) ^k	Soft surface	0.702	4	9.18E-03	320
		Hard surface	1.76	2	1.15E-02	250
	Space Spray (PP) - Metered Release automatic dispenser ^l	Soft surface	0.0165	4	2.16E-04	13,000
		Hard surface	0.0413	2	2.70E-04	11,000

Bolded values indicate that the target MOE was not met, and risks were not shown to be acceptable.

OtM = object-to-mouth; MOE = margin of exposure; ET = exposure time; PP = pressurized product; T = target MOE; res = residential area(s); com = commercial-class product; BB = bed bug; max = maximum; 2nd = second; 3rd = third

^a Object residue is based on the deposited residue and chemical-specific fraction transferred values of 1% for lawns and turf, 2% for soft surfaces, 5% for hard surfaces. These values are the same as the transferrable residue values used for dermal exposure.

^b Exposure time based on values from the USEPA Residential SOPs (2012).

^c Oral Exposure (mg/kg bw/day) = [Object Residue ($\mu\text{g}/\text{cm}^2$) \times 0.001 mg/ μg \times Surface Area of object mouthed (10 cm²/event) \times (Exposure Time (hr) \times Replenishment Intervals (4/hr)) \times (1 - (1 - Saliva Extraction Factor (0.48)) Number events per hour/Replenishment Intervals (4/hr))] / Body Weight (11 kg), as in the USEPA Residential SOPs (2012). Number events per hour is 9 for lawns and turf and 14 for hard and soft surfaces.

^d OtM Oral MOEs for the intermediate-term exposure duration are based on a NOAEL of 2.9 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100. Since the point of departure for assessing short-term object-to-mouth oral exposure scenarios was higher (15.5 mg/kg bw/day) and had the same target MOE (100), the intermediate-term object-to-mouth assessments address the short-term object-to-mouth exposure scenarios as well.

^e Based on maximum commercial-class product can size of 33.6 g a.i./can (700 g can, 4.8% piperonyl butoxide). This can size addresses the highest domestic-class product can size registered for this use.

^f Based on maximum commercial-class liquid product rate of 0.1680 g a.i./m² for outdoor space sprays for mosquito abatement. Also includes the next highest rate of 0.001805 g a.i./m², which is considered in the aggregate risk assessment.

^g Based on the maximum commercial-class liquid product rate of 40.2 g a.i./m² for surface spray broadcast applications. No other application methods were registered for this rate.

^h Based on the second highest commercial-class liquid product rate registered for residential areas and the maximum domestic-class pressurized product application rate of 1.10 g

a.i./m². The commercial-class liquid rate of 2.76 g a.i./m² assessed for dermal exposure is not for use in residential areas; children are not expected to be present during or after application, so a quantitative incidental oral risk assessment was not conducted.

i Based on the third highest commercial-class liquid product rate registered for residential areas and the maximum domestic-class liquid product application rate of 0.813 g a.i./m². This is also the highest registered rate for bed bug applications. Bed bug crack and crevice: Assumes pest control operators (PCO) will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture.

j Based on maximum commercial-class liquid product rate of 0.0775 g a.i./m³. This addresses domestic-class liquid products applied using a trigger spray bottle.

k Based on maximum commercial-class pressurized product rate of 0.144 g a.i./m³. This rate addresses the domestic-class rate of 0.125 g a.i./m³.

^l Object residue calculation was updated to be based on the application rate per spray event and room volume, which is consistent with the space spray scenario. In addition, the residues were extrapolated to estimate what could be deposited in a day (24 hours).

Table 14 Long-term residential postapplication object-to-mouth exposure and risk assessment for children (1 to <2 years) – expansion of assessed rates - indoor environment surface applications (bed bugs)

Exposure scenario ^a		Object residue (µg/cm ²) ^b	ET (hr/day) ^c	Oral exposure (mg/kg bw/day) ^d	OtM MOE ^e (T = 100)	
Indoor environments (for example, residential and commercial/ industrial/ institutional sites, agricultural premises)	Broadcast (0.813 g a.i./m ²) ^g	Soft surface	1.63	4	2.03E-02	140
		Hard surface		2	1.02E-02	290
	Perimeter/Spot/Bed bug (Coarse and Pin Stream) (Highest domestic-class BB rate: 1.1 g a.i./m ²) ^f	Soft surface	1.10	4	1.38E-02	210
		Hard surface		2	6.88E-03	420
	Bed bug crack and crevice (Commercial application only) (max com BB rate: 0.813 g a.i./m ²) ^g	Soft surface	0.407	4	5.08E-03	570
		Hard surface		2	2.54E-03	1100
	Space Spray (PP, including total release fogger) ^h	Soft surface	0.446	4	5.58E-03	520
		Hard surface		2	2.79E-03	1000

OtM = object-to-mouth; MOE = margin of exposure; ET = exposure time; T = target MOE; com = commercial-class product; BB = bed bug

^a Assessed only those scenarios for which risks were shown to be acceptable in the refined intermediate-term object-to-mouth risk assessment (Appendix V, Table 13).

^b Object residue is based on the deposited residue and chemical-specific (50th percentile) fraction transferred values of 2% for both soft and hard surfaces. These values are the same as the transferrable residue values (soft surfaces) used for dermal exposure.

^c Exposure time based on values from the USEPA Residential SOPs (2012).

^d Oral exposure (mg/kg bw/day) = [Object Residue (ug/cm²) × 0.001 mg/ug × Surface Area of object mouthed (10 cm²/event) × (Exposure Time (hr) × Replenishment Intervals (4/hr)) × (1 - (1 - Saliva Extraction Factor (0.48))^{Number events per hour (12)/Replenishment Intervals (4/hr)})] / Body Weight (11 kg), as in the USEPA Residential SOPs (2012).

^e OtM Oral MOEs for the long-term exposure duration are based on a NOAEL of 2.9 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100.

^f This is the highest rate where risks were acceptable for the intermediate-term assessment for perimeter/spot/bed bug. Based on the second highest commercial-class liquid product rate registered for residential areas and the maximum domestic-class pressurized product application rate of 1.10 g a.i./m².

^g This is the highest rate where risks were acceptable for the intermediate-term assessment for broadcast application. Based on the third highest commercial-class liquid product rate registered for residential areas and the maximum domestic-class liquid product application rate of 0.813 g a.i./m². This is also the highest registered rate for bed bug applications. Bed bug crack and crevice: Assumes pest control operators (PCO) will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture.

^h Highest space spray application rate for bed bugs (commercial-class pressurized product). Addresses other space sprays registered for use on bed bugs.

Appendix VI Revised aggregate exposure and risk assessments for piperonyl butoxide

Details for the revised aggregate risk assessment are included in this appendix. Please refer to PRVD2020-09 for additional information.

Aggregate exposure and risk assessment

The aggregate assessments were updated, as the underlying route-specific and scenario-specific residential exposure assessment and outcomes were revised from PRVD2020-09. Results are summarized in Tables 1 and 2. Risks were acceptable for all scenarios provided that the mitigation measures considered for route- and scenario-specific assessments are implemented (Table 1, Appendix V). This includes restriction of the application rates and treatment types as noted in Appendix IV.

Table 1 Short- to intermediate-term aggregate exposure and risk assessment

Scenario	Co-occurring exposures	Applicator inhalation exposure (mg/kg bw/day) ^a	Postapplication inhalation exposure (mg/kg bw/day) ^a	Total inhalation exposure (mg/kg bw/day) ^b	Inhalation MOE ^c	Incidental oral exposure (mg/kg bw/day) ^d	Dietary exposure (mg/kg bw/day) ^e	Total oral exposure (mg/kg bw/day) ^f	Oral MOE ^g	Aggregate MOE (T=100) ^h
Adults										
Outdoor and indoor/greenhouse plants	Applicator inhalation exposure dietary exposure	5.37E-03 ⁱ	Minimal ⁱ	5.37E-03	7500	N/A	5.16E-03	5.16E-03	3000	2100
Outdoor areas after space spray application for flying insects (for example, mosquito abatement)- PP	Applicator inhalation exposure postapplication inhalation exposure dietary exposure	2.69E-03 ^j	1.41E-03 ^j	4.10E-03	9900	N/A	5.16E-03	5.16E-03	3000	2300
Outdoor areas after space spray application for flying insects (for example, mosquito)	Postapplication inhalation exposure dietary exposure	N/A	4.33E-04 ^k	4.33E-04	93 000	N/A	5.16E-03	5.16E-03	3000	2900

Scenario	Co-occurring exposures	Applicator inhalation exposure (mg/kg bw/day) ^a	Postapplication inhalation exposure (mg/kg bw/day) ^a	Total inhalation exposure (mg/kg bw/day) ^b	Inhalation MOE ^c	Incidental oral exposure (mg/kg bw/day) ^d	Dietary exposure (mg/kg bw/day) ^e	Total oral exposure (mg/kg bw/day) ^f	Oral MOE ^g	Aggregate MOE (T=100) ^h
abatement)- Liquid (commercial applicator only)										
Indoor Environments (surface spray)	Applicator inhalation exposure dietary exposure	1.29E-02 ^l	Minimal ^l	1.29E-02	3100	N/A	5.16E-03	5.16E-03	3000	1500
Indoor Environments (space sprays)	Applicator inhalation exposure postapplication inhalation exposure dietary exposure	6.71E-04 ^m	1.44E-03 ^m	2.11E-03	19 000	N/A	5.16E-03	5.16E-03	3000	2600
Children (1 to <2 years)										
Outdoor areas after space spray application for flying insects (for example, mosquito abatement)- PP	Postapplication inhalation exposure incidental oral exposure dietary exposure	N/A	5.27E-03 ⁿ	5.27-03	7,700	3.51E-02 ^o	1.79E-02	5.30E-02	290	280
Outdoor areas after space spray application for flying insects (for example, mosquito abatement)- Liquid (commercial applicator only)	Postapplication inhalation exposure incidental oral exposure dietary Exposure	N/A	1.62E-03 ^p	1.62E-03	250 000	8.10E-05 ^q	1.79E-02	1.80E-02	860	830

Scenario	Co-occurring exposures	Applicator inhalation exposure (mg/kg bw/day) ^a	Postapplication inhalation exposure (mg/kg bw/day) ^a	Total inhalation exposure (mg/kg bw/day) ^b	Inhalation MOE ^c	Incidental oral exposure (mg/kg bw/day) ^d	Dietary exposure (mg/kg bw/day) ^e	Total oral exposure (mg/kg bw/day) ^f	Oral MOE ^g	Aggregate MOE (T=100) ^h	
Indoor Environments (surface spray)	Postapplication inhalation exposure incidental oral exposure dietary exposure	Minimal (assessed qualitatively) ^f					1.25E-02 ^s	1.79E-02	3.04E-02	510	510
Indoor Environments (space spray)	Postapplication inhalation exposure incidental oral exposure dietary exposure	N/A	1.13E-02 ⁱ	1.13E-02	3600	5.39E-03 ^u	1.79E-02	2.33E-02	660	560	

MOE = margin of exposure; T = target MOE; N/A = not applicable.

^a Applicator (Adults) or postapplication (adults or children) inhalation exposure to aerosols. Highest inhalation exposure scenario where risks were shown to be acceptable was used for the aggregate risk assessment.

^b Total Inhalation Exposure (mg/kg bw/day = applicator + postapplication inhalation exposure).

^c Inhalation MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 40.4 mg/kg bw/day from a 90-day inhalation toxicity study in rats and a target MOE of 100.

^d Incidental oral exposure used for aggregate risk assessment only applicable for children.

^e Chronic dietary exposure is based on information provided in the dietary risk assessment.

^f Total Oral Exposure (mg/kg bw/day) = incidental oral exposure (for children) + Chronic dietary exposure.

^g Total Oral MOEs for short- to intermediate-term exposure durations are based on a NOAEL of 15.5 mg/kg bw/day from a 12-month oral toxicity study in dogs and a target MOE of 100.

^h Aggregate MOE = $1/((1/\text{MOE}_{\text{inhalation}}) + (1/\text{MOE}_{\text{oral}}))$.

ⁱ Applicator exposure for outdoor/indoor/greenhouse plants based on scenario with highest rate (aerosol RTU can for outdoor stinging insect nest and indoor greenhouse/plants) (Appendix V, Table 4). Postapplication inhalation exposure was assessed qualitatively and expected to be low.

^j Applicator and postapplication inhalation exposure based on PP formulation scenario with highest rates for space spray: outdoor areas (Appendix V, Table 4 and Appendix V, Table 9.2). Although the surface spray applicator inhalation exposure was higher (Appendix V, Table 4), postapplication inhalation exposure is minimal. Space spray was considered the higher inhalation scenario.

^k Postapplication exposure based on liquid formulation scenario using the next highest rate 18.05 g a.i./ha (Appendix V, Table 9.1). The higher rate was not used as risks were identified and the product will be cancelled. No handler exposure as this is a commercial-class product with use only by commercial applicators.

^l Applicator inhalation exposure based on dust formulation (shaker can), which was the highest inhalation exposure for residential applicators for indoor surface applications (Appendix V, Table 4). Postapplication inhalation exposure for adults for surface sprays was assessed qualitatively and expected to be low (minimal).

^m Applicator inhalation exposure based on domestic-class PP formulation indoor environment space spray scenario (Appendix V, Table 4). Postapplication inhalation exposure for adults from the domestic-class PP formulation for indoor space sprays where the rate is limited to 0.0050g a.i./m³ (Appendix V, Table 9.3). For commercial-class products, postapplication inhalation exposure is also expected to be low, provided that a 2-hour re-entry interval is followed.

ⁿ Postapplication inhalation exposure for children based on PP formulation space spray scenario for outdoor areas (Appendix V, Table 9.2).

^o Postapplication incidental oral exposure based on PP formulation space spray scenario for outdoor areas (Appendix V, Table 11).

^p Postapplication exposure based on liquid formulation scenario using the next highest rate 18.05 g a.i./ha (Appendix V, Table 9.1). The higher rate was not used as risks were identified and the product will be cancelled.

^q Postapplication incidental oral exposure based on liquid formulation scenario using next highest rate 18.05 g a.i./ha (Appendix V, Table 11). The higher rate was not used as risks were identified and the product will be cancelled.

^r Postapplication inhalation exposure for children for surface sprays was assessed qualitatively and expected to be low (minimal).

^s Postapplication incidental oral exposure based on indoor environment broadcast surface spray scenario at highest rate where risks are acceptable- 0.813 g a.i./m² (Appendix V, Table 13). This scenario addresses exposure for all other surface spray scenarios with acceptable risks.

^t Postapplication inhalation exposure for children from the domestic-class PP formulation for indoor space sprays where the rate is limited to 0.0050 g a.i./m³ (Appendix V, Table 9.3)

^u Postapplication incidental oral exposure based on PP formulation for indoor space sprays (Appendix V, Table 13).

Table 2 Long-term aggregate oral exposure and risk assessment for children (1 to <2 years) – indoor environment bed bug applications (soft surfaces)

Scenario	Rate ^a	Treatment type ^b	Incidental oral exposure (mg/kg bw/day)	Chronic dietary exposure (mg/kg bw/day) ^c	Aggregate MOE ^d (T=100)
Surface spray	1.10 g a.i./m ²	Perimeter/Spot/Bed bug (Coarse and Pin Stream)	4.21E-03	1.79E-02	130
	0.813 g a.i./m ²	Broadcast	6.22E-03	1.79E-02	120
		Perimeter/Spot (Coarse and Pin Stream)	3.11E-03		140
		Bed bug crack and crevice	1.55E-03		150
Space spray	0.0915 g a.i./m ³	N/A	1.71E-03	1.79E-02	150

Form. = formulation; MOE = margin of exposure; ET = exposure time; PP = pressurized product; DU = dust; T = target MOE; FHE = food handling establishment

^a Showing only results from treatment to soft surfaces as this scenario presents greater exposure than treatment to hard surfaces. Treatment type is differentiated by deposited residue (fraction of label application rate): 100% for broadcast, 50% for perimeter/spot, 25% for commercial applicator-only bed bug crack and crevice, and 10% for crack and crevice. Bed bug crack and crevice: Assumes pest control operators (PCO) will treat for bed bugs using crack and crevice treatment as well as on tufts and seams of mattresses and furniture. This results in greater exposure than the standard crack and crevice method, but less than the perimeter/spot method.

^b The highest registered rates specified for bed bug treatment were assessed, where risks were shown to be acceptable in the route-specific assessments.

^c Chronic dietary exposure is based on information provided in the dietary risk assessment.

^d Aggregate MOE = NOAEL / (EXPO_{incidental oral} + EXPO_{Dietary}), where NOAEL (2.9 mg/kg bw/day from the 12-month oral toxicity study in dogs) is the endpoint selected for long-term aggregate oral exposure; EXPO is exposure (mg/kg bw/day); and the target MOE is 100.

Appendix VII References considered following publication of PRVD2020-09

Note that the following includes only references that were not previously considered in PRVD2020-09.

Information considered in the updated toxicology assessment

Additional published information considered

PMRA document number	Title
3242169	Harkema, J.R., Nikula, K.J. and Haschek, W.M. 2018. Chapter 14. Respiratory System. Fundamentals of Toxicologic Pathology. 3rd Edition. Wallig, M., et al., Ed. Academic Press.
3279521	Kaufmann, W., Bader, R., Earnst, H., Harada, T., Hardisty, J. and Rosenbruch, M., 2009. 1st International ESTP Expert Workshop: Larynx squamous metaplasia, A re-consideration of morphology and diagnostic approaches in rodent studies and its relevance for human risk assessment. Experimental and Toxicologic Pathology, 61: 591-603.

Information considered in the updated occupational and non-occupational assessment

List of studies/information submitted by registrant

PMRA document number	Title
3321433	Boatwright, T. 2009. A Study for Measurement of Air Concentration of Cyfluthrin and Prallethrin Following Application of KJM (Notebook No. 16543P163-2). Golden Pacific Laboratories, LLC (GPL). Study Number: 080290. Feb.20, 2009.

List of studies/information submitted by the Task Forces

PMRA document number	Title
2812971	Acedo, K.P. 2016. Determination of Concentration of Prallethrin, Piperonyl Butoxide, and MGK-264 in Air and on Surfaces Following the Use of Multicide® Flying Insect Killer 27471. Feb.3, 2016. Golden Pacific Laboratories. GLP Study No 130507. McLaughlin Gormley King Co. (MGK).

Information considered in the updated value assessment**Published information**

PMRA document number	Title
3380836	Canadian Grain Commission. Accessed 2022-08-17. Indianmeal Moth. https://grainscanada.gc.ca/en/grain-quality/manage/identify-an-insect/secondary-insect-pests/stored-product-moths.html .
3380840	Canadian Grain Commission. Accessed 2022-08-17. Angoumois Grain Moth. https://grainscanada.gc.ca/en/grain-quality/manage/identify-an-insect/secondary-insect-pests/stored-product-moths.html