Special Review Decision SRD2021-01

# Special Review of Tetrachlorvinphos and Its Associated End-use Products

*Final Decision Document*

*(publié aussi en français)*

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## Special review decision

Pursuant to subsection 17(1) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) conducted a special review of tetrachlorvinphos, based on the toxicology information submitted under section 12 of the *Pest Control Products Act*, following the re-evaluation of tetrachlorvinphos (Canada, 2003; and Canada, 2004). The aspects of concern identified for the special review are potential occupational and residential risks. Health Canada evaluated the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. Please refer to the PMRA Guidance Document, *Approach to Special Reviews of Pesticides*, for additional information on special review triggers and the processes.

This document presents the final regulatory decision[1] for the special review of tetrachlorvinphos. All pest control products containing tetrachlorvinphos that are registered in Canada are subject to this special review decision (Appendix I). Prior to finalizing this decision, Health Canada published the Proposed Special Review Decision, PSRD2019-04, *Special Review of Tetrachlorvinphos and Its Associated End-use Products*[2] for 45-day consultation.

Comments and additional information were received during consultation period. Comments are summarized in Appendix II with the responses from Health Canada. The final special review decision considered the comments and information received during the consultation of PSRD2019-04. The outcome of the revised assessment of the aspects of concern based on additional information received is outlined below:

- The received information did not result in a change to the toxicology reference values established for the human health risk assessment in PSRD2019-04.
- Additional information resulted in revisions to the occupational and residential risk assessments of certain uses (see Science evaluation update and Appendix III for more details) and did result in changes to the proposed special review decision as described in PSRD2019-04:
    - The non-cancer and cancer handler risks for applications of the wettable powder formulation to poultry dust boxes are shown to be acceptable and the use will be retained. An additional statement will be added to labels to prevent handlers from mixing the product with their hands, as the exposure assessment does not account for hand mixing.
    - The non-cancer and cancer handler risks for mechanically-pressurized handgun application to poultry facilities for fowl tick treatment are shown to be acceptable with additional mitigation measures (limiting the amount handled per day and reducing the spray volume) and the use will be retained.

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

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

- The non-cancer handler risks for rotary or mechanical dust application of the wettable powder formulation to floors of poultry facilities are not shown to be acceptable even with additional personal protective equipment (PPE). Therefore, the use will be cancelled.
- Residential postapplication dermal non-cancer and cancer risks resulting from exposure to pet collars are not shown to be acceptable when using data from the new pet collar study. In addition, risks were not shown to be acceptable for exposure when applying pet collars (PSRD2019-04). Pet collar products will be cancelled due to application and postapplication risks.

Following an evaluation of the aspects of concern, Health Canada has determined that continued registration of certain uses/products containing tetrachlorvinphos is acceptable with additional mitigation measures (Appendix IV). On this basis, Health Canada is confirming the registration for the following products containing tetrachlorvinphos for sale and use in Canada with additional risk mitigation measures, pursuant to subsection 21(1) of the *Pest Control Product Act*:

**Commercial-class**

- Ear tag product
- Wettable power product
  - Roost paint application to treat lice, mites, and lesser mealworms.
  - Handheld spray application to poultry to treat lice and mites.
  - Handheld spray application to poultry house floor management to treat lice, mites, and lesser meal-worms.
  - Handheld spray application to poultry droppings, manure piles, garbage piles, and under feed troughs to treat maggots.
  - Handheld spray application to livestock premises (1% and 2% dilution) to treat flies.
  - Application of the wettable powder formulation to poultry dust boxes to treat lice and mites.
  - Handheld spray application to poultry housing walls, ceilings, floor cracks and crevices to treat fowl ticks.

**Domestic-class**

- Flea and tick liquid (trigger spray) products

The assessment indicated that the potential risk to human health for the following uses of tetrachlorvinphos is not considered to be acceptable, and these uses are cancelled, pursuant to subsection 21(2)(b) of the *Pest Control Product Act*:

**Commercial-class**

- Wettable powder product.
  - Rotary or mechanical dust application of the wettable powder formulation to floors of poultry facilities

**Domestic-class**

- All flea and tick powder/dust products.
- All flea and tick pet collar products.

## Next steps

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels sold by registrants no later than 24 months after the publication date of this 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.

Certain tetrachlorvinphos products are to be cancelled since these product labels have no uses that are acceptable for continued registration as a result of this special review. Products that are cancelled will be phased out following the implementation timeline outlined below:

- One (1) year of sale by registrant from the publication date of this decision document, followed by;
- One (1) year of sale by retailer from the last date of sale by registrant, followed by;
- One (1) year of permitted use from the last date of sale by retailer.

## Other information

Any person may file a notice of objection[3] regarding this decision on tetrachlorvinphos within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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

## Science evaluation update

### 1. Toxicology summary

In response to PSRD2019-04, the registrant provided benchmark dose analyses for several parameters in the developmental neurotoxicity study, and suggested that the results of these analyses be used to refine the point of departure selected for use in the health risk assessment. Overall, the review of these comments and new analyses did not result in a change to the toxicology reference values established for the human health risk assessment that were outlined in the 2019 Proposed Special Review Decision for tetrachlorvinphos.

### 2. Updated occupational and residential exposure assessment summary

The following occupational and residential exposure and risk assessments for tetrachlorvinphos were updated in consideration of the comments received during the consultation period. All other assessments and conclusions from the PSRD2019-04 remain the same.

**Mixer/loader/applicator exposure and risk assessment**

- Occupational mixer/loader/applicator exposure and risk from dust application of the wettable powder formulation to poultry using a dust box.
    - Based on comments received from the registrant, Health Canada updated the assessment to include only mixer/loader exposure. Handler tasks for dust box application include the opening of the wettable powder product, pouring the powder into the dust box, and mixing the components. In addition, shaker cans are not used in this scenario. Therefore, only PHED mixer/loader wettable powder data were used. The PHED mixer/loader unit exposure data are lower than previous estimates, which added surrogate USEPA Residential standard operating procedure (SOP) unit exposure values for shaker can application. All other inputs from the previous assessment remain the same.
    - The non-cancer and cancer handler risks for dust box are shown to be acceptable (Appendix III, Table 1) and the use will be retained. An additional statement will be added to labels to prevent handlers from mixing the product with their hands, as the exposure assessment does not account for hand mixing.
- Occupational mixer/loader/applicator exposure and risk from rotary or mechanical dust application of the wettable powder formulation to floors of poultry facilities.
    - Following consideration of comments received from the registrant, Health Canada updated the assessment using dermal and inhalation unit exposure values taken from the USEPA OPP Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (2020) for loading/applying with a plunger duster. A 90% protection factor was applied to hand unit exposures to account for chemical-resistant gloves and a 75% protection factor was applied for body unit exposures to account for coveralls over long-sleeve shirt and long pants. An 80% protection

factor was applied to inhalation unit exposures to account for a filtering face-piece respirator (dust mask). For additional details, refer to Appendix III. The PHED mixer/loader unit exposure values were removed in the updated assessment as only loading/applying is expected. Surrogate shaker can unit exposure data were also not included, since this equipment is not expected to be used. All other inputs remain the same.

- Mixer/loader/applicator risks were not shown to be acceptable even with consideration of additional PPE (Appendix III, Table 1). Therefore, this use will be cancelled.

- Occupational mixer/loader/applicator exposure and risk assessment for mechanically-pressurized handgun application to poultry facilities for fowl tick treatment.

  - In PSRD2019-04 this use was proposed for cancellation since risks were not shown to be acceptable for mixer/loader and applicators using a mechanically-pressurized handgun (MPHG). Further mitigation options were considered for this use. Limiting the amount handled to 4.5 kg a.i. per day (9 kg of product) and reducing the spray volume to 3 L/10 $m^2$ would result in acceptable MOEs (Appendix III, Table 1). The mitigation will allow a handler to treat 1500 $m^2$ per day, which is the size of a typical broiler growing facility.

**Residential exposure and risk assessment**

- Residential postapplication and application exposure and risk assessment for tetrachlorvinphos pet collars.

  - Based on the registrant's comments and study submitted regarding the physical nature of tetrachlorvinphos residues from the pet collar (liquid vs dust), Health Canada agrees that the residues released from the pet collar are not likely to be airborne like a dust. Therefore, transferrable residues were not assessed as dusts.

  - A new study was submitted that examined the tetrachlorvinphos transferable residue on dogs that wore a pet collar for 10 days. Transferable residues were obtained from gloves after performing 5, 10, or 25 petting simulations. The data from the 25 petting simulation group were used in the updated postapplication exposure assessment for pet collars. For additional details, refer to Appendix III.

  - A modified postapplication dermal exposure equation was used as per registrant comments. The equation does not use transfer coefficients. Instead, the direct transferable residue data from the exposure study noted above are used. The equation assumes 25 petting simulations are performed per hour and 0.5 to 1 hour of exposure time per day depending on the lifestage and type of risk assessment (non-cancer or cancer).

- Scaling factors from the 2012 United States Residential SOP were used to translate the study data (based on adult hand sizes and medium sized dogs) to youth and children, and to different size dogs and cats. For additional details, refer to Appendix III.

- Residential postapplication dermal non-cancer and cancer risks were not shown to be acceptable when using data from the new pet collar study (Appendix III, Tables 2 and 3).

- The postapplication hand-to-mouth exposure assessment was also updated since it relies on estimates from the postapplication dermal assessment. Non-cancer and cancer risks were shown to be acceptable for hand-to-mouth exposure (Appendix III, Tables 4 and 5).

- In PSRD2019-04, risks were also not shown to be acceptable when applying pet collars. There were no comments received for this assessment. Pet collar products will be cancelled due to application and postapplication risks.

- An aggregate assessment was not conducted for pet collars as risks were identified from the dermal route alone.

- Residential postapplication exposure and risk assessment for tetrachlorvinphos domestic-class dust products.

  - In PSRD2019-04, risks were not shown to be acceptable for postapplication exposure to domestic-class dust products. There were no comments received for this assessment. Domestic-class dust products will be cancelled due to postapplication risks.

## 3. Health incident reports

Since the publication of PSRD2019-04, Health Canada has received two additional human incident reports from Canada related to the aspects of concern for tetrachlorvinphos (from 2 October 2018 to 30 November 2020). In the first incident, an individual experienced symptoms including dysguesia (a bad taste in the mouth) and cardiac arrhythmia after applying a domestic-class pet collar containing tetrachlorvinphos to his cat. In the second incident, an individual experienced muscle twitching on her forehead after applying an unknown amount of flea and tick cat powder containing tetrachlorvinphos to her cat. In both cases, there was insufficient information regarding the reported exposures to assess an association to the pesticide.

As the currently registered domestic-class pet collars and powder/dust products containing tetrachlorvinphos will be cancelled, and additional mitigation measures and label amendments aimed at minimizing the likelihood of exposure are required for domestic-class trigger sprays, no additional mitigation is recommended based on the updated incident report review.

# List of abbreviations

| | |
|---|---|
| AHETF | Agricultural Handler Exposure Task Force |
| a.i. | active ingredient |
| ATPD | Area/Animal Treated per Day |
| BMD | Benchmark dose |
| BMDL | Benchmark dose lower confidence interval |
| BMR | Benchmark response |
| bw | Body weight |
| CR | Chemical-resistant |
| DCA | Dicarpryl Adipate |
| DE | Dermal Exposure |
| DER | Data Evaluation Record |
| DNT | Developmental neurotoxicity |
| EF | Exposure Frequency |
| $F_{a.i.}$ | Fraction of a.i. on one hand |
| FM | Fraction of Hand Surface Area Mouthed |
| ET | Exposure Time |
| Freq_HtM | Hand-to-Mouth Events/hr |
| HR | Hand Residue Loading/hr |
| HtM | Hand-to-Mouth |
| kg | kilogram |
| LADD | Lifetime Average Daily Dose |
| LOAEL | Lowest observed adverse effect level |
| LOQ | Limit of Quantitation |
| mg | milligram |
| MLA | Mixer/Loader/Applicator |
| MOE | Margin of Exposure |
| MPHG | Mechanically Pressurized Handgun |
| N_Replen | Number of Replenish Intervals/hr |
| NOAEL | No observed adverse effect level |
| OPP | Office of Pesticide Programs |
| ORETF | Outdoor Residential Exposure Task Force |
| PCPA | Pest Control Products Act |
| PHED | Pesticide Handler Exposure Database |
| USEPA | United States Environmental Protection Agency |
| PND | Postnatal day |
| PPE | Personal Protective Equipment |
| PSRD | Proposed Special Review Decision |
| SE | Saliva Extraction Factor |
| SOP | Standard Operating Procedure |
| SRD | Special Review Decision |
| TC | Transfer coefficient |
| TCVP | Tetrachlorvinphos |
| WD | Work days |
| WP | Wettable Powder |
| Yr | Year |

# Appendix I Registered products containing tetrachlorvinphos as of 17 December 2020

## Table 1 Products requiring label amendments

| Registration Number | Marketing Class | Registrant | Product Name | Formulation Type | Guarantee[1] |
|---|---|---|---|---|---|
| 23019 | Technical Grade Active Ingredient | The Hartz Mountain Corporation | Hartz Rabon Technical Insecticide (Tetrachlorvinphos) | Solid | 98.7% |
| 25338 | Technical Grade Active Ingredient | Elanco Canada Limited | Technical Rabon Insecticide | Dust or powder | 98.7% |
| 17415 | Commercial | Elanco Canada Limited | Debantic 50 WP Insecticide Poultry and Livestock Premises Spray | Wettable powder | 50% |
| 22880 | Commercial | Bayer Inc. | Ectogard Insecticide Cattle Ear Tag | Solid | 14.0% |
| 25654 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Spray For Dogs | Solution | 1.08% |
| 25655 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Spray For Cats | Solution | 1.08% |
| 30181 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Plus Flea & Tick Spray For Dogs With Aloe | Solution | Tetrachlorvinphos 1.08% s-methoprene 0.07% |

[1] Percent of tetrachlorvinphos unless stated otherwise

## Table 2 Products cancelled as a result of this special review

| Registration Number | Marketing Class | Registrant | Product Name | Formulation Type | Guarantee[1] |
|---|---|---|---|---|---|
| 13266 | Domestic | Hartz Canada Inc. | Hartz Incontrol Flea & Tick Collar For Cats | Slow release generator | 14.55% |
| 16673 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Powder For Dogs | Dust or powder | 3.3% |
| 17959 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Powder For Cats | Dust or powder | 3.3% |
| 18108 | Domestic | Hartz Canada Inc. | Hartz Incontrol Flea & Tick Collar For Dogs | Slow release generator | 14.55% |
| 25381 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Plus Flea & Tick Collar For Cats & Kittens | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 25382 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Plus Flea & Tick Collar For Dogs & Puppies | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 25620 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Collar For Dogs | Slow release generator | 14.55% |
| 25621 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Collar For Cats & Kittens | Slow release generator | 14.55% |
| 28355 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Reflective Flea & Tick Collar For Dogs & Puppies | Slow release generator | 14.55% |

| Registration Number | Marketing Class | Registrant | Product Name | Formulation Type | Guarantee[1] |
|---|---|---|---|---|---|
| 28356 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Reflective Flea & Tick Collar For Cats & Kittens | Slow release generator | 14.55% |
| 29475 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea & Tick Collar For Large Dogs | Slow release generator | 14.55% |
| 29476 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Flea And Tick Collar For Puppies | Slow release generator | 14.55% |
| 29720 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Plus Flea & Tick Collar For Dogs And Puppies With Reflect-X Shield | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 29721 | Domestic | Hartz Canada Inc. | Hartz Ultraguard Plus Flea & Tick Collar For Cats And Kittens With Reflect-X Shield | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 31439 | Domestic | Wellmark International | Vet-Kem Breakaway Flea & Tick Collar For Cats & Kittens | Slow release generator | 14.55% |
| 31440 | Domestic | Wellmark International | Vet-Kem Flea & Tick Collar For Dogs | Slow release generator | 14.55% |
| 31441 | Domestic | Wellmark International | Vet-Kem Ovitrol Breakaway Dual Action Flea & Tick Collar For Cats & Kittens | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 31443 | Domestic | Wellmark International | Vet-Kem Ovitrol Dual Action Flea & Tick Collar For Dogs & Puppies | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 31444 | Domestic | Wellmark International | Zodiac Breakaway Flea & Tick Collar For Cats & Kittens | Slow release generator | 14.55% |
| 31445 | Domestic | Wellmark International | Zodiac Flea & Tick Collar For Dogs | Slow release generator | 14.55% |
| 31446 | Domestic | Wellmark International | Zodiac Power Band Plus Breakaway Dual Action Flea & Tick Collar For Cats & Kittens | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |
| 31473 | Domestic | Wellmark International | Zodiac Power Band Plus Ii Dual Action Flea & Tick Collar For Dogs & Puppies | Slow release generator | Tetrachlorvinphos 14.55% s-methoprene 1.02% |

[1] Percent of tetrachlorvinphos unless stated otherwise

# Appendix II Comments and responses

Health Canada received comments from stakeholders in response to the consultation document Proposed Special Review Decision, PSRD2019-04, *Special Review of Tetrachlorvinphos and its Associated End-Use Products*. The consolidated comments related to the aspects of concern of this special review and Health Canada responses to those comments are provided below.

## 1.1 Comments related to toxicology

**Comment relating to the use of benchmark dose (BMD) analysis for refinement of the point of departure in the developmental neurotoxicity (DNT) study:**
The registrant submitted benchmark dose analyses (PMRA# 3003632) for several offspring parameters that were described in the original DNT study report in order to refine the points of departure for these endpoints. These included pup body weight, pup body weight gain, average brain weight, and average corpus callosum and hippocampal gyrus lengths. The registrant suggested using benchmark dose lower confidence limits (BMDLs; ranging from 15 to 56 mg/kg bw/day) instead of the point of departure that Health Canada had established for the DNT study (No Observed Adverse Effect Level (NOAEL) of 10 mg/kg bw/day).

**Health Canada response:** In the tetrachlorvinphos special review PSRD2019-04, toxicology reference values for all scenarios in the non-cancer human health risk assessment were established based on the point of departure for offspring effects observed in the DNT study. The primary endpoints of concern were behavioural effects in learning and memory tests, and changes to both brain morphology and weight. These effects were considered together in a weight of evidence, which collectively pointed to an effect on neurodevelopment. At the Lowest Observed Adverse Effect Level (LOAEL) in this study, effects on learning and memory and decreased corpus callosum length in both sexes at postnatal day (PND) 70, as well as decreased hippocampus length in females at PND 70, were observed. At the next higher dose level, effects on learning and memory were also observed in PND 22 pups, and decreases were observed in brain weight at all time points, as well as in lengths of additional brain regions in both PND 22 and 70 rats. Standard uncertainty factors of 10-fold each for interspecies extrapolation and intraspecies variability were applied. The *Pest Control Product Act* (PCPA) factor was reduced to threefold for the reasons outlined in the *Pest Control Product Act* Hazard Characterization section of PSRD2019-04, resulting in a target margin of exposure or composite assessment factor of 300 for the various scenarios.

The refinement exercise (BMD analysis) undertaken by the registrant considered quantitative aspects of the dose-response curve for only some of the individual parameters from the DNT study, and used methods for establishing benchmark dose responses (BMRs) that are more commonly used for other biological endpoints, such as the use of one standard deviation, or a predetermined percent change from control (for example 5 or 10%). Several limitations were noted with the registrant's approach, including the fact that neurobehavioral outcomes were not included in the analysis, and that each of the endpoints in the DNT study were examined in isolation. This is divergent from the approach used in PSRD2019-04, in which all effects indicative of developmental neurotoxicity were considered in a weight of evidence analysis.

Further, while the analyses performed by the registrant, in theory, can allow for the shift of a point of departure to a predetermined level of response or activity (that is, the BMR), rather than the pre-selected doses, there is currently no consensus in the broader scientific community regarding appropriate magnitudes for BMRs for neurodevelopmental endpoints.

In conclusion, the presence of effects on offspring brain weight and morphology remain undisputed, and support the neurobehavioral findings observed at the LOAEL of 50 mg/kg bw/day. The registrant's use of BMD modelling to refine the selected points of departure from the DNT study does not address all of the weight of evidence considerations for the neurotoxic potential of tetrachlorvinphos in the young. As such, there is no impact on the toxicology conclusions outlined in PSRD2019-04 and the toxicology reference values previously established by Health Canada remain unchanged.

## 1.2 Comments related to exposure

The comments and responses related to the tetrachlorvinphos occupational and residential exposure and risk assessment are summarized below.

### 1.2.1 Comments from Bayer Animal Health and Bayer Crop Sciences

**Comment 1**
The registrant proposed alternate unit exposures for various scenarios (wettable powder/dust formulation assessment).

**Health Canada response:** Studies to estimate exposure during mixing, loading and applying a wettable powder formulation as a dust using a dust box or a rotary/mechanical duster were not available. Therefore, in PSRD2019-04, exposures for these scenarios were based on available studies for other scenarios considered to have exposures similar to the dust box or rotary/mechanical duster. However, in their comments to PSRD19-04, the registrant described these scenarios as being similar to pouring the powder/dust into a hopper and stirring the material in the hopper with a stick. They requested that Health Canada use an Agricultural Handlers Exposure Task Force (AHETF) study for these scenarios, noting that exposure would occur during mixing and loading, but that exposure during application does not need to be considered. Further, the registrant stated that shaker cans are not used for these scenarios.

Health Canada considered the comments and have revised the occupational exposure assessment, accordingly (see Science evaluation update for details). A summary of the updates is as follows:

- The use of a shaker can for these scenarios has been removed.

- Health Canada agrees that application to poultry using a dust box would be similar to the scenario described by the registrant and the assessment has been updated with the use of mixer/loader unit exposure data only. It is noted that this use scenario involves the pouring and mixing of the powder product into the dust box. Therefore, the Pesticide Handler Exposure Database (PHED) mixer/loader data for wettable powder was used (as in the PSRD2019-04). The PHED mixer/loader unit exposure value is higher than the cited value in the AHETF study but still lower than previous estimates in PSRD2019-04, which added unit exposure data for shaker can application. The updated assessment indicates that the health risk to occupational handlers is acceptable. Use of unit exposures

from the AHETF study are not required at this time, since risks were shown to be acceptable using the unit exposures from PHED data. Thus, the use on poultry using dust boxes will be retained. A statement will be added to labels to indicate that handlers should not mix the dust with their hands, as exposure estimates do not account for hand mixing of dust box components.

- Health Canada does not agree that the use of exposure data for mixer/loader alone is sufficiently representative or protective of handler exposure when using a rotary or mechanical duster. There is potential for exposure during loading of the powder into the duster as well as during application, when airborne particles may be present. The occupational assessment was updated using unit exposure values from the USEPA OPP Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (2020) for plunger dusters. The values are based on the same studies that were used to calculate plunger duster unit exposure in the 2012 USEPA Residential SOPs, with application of PPE protection factors for coveralls over long-sleeve shirt and long pants, and chemical resistant gloves. A protection factor was also applied to inhalation applicator exposure estimates to account for a filtering face-piece respirator (dust mask). The PHED mixer/loader unit exposures were removed in the updated assessment, as only loading/applying is expected.

  Occupational risks for rotatory duster application are not shown to be acceptable even with consideration of additional personal protective equipment. Therefore, this use will be cancelled and all label directions for dust application using a rotary or mechanical duster to poultry house flooring to treat lice, mites and lesser mealworms will be removed.

**Comment 2**
Bayer Animal Health proposes that the risk to fowl tick use be mitigated by limiting this use to low pressure backpack sprayers.

**Health Canada response:** Limiting the amount of tetrachlorvinphos handled per day and reducing the label spray volume can mitigate the potential risks for mechanically-pressurized handgun application to treat for fowl ticks (see Science evaluation update for details). The use and application method is acceptable provided that handlers do not use more than 4.5 kg of active ingredient or 9 kg of product per day and reducing the label spray volume to 3 L/10 $m^2$ from 3–4 L/10 $m^2$. The limit will allow a handler to treat 1500 $m^2$ per day, which is the typical size of a broiler growing facility.

### 1.2.2 Comments from Saskatchewan Ministry of Agriculture

**Comment 1**
Comments were provided on the personal protective equipment (PPE) considered in the assessment, versus that noted on product labels.

**Health Canada response:** Studies to estimate exposure during mixing/loading and applying a WP formulation as a dust to poultry or in poultry facilities were not available. Occupational exposure for these scenarios was assessed using a combination of studies as surrogate data. Specifically, for mixing and loading a wettable powder, PHED studies with baseline clothing and PPE (long-sleeved shirt, long pants and chemical-resistant gloves) were used. For application, surrogate unit exposure data from the USEPA Residential SOPs (2012) were used, for which the data were only available for applicators wearing short-sleeves and shorts. The use of the surrogate residential unit exposure data is a conservatism in the assessment, as residential applicators are assumed not to wear work clothing or have access to PPE. Surrogate residential exposure data were used due to a lack of adequate chemical-specific and generic exposure data to support the use. In regards to ear tags, minimal exposure was assumed for applicators in consideration of its formulation, application method, and PPE requirements.

As noted in Health Canada's response in Section 1.2.1, an updated occupational exposure assessment was conducted for the commercial dust scenarios in consideration of the comments submitted.

**Comment 2**
Additional clarifications on the basis of the proposal to remove the use to treat for fowl ticks was requested.

**Health Canada response:** In PSRD2019-04, occupational risks were not shown to be acceptable for fowl tick treatment because the application rate is higher than other comparable spray application uses. The application rate for fowl ticks is 3–4 litres of 1% solution per 10 $m^2$ of walls, ceilings, floor cracks and crevices. As a comparison, the rate for lice, mites, and lesser mealworms is 1–4 litres of 1% solution per 100 $m^2$ of floor. Further mitigation measures including those proposed by the registrant will allow a handler to treat 1500 $m^2$ per day, which is the typical size of a broiler growing facility. Please refer to Section 1.2.1.

**Comment 3**
A comment was received on why short-sleeved shirts and shorts were assumed as PPE for the application of dusting powders for companion animals given that the Hartz dusting powder label indicates contact with skin, clothing and eyes must be avoided. The comment also noted observed adverse reactions from Hartz products in dogs and cats.

**Health Canada response:** Personal protective equipment are specified for commercial-class products, which would primarily be used by professionals or workers. Health Canada assumes that workers would have access to appropriate PPE and would be trained in their use. For domestic-class products, such as the Hartz product noted above, while gloves, specific clothing, or label directions to avoid exposure may be specified on labels, the standard assumption for risk assessment is that residential applicators would be wearing short-sleeved shirts and short pants.

In PSRD2019-04, domestic-class dust products for use on companion animals were proposed for cancellation, since human health risks for application were not shown to be acceptable. There are no changes made to the risk assessment or risk conclusions following the publication of the PSRD2019-04, and, these products will be cancelled.

With these measures, no further analysis of companion animal incident reports involving domestic-class tetrachlorvinphos products is required at this time. For more information on human incident reports, please refer to Section 3 of the Science evaluation update.

**Comment 4**
Concern was expressed with the proposal to remove products from commercial use, particularly as it applies to commercial poultry. Tetrachlorvinphos wettable powders, like Debantic and Rabon, are two products labelled for the treatment of mites. Ectiban (containing permethrin) is the other product. Any potential restriction in usage or ability to source different products may pose significant risk to the industry. Resistance management of pests in commercial poultry production will be impossible with only one mode of action. Given the limited number of available products, the use of Debantic is essential for mite control and the product should be applied to not only the floor, but also directly to the birds to fully eliminate an infestation.

**Health Canada response:** Health Canada recognises the value of tetrachlorvinphos for control of mites, ticks, and other insect pests on poultry and their housing. The alternative active ingredient to tetrachlorvinphos for management of these pests are limited to synthetic pyrethroids, which come from the same mode of action group. Health Canada also concurs that insecticides from more than one mode of action is required for sustainable resistance management.

Based on the additional information received during consultation, Health Canada revised the assessment. Health risks were shown to be acceptable for handheld spray applications of wettable powders to treat lice and mites on poultry and in poultry facilities with additional risk mitigation measures. In addition, risks were shown to be acceptable for direct application of the wettable powder as a dust to poultry using a dust box (refer to Section 1.2.1). These uses will be available to producers to manage labelled pests, and reduce resistance development.

### 1.2.3 Comments from Hartz Mountain Corporation

Comments and data were submitted by Hartz Mountain Corporation in regards to the postapplication dermal exposure assessment for pet collars. Comments related to the exposure assessment and risk assessments are summarized below according to topic.

**Comment 1: Physical nature of tetrachlorvinphos pet collar residues**
Tetrachlorvinphos and a collar plasticizing agent are present and released together from the collar. The residue combination is present in a damp semi-solid state at room temperature and is lipophilic. The plasticizing agent serves as an emollient that delivers tetrachlorvinphos residues to the fur and sebum to facilitate the movement of residues across the surface of the pet. The residue mixture with sebum behaves as a sticky semi-solid paste that is not likely to be airborne. Data from the submitted studies confirm the presence of tetrachlorvinphos and the plasticizing agent in the collar/pet fur/gloves and the movement of the residues from the collar to various regions on the treated pet.

**Health Canada response:** The rationale is accepted and dust transfer coefficients are not used in the updated postapplication assessment for tetrachlorvinphos pet collars.

**Comment 2: Transferable residues**
A new transferable residue pet collar study was submitted during the comment period including a USEPA-approved method for petting simulations (PMRA# 3003633 and 3003634). The data provides a more robust value for percent transferable residue (0.17% transferable residues at Day 10 after application, following 25 petting simulations or 75 pet strokes) as compared to the transferable residue based on the Davis et al. (2008) study.

**Health Canada response:** The cited pet collar postapplication exposure study has been reviewed and the transferable residue has been incorporated into the pet collar postapplication assessment. The updated transferable residue data supersedes the previous estimates based on the Davis et al. 2008 study. Risks were not shown to be acceptable in the updated risk assessment. Therefore, the pet collar use will be cancelled. Please refer to Science evaluation update for details.

**Comment 3: Modified postapplication dermal exposure equation**
A modified pet collar postapplication exposure equation that was used in the 2019 PMRA assessment for dinotefuran spot-on products can also be used for the tetrachlorvinphos pet collar assessment. This equation does not include the transfer coefficient parameter and its associated overestimation bias.

**Health Canada response:** Health Canada has updated the assessment using an approach similar to what was used for dinotefuran. This includes not using transfer coefficients in the equation. However, Health Canada used a modified equation as there are some differences with the dinotefuran assessment (for example, dinotefuran is not used in pet collars and label use directions are different for the two products; as well, the underlying exposure studies for the two products have different protocols). The modified equation utilizes the direct transferable residue data from the submitted study noted in Comment 2. The transferable residue was determined by performing 25 petting simulations (assumed on a per hour basis in the equation) on treated pets. Scaling factors for pet sizes and lifestage surface area differences were also applied to the equation. Risks were not shown to be acceptable in the updated risk assessment. Therefore, the pet collar use will be cancelled. Please refer to Appendix III and the Science evaluation update section for details.

**Comment 4: Dermal absorption**
Hartz reiterated the conservatisms and limitations in the in vivo rat dermal absorption study that was used to estimate a dermal absorption value, and indicated the willingness to develop new in vitro rat and human data to resolve the overestimation bias that may arise from the use of an in vivo rat dermal absorption study to estimate absorption to human skin.

**Health Canada response:** The current exposure and risk assessment for tetrachlorvinphos was based on the data available at this time. However, registrants have the option to submit studies and additional information to Health Canada to amend a registration. All new applications will be assessed according to Regulatory Directive, DIR2017-01, *Management of Submissions Policy*.

**Comment 5: Transfer coefficients**
Biomonitoring and t-shirt data from the study by Davis et al., (2008) was proposed for deriving transfer coefficients, rather than the approach presented in PSRD2019-04.

The raw data from the biomonitoring phase of the Davis et al. study was provided along with calculations on the transfer coefficients (PMRA# 2985709) for the biomonitoring (~1700 $cm^2$/hr) and the t-shirt data (400 $cm^2$/hr).

**Health Canada response:** The postapplication exposure assessment for pet collars has been updated and uses exposure data directly from the newly submitted transferable residue study. The study determines transferable residues by measuring residues on the hands (via gloves) after performing petting simulations on a treated animal. A modified postapplication equation was also used, which does not include the transfer coefficients parameter and assumes 25 petting simulations per hour. As such, there is no longer a need to derive transfer coefficients based on the t-shirt or biomonitoring data from the Davis et al., study, which was not considered appropriate due to study design. Risks were not shown to be acceptable in the updated risk assessment. Therefore, the pet collar use will be cancelled. Please refer to Appendix III and the Science Evaluation Update section for details.

**Comment 6: Contact frequency and duration with pets**
It was noted that SOP for Residential Risk Assessment (USEPA, 2012) appear to overestimate potential exposure time of very young children by more than an order of magnitude. Alternate studies were cited for information on contact time between young children and animals.

**Health Canada response:** The exposure time estimate in the USEPA Residential SOPs is based on the exposure factors handbook and represents daily contact associated with pet care (for example, feeding, playing, walking). The data included the entirety of time spent daily with an animal by study volunteers, and likely captures high, as well as low contact activities. The estimate is combined with the transfer coefficient to determine the amount of treated surface area contact in a day. As such, the exposure time as expressed in the Residential SOP equation does not implicitly assume continuous contact or exposure over this time period, and is not the same or comparable to the exposure time (of contact events) noted in the studies cited by the registrant in their comment. Transfer coefficients are also scaled down accordingly for children relative to adults to account for their smaller size. When using the transfer coefficient for liquid formulations, children are assumed to have contacted 1400 $cm^2$ of treated surface area in a single day based on a TC of 1400 $cm^2$/hour and 1 hour of exposure time per day. This contact area is equivalent to petting 20% of the total surface area for a medium sized dog (7000 $cm^2$) and 55% of the surface area for a medium sized cat (2500 $cm^2$), and is not considered to be an overly conservative estimate. Conversely, when using information from Yeung et al., (2006) cited by the registrant, 8.32 seconds of contact time per day (3.2 seconds average contact time per event with an animal × 2.6 contact events per hour × 1 hour exposure time per day) would equate to a contact area of 3.2 $cm^2$, which is not considered appropriate for use in the updated assessment.

### 1.2.4 Comment from Wellmark International

**Comment 1**
The PMRA uses a dermal absorption factor from a rat in vivo study to estimate dermal absorption in humans, despite significant evidence that the absorption factor in humans is less than that in rats.

**Health Canada response:** The current exposure and risk assessment for tetrachlorvinphos was based on the data currently available. A chemical-specific triple-pack study in which in vivo rat dermal absorption data combined with rat-human in vitro data and conducted according to current standards may refine the dermal absorption estimate. Correction factors are generally not used to account for human and rat dermal absorption differences in the absence of chemical-specific data. The tetrachlorvinphos in vivo rat dermal absorption study is the best available data at this time to estimate dermal absorption.

**Comment 2: Contact frequency and duration with pets**
Similar to Comment 6 from Hartz, it was noted that the USEPA Residential SOPs (USEPA 2012) appear to overestimate potential dermal and oral exposure of very young children, in contrast to information in the available literature.

**Health Canada response:** The postapplication exposure assessment for pet collars has been updated and uses a modified exposure equation and exposure data from the newly submitted pet collar exposure study. Please refer to Science evaluation update and Appendix III for details.

**Comment 3**
It was stated that the Mester (1988) study used to derive transfer coefficients for liquid products was not methodologically appropriate for derivation of a transfer coefficient to estimate pet exposure.

**Health Canada response:** There are no transfer coefficient studies available for pet collar products, and as such, surrogate transfer coefficients based on a shampoo study were used in PSRD2019-04.

Based on the additional information received during consultation of PSRD2019-04, an updated postapplication assessment for pet collars was conducted, which uses a modified postapplication equation. This equation does not require the use of transfer coefficients. Risks were not shown to be acceptable in the updated risk assessment. Therefore, the pet collar use will be cancelled. Please refer to Science Evaluation Update and Appendix III for details.

**Comment 4**
It is not clear how the PMRA could reach a conclusion that the collars must be cancelled when the USEPA has made no such decision.

**Health Canada response:** The PSRD2019-04 pet collar assessment was based on 2012 USEPA Residential SOP inputs, as well as chemical-specific exposure data from the published Davis et al., study (PMRA# 2862263). Details on the risk assessment and study review were provided in Appendix IV and V of PSRD2019-04.

The conclusions and inputs for the pet collar exposure assessment were similar to the 2016 USEPA Tetrachlorvinphos Assessment. The Health Canada risk assessment was based on the toxicology assessment as outlined in Appendix III of PSRD2019-04, which includes consideration of Health Canada's PCPA factor for risk assessment.

As noted in PSRD2019-04, application and postapplication risks were not shown to be acceptable for pet collar uses and were proposed for cancellation. The postapplication assessment for pet collars was updated based on additional information received during the comment period; however, risks were not shown to be acceptable. Therefore, the pet collar use will be cancelled. Please refer to Science evaluation update and Appendix III for details.

**Comment 5**
Task Force information related to exposure assessment is being developed and will be available in the future. The Task Force requested that any decisions about the pet collars be postponed until the Task Force work is complete.

**Health Canada response:** The current exposure and risk assessment for tetrachlorvinphos is based on the data and information available at this time. Please refer to section 1.2.3 (Comment 4) for information on how the new Task Force information can be submitted to Health Canada for amending a registration.

# Appendix III Revised human health risk assessment

## 3.1 Occupational and residential assessments

### Table 1 Short to intermediate-term mixer/loader/applicator non-cancer and cancer exposure and risk assessment

| Use | Formulation | Application Method | Application Rate | ATPD | Exposure (µg/kg bw/day)[1] | | MOE (Target = 300)[2] | | | Cancer | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Dermal | Inhalation | Dermal | Inhalation | Combined | WD/Year | LADD[3] | Risk[4] |
| Single Layer, CR Gloves (Mixer/Loader) | | | | | | | | | | | | |
| Poultry Dust Box | WP | M/L Dust Box | 0.75 g a.i./bird | 1000 bird | 1.10 | 0.53 | 9100 | 19000 | 6200 | 30 | 0.068 | $1 \times 10^{-7}$ |
| Coveralls, CR Gloves, Filtering Face Piece Respirator (Dust Mask) (Loader/Applicator). | | | | | | | | | | | | |
| Poultry Floor | WP | Rotary Duster | 3.75 g a.i./$m^2$ | 100 $m^2$ | 46.83 | 3.52 | **214** | 2800 | **199** | 30 | 2.12 | $4 \times 10^{-6}$ |
| Coveralls, CR Glove, Respirator (MLA) | | | | | | | | | | | | |
| Poultry House - Fowl Tick Spray | WP | MPHG[5] | 4 g a.i./$m^2$ | 3000 $m^2$ | 92.50 | 1.20 | **108** | 8300 | **107** | 30 | 3,95 | $1 \times 10^{-7}$ |
| | | | 3 g a.i./$m^2$ | 1500 $m^2$ | 34.69 | 0.45 | 288 | 22000 | 285[6] | 30 | 1.48 | $3 \times 10^{-6}$ |

ATPD = Area/Animal Treated per Day, MOE = Margin of Exposure, WD/Yr = Work Days/Year, LADD = Lifetime Average Daily Dose (µg/kg bw/day), MLA = Mixer/Loader/Applicator, CR = Chemical-resistant, MPHG = Mechanically-Pressurized Handgun, WP = Wettable Powder

1 Exposure (µg/kg bw/day) = Application Rate × ATPD ÷ 1000 g/kg × Unit Exposure (µg/kg a.i.) ÷ Body Weight (80 kg). A 22% dermal absorption factor was applied to dermal exposure estimates. Unit exposure estimates can be found in Section 3.2 below

2 MOE = NOAEL (mg/kg bw/day) ÷ Exposure (µg/kg bw/day) × 1000 × µg/mg. NOAEL = 10 mg/kg bw/day based on an oral study. Target MOE = 300. Shaded cells indicate MOEs that are <300.

3 LADD (µg/kg bw/day) = (Dermal Exposure + Inhalation Exposure) (µg/kg bw/day) × WD/Year ÷ 365 days/year × Work Duration (40 years) ÷ Life Expectancy (78 years)

4 Cancer Risk = $q_1^*$ × LADD ÷ 1000 µg/mg. $q_1^* = 1.83 \times 10^{-3}$ $(mg/kg\ bw/day)^{-1}$

5 1500 $m^2$ × 3 g a.i./$m^3$ (3 L of 0.1% solution per 10 $m^2$) equates to 4.5 kg of a.i. handled per day

6 The MOE of 285 is below the target MOE of 300 but is acceptable when conservatisms such as the dermal absorption estimate are considered. Refer to PSRD2019-04 for information on the dermal absorption estimate.

## Table 2 Postapplication non-cancer dermal exposure and risk estimates for pet collars

| Animal | Life Stage | Transferable Residue (mg/hr)[1] | Pet Size Scaling Factor[2] | Surface Area Scaling Factor[2] | Exposure Time (hr/day) | Dermal Exposure[3] (mg/kg bw/day) | MOE[4] |
|---|---|---|---|---|---|---|---|
| Small Dog | Adults | 4.776 | 1.63 | 1.00 | 0.77 | 0.016 | 610 |
| | Children 1<2 yr | 4.776 | 1.63 | 0.27 | 1.00 | 0.042 | 240 |
| Medium Dog | Adults | 4.776 | 1.00 | 1.00 | 0.77 | 0.010 | 990 |
| | Children 1<2 yr | 4.776 | 1.00 | 0.27 | 1.00 | 0.026 | 390 |
| Large Dog | Adults | 4.776 | 0.74 | 1.00 | 0.77 | 0.007 | 1300 |
| | Children 1<2 yr | 4.776 | 0.74 | 0.27 | 1.00 | 0.019 | 530 |
| Small Cat | Adults | 4.776 | 2.07 | 1.00 | 0.77 | 0.021 | 480 |
| | Children 1<2 yr | 4.776 | 2.07 | 0.27 | 1.00 | 0.053 | 190 |
| Medium Cat | Adults | 4.776 | 1.63 | 1.00 | 0.77 | 0.016 | 610 |
| | Children 1<2 yr | 4.776 | 1.63 | 0.27 | 1.00 | 0.042 | 240 |
| Large Cat | Adults | 4.776 | 1.20 | 1.00 | 0.77 | 0.012 | 820 |
| | Children 1<2 yr | 4.776 | 1.20 | 0.27 | 1.00 | 0.031 | 320 |

MOE = Margin of Exposure, Yr = Year

1 Refer to Section 3.3 below for the calculation of transferable residues.

2 Refer to Section 3.4 below for the calculation of scaling factors.

3 Dermal Exposure (mg/kg bw/day) = Transferable residue × Pet Size Scaling Factor × Surface Area Scaling Factor × Exposure Time × Dermal Absorption (22%) ÷ BW (80 kg for Adults, 11 kg for Children)

4 MOE = NOAEL ÷ Exposure. NOAEL = 10 mg/kg bw/day based on an oral study. Target MOE = 300. Shaded cells indicate MOEs that are <300.

## Table 3 Postapplication dermal LADD and cancer risk estimates for pet collars

| Animal | Life Stage | Transferable Residue (mg a.i./hr)[1] | Pet Size Scaling Factor[2] | Hand Size Scaling Factor[2] | ET (hrs/day) | EF (days/yr) | Exposure Years | Dermal LADD[3] (mg/kg bw/day) | Lifetime Cancer Risk[4] |
|---|---|---|---|---|---|---|---|---|---|
| Small Dog | Adult | 4.776 | 1.63 | 1.00 | 0.5 | 90 | 35 | 1.18 × 10-3 | $4 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 1.63 | 0.83 | 0.42 | 90 | 5 | $1.66 \times 10^{-4}$ | |
| | Child 1<2 yr | 4.776 | 1.63 | 0.27 | 1 | 90 | 5 | $6.70 \times 10^{-4}$ | |
| Medium Dog | Adult | 4.776 | 1.00 | 1.00 | 0.5 | 90 | 35 | $7.27 \times 10^{-4}$ | $2 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 1.00 | 0.83 | 0.42 | 90 | 5 | $1.02 \times 10^{-4}$ | |
| | Child 1<2 yr | 4.776 | 1.00 | 0.27 | 1 | 90 | 5 | $4.11 \times 10^{-4}$ | |
| Large Dog | Adult | 4.776 | 0.74 | 1.00 | 0.5 | 90 | 35 | $5.34 \times 10^{-4}$ | $2 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 0.74 | 0.83 | 0.42 | 90 | 5 | $7.50 \times 10^{-5}$ | |
| | Child 1<2 yr | 4.776 | 0.74 | 0.27 | 1 | 90 | 5 | $3.02 \times 10^{-4}$ | |

| Animal | Life Stage | Transferable Residue (mg a.i./hr)[1] | Pet Size Scaling Factor[2] | Hand Size Scaling Factor[2] | ET (hrs/day) | EF (days/yr) | Exposure Years | Dermal LADD[3] (mg/kg bw/day) | Lifetime Cancer Risk[4] |
|---|---|---|---|---|---|---|---|---|---|
| Small Cat | Adult | 4.776 | 2.07 | 1.00 | 0.5 | 90 | 35 | $1.51 \times 10^{-3}$ | $5 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 2.07 | 0.83 | 0.42 | 90 | 5 | $2.12 \times 10^{-4}$ | |
| | Child 1<2 yr | 4.776 | 2.07 | 0.27 | 1 | 90 | 5 | $8.52 \times 10^{-4}$ | |
| Medium Cat | Adult | 4.776 | 1.63 | 1.00 | 0.5 | 90 | 35 | $1.18 \times 10^{-3}$ | $4 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 1.63 | 0.83 | 0.42 | 90 | 5 | $1.66 \times 10^{-4}$ | |
| | Child 1<2 yr | 4.776 | 1.63 | 0.27 | 1 | 90 | 5 | $6.69 \times 10^{-4}$ | |
| Large Cat | Adult | 4.776 | 1.20 | 1.00 | 0.5 | 90 | 35 | $8.72 \times 10^{-4}$ | $3 \times 10^{-6}$ |
| | Youth 11<16 yr | 4.776 | 1.20 | 0.83 | 0.42 | 90 | 5 | $1.22 \times 10^{-4}$ | |
| | Child 1<2 yr | 4.776 | 1.20 | 0.27 | 1 | 90 | 5 | $4.93 \times 10^{-4}$ | |

ET = Exposure Time, EF = Exposure Frequency, LADD = Lifetime Average Daily Dose, Yr = Year

1 Refer to Section 3.3 below for the calculation of transferable residues.
2 Refer to Section 3.4 below for the calculation of scaling factors.
3 Dermal LADD (mg/kg bw/day) = Transferable Residues × Pet Size Scaling Factor × Hand Size Scaling Factor × ET × Dermal Absorption (22%) ÷ BW (Adults: 80 kg Youth: 32 kg, Children: 11 kg) × EF ÷ 365 days/year × Exposure Years ÷ Life Expectancy (78 years)
4 Cancer Risk = LADD × $q_1$*. $q_1$* = $1.83 \times 10^{-3}$ (mg/kg bw/day)$^{-1}$. Shaded cells indicate cancer risks greater than $1 \times 10^{-6}$.

## Table 4 Postapplication non-cancer hand-to-mouth exposure and risk estimates for pet collars

| Exposure Scenario | Animal | $F_{a.i.}$ | DE[1] (mg/hr) | HR[1] (mg/hr) | $F_M$ | ET (hr/day) | N_Replen (interval/hr) | SE | Freq_HtM (events/hr) | HtM Exposure[2] (mg/kg bw/day) | MOE[3] |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Hand-to-Mouth | Small Dog | 0.04 | 2.10 | 0.042 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0005 | 21000 |
| | Medium Dog | 0.04 | 1.29 | 0.026 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0003 | 34000 |
| | Large Dog | 0.04 | 0.95 | 0.019 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0002 | 47000 |
| | Small Cat | 0.04 | 2.67 | 0.053 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0006 | 16000 |
| | Medium Cat | 0.04 | 2.09 | 0.042 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0005 | 21000 |
| | Large Cat | 0.04 | 1.54 | 0.031 | 0.13 | 1 | 4 | 0.48 | 20 | 0.0004 | 29000 |

$F_{a.i.}$ = Fraction of a.i. on one hand, DE = Dermal Exposure/hr, HR = Hand Residue Loading/hr, $F_M$ = Fraction of Hand Surface Area Mouthed, ET = Exposure Time, N_Replen = # of Replenish Intervals/hr, SE = Saliva Extraction Factor, Freq_HtM = Hand-to-Mouth Events/hr, MOE = margin of exposure

[1] DE (mg/hr) = Dermal Exposure (mg/kg bw/day) × BW (11 kg) ÷ ET. HR = $F_{a.i.}$ × DE ÷ 2 hands. Refer to Table 2 for details on the dermal exposure estimates.
[2] Hand-to-Mouth Exposure (mg/kg bw/day) = HR × $F_M$ × ET × N_Replen × [(1-(1-SE)$^{Freq\_HtM}$] ÷ BW(11 kg).
[3] MOE = NOAEL ÷ Exposure. NOAEL = 10 mg/kg bw/day based on an oral study.

## Table 5 Postapplication hand-to-mouth LADD and cancer risk estimates for pet collars

| Exposure | Surface or Animal | $F_{a.i.}$ | DE[1] (mg/hr) | HR[1] (mg/hr) | FM | ET (hr/day) | N_Replen (interval/hr) | SE | Freq_HtM (events/hr) | EF (days/yr) | Exposure (years) | LADD[2] (mg/kg bw/day) | Cancer Risk[3] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Hand-to-Mouth | Small Dog | 0.04 | 2.12 | 0.042 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $6.57 \times 10^{-6}$ | $1 \times 10^{-8}$ |
| | Medium Dog | 0.04 | 1.30 | 0.026 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $4.03 \times 10^{-6}$ | $7 \times 10^{-9}$ |
| | Large Dog | 0.04 | 0.96 | 0.019 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $2.96 \times 10^{-6}$ | $5 \times 10^{-9}$ |
| | Small Cat | 0.04 | 2.70 | 0.054 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $8.36 \times 10^{-6}$ | $2 \times 10^{-8}$ |
| | Medium Cat | 0.04 | 2.11 | 0.042 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $6.55 \times 10^{-6}$ | $1 \times 10^{-8}$ |
| | Large Cat | 0.04 | 1.56 | 0.031 | 0.12 | 1 | 4 | 0.48 | 14 | 90 | 5 | $4.83 \times 10^{-6}$ | $9 \times 10^{-9}$ |

$F_{a.i.}$ = Fraction of a.i. on one hand, DE = Dermal Exposure/hr, HR = Hand Residue Loading/hr, FM = Fraction of Hand Surface Area Mouthed, ET = Exposure Time, N_Replen = # of Replenish Intervals/hr, SE = Saliva Extraction Factor, Freq_HtM = Hand-to-Mouth Events/hr, EF = Exposure Frequency, LADD = Lifetime Average Daily Dose
[1] DE (mg/hr) = Dermal Exposure (mg/kg bw/day) × BW (11 kg) ÷ ET. HR = $F_{a.i.}$ × DE ÷ 2 hands. Refer to Table 2 for details on the dermal exposure estimates.
[2] HtM LADD (mg/kg bw/day) = HR × FM × ET × N_Replen × [(1-(1-SE)$^{Freq\_HtM}$] ÷ BW(11 kg) ) × EF ÷ 365 days/yr × Exposure Years ÷ Life Expectancy (78 years).
[3] Cancer Risk = LADD × $q_1$*. $q_1$* = $1.83 \times 10^{-3}$ (mg/kg bw/day)$^{-1}$

### 3.2 Surrogate unit exposure for rotary or mechanical duster

The unit exposure values for residential dust plunger scenarios were used as surrogate data to assess commercial applicator exposure for rotary or mechanical duster application to poultry house flooring. Additional protection factors were applied to the estimates to account for label PPE requirements for coveralls over long-sleeve shirt and long pants, and a filtering face-piece respirator (dust mask) for applicators, as residential scenarios are based on data from applicators wearing shorts and short-sleeved shirts, shoes, and socks. The unit exposures were taken from the USEPA OPP Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (2020) instead of the 2012 Residential SOPs, since protection factors were calculated in the occupational handler unit exposure tables.

### Table 3.2.1 Plunger duster unit exposure values

| Scenario | Formulation | Application Equipment | PPE | Unit Exposure Values (mg/kg a.i. handled) | | Source (Task Force) |
|---|---|---|---|---|---|---|
| | | | | Dermal | Inhalation | |
| Rotary/Mechanical Duster | Dust/Powder | Dust Plunger | Short sleeve shirt, short pants, socks, shoes[1] | 552 | 3.75 | ORETF |
| | | | Coveralls over a single layer, filtering face-piece respirator (dust mask[2]) | 45.4 | 0.75 | ORETF |

PPE = Personal Protective Equipment, ORETF = Outdoor Residential Exposure Task Force

1 Previous estimates based on the 2012 USEPA Residential SOPs.

2 A 90% protection factor was applied to hand unit exposures to account for chemical-resistant gloves, while a 75% protection factor was applied to body unit exposures to account for coveralls over a single layer. The dermal unit exposure was taken from the USEPA OPP Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (2020). An 80% protection factor was applied to inhalation unit exposures to account for a filtering face-piece respirator (dust mask).

## 3.3 Chemical-specific postapplication pet collar exposure data

A number of pet collar studies were submitted in response to PSRD2019-04. The studies were conducted to examine the physical nature of tetrachlorvinphos residues from the collar and to determine transferable residues on treated pets. The studies were also submitted to the USEPA and the Data Evaluation Reports (DERs) for the studies are available to the public. The USEPA DERs for most studies are considered adequate and adopted for this review. The final transferable residue study (PMRA# 3003633/3003634) was reviewed internally as 1) the study data is the main component in the updated pet collar postapplication exposure assessment and 2) the study discussion referenced a past Health Canada review for dinotufuran (PRD2019-01).

Regarding the physical state of tetrachlorvinphos pet collar residues, the registrant has indicated that tetrachlorvinphos and a collar plasticizing agent, dicarpryl adipate (DCA), are released together from the collar. Information was provided to indicate that tetrachlorvinphos and DCA are present as a viscous liquid or paste at room temperature depending on the mixture ratio and is lipophilic in nature (PMRA# 2895709). DCA serves as an emollient that delivers tetrachlorvinphos residues to the fur and sebum to facilitate its movement across the surface of the pet. The mixture with sebum behaves as a sticky semi-solid paste that is not likely to be airborne like a dust. Data from the submitted studies confirm the presence of tetrachlorvinphos and DCA residues in the collar/fur/gloves and the movement of the residues from the collar to various regions on the treated pet. Health Canada accepts the rationale, and the postapplication assessment to pet collar residues was assessed assuming liquid transfer, as opposed to transfer of dust residues.

There were two transferable residue studies submitted; the first study determined residues on day 3 after the application, while the second study determined residues on day 10. Tetrachlorvinphos pet collars may be worn for several months and the previous Davis et al. study (PMRA# 2862263) found peak transferable residues on day 7. Therefore, the day 10 transferrable residue data from the second study was used since residues may not have fully dispersed from the collar after 3 days.

Determination of transferable residues of TCVP and DCA obtained by cotton glove petting strokes from the hair coat of dogs following pet collar (PMRA# 3003633/3003634).

The study was conducted to determine transferable residues of tetrachlorvinphos and DCA after pet collar application to laboratory dogs.

Nine beagles or beagle mixes were placed into three groups of three. The groups underwent 5, 10, or 25 petting simulations. With a petting simulation involving 3 strokes: first stroke on the right side, second stroke on the left side, and last stroke along the backline. The simulations were performed using a mannequin hand covered with 3 layers of cotton gloves. After petting, the gloves were removed, placed into bottles and shipped for analysis. Video footage of petting simulations was provided (PMRA# 3005090, 3005091, 3005092).

The dogs were acclimatized for 1 week prior to application and underwent the petting simulations 4 days prior to the application to collect non-treatment control samples. Hartz Ultra Guard Flea and Tick Collars were used as the test collar. All collars were weighed prior to application. The collars were unrolled and stretched to activate, and placed around the neck. The collars were adjusted and trimmed for proper fitting. The piece of excess collar was weighed in order to calculate the weight on the remaining collar. The collars were worn for 10 days prior to petting and removed for final analysis after the petting simulations were performed. Each collar was removed on day 10, weighed, and sampled from the middle and analyzed for tetrachlorvinphos and DCA. The collar from one dog in each group was also analyzed in triplicate (left, middle, and right side of the collar) in order to verify whether the loss of residues was uniform across the length of the collars. The results are provided in Table 3.3.2.

Samples were analyzed by gas chromatography using an external standard method with multi-level calibration standard curves. The field recovery of fortified cotton glove samples was conducted during the days when the petting events took place. The results for field recovery are provided in Table 3.3.1; the method and results are considered to be adequate.

The final weight for most collars after application was 3–9% less than the initial weight and the final tetrachlorvinphos concentration ranged from 10–13% (Table 3.3.2). The initial concentrations were assumed to be at the label concentration of 14.55%. Tetrachlorvinphos concentrations did not significantly differ between the left, middle, and right regions of each collar, although residues were slightly higher on the right side of the collar in all three samples tested (Table 3.3.3).

The results for tetrachlorvinphos residues on gloves are provided in Table 3.3.4. Total tetrachlorvinphos residues were calculated by adding residues from the outer layer glove and the second layer glove. The majority of the total residues found were attributed to the outer glove (>90%). For the second layer gloves, the LOQ level (120 µg) was assumed when residues were <LOQ in the sample, as residues were found above 120 µg in some of the replicates. There were no residues detected in any third layer glove samples and it was not included in the calculations. The tetrachlorvinphos data was not corrected for field recoveries as recoveries were greater than 95% for field fortified samples at 2000 µg and 4000 µg per glove, which are in the range of residue levels found on the out layer gloves. Field samples fortified at the LOQ level had lower than 95% recoveries; however, residues on the second layer glove that were at/close to the LOQ were not corrected as it had minimal impact on the total residue estimates. Total average tetrachlorvinphos residues were: 2872 µg/glove (0.10% of rate) for the 5 petting simulation group, 2821 µg/glove (0.10% of rate) for the 10 petting simulation group, and 4776 µg/glove (0.18% of rate) for the 25 petting simulation group.

Although DCA residues were measured, they were not used in the assessment.

The following limitations are noted in the study:

- Use of mannequin hand to perform petting simulations may underestimate exposure as compared to a real hand, which can better contour to the skin.
- Using only one breed of dog (beagle) may not be representative of other dog and cat breeds with different sizes and fur types.
- Use of one testing duration does not allow for the determination of transferable residues over time.
- The petting simulation does not include the neck region where residues are likely to be the highest.
- One collar (MC4144) from the 25 petting simulation group had low residue transfer from the collar (<2% weight loss, 14.7% guarantee), which may have resulted in lower transferable residues for the sample as compared to other samples in the group. The residue value for this replicate lowers the average transferable residue estimate and may potentially underestimate exposure.

The transferrable residue estimate (0.18% of rate) from this study is approximately twofold lower compared to the previous estimate (0.40% of rate) based on the Davis et al. study and used in PSRD2019-04. This may be attributed to the limitations noted above and the following differences:

- Dogs were petted for 5 minutes using human volunteers instead of performing petting simulations with a mannequin hand.
- The petting was performed on the neck region or on the back region instead of strokes on the right, left, and back sides.
- Use of different dog breeds from households instead of laboratory animals.

Although limitations were identified, the study (PMRA# 3003633/3003634) is considered acceptable and is used in the updated assessment. The petting protocol was approved by the USEPA and the study contains more information compared to the Davis et al. study including information on field control recoveries, pet collar weights and guarantees, and the conditions of the test dogs. The use of the study data is not considered to be conservative considering the study limitations and uncertainties noted.

In addition to using the data from the new study, the authors suggested the use of a modified postapplication exposure equation that was used in the 2019 Health Canada assessment for dinotefuran dog spot-on products (PRD2019-01). This equation involves the direct use of the glove residue data and forgoes the use of TCs from the 2012 USEPA Residential SOPs equations, thereby assuming a set amount of petting strokes per day instead of a set amount of treated surface area contact. Health Canada agrees that using the modified equation and glove residue data directly will reduce the uncertainty attributed to transfer coefficients. The average total glove residue data (4776 µg) from the 25 petting simulation group was used in the updated assessment. In other words, exposure is based on residue transfer from performing 25 petting simulations per hour on a treated pet. There is also an implicit assumption that pet owners will only have one treated pet in the household at a time.

The updated assessment for tetrachlorvinphos also differs from the dinotefuran assessment in the use of scaling factors (see Section 3.4).

### Table 3.3.1 Field Fortification Summary

| Fortification Level (µg a.i./glove) | Glove Replicate | Tetrachlorvinphos Recovery |
|---|---|---|
| Samples taken at 10 days after application | | |
| 120 (LOQ) | 1 | 77.0 |
| | 2 | 97.4 |
| 2000 | 1 | 119.5 |
| | 2 | 109.4 |
| 4000 | 1 | 104.3 |
| | 2 | 107.3 |

## Table 3.3.2 Pet Collar Data Summary

| ID | Dog Weight (lb) | Dog SA ($cm^2$)[1] | Collar Length (cm) | Collar Weight (g) | | Weight Change | | Final TCVP Guarantee |
|---|---|---|---|---|---|---|---|---|
| | | | | Initial | Final | (g) | % Initial | |
| MC1461 | 24.7 | 5275 | 40.0 | 20.06 | 19.03 | 1.03 | 5.1% | 10.6% |
| MC4776 | 16.7 | 4090 | 33.2 | 17.35 | 16.60 | 0.75 | 4.3% | 11.0% |
| MC5608 | 28.8 | 5829 | 39.0 | 19.46 | 18.86 | 0.60 | 3.1% | 12.5% |
| Average | 23.4 | 5065 | 37.4 | 18.95 | 18.16 | 0.79 | 4.2% | 11.4% |
| MC3326 | 23.9 | 5164 | 37.3 | 19.45 | 18.49 | 0.96 | 5.0% | 10.3% |
| MC1052 | 32.3 | 6280 | 39.3 | 20.95 | 19.11 | 1.85 | 8.8% | 10.9% |
| MC9343 | 24.9 | 5503 | 38.2 | 19.81 | 18.92 | 0.89 | 4.5% | 10.4% |
| Average | 27.0 | 5649 | 38.3 | 20.07 | 18.84 | 1.23 | 6.1% | 10.5% |
| MC4574 | 20.4 | 4659 | 33.9 | 17.46 | 16.88 | 0.58 | 3.3% | 13.2% |
| MC2938 | 26.6 | 5536 | 37.7 | 19.38 | 18.78 | 0.60 | 3.1% | 12.9% |
| MC4144 | 26.1 | 5468 | 40.2 | 19.98 | 19.62 | 0.36 | 1.8% | 14.7% |
| Average | 24.4 | 5221 | 37.3 | 18.94 | 18.43 | 0.51 | 2.7% | 13.6% |

SA = Surface Area, TCVP = Tetrachlorvinphos

[1] Surface area ($cm^2$) = $12.3 \times (\text{Pet Weight (lbs)} \times 454)^{0.65}$

## Table 3.3.3 Guarantee in Different Regions of the Collar

| ID | Collar Side | % Guarantee Tetrachlorvinphos |
|---|---|---|
| MC4776 | Left | 9.4 |
| | Middle | 9.8 |
| | Right | 10.1 |
| MC3326 | Left | 9.2 |
| | Middle | 9.5 |
| | Right | 10.0 |
| MC4574 | Left | 10.83 |
| | Middle | 11.31 |
| | Right | 11.74 |

### Table 3.3.4 Tetrachlorvinphos Transferable Residues on Day 10 after Application

| ID | Petting Events | Rate[1] (g a.i.) | Tetrachlorvinphos Residues (µg) | | | | % Rate[4] |
|---|---|---|---|---|---|---|---|
| | | | Glove 1 | Glove 2 | Glove 3 | Total[3] | |
| MC1461 | 5 | 2.92 | 2964 | 120[2] | <120 | 3084 | 0.11% |
| MC4776 | 5 | 2.52 | 2993 | 144 | NA | 3137 | 0.12% |
| MC5608 | 5 | 2.83 | 2263 | 131 | <120 | 2525 | 0.08% |
| Average | 5 | 2.76 | 2740 | 132 | <120 | 2872 | 0.10% |
| MC3326 | 10 | 2.83 | 3780 | 120[2] | <120 | 3900 | 0.14% |
| MC1052 | 10 | 3.05 | 2788 | 120[2] | <120 | 2908 | 0.10% |
| MC9343 | 10 | 2.88 | 1536 | 120[2] | <120 | 1656 | 0.06% |
| Average | 10 | 2.92 | 2701 | 120 | <120 | 2821 | 0.10% |
| MC4574 | 25 | 2.54 | 5906 | 161.0 | <120 | 6067 | 0.24% |
| MC2938 | 25 | 2.82 | 5166 | 132.7 | <120 | 5299 | 0.19% |
| MC4144 | 25 | 2.91 | 2842 | 120[2] | <120 | 2962 | 0.10% |
| Average | 25 | 2.76 | 4638 | 138 | <120 | 4776 | 0.18% |

1 Rate was calculated using the initial collar weight × 14.55% guarantee
2 Residues were assumed to be at the LOQ (120 µg) when reported as <LOQ for calculation purposes
3 Total residues were calculated by adding residues from glove 1 and 2
4 % Rate = Total residue ÷ Rate × 1000 µg/g

## 3.4 Scaling Factors

Scaling factors from the 2012 USEPA Residential SOPs were used in the updated assessment in order to as translate the data to youth and children, and to different size dogs and cats. The scaling factors from the 2012 USEPA Residential SOPs differ from the dinotefuran assessment, which derived scaling factors directly from the 2011 USEPA Exposure Factors Handbook. In addition, dinotefuran spot on products specify rates on a per kg basis whereas pet collar rates are dependent on the neck circumference and pet size.

- Scaling factors for pet sizes were based on the rate to surface area ratio for the pet size category divided by the rate to surface area ratio for medium size dogs, which are the size of dogs used in the pet collar transferable residue study. The surface area estimates are based the USEPA 2012 Residential SOPs. The rates for pet collars were calculated based on the size of domestic collars, guarantee, and pet size categories. The net contents of the collars range from 22–36.4 grams for dogs and 15–21.6 grams for cats. The minimum collar weights were used for small size dogs and cats, average collar weights were used for medium sized dogs and cats, and maximum collar weights were used for large dogs and cats. The rates were not used to calculate transferable residues as the transferable residue estimate was directly taken from the pet collar transferable residue study. The scaling factors were greater for smaller pet categories as the rate declined at slower rate relative to the surface area decline, thereby increasing the amount of transferable residues on a per surface area basis. The scaling factors are presented in Table 3.4.1.

- Scaling factors for children and youth surface areas were based on the lifestage surface area adjustment factors from the 2012 USEPA Residential SOPs. The scaling factors are presented in Table 3.4.2.

### Table 3.4.1 Pet Size Scaling Factor

| Pet Category | Pet Weight Range (lb)[1] | Collar Net Contents (g)[2] | Guarantee | Rate (g a.i./pet)[3] | Surface Area ($cm^2$)[1] | Scaling Factor[4] |
|---|---|---|---|---|---|---|
| Small Dog | ≤ 20 | 22.0 | 14.55% | 3.201 | 3000 | 1.63 |
| Medium Dog | 21-50 | 31.5 | 14.55% | 4.583 | 7000 | 1.00 |
| Large Dog | ≥50 | 36.4 | 14.55% | 5.296 | 11000 | 0.74 |
| Small Cat | ≤ 5 | 14.0 | 14.55% | 2.037 | 1500 | 2.07 |
| Medium Cat | 6-12 | 18.3 | 14.55% | 2.663 | 2500 | 1.63 |
| Large Cat | ≥ 13 | 21.6 | 14.55% | 3.143 | 4000 | 1.20 |

1 Pet weight ranges and surface areas are from the 2012 USEPA Residential SOPs

2 The net contents of the registered collars range from 22–36.4 grams for dogs and 15–21.6 grams for cats. The minimum collar weights were used for small size dogs and cats, average collar weights were used for medium sized dogs and cats, and maximum collar weights were used for large dogs and cats

3 Rate = net contents × Guarantee

4 Scaling factor = $\frac{\text{Rate of Target Pet Category} \div \text{Surface Ara of Target Pet Category}}{\text{Rate for Medium Size Dogs} \div \text{Surface Ara of Medium Size Dogs}}$

### Table 3.4.2 Surface Area Scaling Factor

| Lifestage | Surface Area Adjustment Factor |
|---|---|
| Adults | 1.00 |
| Youth 11 to <16 years | 0.82 |
| Children 1 to <2 years | 0.27 |

1 From the 2012 USEPA Residential SOPs

# Appendix IV Label amendments for products containing Tetrachlorvinphos

The label amendments proposed below do not include all label requirements for individual products, such as disposal statements, and precautionary statements. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

## 1. Technical grade products and commercial class end-use products

Based on the toxicology assessment, both technical and commercial class product label text should be expanded and/or standardized as follows:

### Toxicological information

"Tetrachlorvinphos is a cholinesterase inhibitor. Typical symptoms of overexposure to cholinesterase inhibitors include headache, nausea, dizziness, sweating, salivation, runny nose and eyes. This may progress to muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps and diarrhea in more serious poisonings. A life-threatening poisoning is signified by loss of consciousness, incontinence, convulsions and respiratory depression with a secondary cardiovascular component. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate degree of exposure (baseline data are useful). Atropine, only by injection, is the preferable antidote. Oximes, such as Pralidoxime Chloride, may be therapeutic if used early; however, use only in conjunction with atropine. In cases of severe acute poisoning, use antidotes immediately after establishing an open airway and respiration. With oral exposure, the decision of whether to induce vomiting or not should be made by an attending physician."

## 2. Commercial-class products

### Poultry and livestock premise use (for example, Registration No. 17415):

Remove the following use and associated directions for use from the Label:

- Dust application using a rotary or mechanical duster to poultry house flooring to treat lice, mites, and lesser meal-worms

Under the DIRECTIONS FOR USE (Poultry)

- **lice and mites:** floor management dust box, 50% WP solution, change remarks to "Mix evenly throughout top layer of box contents with tool (i.e., shovel) using 150 g/100 birds. DO NOT mix box contents with hands."

- **fowl tick:** all types, 1.0% solution, change remarks to: "Apply 3 litres/ 10 sq. m. thoroughly to walls, ceilings, floor cracks and crevices with a power sprayer. DO NOT apply more than 9 kg of product [4.5 kg a.i.] per day. This is equivalent to spraying 450 L of 1% solution in a single day."

Under “PRECAUTIONS”, replace the existing “Operator Function” and “Required Protective Equipment” table with the following table:

| Activity | Required Protective Equipment |
|---|---|
| Loading and mixing powder/dust to poultry dust boxes. | Long-sleeved shirt, long pants, socks and shoes, chemical-resistant gloves, and a NIOSH-approved N95 (minimum) filtering face-piece respirator (dust mask) that is properly fit tested. |
| Mixing and loading wettable powder with water and/or applying the solution with a backpack or mechanically pressurized handgun. | Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks and shoes, 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. |
| Mixing and loading wettable powder with paint and/or applying the mixture with a paintbrush or airless sprayer. | Long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. |

Add the following Precautionary Statements:

- DO NOT apply when people or pets are present.
- DO NOT allow people or pets to enter treated areas until sprays have dried.
- DO NOT apply by handheld mist blower or fogger.
- DO NOT apply as a space spray.
- 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.
- This product is not to be used in or around homes or other residential areas such as parks, school grounds and/or playing fields. Residential areas are defined as any use site where the general public, including children, could be exposed during or after application. It is not for use by homeowners.

**3. Domestic-class products:**

The following end-use products are to be cancelled:

- All tetrachlorvinphos flea and tick powder/dust products for pets and pet bedding.
- All tetrachlorvinphos flea and tick pet collar products.

The following label instructions are to be added for trigger spray products:

- Cat Products: Spray 15–25 strokes for a small cat (5 lbs or less). Spray 25–35 strokes for a medium or large cat (greater than 5 lbs).

- Dog Products: Spray 25–35 strokes for small dogs (20 lbs or less). Spray 30–40 for a medium dog (21–50 lbs). Spray 40–70 strokes for a large dog (greater than 50 lbs).

Precautionary statement for trigger spray Products:

- DO NOT apply to furniture, mattresses, linens, pet bedding, toys or clothing.

Based on the toxicology assessment, the label text on domestic-class products should be expanded and/or standardized as follows:

**Toxicological information**

"This product contains a pesticide that is a cholinesterase inhibitor (anti-cholinesterase compound). Symptoms of human poisoning may include headache, weakness, sweating, blurred vision, nausea and diarrhea. Obtain medical attention or call a poison control centre at once. Atropine is antidotal."

# References

## Toxicology

### List of studies/information submitted by registrant

| PMRA Document Number | Reference |
|---|---|
| 3003632 | 2019, Benchmark Benchmark Dose Estimates Based on Oral (Gavage) Developmental Neurotoxicity Study of Tetrachlorvinphos in Crl:CD (SD)IGS BR VAF/Plus Rats, DACO: 4.5.12 |

## Occupational and residential exposure

### List of studies/information submitted by registrant

| PMRA Document Number | Reference |
|---|---|
| 2933691 | 2018, Determination of available transferable residues of TCVP and DCA onto pet hair during normal use, DACO: 5.14 |
| 2933692 | 2018, Determination of available transferable residues of TCVP and DCA onto pet hair during normal use, DACO: 5.14 |
| 3003633 | 2019, Determination of transferable residues of TCVP and DCA released onto cotton gloves from petting simulations, DACO: 5.11 |
| 3003634 | 2019, Determination of Transferable Residues of TCVP and DCA Obtained by Cotton Glove Petting Stokes from the Hair Coat of Dogs Following Pet Collar Use, DACO: 5.11 |
| 3003635 | 2019, Meeting Slides May 17, 2019 Conference Call, DACO: 5.11 |
| 3005090 | 2019, Video of Dog Petting at Three Levels - 5 second simulation, DACO: 5.14 |
| 3005091 | 2019, Video of Dog Petting at Three Levels - 10 second simulation, DACO: 5.14 |
| 3005092 | 2019, Video of Dog Petting at Three Levels - 25 second simulation, DACO: 5.14 |

### Additional information considered

### Published information

| PMRA Document Number | Reference |
|---|---|
| 2409268 | United States Environmental Protection Agency, 2012, Standard Operating Procedures for Residential Pesticide Exposure Assessment, DACO: 12.5.5 |
| 3151116 | United States Environmental Protection Agency, 2019, TCVP: Review and Summary of Residue Transfer Studies Submitted, DACO: 12.5 |

| PMRA Document Number | Reference |
|---|---|
| 3151121 | United States Environmental Protection Agency, 2019, TCVP: Data Evaluation Record for the Study - Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing, DACO: 12.5 |
| - | United States Environmental Protection Agency, 2020. Occupational Pesticide Handler Unit Exposure Surrogate Reference Table. DACO: 12.5 |