



Consumer Product Safety

Re-evaluation Decision RVD2016-02, Carbaryl

Pest Management Regulatory Agency

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Re-evaluation Decision

After a thorough re-evaluation of the insecticide carbaryl, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#) and [Regulations](#), is granting continued registration of certain products containing carbaryl for sale and use in Canada.

An evaluation of available scientific information found that, under the revised conditions of use:

- Certain uses of carbaryl products have value in Canada and do not pose unacceptable risks to human health or the environment. These uses include commercial products applied in agricultural, non-crop and forestry settings, other than those noted below. As a requirement for continued registration of these carbaryl uses, new risk reduction measures are required. No additional data are requested at this time.
- Certain uses of carbaryl must be removed from the current carbaryl labels because they are not supported by the technical registrant. These uses are as follows and were not included in the risk assessment:
 - Indoor pest control uses including greenhouses, residences, food and feed handling establishments and barns and livestock production areas
 - Aerosol products
 - Agricultural dust uses

- Bran bait application to residential garden
 - Livestock for food
 - Livestock for non-food
 - Companion animals
 - Granular bait products for ornamental gardens
 - Applications by hand, spoon and bellygrinder
- Certain products or uses pose risks of concern to human health and do not meet Health Canada's current standards for human health protection. As a result, the following products or uses will be cancelled:
 - All domestic class products
 - Commercial application of carbaryl in residential settings including ornamentals, vegetable gardens and fruit trees in residential areas
 - All turf applications in commercial and residential areas, including lawns, sod farms and golf courses
 - Various crops (alfalfa, apples (insecticide use), apricot, barley, broccoli, Brussels sprouts, cabbage, cauliflower, cherries, clover, corn (sweet & field), grapes, kale, oats, peach, pears, peppers, plums, prunes, rye, snapbeans (hand harvest only), strawberries, sweet white lupin, wheat); and
 - Balsam fir, spruce, farm woodlots, municipal parks and rights-of-way for control of spruce budworm.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. [Regulatory Directive DIR2001-03, PMRA Re-evaluation Program](#), presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies, and any other relevant information available.

The regulatory approach for the re-evaluation of carbaryl was first presented in [Proposed Re-evaluation Decision PRVD2009-14, Carbaryl](#). This Re-evaluation Decision describes this stage of PMRA's regulatory process for the re-evaluation of carbaryl and summarizes the Agency's decision and the reasons for it.

Comments received during the consultation process were taken into consideration. These comments and new data/information resulted in revisions to some parts of the risk assessments, however, did not result in substantial changes to the proposed regulatory decision as described in PRVD2009-14. Appendix I of Re-evaluation Decision RVD2016-02, *Carbaryl* summarizes comments received and provides the PMRA's response.

To comply with this decision, the following implementation timelines must be followed. Registrants of end-use products containing carbaryl will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Label changes:

The required mitigation measures (Appendix V of Re-evaluation Decision RVD2016-02,

Carbaryl) must be implemented on all commercial product labels sold by registrants as soon as possible but no later than 24 months after the publication date of RVD2016-02, *Carbaryl*.

Domestic products:

The last sale of all domestic products by Registrants and Retailers is 12 months and 24 months following the publication date of RVD2016-02, *Carbaryl*, respectively. The registration of these products will expire 36 months following the publication date of RVD2016-02, *Carbaryl* (Appendix VI of RVD2016-02).

Water soluble packaging requirements:

An application to register a new product in water soluble packaging is required within 24 months following the publication date of RVD2016-02, *Carbaryl* (Appendix VI of RVD2016-02).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent risks of concern to people and the environment from the use of pest control products. Health or environmental risk is considered of no concern if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration. The Act also requires that products have value when used according to the label directions. Requirements of continued registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive populations subgroups in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information, please refer to the following:

- [Protecting Your Health and the Environment](#)
- [Pesticide Registration Process](#)
- [Pesticide Risk Reduction Program](#)

What is Carbaryl?

Carbaryl is a broad spectrum Resistance Management Group 1A (carbamate) insecticide. In Canada, it is registered to control a wide range of arthropod pests including beetles, moths, fleas, flies, lice, mites, sawflies, crickets, earwigs, grasshoppers, millipedes, sow bugs, thrips, ticks and cockroaches. It is also registered for use in apple thinning.

Carbaryl is used on both agricultural and non-agricultural sites including feed crops, industrial oil seed and fibre crops, livestock, greenhouse tobacco seedlings, companion animals, structures, forestry, food crops, turf, lawns and ornamentals. It is applied by both ground and aerial equipment.

Health Considerations

Can Approved Uses of Carbaryl Affect Human Health?

Carbaryl is unlikely to affect human health when used according to the revised label directions, which include additional risk-reduction measures.

Potential exposure to carbaryl may occur through the diet (food and water), by applying the product or by entering treated sites. When assessing health risks, two key factors are considered:

- the dose at which no health effects occur and
- the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

Toxicology studies on laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when carbaryl products are used according to label directions.

The acute toxicity of carbaryl ranged from moderate to high via the oral route of exposure. It was of low acute toxicity via the dermal and inhalation routes of exposure. Carbaryl was mildly irritating to eyes, but non-irritating to skin and not a skin sensitizer.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as information from the published scientific literature were assessed for the potential of carbaryl to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoints for risk assessment included effects on the nervous system. In addition, there was evidence that young animals were more sensitive than adult animals to carbaryl toxicity as demonstrated by the effects on the nervous system at lower levels than adults. Longer-term dosing with carbaryl resulted in tumors of the blood in mice.

Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Risks in Residential and Other Non-Occupational Environments

Residential uses of carbaryl on turf, ornamentals, fruit trees and vegetable gardens are of concern. These uses will be cancelled.

Carbaryl is registered for use on turf, and on residential ornamental and vegetable gardens. Estimates of exposure using turf transferable residue data and dislodgeable foliar data, as well as carbaryl specific biomonitoring data did not achieve the target margin of exposure (MOE) and/or aggregate risk index for adults and children for all postapplication exposure scenarios and some application scenarios, and are therefore of concern. Risks of concern remained even after consideration of all feasible mitigation measures.

As a result, all residential uses of carbaryl must be cancelled. This includes cancellation of all domestic-class products and commercial applications in residential areas. Applications on turf, golf courses, ornamentals, vegetable gardens and fruit trees in residential areas will not be permitted. Residential areas are defined as sites where bystanders including children could be exposed during or after application. This includes homes, schools, public buildings or any other areas where the general public including children could be exposed.

As described in PRVD2009-14, carbaryl is currently registered in use scenarios that could potentially include Pick-Your-Own (PYO) operations. When the updated use refinements, product discontinuations and risk mitigation measures are taken into account, aggregate exposure for PYO patrons is not of concern.

Cancer risks are not of concern to any residential population for the remaining uses of carbaryl.

Occupational Risks from Handling Carbaryl

Mixer/Loader/Applicator

The majority of risks for mixers, loaders and applicators are not of concern provided additional mitigation measures are followed.

Occupational risk assessments from handling carbaryl consider exposure to workers who mix, load, and apply the pesticide. Most uses for agricultural scenarios have margins of exposure that are not

of concern, provided that engineering controls or personal protective equipment are used. These measures are needed to minimize potential exposure and protect workers' health.

All non-cancer risk estimates for lawn care operators applying carbaryl to residential turf, as well as for golf course and sod farm workers applying carbaryl, did not reach the target margin of exposure and/or aggregate risk index for broadcast treatments, even with maximum personal protective equipment and engineering controls, and are therefore of concern. These uses must be cancelled.

Risks of concern were identified in PRVD2009-14 for agricultural workers using hand held equipment. However, with the updated use refinements, product discontinuations and risk mitigation measures taken into account, occupational risk from the use of hand held equipment is no longer of concern.

The mixer/loader/applicator risk assessment for carbaryl was revised for tobacco and canola, based on new data and updated use information provided by registrants and stakeholders during the comment period for PRVD2009-14. Mitigation options proposed by registrants and stakeholders were also carefully considered. These data and the revised risk assessment are presented in Appendix II of Re-evaluation Decision RVD2016-02, *Carbaryl*. With the risk mitigation, the exposure during mixing, loading and applying for tobacco and canola reach target MOEs and are not of concern.

For other uses, while the additional information resulted in a more accurate risk assessment and more refined mitigation measures for certain uses, the overall risk conclusions did not change significantly from those presented in PRVD2009-14. As occupational mixer/loader/applicator risks of concern for certain uses could not be addressed, the following uses must be cancelled:

- alfalfa,
- barley,
- broccoli,
- Brussels sprouts,
- cabbage,
- cauliflower,
- cherries,
- clover,
- oats,
- pears,
- peppers,
- plums,
- rye,
- strawberries and wheat.

Cancer risks are not of concern to mixers, loaders or applicators for the remaining uses of carbaryl.

Postapplication Workers

Most occupational postapplication risks are not of concern based on revised label directions. Risks for certain uses could not be mitigated and must be cancelled.

Postapplication risk assessments consider exposure to workers entering treated areas. The postapplication risk assessment for carbaryl was revised based on new data and updated use information provided by registrants and stakeholders during the comment period for PRVD2009-14. Mitigation options proposed by registrants and stakeholders were also carefully considered. These data and the revised risk assessment are presented in Appendix IV of Re-evaluation Decision RVD2016-02, *Carbaryl*.

Target MOEs for certain uses of carbaryl are achieved when revised conditions of use and risk reductions measures, such as increased restricted-entry intervals (REIs), are considered. The

revised conditions of use are presented in Appendix V of Re-evaluation Decision RVD2016-02, *Carbaryl*. The uses acceptable for continued registration are:

- Asparagus and asparagus ferns,
- beans,
- beet (root/top),
- blueberries,
- bran bait applications (non-residential),
- cane berries,
- canola,
- carrots,
- celery,
- choke cherries,
- cranberries,
- cucumbers,
- ditch banks,
- eggplants,
- forests and woodlots,
- green ash,
- high value trees,
- horseradish,
- kohlrabi,
- leafy vegetables,
- melons,
- ornamental trees,
- parsnips,
- peas,
- potatoes,
- pumpkins,
- rutabaga (root),
- salsify (root/top),
- snapbeans (mechanical harvest),
- squash,
- trap trees,
- tobacco,
- tomatoes and turnip (root/top).

For other uses, while the additional information resulted in an exposure assessment that may more accurately reflect typical use conditions, the overall risk conclusions did not change significantly from those presented in PRVD2009-14. As postapplication risks of concern could not be addressed through agronomically feasible REIs, the following uses must be cancelled:

- alfalfa,
- apples (for insect control),
- apricot,
- barley,
- broccoli,
- Brussels sprouts,
- cabbage,
- cauliflower,
- cherries,
- clover,
- corn (sweet & field),
- grapes,
- kale,
- oats,
- peach,

- pears,
- plums,
- prunes,
- rye,
- snapbeans (hand harvest only),
- strawberries,
- sweet white lupin,
- wheat,
- balsam fir,
- spruce,
- farm woodlots,
- municipal parks and rights-of-way for control of spruce budworm.

Cancer risks are not of concern to postapplication workers for the remaining uses of carbaryl.

The use of carbaryl for apple thinning is unlikely to be of concern for postapplication workers when used in accordance with the revised label directions.

The risk assessment for the apple thinning use was revised and refined based on updated use information, revised application rates, and other information provided by registrants and stakeholders. Information on modern apple orchard production indicated that the majority of apple orchards have transitioned to high density plantings (or are in the process of transitioning). Postapplication exposure to workers is expected to be lower with high density trellis plantings than with standard trees. Revised conditions of use for apple thinning have been developed as follows to reflect use in high density apple orchards as well as for standard orchard plantings:

- For orchards that have transitioned to high density trellis production architecture (for example, spindle or super spindle trees):
 - Maximum seasonal rate of 1.5 kg a.i./ha and an REI of 14 days for hand thinning
- For orchards that have not transitioned to high density trellis production architecture (for example, dwarf, semi-dwarf and full sized trees):
 - Maximum seasonal rate of 1 kg a.i./ha and an REI of 17 days for hand thinning

Additional label amendments described in Appendix V of Re-evaluation Decision RVD2016-02, *Carbaryl* must also be implemented as required.

Residues in Food and Water

Dietary risks from food and water are not of concern when risk reduction measures are implemented.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is not of concern if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to carbaryl was estimated from residues in treated crops and drinking water, including the most highly exposed sub-populations (for example, infants and children one to six years old). Data from the Canadian Food Inspection Agency, the United States Department of Agriculture Pesticide Data Program (USDA PDP), field trials, processing factors and percent crop treated (%CT) were used to estimate residue levels. As well, information on drinking water was used to estimate both the acute and chronic (non-cancer and cancer) aggregate exposures and

risks.

Short term (acute), long term (chronic) and lifetime cancer exposure estimates were determined for different sub-populations representing different ages, genders and reproductive status. The maximum degree of refinement possible, based on all available information, was used in both the non-cancer and cancer dietary assessments.

As noted in PRVD2009-14, aggregate dietary exposure to carbaryl (that is, from food and drinking water) represented 2% of the chronic reference dose, while the lifetime cancer risk estimate was 7×10^{-8} for the general population. As a result, chronic and cancer risks were not of concern. However, the acute aggregate dietary exposure estimate for carbaryl was 117% and 393% of the acute reference dose for the general population and all infants, respectively, when using drinking water inputs based on modelling data. This represented a potential risk of concern for acute dietary exposure.

The acute aggregate dietary assessment in PRVD2009-14 was updated to reflect the revised use pattern. Previously the drinking water assessment included carbaryl applications to turf. However, since the use of carbaryl on residential turf, golf courses and sod farms is to be cancelled due to residential and occupational risk concerns, the drinking water modelling is now based on carbaryl applications to field crops. As a result, the revised acute aggregate dietary exposure for carbaryl is 41% of the acute reference dose for the general population, and ranges from 31 to 107% for the various population subgroups. The highest exposure at 107% occurs for all infants and is not of concern due to conservative (high-end) assumptions in the exposure assessment, attributable primarily to the use of water modelling data to estimate drinking water exposures.

The [Food and Drug Act](#) prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established [maximum residue limit](#) (MRL). While pesticide MRLs are specified through the evaluation of scientific data under the *Pest Control Products Act*, the MRLs for carbaryl were established under the *Food and Drugs Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

MRLs for carbaryl are currently specified for a wide range of commodities ([MRL database](#)). Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm.

The MRLs for barley, oats and rye will be revoked following the cancellation of the associated uses in Canada. As there are no American tolerances or [Codex](#) MRLs for these uses, this action will not impact trade.

Environmental Considerations

What Happens When Carbaryl is Introduced into the Environment?

When used according to the revised label directions, carbaryl is not expected to pose risk of concern to the environment.

When carbaryl is released into the environment some of it can be found in soil and surface water. Carbaryl is quickly broken down by soil microbes and by chemical reaction in water and is not expected to persist in the environment. Although laboratory studies indicate that carbaryl is mobile in soil, field studies suggest carbaryl is broken down quickly and is unlikely to reach groundwater.

Under controlled laboratory conditions, carbaryl can be toxic to some non-target species, such as bees, beneficial insects, birds, wild mammals, aquatic invertebrates and fish. If carbaryl is used at labelled application rates without any risk reduction measures, it has the potential to cause adverse effects in the organisms listed above. Therefore, mitigation measures are required in order to reduce potential exposure of non-target organisms and reduce environmental risks. When

carbaryl is used in accordance with the revised label and the required risk reduction measures are applied, the resulting environmental risk posed by carbaryl is considered to be acceptable.

Value Considerations

What is the Value of Carbaryl?

Carbaryl contributes to insect pest management in agriculture, forestry and ornamental production in Canada.

In Canada, carbaryl is used extensively and is integral to the management of insect pests in many crops, forestry and ornamental production. It is the only registered active ingredient in Canada for the control of certain insect pests.

Carbaryl contributes to sustainable pest management by playing an important role in prevention of the development of insecticide resistance when used in rotation with insecticides of different modes of action.

Carbaryl is also used to thin apples. The thinning of developing fruit is a critical step in the economical production of apples as it results in larger apples of higher quality. Of the registered chemicals for apple thinning, carbaryl is considered the most versatile and effective thinning agent for growers to use. Carbaryl is used alone or in combination with one of the following:

- naphthalene acetic acid (NAA) marketed as Fruitone-N; or
- benzyladenine (BA) marketed as Accel, MaxCel and Cilis.

Incident Reports

As of 30 July 2015, the Incident Reporting Program has received 49 human, 79 domestic animal and 13 environment incidents for carbaryl. Most incidents were minor in severity. All but a few of the human and domestic animal incidents involved the use of domestic class products. The discontinuation of such uses should reduce the occurrence of future incidents involving carbaryl. There was one major environment incident in which fish were killed when water that was used to extinguish a chemical warehouse fire was released into a nearby stream. The remaining environment incidents were minor in severity and involved plant damage or honeybee mortality. Honeybee mortality was reported in five of the incidents; however, other chemical active ingredients in addition to carbaryl were also reported.

Organisation for Economic Co-operation and Development Status of Carbaryl

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments of member countries can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration of recent developments and new information on the status of the active ingredient in other jurisdictions, including OECD member countries.

Carbaryl is currently registered in some OECD countries, including the United States, Australia and New Zealand.

The European Commission prohibited the use of carbaryl as a plant protection product in 2007 for health and environmental reasons. Therefore, pursuant to subsection 17(2) of the *Pest Control Products Act*, the PMRA has initiated a special review of pest control products containing carbaryl based on the 2007 European Commission decision (REV2013-06). The PMRA will publish its proposed special review decision once completed.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to [protect human and environmental health](#). These directions must be followed by law. Appendix II of Re-evaluation Decision RVD2016-02, *Carbaryl* lists all current products containing carbaryl. Further risk-reduction measures are required to address potential risks of concern identified in this assessment (Appendices V and VI of Re-evaluation Decision RVD2016-02, *Carbaryl*). The following key risk-reduction measures are required.

Key Risk-Reduction Measures

Human Health

After consideration of all possible mitigation measures, the following uses must be cancelled due to residential and/or occupational risk concerns:

- All domestic class products
- Commercial application of carbaryl in residential settings including ornamentals, vegetable gardens and fruit trees in residential areas
- All turf applications in commercial and residential areas, including sod farms and golf courses
- Various crops (alfalfa, apples (for insect control), apricot, barley, broccoli, Brussels sprouts, cabbage, cauliflower, cherries, clover, corn (sweet & field), grapes, kale, oats, peach, pears, peppers, plums, prunes, rye, snapbeans (hand harvest only), strawberries, sweet white lupin, wheat, Balsam fir, spruce, farm woodlots, municipal parks and rights-of-way for control of spruce budworm.

For all other uses, to protect mixer/loader/applicators using commercial products, additional mitigation measures such as personal protective equipment and engineering controls are required. All carbaryl products currently registered as wettable powders must be packaged in water soluble packaging.

For all other uses, to protect workers entering treated sites, revised restricted-entry intervals as well as revised application frequencies and intervals are to be added to product labels.

For the apple thinning use, revised conditions of use include minimizing the application rate, updated REIs, and label recommendations to reduce exposure, such as the use of chemical-resistant gloves during hand-thinning.

Precautionary statements to avoid drift to areas of human habitation or areas of human activity are to be added to product labels.

The Toxicological Information section on labels is to be updated to include additional information about symptoms and treatment for over-exposure.

Environment

- Precautionary statements include statements to reduce runoff and revised spray buffer zones for non-target aquatic habitats.
- Changes to application timing, including restriction of application during bloom for some crops, are required as a result of the pollinator risk assessment.

What Additional Scientific Information is Being Requested?

No data are required under section 12 of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection regarding this decision on carbaryl within 60 days from the date of publication of Re-evaluation Decision RVD2016-02, *Carbaryl*. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the [Pesticides and Pest Management](#) portion of Health Canada's website ([Request a Reconsideration of Decision](#)), or contact the PMRA's [Pest Management Information Service](#).

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