PMRA Guidance Document

Structural Pest Control Products: Label Updates

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Table of contents

| 1.0 | Purpose | 1 |
|---------|---|---|
| 2.0 | Background | 1 |
| 3.0 | Structural Pest Control Product Application Types | 3 |
| 4.0 | Human Health Precautionary Statements | 3 |
| 5.0 | Implementation | 3 |
| 6.0 | Conclusion | 5 |
| List of | f Abbreviations | 6 |
| Appen | ndix I Comments Received on PRO2018-04 and PMRA Responses | 7 |
| Appen | ndix II Application Type Definitions for Inclusion on Proposed / Registered Labels | 8 |
| Appen | ndix III Human Health Precautionary Statements for Inclusion on Proposed/Registered | |
| | Labels | 0 |
| Appen | ndix IV Droplet Size Categories1 | 2 |
| Refere | ences | 3 |

1.0 Purpose

The purpose of this Pest Management Regulatory Agency Guidance Document is to inform all stakeholders of standard definitions of application types and human health precautionary label statements for structural pest control products (SPCPs). The revised definitions will provide a uniform language through which all stakeholders in the structural pest control industry can communicate. Also, the human health precautionary statements will help facilitate consistency in the language used for various risk mitigation measures to minimize exposure to those applying the SPCPs and those entering and/or residing in treated areas.

The definitions and precautionary statements apply to both restricted/commercial and domestic marketing class end-use products.

2.0 Background

In December 2018, Health Canada's Pest Management Regulatory Agency (PMRA) published Regulatory Proposal <u>PRO2018-04</u>, *Structural Pest Control Products: Label Updates*, to update and standardize definitions and human health precautionary statements for structural pest control product labels. This document (PRO2018-04) provided a background of the proposal and information on the focused label improvement initiative. The proposal sought comments from the general public and key stakeholders on the proposed changes to the application type definitions and human health precautionary statements. As a result of the consultation, comments were received from five stakeholders and are summarized in Appendix I of this guidance document. In response to these comments, minor modifications (primarily providing more clarity) were made to the document, which now serves as the basis for this PMRA Guidance Document.

While this document primarily pertains to conventional chemical pest control products, the information provided will be considered when establishing directions for human health precautionary label statements for biopesticides (in other words, microbials, semiochemicals and pheromones, and non-conventional chemical pesticides), when applicable.

Structural Pest Control Products

For the purposes of this document, structural pest control products (SPCPs) are defined as products used to kill/control/repel invertebrate pests that affect a structure or its inhabitants and are applied within, outdoors on the exterior surfaces of, and, within a 1 m exterior perimeter of a structure. Indoor applications may include the contents of the structure, but only when specified on the label. This definition of SPCPs excludes mothballs, termiticides, fumigants, outdoor fogging and outdoor misting systems.

SPCPs can be applied onto surfaces or into the air of structures as either a surface or space application.

- 1. Surface application 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.
- 2. Space application 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.

Structures to which SPCPs are applied include non-food storage/processing areas of residential, farm and office buildings, air, land and sea transport vehicles, and commercial, farm (greenhouses, mushroom houses, etc.) and residential buildings (hospitals, nursing homes, etc.) where food commodities are stored, grown or processed. Excluded are underwater structures.

A structure can be a building or non-building to which a pesticide may be applied. Buildings are considered as any structure used or intended for supporting or sheltering any use or occupancy (NRC, 2015). Types of buildings include but are not limited to homes, schools, offices, animal housing, greenhouses and mushroom houses, factories, food and non-food storage facilities and food processing facilities. Non-buildings are those that are not designed for continuous human or domestic animal occupancy. Types of non-buildings include but are not limited to parking structures, roads/driveways, perimeter barriers such as fences or retaining walls, utilities (such as sewers, drains, telephone poles), patios and decks.

A residential structure is one where the general public, including children, could be exposed during or after application. Residential structures include, but are not limited to, homes, garages, schools, restaurants, hotels/motels, public buildings or any other structures where the general public including children may potentially be exposed. Non-residential structures 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, cargo areas, railcars); animal housing (for example, livestock housing, pet kennels); and areas within specific residential structures where the general public, including children, will have no access such as furnace rooms, storage areas in multi-unit dwellings, etc.

Consistency in Label Statements for Structural Pest Control Products

During the scientific review of SPCPs, the PMRA may make changes to the Registrant-provided label statements in order to better reflect the underlying risk assessment, in addition to providing more clarity on statements that communicate risk mitigation measures, the supported use pattern, best practice statements, etc.

To facilitate consistency in this process, the PMRA undertook a focused initiative to standardize the definitions of application types and human health precautionary statements for SPCPs that are used within, outdoors on the exterior surfaces of, and, within a 1 m exterior perimeter of a structure.

The *Standard for Pesticide Education, Training and Certification in Canada,* specifically the 2005 Structural Module of the Basic Knowledge Requirements for Pesticide Education, and United States Environmental Protection Agency's 2012 Residential Standard Operating Procedures were relied upon as key documents for standardizing application type definitions. The human health precautionary statements were based on statements already present on existing labels or as identified by key stakeholders.

Consultation/Engagement

Key stakeholders within the SPCP industry were engaged with a specific consultation request to provide input on the proposed label statements prior to the publication of the regulatory proposal document, PRO2018-04. Specifically, the Canadian Pest Management Association, CropLife Canada, Canadian Consumer Specialty Products Association and the Federal/Provincial/Territorial Committee on Pesticides and Pest Management were consulted to provide feedback and recommendations on the proposed application type definitions and human health precautionary statements. Through this targeted consultation process, the number of definitions was expanded, definitions were simplified and streamlined, and implementation of the label amendment process was clarified.

Additional stakeholder comments were received during the public consultation period for PRO2018-04 and are summarized in Appendix I. These comments were taken into consideration and minor modifications were made, where appropriate, to the definitions and precautionary statements. The finalized tables are presented in Appendices II to IV.

3.0 Structural Pest Control Product Application Types

The definitions of the most common application types are listed in Appendix II.

These definitions are to be applied on the labels of all formulation types but may have to be tailored/adjusted for non-liquid formulations (dusts, aerosols, etc.), as necessary.

4.0 Human Health Precautionary Statements

The standard human health precautionary statements presented in Appendix III are for the most common uses of SPCPs and for those uses that represent the greatest risk to the applicator and populations exposed to residues after application.

These statements are intended for inclusion by registrants on SPCP labels of the end-use products, when appropriate, based on the use pattern. Over time, these precautionary statements may be updated as new information or data are received and reviewed by the Agency.

5.0 Implementation

To communicate these changes to both commercial and domestic product end-users, the labels of commercial and domestic marketing class end-use products for SPCPs will be systematically amended by using the approaches noted below (1-4). The appropriateness of the statements will be determined by both the applicant/registrant and the PMRA, based on the use pattern of the

end-use product, any data submitted by the applicant, and level of risk to human health. For example, it is not required that a space spray product label states, "DO NOT apply when a food/feed processing facility is in operation." if PMRA has approved the use in those areas during facility operation.

The training module for commercial pest control operators (PCOs) or pest management professionals (PMPs) will also be updated. The definitions in this PMRA Guidance Document will be used to replace and augment those currently within the Structural Module for Basic Knowledge Requirements under Application Techniques. Changes will be made to the module when it is updated by the Working Group on Pesticide Education, Training and Certification (WGPETC).

1) Registered Structural Pest Control Products with an Active Submission

Changes and updates relating to definitions and human health precautionary statements, as presented in Appendix II and III, to the labels of registered SPCPs not under re-evaluation will be made through an ongoing submission which contains a labelling component.

2) Registered Structural Pest Control Products with No Active Submission

Registrants of SPCPs with no upcoming or active submission can update their labels through a Category C submission within 60 months of the publication of this PMRA Guidance Document.

3) Registered Structural Pest Control Products Under Re-evaluation

As part of the label updates resulting from re-evaluation, registrants will be required to include relevant updates for any SPCPs, taking into consideration the information presented in this PMRA Guidance Document.

4) New Structural Pest Control Products

The proposed labels of SPCPs submitted to the Agency for initial registration must include the definitions and precautionary statements provided in this PMRA Guidance Document.

If any changes to the definitions or precautionary statements are required for reasons specific to the use pattern of the end-use product, formulation or active ingredient, a rationale must be provided. For example, if the applicant requests to increase indoor perimeter treatment of a building (such as a livestock or animal housing structure) to 1 m from 0.3 m from the wall, a rationale must be provided under DACO 10 to support the need for a larger treatment area based on the activity of the pest. Under DACO 5, the applicant will also need to justify that the additional surface area of treatment will not result in an increase in exposure.

6.0 Conclusion

Implementation of the definitions of application types and human health precautionary statements by the PMRA, stakeholders such as PCOs/PMPs, provincial and territorial pesticide licensing/certification and education bodies, and applicants/registrants will take effect at the time of publication of this PMRA Guidance Document.

The collaborative efforts put forth in the development of these statements will result in greater consistency in the use of these statements and allows a better understanding of how SPCP products are to be used.

List of Abbreviations

| PCO | Pest Control Operator |
|--------|---|
| PMP | Pest Management Professional |
| PMRA | Pest Management Regulatory Agency |
| PRO | Regulatory Proposal |
| SPCP | Structural Pest Control Product |
| VMD | Volume Median Diameter |
| WGPETC | Working Group on Pesticide Education, Training and Certification. |

| Appendix I Comments Received on PRO2018-04 and PMRA Responses |
|---|
|---|

| Organization | Summary of Comments | PMRA Response |
|--|---|---|
| CropLife Canada (CLC) Canadian Pest Management Association | Continue to maintain an open dialogue with the PMRA when implementing these label updates, ensure appropriate statements are put on labels for the specific use pattern of an end-use product. Requested that labels be updated in a timely fashion. Ensure appropriate statements are put on labels for the specific use pattern of an end-use product | As noted in Section 5.0, the onus is on both the applicant and PMRA to determine the appropriate label statements. Labels will be updated using one of the four approaches indicated in this Guidance Document, within the timeframes associated with each approach. |
| Alberta Environment and Parks | Proposal to amend the ventilation statement to enable it to be more enforceable and requested a change to the crack and crevice definition to be less restrictive by removing, "It does not include the treatment of exposed surfaces." | The ventilation statement was revised to add clarity. The crack and crevice statement could not be changed for the following reason: Limiting the location of application is necessary to allow for risk mitigation when there are human health concerns from other treatment types; The definition is consistent with that in the Structural Module; and The proposed revision would result in an indoor perimeter (pin stream) application and thus negate the difference between crack and crevice and pin stream application. |
| Canadian Environmental Law Association | Recommend making labels more visibly and linguistically accessible and establishing a consistent definition of residential areas. | These recommendations are outside of the scope of this project but will be considered under other label improvement initiatives. |
| Premier Tech | Recommended changes to the French translations. | Changes were accepted |

Appendix II Application Type Definitions for Inclusion on Proposed / Registered Labels

| Application Type ¹ | Definition |
|---|--|
| Outdoor Structural Broadcast | Outdoor broadcast application is to large outdoor structural surfaces (roofs, walls, |
| | doors, windows and foundations). ² |
| Outdoor Perimeter ^{3,4} | Outdoor perimeter application is 1 m or less out from the building's foundation |
| | and to a maximum height of 1 m starting where the foundation meets the ground. |
| 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 (coarse | Indoor perimeter application is less than 0.3 m wide along the edges of a room to |
| droplet or particle size) | baseboards, wall-floor and ceiling-wall joints, and around doorways or windows. |
| Indoor Perimeter (pin stream, | Indoor perimeter application is less than 0.1 m wide along the edges of a room |
| coarse droplet or particle size). | using a pin stream nozzle to baseboards, wall-floor and ceiling-wall joints, and |
| For commercial marketing | around doorways or windows. |
| class end-use products only. | • |
| Spot | Spot application is localized to a surface area not more than 0.2 m ² . Spots are not |
| - | to be adjoining. The combined area of spots is not to exceed 10% of the total |
| | surface area of a room. |
| | |
| | Exception for gel or paste baits not applied in bait stations: A spot application is |
| | an open, localized placement of bait in areas inaccessible to children and pets [and |
| | livestock]. ⁵ Locations of treatment may include under sinks and under heavy |
| | appliances (for example, fridge or stove). |
| 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. |
| Furniture Treatment, ⁶ including | Broadcast - Broadcast application covers large areas or the entire surface of listed |
| but not limited to upholstered | items. |
| furniture, hard surface | Spot – Spot application is up to 10% of the surface of the treated item. |
| furniture, mattresses, box | Crack and crevice – Crack and crevice treatments are applications to junction |
| spring, pet bedding, bed | points on items. |
| frames, dressers, curtains, | Tufts and/or seams (mattresses and upholstered furniture only) – Tufts and/or |
| picture frames, wall coverings, | seam treatment is to the junction of two or more pieces of fabric and any |
| hollow furniture legs, etc. | decorative trim (for example, buttons). |
| Equipment Treatment, | Void – Void treatment targets inaccessible empty spaces of items. For example, |
| including those used in food | inside the dust cover on the underside of furniture or hollow table legs. |
| and feed establishments, | |
| garbage can(s)/dumpsters, etc. | |
| Space ⁷ | Space application is a suspension of fine droplets (0.1 to 100µm) ⁸ in the air within |
| | an indoor space. |
| ¹ Unless otherwise specified, the ap | plication types and definitions are for indoor application only. |

² Other locations can be considered on a case-by-case basis (for example, porches, patios) if the relevant USC is requested.

³ The limitation of 1 m is based on the USEPA Residential SOP, Section 3 Lawns/Turf as the maximum distance from a house for which a post-application human health risk assessment for lawns/turf does not have to be conducted.

⁴ An outdoor perimeter application of a structural pest control product could result in exposure to pollinators; thus, additional environmental toxicity data under DACO 9.2.4 (Bees/Insect Pollinators) may be required.

⁵ Livestock may need to be included if applicable to the use pattern.

⁶ Unless a restrictive statement is added limiting the treatment of furniture to only the outside, it is assumed the generic use of 'furniture' on labels includes both the inside and outside (for example dressers, storage chests).

- 7 This definition does not include fumigants, outdoor fogging and outdoor misting systems. A fumigant is a chemical, which at a specific temperature and pressure, can exist in a gaseous state in sufficient quantities to be lethal to a pest organism (WGPETC, 2005). Outdoor fogging and outdoor misting systems are outside the scope of this guidance document. The droplet size is defined by the American Society of Agricultural and Biological Engineers (ASABE, 2009; Appendix III). When adding this definition to labels, do not include the droplet size for ready-to-use end-use products.
- 8

Appendix III Human Health Precautionary Statements for Inclusion on Proposed/Registered Labels

| | Surface Application | Space Application | |
|--|---|---|--|
| Precaut | tionary Statement | Precautionary Statement | |
| Comme | ercial Marketing Class Products | Commercial Marketing Class Products | |
| 1. 2. | Wear a long-sleeved shirt, ¹ long pants, ¹ chemical- resistant gloves, socks and shoes during [mixing, loading,] ² application, clean-up and repair. DO NOT apply to overhead areas or in confined spaces ³ without appropriate respiratory and eye | Wear a long-sleeved shirt,¹ long pants,¹ chemical resistant gloves socks and shoes during [mixing, loading,]² application, clean-up and repair. When applying to overhead areas or in confined spaces,³ wear appropriate respiratory and eye | |
| 3. | protection. ⁴ 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. ⁴ | 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 | |
| | For broadcast, perimeter and spot spray (liquid formulation) applications, add "Use a coarse ⁵ droplet size and low pressure spray not exceeding 345 kPa (50 psi) to avoid splashing onto non- target surfaces." DO NOT apply when a food/feed processing | operational may also be used.4. DO NOT apply when a food/feed processing facility is in operation. | |
| D | facility is in operation. ⁴ | | |
| | ic Marketing Class Products | Domestic Marketing Class Products | |
| 1. 2. | DO NOT apply to overhead areas or in confined spaces (for example, attics, crawlspaces). ⁴ Ventilate treated areas after application by opening windows and doors or using fans, where required, to aid in the circulation of air. ⁴ | Ventilate treated areas after application by opening windows and doors or using fans, where required, to aid in the circulation of air. | |
| Comme | ercial and Domestic Marketing Class Products | Commercial and Domestic Marketing Class Products | |
| 1. 2. 3. 4. 5. 6. 7. | DO NOT apply when people or pets [or livestock] ⁶ are present. Liquid/Aerosol end-use products - DO NOT allow people or pets [or livestock] ⁶ to enter treated areas until sprays have dried. Dust end-use products – DO NOT allow people or pets [or livestock] ⁶ to enter treated areas until dusts have settled. Liquid/Aerosol end-use products – DO NOT allow spray to drip or allow drift onto non-target surfaces. ⁴ Dust end-use products – DO NOT allow dust to deposit onto non-target surfaces. DO NOT apply to surfaces that may come into contact with food/feed. ⁷ Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment. DO NOT apply as a [space spray] ⁸ or [broadcast | DO NOT apply when people or pets [or livestock]⁶ are present. DO NOT remain in treated areas after application. DO NOT allow people or pets [or livestock]⁶ to enter treated areas until [sprays have settled] or [XX¹⁰ minutes after application].¹¹ Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash following treatment. | |
| | or indoor perimeter or spot] ⁹ treatment. statements for end-use products approved for use resses and furniture: | | |

| Surface Application | Space Application | |
|--|--|--|
| Precautionary Statement | Precautionary Statement | |
| 9. DO NOT use on items which can be laundered (for example, pillows, bedding, toys, clothing | | |
| etc.). | | |
| Remove bedding before treating mattresses. Treated mattress must be dry before replacing laundered bedding. | | |
| 11. 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. | | |
| 12. When approved for tuft and/or seam application only, add, "DO NOT apply to the entire mattress or piece of furniture. Apply to tufts [and/or] seams only." | | |
| Statement for end-use products which are approved to control a pest (in other words, bed bugs, fleas) that can be found on mattresses and furniture but the latter are not specifically stated on the label: 13. DO NOT apply to furniture, mattresses, linens, pet bedding, toys or clothing. | | |
| Generic statements for void application: | | |
| 14. Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non- target surfaces must be removed by the | | |
| applicator. | | |
| The requirement for a long-sleeve shirt and long pants is consider Mixing and loading is not applicable for ready-to-use end-use pro Confined space as described by the Canadian Centre for Occupat Not necessary to include for gel or paste bait end-use products. T depend on the overall use pattern of the product. | ducts and so should be removed from the label statement. | |

⁵ Coarse droplet size as defined by the American Society of Agricultural and Biological Engineers (ASABE, 2009).

⁶ Livestock may need to be included if applicable to the use pattern.

- ⁷ For end-use products which are not allowed for use in food/feed processing facilities.
- ⁸ This restriction must be added when only surface application types are supported on the label.
- ⁹ The surface application types not requested or supported by the PMRA must be listed here.
- ¹⁰ The duration prior to entry is based on the settling time of an end-use product as per the most recent USEPA Residential Standard Operating Procedure.
- ¹¹ Not applicable to metered mists which are permanently installed.

Appendix IV Droplet Size Categories

The droplet classifications used within this document are defined by the American Society of Agricultural and Biological Engineers (ASABE, 2009). The volume median diameter (VMD) is the value where 50% of the total volume or mass of liquid spray is made up of droplets larger than and 50% smaller than this value.

| ASABE ¹ | VMD Range | Sub Category ² | VMD Range |
|--------------------|------------------|---------------------------|------------------|
| Classification | (micrometre, µm) | | (micrometre, µm) |
| | | Vapour | < 0.001 |
| Extremely Fine | <60 | Fume/Smokes | 0.001 to 0.1 |
| | | Aerosols/Fogs | 0.1 to 50 |
| Very Fine | 61–105 | Mist | 50 to 100 |
| Fine | 106–235 | | |
| Medium | 236–340 | Fine Fan Spray | 100 to 400 |
| Coarse | 341–403 | | |
| Very Coarse | 404–502 | Coarse Fan Spray | >400 |

¹ American Society of Agricultural and Biological Engineers (ASABE) developed the ASABE S572.1 Droplet Size Classification. This is the standard currently used by the PMRA's Environmental Assessment Directorate.

² Referenced from Mallis A. 2004. Handbook of pest control: the behavior, life history, and control of household pests. 9th ed. New York : Mac Nair-Dorland

References

American Society of Agricultural and Biological Engineers (ASABE). 2009. ASAE S572.1. Spray Nozzle Classification by Droplet Spectra. Am. Soc. Agric. Eng., St. Joseph, MI.

Canadian Centre for Occupational Health and Safety (CCOHS). 2018. Confined Space – Introduction. https://www.ccohs.ca/oshanswers/hsprograms/confinedspace_intro.html. Accessed May 16, 2018

Mallis, A. 2004. Handbook of Pest Control. The Behaviour, Life History, and Control of Household Pests. 9th Edition. Story Hedges (Ed). GIE Media, Inc.

National Research Council of Canada (NRC). 2015. National building code of Canada, 2015 / issued by the Canadian Commission on Building and Fire Codes, National Research Council of Canada. Ottawa, Ont. 14th Ed.

United States Environmental Protection Agency (USEPA). 2012. Standard Operating Procedures for Residential Pesticide Exposure Assessment. Oct. 2012. https://www.epa.gov/sites/production/files/2015-08/documents/usepa-opp-hed_residential_sops_oct2012.pdf, Accessed May 9, 2019

Working Group on Pesticide Education, Training and Certification (WGPETC). 1995. Standard for Pesticide Education, Training and Certification in Canada. Fumigation Module. Basic Knowledge Requirements for Pesticide Education in Canada. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/education-training-materials.html, Accessed May 14, 2019

Working Group on Pesticide Education, Training and Certification (WGPETC). 2005. Standard for Pesticide Education, Training and Certification in Canada. Structural Module. Basic Knowledge Requirements for Pesticide Education in Canada. Second Edition. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reportspublications/pesticides-pest-management/education-training-materials.html, Accessed May 14, 2019