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Use of Unlabelled Tank Mixes of Commercial Class Pest Control Products Used for Crop Production or Vegetation Management

Frequently Asked Questions

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This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Introduction

On October 27, 2009, the PMRA published a memorandum to all applicants, registrants and their regulatory representatives regarding the use of unlabelled tank mixes of commercial class pest control products used for crop production or vegetation management. The memorandum clarified the PMRA's position with regard to these types of tank mixes and made allowances for their use, if certain conditions were met. The memorandum is available on the Health Canada Web site at the following address:

http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/prod/_memorandum-note/mixes-melanges-eng.php

To provide guidance on how the document is to be interpreted, answers to some frequently asked questions are presented below. Many of the questions relate to which types of uses are considered to be crop-production or vegetation-management uses and are beyond the scope of the memorandum. A summary of these uses can be found in Table 1, at the end of this document. The answers are provided under the assumption that the six conditions, described in the memorandum, have all been met.

The specific conditions described in the memorandum are as follows:

1. Each tank-mix partner is registered for use in Canada on the crop of interest, including genetically modified crops.
2. The tank mix only includes an adjuvant, when specifically required by one of the tank-mix partner labels. If an adjuvant is not required on the label of any tank-mix partner, then no adjuvant may be added to the tank mix.
3. The application timings of all tank-mix partners are compatible with crop and pest staging.
4. Each tank mix partner is applied in accordance with its registered product label (e.g. Directions for Use, Precautions, Buffer Zones, etc.). In cases where information on the tank-mix partner labels differs between them, the most restrictive directions must be followed.
5. The tank mix is not specifically excluded or contraindicated on either tank-mix partner label.
6. The use of the tank mix provides additional value to the user (e.g. increased scope of pests controlled, contributes to resistance management or integrated pest management, cost or time savings).

Some of the answers make reference to use-site categories (USC). The PMRA has developed and described USCs to group-use scenarios (a combination of the purpose of the pesticide and where it is used) that are similar in nature, as a guide for developing data requirements. For a full description of USCs, please refer to REG2003-01 Guidance on Selecting the Correct Category for Pest Control Product Submissions (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/reg2003-01/index-eng.php).

Frequently Asked Questions

Q1: What is meant by a crop-production use?

A1: A crop-production use is directly related to the activities associated with growing a plant that is intended to be used by humans for any variety of purposes. This includes plants grown for food, feed, fibre and ornament, among others. Tank mixes including any combination of herbicides, insecticides, fungicides or plant-growth regulators may be used for crop production uses during any stage of production (from pre-planting to post-harvest), but excludes applications during storage. In terms of use-site categories, crop-production uses within the scope of the tank-mix policy would fall under:

- USC 4: Forests and Woodlots
- USC 5: Greenhouse Food Crops
- USC 6: Greenhouse Non-Food Crops
- USC 7: Industrial Oil Seed Crops and Fibre Crops
- USC 10: Seed Treatments Food and Feed
- USC 11: Seed Treatments Non-Food
- USC 13: Terrestrial Feed Crops
- USC 14: Terrestrial Food Crops
- USC 27: Ornamentals Outdoor
- USC 30: Turf

Q2: What is meant by a vegetation-management use?

A2: Vegetation management within the scope of this memorandum refers to the management or control of undesirable vegetation (weeds). Therefore, tank mixes including only herbicides would be considered as vegetation-management uses. Tank mixes that include insecticides or fungicides are not within the scope of vegetation management. In terms of use-site categories, vegetation-management uses within the scope of the tank-mix policy would fall under:

- USC 4: Forests and Woodlots
- USC 5: Greenhouse Food Crops
- USC 6: Greenhouse Non-Food Crops
- USC 7: Industrial Oil Seed Crops and Fibre Crops
- USC 13: Terrestrial Feed Crops
- USC 14: Terrestrial Food Crops
- USC 16: Industrial and Domestic Vegetation Control for Non-Food Sites
- USC 27: Ornamentals Outdoor
- USC 30: Turf

Q3: What type of guidance may registrants, extension specialists and crop advisors provide regarding these types of unlabelled tank mixes?

A3: In the interest of providing users of these types of tank mixes with the best information available, guidance may be provided verbally or in writing (i.e. compatibility charts). Registrants, extension specialists and crop advisors are under no obligation to provide guidance, but they may choose to do so at their discretion. The guidance provided could identify, at the same time, tank mixes that are compatible and those that are not, and may be published as part of a crop production guide or as a stand-alone document.

Q4: Can these types of unlabelled tank mixes be applied to non-crop areas?

A4: Provided that the conditions of the memorandum are met and that the tank-mix partners include herbicides only, these types of tank mixes may be applied to non-crop areas, as this would be considered as a vegetation-management use. Vegetation management within the scope of this memorandum refers to the management of weeds. Therefore, tank mixes, including insecticides or fungicides, are not within the scope of vegetation management. Non-crop areas could include roadsides, rights of way and industrial sites.

Q5: Are unlabelled tank mixes for pest control in crop-storage areas permitted within the scope of the memorandum?

A5: No, applications to crop-storage areas (e.g. barns and storage bins) are not considered to be crop-production or vegetation-management uses. These types of applications fall under USC 12: Stored Food and Feed and are not within the scope of the memorandum.

Q6: Are uses in forestry permitted within the scope of the memorandum?

A6: Yes, in the context of the memorandum, forestry uses are considered to fall within the scope of crop production.

Q7: Are uses on ornamental plants permitted within the scope of the memorandum?

A7: Yes, uses on ornamental plants are considered to fall within the scope of crop production.

Q8: Are greenhouse uses permitted within the scope of the memorandum?

A8: Yes, greenhouse uses, for both food crops and ornamental plants, are considered to fall within the scope of crop production.

Q9: Are uses on golf courses permitted within the scope of the memorandum?

A9: Yes, in the context of the memorandum, golf-course uses are considered to fall within the scope of crop production.

Q10: Are unlabelled tank mixes with fertilizers permitted within the scope of the memorandum?

A10: Yes, unlabelled tank mixes that incorporate a fertilizer as part of the spray carrier are permitted within the scope of the memorandum, provided that no additional claims are made. However, the addition of a fertilizer to the spray carrier may result in a greater chance of host-crop injury so initial use should be limited to a small area to confirm results prior to widespread use.

Q11: Are unlabelled tank mixes that include a biopesticide permitted within the scope of the memorandum?

A11: Yes, however, unlabelled tank mixes with biopesticides may have the potential for decreased efficacy on one or both tank-mix partners, particularly in the case of biopesticides, where the active ingredient is a living organism.

Q12: Are post-harvest applications of unlabelled tank mixes permitted within the scope of the memorandum?

A12: Yes, post-harvest applications are considered to fall within the scope of crop production, provided the applications are not made to stored food or feed during the storage period (USC 12: Stored Food and Feed). Examples of post-harvest applications that are permitted within the scope of the memorandum are as follows: weed-control applications to a field, following crop harvest; applications to a harvested crop commodity, prior to being placed in storage.

Q13: Are unlabelled tank mixes that include a plant-growth regulator permitted within the scope of the memorandum?

A13: Yes, unlabelled tank mixes that include a plant-growth regulator are considered to be within the scope of the memorandum.

Q14: Are unlabelled tank mixes that include restricted commercial class products or products with restricted uses permitted within the scope of the memorandum?

A14: Yes, provided the conditions in the memorandum are met, and all other restrictions associated with the product or its use have been satisfied.

Q15: Are uses on livestock permitted within the scope of the memorandum?

A15: No, although the use of pesticides on livestock would be considered an agricultural use, it is not a use related to crop production. Applications of pesticides to livestock fall under USC 8: Livestock for Food and USC 9: Livestock Non-Food and are not within the scope of the memorandum.

Q16: Do domestic class products fall within the scope of the memorandum?

A16: No, the memorandum only applies to commercial class products used for crop production or vegetation management. Domestic class products are excluded.

Q17: Can unlabelled tank mixes of commercial class products be applied in residential areas?

A17: Yes, provided the products are registered for use in residential areas, and all the conditions outlined in the memorandum are met.

Q18: Some registered product labels contain general statements precluding the use of tank mixes that do not appear on the product label. Can these types of statements be added to or removed from the label?

A18: Yes, these types of general label statements may be added to or removed from a registered product label at the registrant's discretion. The addition or removal of these types of statements may be done through notification. The memorandum should be cited in the documentation accompanying the notification. Details of the notification process can be found in DIR2001-04, *Notification/Non-notification*. However, it is important to note that existing label statements precluding tank mixes with specific pest control products may not be removed via notification.

Q19: If a product has a statement on the label that says "Do not mix this product with any other products other than those listed in the tank mix recommendations" (or similar), does that statement constitute a specific prohibition of the mixing of a non-listed product?

A19: Yes, if a product label contains a statement that specifically precludes tank mixtures, other than those appearing on the label, then the types of unlabelled tank mixes specified in the memorandum would not be permitted. However, the registrant has the option of amending the product label to remove that statement, at which time the types of unlabelled tank mixes specified in the memorandum would be permitted.

Q20: If two registered products are packaged together, what are the labelling requirements for the packaging?

A20: The outer packaging used to bundle the two products together must indicate the crop(s) on which the bundled products are to be used. This may be done using packaging printed for the specific use. A unique marketplace name may be assigned to the combination and may appear on the outer packaging. The outer packaging must also indicate the postal address of the registrant, the registered product names, registration numbers, guarantees, net contents and precautionary symbols of each individual product contained within it. The registered labels must be provided for each tank-mix partner. Additional information, such as specific mixing directions, may be included inside the packaging, as well as instructions for handling broken cartons, if necessary.

Q21: What is required to amend a registered product label so that a tank mix, which meets the conditions outlined in the memorandum, may be added?

A21: The data requirements to add a tank mix to a product label have not changed. The addition of a tank mix, meeting the conditions outlined in the memorandum, would generally qualify for a Category C “Fast track” submission.

Q22: The memorandum indicates that use of an unlabelled tank mix may result in decreased efficacy or increased crop injury. Why would the PMRA permit unlabelled tank mixes to be applied when these risks are possible?

A22: A full review of a product’s efficacy and potential for crop injury is conducted before the product is registered for use alone. The PMRA recognizes that the potential for decreased efficacy or crop injury exists, when pest control products are applied as a tank mix. However, this risk can be somewhat mitigated by allowing registrants and other knowledgeable parties to provide additional verbal or written information (in the form of compatibility charts, fact sheets, etc.) regarding the compatibility of various products, when applied as a tank mix. Furthermore, there may be additional benefits associated with the use of tank mixes, as outlined in the memorandum. These may include a broadening of the spectrum of pests controlled, a contribution to resistance management or integrated pest management, and cost or time savings. Overall, the risks associated with the use of a tank mix may be acceptable, in light of the additional benefits.

Q23: Why are tank mixes with adjuvants not within the scope of the memorandum?

A23: The inclusion of an adjuvant in a tank mix has the potential to significantly increase the risk of crop injury, particularly in the case of herbicides. It also has the potential to increase pesticide residue levels in the harvested commodity, which may result in residues exceeding established maximum residue limits (MRLs). For these reasons, adjuvants are specifically not included within the scope of the memorandum.

Q24: If both tank-mix partner labels require the addition of an adjuvant should the adjuvant be added to the spray tank twice (i.e. once for each tank-mix partner)? What should be done if a different adjuvant is required for each of the tank-mix partners? What if the adjuvant-application rate differs between the two product labels?

A24: In cases where both tank-mix partner labels require the addition of the same adjuvant in the same amount, the adjuvant should only be added to the spray tank once. If the tank mix partner labels require either the addition of different adjuvants, or the same adjuvant in different amounts, then the application of those products as a tank mix would not fall within the scope of the memorandum, as at least one of the products would not be applied in accordance with its respective label.

Q25: If one tank-mix partner label requires the addition of an adjuvant and the other tank-mix partner label specifically precludes the addition of an adjuvant, can these two products be applied as a tank mix within the scope of the memorandum?

A25: No, in this case, both the inclusion and exclusion of the adjuvant from the tank mix would result in one of the tank-mix partners not being applied in accordance with its respective label.

Table 1: Summary of crop-production and vegetation-management uses considered to be within the scope of the memorandum, and uses that are considered not to be within the scope of the memorandum.

<p>Crop-production uses:</p> <ul style="list-style-type: none">• Agricultural crop uses (field and greenhouse);• Forestry uses;• Turf uses;• Ornamental plant uses (field and greenhouse);• Post-harvest applications (excluding stored food and feed);• Tank mixes that include herbicides, insecticides, fungicides and plant-growth regulators;• Tank mixes that include restricted products or uses;• Tank mixes that include fertilizers;• Tank mixes that include biopesticides;• USC 4, 5, 6, 7, 10, 11, 13, 14, 27 and 30.
<p>Vegetation-management uses:</p> <ul style="list-style-type: none">• Tank mixes containing only herbicides applied to non-crop areas (e.g. roadsides, rights of way, industrial sites, etc.);• USC 4, 5, 6, 7, 13, 14, 16, 27 and 30.
<p>Uses not within the scope:</p> <ul style="list-style-type: none">• Tank mixes that include products other than herbicides to non-crop areas;• Tank mixes that include adjuvants not specifically required by a product label;• Applications to crop-storage areas (e.g. in barns and storage bins);• Applications to stored food and feed while in storage;• Livestock uses;• Domestic class products;• USC 8, 9 and 12, among others.