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Re-evaluation Decision

RVD2019-01

# 2,4-DB and Its Associated End-use Products

*Final Decision*

*(publié aussi en français)*

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## Re-evaluation Decision

Under the authority of the *Pest Control Products Act*, all registered pesticides must be regularly re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental safety standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

2,4-DB is a herbicide registered to control a wide spectrum of broadleaf weeds in major legume forage crops, cereals (wheat, barley and oats), field corn, widely sown forage grasses and pastures containing forage legumes. Currently registered products containing 2,4-DB are listed in Appendix I.

The regulatory approach for the re-evaluation of 2,4-DB was first presented in the Proposed Re-evaluation Decision PRVD2018-08, *2,4-DB and Its Associated End-Use Products*.<sup>1</sup> PRVD2018-08 proposed continued registration provided that proposed risk mitigation measures are implemented including the removal of unsupported uses. Health Canada received comments relating to the health assessments, which are summarized in Appendix II along with the responses by Health Canada. These comments resulted in revisions to the health risk assessments (see Science Evaluation Update), and subsequently, in changes to the proposed regulatory decision as described in PRVD2018-08.

This document presents the final re-evaluation decision<sup>2</sup> for 2,4-DB, including the required risk mitigation measures to protect human health and the environment. All products containing 2,4-DB that are registered in Canada are subject to this re-evaluation decision.

### Outcome of Science Evaluation

Following the consultation on the proposed re-evaluation decision, Health Canada revised the occupational risk assessment based on the comments received relating to the use of 2,4-DB on pure stands of cereals (wheat, barley and oats). Health risks from 2,4-DB and its associated end-use products have been shown to be acceptable for all uses of 2,4-DB when used according to the revised label directions, except field corn which was not supported by manufacturers. The environmental risks associated with the use of 2,4-DB and its related end-use products are acceptable when products are used according to the revised label directions.

### Regulatory Decision for 2,4-DB

Health Canada has completed the re-evaluation of 2,4-DB. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing 2,4-DB is acceptable. An evaluation of available scientific information found that

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

uses of 2,4-DB products meet current standards for protection of human health and the environment when used according to the revised label directions, which include new mitigation measures. The use of 2,4-DB on field corn will be removed from labels as it was not supported by manufacturers. Label amendments, as summarized below and listed in Appendix IV, are required. No additional data are required.

## **Risk Mitigation Measures**

Registered pesticide product labels include specific direction for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The key risk mitigation measures required, as a result of the re-evaluation of 2,4-DB, are summarized below. Refer to Appendix IV for details.

### **Uses not supported by manufacturers for re-evaluation and will be removed from all product labels**

- Field corn.

## **Human Health**

### Label improvements to meet current standards

- A minimum rotational crop plant-back interval of 30 days must be observed for all crops other than those listed on the label.
- The current label restrictions for grazing livestock on treated crops should be amended to include hay.

### Risk mitigation

- To protect mixer/loader/applicators:
  - Wear a minimum level of protective clothing: long-sleeved shirt, long pants, shoes and socks, and chemical-resistant gloves.
  - When mixing and loading large amounts of active ingredient (greater than 247 kg a.e./day), use a closed mixing/loading system.
  - For groundboom application involving amounts greater than 247 kg a.e./day, use a closed cab tractor.
- To protect workers entering treated sites:
  - A 3 day restricted-entry interval (REI) for scouting in cereals (wheat, barley and oats) is required.
  - A 12 hour REI for all other crops and activities is required.

## Environment

- Addition of precautionary label statements regarding toxicity to non-target terrestrial plants and aquatic organisms.
- Addition of statements to reduce the potential for runoff to adjacent aquatic areas.
- To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.
  - Avoid application when heavy rain is forecast.
  - Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.
- Addition of spray buffer zones for non-target terrestrial habitats: 1–2 meters for ground applications and 55–75 meters for aerial applications.

## Next Steps

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

## Other Information

Any person may file a notice of objection<sup>3</sup> regarding this decision on 2,4-DB within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of Canada.ca (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*

# Science Evaluation Update

## 1.0 Impact on Human and Animal Health

### 1.1 Toxicology Assessment for 2,4-DB

No comments specific to toxicology assessment were received. There were no changes to the toxicology assessment from PRVD2018-08.

### 1.2 Dietary Exposure and Risk Assessment

In PRVD2018-08, dietary risks were shown to be acceptable. During the PRVD consultation period, comments were received requesting that the supported uses on cereals (wheat, barley and oats) underseeded with legume or grass forages be extended to pure stands of those same cereals, in the event the forage seedlings fail to thrive and the underseeded cereal becomes a pure cereal stand (refer to Appendix II). Health Canada data requirements and conclusions of the food residue chemistry assessment are equally applicable to cereal crops underseeded with legume or grass forage and pure stands of those same cereals. The resulting dietary exposure is the same; therefore, no changes were required to the dietary risk assessment as a result of comments submitted during the PRVD consultation period.

### 1.3 Occupational and Residential Exposure and Risk Assessment

In PRVD2018-08, the occupational risks were shown to be acceptable when used according to the proposed label directions. No comments specific to the occupational risk assessment were received.

The occupational exposure and risk assessments for cereals (wheat, barley, oat) were revisited based on the changes to the supported use pattern, which now includes pure stands of cereals (refer to Section 1.2). The application rates and equipment are the same for pure stands of cereals as those underseeded to forage; therefore, the mixer/loader and applicator risk assessments in PRVD2018-08 addresses all cereals (pure and underseeded) and were not revisited. For postapplication workers, the timing of 2,4-DB application to pure stands of cereals would be later than for cereals underseeded to forage. Therefore, the postapplication risk assessment was revisited (Appendix III). Risks were shown to be acceptable with a three day restricted-entry interval (REI) for scouting in pure stands of cereals and a 12 hour REI for all other activities. Therefore, the REI for cereals will change from the REI of 12 hours for all activities proposed in the PRVD to 3 days for scouting and 12 hours to all other activities. Mitigation measures are outlined in Appendix IV.

As noted in PRVD2018-08, a residential assessment was not required since there are no domestic-class products containing 2,4-DB and commercial application to residential areas is not expected.

## **2.0 Environmental Risk Assessment**

In PRVD2018-08, the environmental risk assessment considered the highest application rates of 2,4-DB (single application of 1720 g a.e./ha). Since the use of 2,4-DB on major legume forage crops, pure and underseeded cereals (wheat, barley and oats), and widely sown forage grasses is applied at a lower rate (1 application of 1410 g a.e./ha), this did not pose additional concern for the environment. Therefore, the environmental risk assessment was not revised.

## **3.0 Conclusion of Science Evaluation**

Health and environmental risks associated with the supported uses of 2,4-DB were found to be acceptable when used according to the revised label directions, which include new mitigation measures. The use of 2,4-DB on field corn, which was not supported by manufacturers, will be removed from labels.

**List of Abbreviations**

a.e.	acid equivalent
ARTF	Agricultural Re-entry Task Force
bw	body weight
cm <sup>2</sup>	centimetres squared
DFR	dislogeable foliar residue
h	hour
ha	hectare
kg	kilogram(s)
LOAEL	lowest observed adverse effect level
max	maximum
mg	milligram(s)
MOE	margin of exposure
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
REI	restricted-entry interval
TC	transfer coefficient

## Appendix I Registered 2,4-DB Products in Canada<sup>1</sup>

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Net Content	Guarantee
22404	Commercial	Interprovincial Cooperative Limited	IPCO Cobutox 600 Emulsifiable Concentrate Herbicide	Emulsifiable concentrate or emulsion	10 L	600 g a.e./L (present as ISO-Octyl Ester)
27911			IPCO Cobutox 625 Herbicide		10 L	625 g a.e./L (present as 2-Ethylhexyl Ester)
28346			Weedaway Cobutox 625 Herbicide		10 L	625 g a.e./L (present as 2-Ethylhexyl Ester)
29566			Agro-flex 2,4-DB ester 625 Herbicide		10 L	625 g a.e./L (present as 2-Ethylhexyl Ester)
27910		Loveland Products Canada Inc.	Caliber 625 Herbicide		10 L	625 g a.e./L (present as 2-Ethylhexyl Ester)
27912		Nufarm Agriculture Inc.	Embutox Liquid Herbicide		1-450 L	625 g a.e./L (present as 2-Ethylhexyl Ester)
19325	Technical Grade Active Ingredient	Nufarm Agriculture Inc.	Marks 2,4-DB Technical Acid	Solid	25 kg	97% (present as acid)
19326			Marks technical 2,4-DB 2-ethylhexyl ester	Solution	204 L	66.2% a.e. (present as 2-Ethylhexyl Ester)

<sup>1</sup> as of 12 December 2018, excluding discontinued products or products with a submission for discontinuation

## **Appendix II Comment(s) and Response(s)**

In response to the consultation for the 2,4-DB proposed re-evaluation decision, the following comments were received:

### **1.0 Comments Related to the Health Risk Assessments**

#### **1.1 Dietary Exposure**

Comments were received from the 2,4-DB Task Force and manufactures of end-use products requesting that the initially supported use on cereals (wheat, barley and oats) underseeded with legume or grass forages be extended to pure stands of those same cereals to remove any end-user doubt regarding the acceptability or marketability of the cereal crop grain following treatment with 2,4-DB, in the event that the forage seedlings fail to thrive and the underseeded cereal becomes a pure cereal stand. Further, the Task Force stated that the data requirements and the dietary risk assessment conclusions would not change for this use pattern.

#### **Health Canada Response**

Health Canada agrees with the 2,4-DB Task Force that data requirements and conclusions of the Food Residue Chemistry assessment are equally applicable to cereal crops underseeded with legume or grass forages and pure stands of those same cereals. The resulting dietary exposure and risk are unchanged.

## Appendix III Occupational Postapplication Exposure and Risk Estimates for 2,4-DB

Details and tables for the revised risk assessment are included in this appendix. Please refer to PRVD2018-08 for additional information.

### Postapplication Exposure in Pure Stands of Cereals.

For workers performing postapplication activities in pure stands of cereals, potential exposure was estimated based on transfer coefficients (TC) from the Agricultural Re-entry Task Force (ARTF) and default dislodgeable foliar residues, as described in PRVD2018-08. Results are summarized in Table 1 below.

**Table 1 Postapplication Exposure and Risk Assessment for Pure Stand of Cereals**

Activity	TC <sup>a</sup> (cm <sup>2</sup> /h)	Max Rate (kg ae/ha)	DFR - Day 0 <sup>b</sup> (µg/cm <sup>2</sup> )	Day 0 MOE <sup>c</sup> (Target=300)	REI <sup>d</sup>
<b>Pure Stand of Cereals (wheat, barley, oats) - 1 application</b>					
Scouting in solid stand conditions	1100	1.41	3.53	224	3 days
Hand weeding	70			3520	12 hours
Mechanical swathing, irrigation (non-hand set)	No TC <sup>e</sup>	12 hours			

TC = transfer coefficient; ae = acid equivalent; Max = maximum label rate; DFR= dislodgeable foliar residues; Day 0 = day of application, after sprays have dried; MOE = margin of exposure; REI = restricted-entry interval.

Shaded cells indicate where the MOE is less than the target MOE and risks are not shown to be acceptable on day 0.

<sup>a</sup> Standard transfer coefficients from the ARTF for wheat, barley, and oats were used.

<sup>b</sup> DFR determined using the default peak DFR of 25% of the application rate. A default dissipation rate of 10%/day was used to calculate MOEs after day 0.

<sup>c</sup> Based on an NOAEL of 20 mg/kg bw/day from an oral rabbit developmental toxicity study and target MOE of 300. A dermal absorption value of 23% was used.

<sup>d</sup> Amount of time required for residues to decline to a level where the MOE reaches the target MOE and risks are shown to be acceptable. The minimum REI of 12 hours was applied when the MOE reached the target MOE on day 0.

<sup>e</sup> Not considered to be a hand labour activity. Postapplication worker risks are acceptable provided the minimum 12 hours REI is followed.

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## Appendix IV Label Amendments for Products Containing 2,4-DB

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

### Uses not supported for re-evaluation and will be removed from all product labels

- Field corn.

### Revise the following use directions as outlined below:

#### For all 2,4-DB product labels:

- On the primary panel, replace “Guarantee” with “Active Ingredient”

#### For PCPA Reg. No. 27910 and 27912

- On the primary panel, the statement which reads “For use in seedling legume and grass forages, cereals, corn, and pastures.” must be revised to read “For use in seedling legume and grass forages, cereals (wheat, barley and oats), and pastures.”
- Under the CROPS, TIMING, RATES AND METHODS OF APPLICATION title, the section for Field Corn must be deleted from the table

#### For PCPA Reg. No. 22404, 27912, 28346 and 29566

- Under LABEL INDEX, delete “Field Corn GO TO Section 4”
- Under LABEL INDEX, adjust the Section number in the “GO TO Section ” statement
- Under DIRECTIONS FOR USE, delete Section 4 and the contents associated with the section.
- Under DIRECTIONS FOR USE, adjust the SECTION numbers accordingly

#### For PCPA Reg. No. 27911, 28346 and 29566

- Under SECTION 7 WEEDS CONTROLLED AND RATES OF APPLICATION, under the title MAXIMUM RECOMMENDED RATES FOR CROPS, revise the phrase which read “Field corn, pastures containing legumes” to read “pastures containing legumes”

## For PCPA Reg. No. 22404

- Revise the title which reads “Use Precautions for Aerial Application (to cereal crops, established pastures and underseeded and direct seeded forages.)” to read “Use Precautions for Aerial Application to cereal crops (wheat, barley and oats) established pastures and underseeded and direct seeded forages.”

## Health

### Label Amendments for Commercial Class End-use Products Containing 2,4-DB

#### General Label Improvements

- The following label statements must be added to the **PRECAUTIONS** of all commercial end-use product labels, unless already present:

“Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.”

#### Personal Protective Equipment

- Label statements must be amended (or added) to include the label directions to the appropriate labels under **PRECAUTIONS**, as outlined in Table 1 below. Note: Protective equipment currently required on product labels, such as coveralls, goggles and respiratory protection, are maintained in the product-specific statements, where present.

**Table 1 PPE Label Statement Modifications for Registered Commercial-Class Products that Contain 2,4-DB**

PCPA Reg. No.	Required Modification to PPE Label Statements under PRECAUTIONS <sup>a</sup>
22404	<p><u>Remove:</u> “Wear goggles or face shield, suitable chemical resistant gloves and protective clothing while handling. WEAR A RESPIRATOR SUITABLE FOR ORGANIC VAPOURS DURING MIXING, LOADING, SPRAYING AND CLEAN-UP.”</p> <p><u>Add, as a new bullet/number under Precautions:</u> “During mixing, loading, application, clean-up and repair, wear a long-sleeved shirt, long pants, chemical-resistant gloves, goggles or face shield, 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. Gloves and goggle/face shield are not required during application within a closed cab or cockpit. Respirators are also not required to be worn inside the closed cab or cockpit as long as the closed cab or cockpit is equipped with an air filtration mechanism.”</p> <p>“If mixing and loading more than [247 kg a.e.]<sup>b</sup> in a day, a closed mix/load system is required.”</p>

PCPA Reg. No.	Required Modification to PPE Label Statements under PRECAUTIONS <sup>a</sup>
	<p>“For groundboom application, if applying more than [247 kg a.e.]<sup>b</sup> in a day, a closed cab tractor is required. A closed cab provides both a physical barrier and respiratory protection (such as dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical-resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab.”</p>
27910	<p><u>Remove:</u>  <b>“Handling the concentrate (mixing and loading):</b> Wear long-sleeved shirt, long pants, coveralls, chemical-resistant gloves, socks and shoes. Rinse gloves before removal.  <b>Handling the dilute spray solution (during application or repairing or cleaning equipment):</b> Wear a long-sleeved shirt, long pants, coveralls, chemical-resistant gloves, socks and shoes. Rinse gloves before removal.  Gloves are not required during application when applicator is in an enclosed tractor.”</p> <p><u>Add:</u>  “Wear coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Rinse gloves before removal. Gloves are not required during application within a closed cab.”</p> <p>“If mixing and loading more than [247 kg a.e.]<sup>b</sup> in a day, a closed mix/load system is required.”</p> <p>“For groundboom application, if applying more than [247 kg a.e.]<sup>b</sup> in a day, a closed cab tractor is required.”</p>
27911, 27912, 28346, 29566	<p><u>Remove:</u>  “Wear a long-sleeved shirt and long pants and chemical resistant gloves during mixing, loading, clean-up and repair.”</p> <p><u>Add, as a new bullet/number:</u>  “Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab.”</p> <p>“If mixing and loading more than [247 kg a.e.]<sup>b</sup> in a day, a closed mix/load system is required.”</p> <p>“For groundboom application, if applying more than [247 kg a.e.]<sup>b</sup> in a day, a closed cab tractor is required.”</p>

PPE = personal protective equipment

<sup>a</sup> Note- only the PPE-related statements are included in this table. Any other precautionary statements on the label (e.g. Keep out of reach of children) should remain as they are currently stated/located.

<sup>b</sup> The amount of active ingredient indicated in the square brackets in the PPE statements (i.e. 247 kg a.e.) is to be converted into the corresponding amount of product by the registrant for each product label.

## Restricted-entry Interval

- The following label statement and table must be amended (or added) to all registered commercial-class product labels under **PRECAUTIONS**:

“**DO NOT** enter or allow workers to enter treated areas during the restricted-entry intervals (REIs) specified in the following table:”

Crop	Postapplication Activity	Restricted-Entry Interval
Wheat, barley, oats	Scouting	3 days
	All other activities	12 hours
Seedling alfalfa and bird's-foot trefoil, seedling clovers, seedling grasses for forage, pastures containing forage legumes	All activities	12 hours

## Directions of Use

- For consistency with current practices, under **DIRECTIONS OF USE**, revise the plant-back interval as follows:

“A minimum rotational crop plant-back interval of 30 days must be observed for crops other than those listed on the label.”

- Current label restrictions for grazing of livestock on treated crops should be amended to include hay. The statement should read:

“Do not cut treated crops for forage or **hay** until 30 days after application.”

## Environment

### Under **ENVIRONMENTAL HAZARDS**, add:

This product contains aromatic petroleum distillates which are toxic to aquatic organisms.

TOXIC to non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

**Under DIRECTIONS FOR USE, add:**

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Reduce drift caused by turbulent wingtip vortices. The nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

**Buffer zones:**

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of application	Crop	Buffer Zones (metres) Required for the Protection of Terrestrial Habitat:	
Field sprayer	Seedling alfalfa (direct or underseeded), Bird's-foot trefoil (direct or underseeded), Seedling clovers (direct or underseeded), Seedling grasses for forage	1	
	Pasture containing forage legumes	2	
Aerial	Seedling alfalfa (direct or underseeded), Bird's-foot trefoil (direct or underseeded), Seedling clovers (direct or underseeded)	Fixed wing	65
		Rotary wing	55
	Pasture containing forage legumes	Fixed wing	75
		Rotary wing	60

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Drift Mitigation page of the Pesticides section of Canada.ca.