Re-evaluation Decision RVD2017-10

Clethodim and its Associated End-use Products

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Re-evaluation Decision

Clethodim is a herbicide used for control of grassy weeds on a variety of broadleaved crops.

Under the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) on a cyclical basis to make sure they continue to meet most recent health and environmental safety standards and continue to have value. The re-evaluation considers data from pesticide manufacturers, published scientific reports, information from other regulatory agencies and other available, relevant information.

After a re-evaluation of clethodim, the PMRA is granting continued registration of products containing clethodim for sale and use in Canada. Registered products containing clethodim are listed in Appendix I. An evaluation of available scientific information found that currently registered uses of clethodim products do not pose unacceptable risks to human health or the environment when used according to the revised conditions of registration, as summarized below. No additional data are required at this time.

Human Health

- Additional label statements to clarify protective equipment for workers applying clethodim.
- Clarification that clethodim is not registered for use in greenhouses.
- A statement to promote best management practices to minimize human exposure from spray drift or spray residues resulting from drift.

Environment

- Spray buffer zones ranging from 1 to 40 meters and 1 to 5 meters to protect non-target terrestrial and aquatic habitats, respectively, from pesticide spray drift.
- Instructions on product labels for reducing run-off.

This re-evaluation decision was proposed in the consultation document, Proposed Re-evaluation Decision PRVD2016-11, *Clethodim*. All comments received during the consultation process were taken into consideration. A summary of comments received on the proposed decision and PMRA's response to these comments is provided in Appendix II.

As a result of the consultation, certain use directions, buffer zones and plant-back intervals proposed in PRVD2016-11 have been revised. The rest of the final re-evaluation decision is consistent with that proposed in PRVD2016-11.

To comply with this decision, the required label amendments (see Appendix III) must be implemented on all end-use products sold by registrants no later than 24 months after the publication date of this document.

A reference list for data used as the basis for the re-evaluation decision is included in PRVD2016-11, and further data submitted during the consultation period and used in this re-evaluation is listed in Appendix IV.

Registrants of products containing clethodim will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Other Information

Any person may file a notice of objection[1] regarding this decision on clethodim within 60 days from the date of publication of this Re-evaluation Decision document. 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 the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA Pest Management Information Service.

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

Appendix I Registered Clethodim Products[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
32334	C	Albaugh, LLC	Clethodim 250	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
22625	C	Arysta Lifescience North America, LLC	Select Emulsifiable Concentrate Postemergence Herbicide	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
31496	C	Arysta Lifescience North America, LLC	Clethodim 360 EC Herbicide	Emulsifiable Concentrate Or Emulsion	360 g a.i./L
26426	C	Bayer Cropscience Inc.	Compass Grass Herbicide	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
27598	C	Bayer Cropscience Inc.	Centurion Emulsifiable Concentrate Post-Emergence Herbicide	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
29277	C	Loveland Products Canada Inc.	Shadow RTM Emulsifiable Concentrate Post-Emergence Herbicide	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
28224	C	Adama Agricultural Solutions Canada Ltd.	Arrow 240 EC Herbicide	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
32495	C	Adama Agricultural Solutions Canada Ltd.	Patron 240 EC	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
32614	C	Newagco Inc	Mpower Independence Herbicide	Emulsifiable Concentrate Or Emulsion	252 g a.i./L
32262	M	Albaugh, LLC	Albaugh Clethodim 37% Mup	Emulsifiable Concentrate Or Emulsion	37%
22624	M	Arysta Lifescience North America, LLC	Clethodim 37% Manufacturing Use Product	Solution	37%
32700	M	Arysta Lifescience North America, LLC	Select 240 Bulk	Emulsifiable Concentrate Or Emulsion	240 g a.i./L
28226	M	Adama Agricultural Solutions Canada Ltd.	Clethodim 37% MUP	Solution	37%
28698	M	Adama Agricultural Solutions Canada Ltd.	Arrow Manufacturing Use Product	Emulsifiable Concentrate Or Emulsion	240 g a.i./L

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
32261	T	Albaugh, LLC	Albaugh Clethodim TGAI	Liquid	94.9%
22623	T	Arysta Lifescience North America, LLC	Clethodim Technical	Liquid	95.0%
28211	T	Adama Agricultural Solutions Canada Ltd.	Clethodim Technical Herbicide	Solution	93.3%
32780	T	Adama Agricultural Solutions Canada Ltd.	Adama Clethodim Technical Herbicide II	Liquid	98.75%
32783	T	Newagco Inc	Newagco Clethodim Technical	Liquid	97%
32469	T	Nufarm Agriculture Inc.	Nufarm Clethodim Technical	Liquid	97.6%
32631	T	Sharda Cropchem Limited	Sharda Clethodim Technical	Liquid	97.5%

[1] As of 24 August 2017, excluding discontinued products or products with a submission for discontinuation
C: Commercial, M: Manufacturing Concentrate, T: Technical Grade Active Ingredient

Appendix II Comments and Responses

1.0 Comments Related to the Health Risk Assessments

1.1 Comments Related to Plant-Back Interval

Comment

The registrant stated that the existing clethodim confined rotational study can be used to support a 30 day plant back on the clethodim label. The registrant submitted additional information and data along with this comment.

PMRA Response

The current labels for clethodim products registered in Canada do not specify any plant-back interval. The existing clethodim confined rotational study was previously reviewed in PRVD2016-11. It was concluded that this study cannot be used as a basis for the establishment of plant-back intervals. As a result, PMRA had proposed that labels for products containing clethodim be amended to specify a 1-year plant-back interval for all non-registered food and feed crops. During the comment period, the registrant submitted additional data to support a 30-day plant-back interval. The submitted raw data on sample storage from the confined rotational crop study were used in conjunction with the existing clethodim confined rotational study to determine the required plant-back interval for rotational crops. Based on the available data, it is unlikely that residues will be present in significant levels in rotational crops 30 days after application of clethodim when clethodim is used according to the label directions registered in Canada. Therefore, the PMRA requires the amendment of all existing labels to specify a plant-back interval of 30 days for all non-registered food and feed crops (see Appendix III). For any future use expansion, the PMRA may request field rotational trials, if needed.

1.2 Comments Related to Enforcement Analytical Method

The registrant questioned the relevance of an enforcement analytical method distinguishing clethodim from sethoxydim. Along with this comment, the registrant submitted a method that is specific for the determination of the metabolites of clethodim and can be used to distinguish clethodim residues from residues of similar herbicides, such as sethoxydim.

PMRA Response

The residue analytical methods previously available to the PMRA for clethodim relied on common moiety methodologies. These methods were considered adequate for residue trial studies. However, as indicated in PRVD2016-11, the existing analytical methods did not distinguish between residues of clethodim (and its metabolites) and sethoxydim (and its metabolites). An enforcement analytical method that differentiates between residues arising from the use of clethodim and those arising from the use of sethoxydim is considered more appropriate for the determination of compliance with the maximum residue limits specified for clethodim. The new method submitted during the consultation period includes procedures for specifically determining and quantifying clethodim and clethodim metabolites in crops and

processed commodities, animal tissues, eggs and milk, using high pressure liquid chromatography (HPLC) employing mass spectrometric (MS/MS) detection. The method was reviewed and found to be suitable for enforcement purposes.

2.0 Comments Related to the Environmental Risk Assessment

2.1 Buffer zone calculations

Comment

The registrant requested that labels for clethodim-containing products specify the use of a coarse spray and 10 km/h wind limits for aerial application, and that the buffer zones should be set using these revised parameters, with the intention of reducing required buffer zones.

PMRA Response

For PRVD2016-11, buffer zones were calculated using an ASAE spray classification of medium and wind speed restriction of 16 km/h for aerial use. Buffer zones were recalculated using an ASAE spray classification of coarse and a 10 km/h wind speed restriction for aerial and field sprayer use. The recalculated buffer zones are lower than those proposed in PRVD2016-11. Based on the risk identified to off-target sensitive habitats, and the new parameters for spray quality and wind speed, buffer zones of up to 40 m are required to protect amphibian, and freshwater and terrestrial habitats.

As a result, directions for use and buffer zones were modified for aerial and field sprayer applications based on these changes in parameters (see Appendix III).

Appendix III Label Amendments for Commercial Class Products Containing Clethodim

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.

Use Precautions:

Replace

- "When handling the concentrate, mixing, loading or during cleanup and repair, wear goggles or face shield, rubber apron, chemically resistant gloves, rubber boots, long sleeved shirt and long legged pants."

With

- "When handling the concentrate, mixing, loading or during cleanup and repair, wear goggles or face shield, rubber apron, chemical-resistant gloves, rubber boots, long-sleeved shirt and long pants. Wear long-sleeved shirt and long pants during application. In addition, for hand-held application equipment, including backpack sprayer, wear chemical-resistant gloves during application."

Add

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

Directions for Use

Add the following statements:

- "Not for use in greenhouses."
- "A 30-day plant-back interval should be observed for all unlabelled crops."

Environmental Hazards:

Add:

TOXIC to aquatic organisms and non-target terrestrial plants.

Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland.

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.

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

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (for example, sandy soil) and/or the depth to the water table is shallow.

Replace:

"Avoid spray drift. Avoid contamination of ponds, streams, rivers and desirable vegetation".

AND

"Avoid contamination of aquatic systems during application. Do not contaminate these systems through direct application, disposal of waste or cleaning equipment".

With:

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Storage:

Replace:

May be stored at any temperature. SHAKE WELL BEFORE USING. Insecticides and fungicides should be segregated from herbicides so as to prevent the possibility of cross contamination.

With:

To prevent contamination, store this product away from food or feed

Buffer Zone Related Label Statements:

For products registered for aerial and field sprayer application, 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 10 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. To 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) and sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands).

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:		
			Freshwater Habitat of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	
Field sprayer	All crops		1	1	1
Aerial*	Canola, flax (including low linolenic acid varieties), field peas, lentils, potatoes, Oriental (brown) mustard (condiment and oilseed types), yellow mustard, soybeans, sunflowers, Brassica carinata, dry bulb onions, garlic	Fixed wing	5	1	40
		Rotary wing	5	1	35
	Dry common beans, Desi and Kabuli chickpeas, pigeon pea	Fixed wing	1	1	20
		Rotary wing	1	1	20

*Aerial buffer zones are required for the following end use products: Select Emulsifiable Concentrate Post-Emergence Herbicide (Reg. No. 22625), Compas Grass Herbicide (Reg. No. 26426), Centurion Emulsifiable Concentrate Post-Emergence Herbicide (Reg. No. 27598), Shadow RTM Emulsifiable Concentrate Post-Emergence Herbicide (Reg. No. 29277), Clethodim 360 EC Herbicide (Reg. No. 31496).

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 and Pest Management portion of the Canada.ca web site.

Appendix IV Additional References

A. List of Studies/Information submitted by Registrant – Unpublished

PMRA Document Number	Reference
2648207	2016. DEREK NEXUS Evaluation: Clethodim Oxazole Sulfone &Clethodim Oxazole Sulfoxide. Arysta LifeScience 15401 Weston Parkway Suite 150, Cary, NC 27513. ALS Study Number 2016-108.
2648206	2002. Validation of the residue analytical method: “determination of clethodim and clethodim metabolites (compound specific) in crops, animal tissues, milk and eggs”. Morse Laboratories Inc. project No. ML01-0970-TOM.
2661275	2016. Buffer Zones for Clethodim Herbicide in Canada; In response to the clethodim PRVD (Submission No.2012-1698). DACO 8.6