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Re-evaluation Note

REV2021-04

# Cancellation of remaining chlorpyrifos registrations under paragraph 20(1)(a) of the *Pest Control Products Act*

*(publié aussi en français)*

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This decision replaces Re-evaluation Note ([REV2021-02](#)<sup>1</sup>), which informed the public that the registrations of the remaining pest control products containing chlorpyrifos were being cancelled due to failure to fulfill the mandatory data requirements under the *Pest Control Products Act*. Re-evaluation Note REV2021-02 of 13 May 2021 did not contain reasons for the phase-out period selected by Health Canada. This decision (REV2021-04) immediately cancels the registrations of the remaining chlorpyrifos products subject to the mandatory data call-in under the *Pest Control Products Act* and provides reasons for the phase-out period.

## Background

The re-evaluation for chlorpyrifos proceeded in several phases: the first phases in 2000, 2003 and 2007 assessed the health risks and some environmental risks, with the full environmental assessment completed in 2020. The final phase of re-evaluation was intended to update the current health risk assessment. The chlorpyrifos re-evaluation decision related to environmental risk (PRVD2019-05<sup>2</sup> and RVD2020-14<sup>3</sup>) resulted in the cancellation of a number of registrations of pest control products. Health Canada also identified additional data needed for the re-evaluation to update the current health risk assessment for the remaining registered products.

On 10 February 2021, Health Canada sent a notice to the two registrants of the remaining products containing chlorpyrifos requiring various data in order to complete the update to the health risk assessment. By that time, only products from these two registrants remained subject to the ongoing re-evaluation with respect to the health risk assessment because all other products containing chlorpyrifos were already in the course of being phased-out following prior cancellation decisions or following voluntary discontinuations. See Appendix I for the complete list of all products containing chlorpyrifos subject to a phase-out period.

As the registrants of chlorpyrifos products were unable to fulfill these data requirements, Health Canada cancelled the registrations of the remaining pest control products containing chlorpyrifos, according to the phase-out timeline below. This timeline was the same as that which was imposed on product registrations cancelled as a result of the environmental risk assessment (RVD2020-14), with the exception of uses on canola and garlic, which were originally extended until 2024 in RVD2020-14, but were then aligned with the same phase-out timeframe as all of the other cancelled uses.

### Phase-out Timeline:

- Last date of sale by registrant: 10 December 2021
- Last date of sale by retailers: 10 December 2022
- Last date of use for all chlorpyrifos uses/products including canola (for alfalfa looper) and garlic (for darksided and redbacked cutworm): 10 December 2023

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<sup>1</sup> REV2021-02, *Update on the re-evaluation of chlorpyrifos*

<sup>2</sup> PRVD2019-05, *Chlorpyrifos and Its Associated End-use Products: Updated Environmental Risk Assessment*

<sup>3</sup> RVD2020-14, *Chlorpyrifos and Its Associated End-use Products (Environment)*

On 13 May 2021, Health Canada published a Re-evaluation Note (REV2021-02) informing the public that the registrations of the remaining pest control products containing chlorpyrifos were being cancelled with a phase-out period due to failure to fulfill the mandatory data requirements. In the Re-evaluation Note, Health Canada did not explain its reasons for applying the phase-out period.

This decision (REV2021-04) confirms the cancellation of the registrations of the remaining products/uses of chlorpyrifos and sets out Health Canada's determination that, in accordance with the *Pest Control Products Act* and [Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review](#),<sup>4</sup> the risks are not imminent and serious during the phase-out period.

### **Final determination with respect to chlorpyrifos**

The remaining products containing chlorpyrifos are now cancelled, effective as the date of this publication, in accordance with Information Note: *Update on implementation of post-market decisions* published 21 December 2021. No manufacturing within Canada or importation into Canada is allowed. The remaining products whose registrations are immediately cancelled are:

- Pyrinex Technical Chlorpyrifos Insecticide (Registration Number 23621)
- Pyrate 480 EC Insecticide (Registration Number 23704)
- Sharda Chlorpyrifos Technical Insecticide (Registration Number 32694)
- Sharphos Insecticide (Registration Number 32768)

Paragraph 21(5)(a) of the *Pest Control Products Act* permits Health Canada to allow existing stocks of cancelled products in Canada to remain authorized for continued possession, handling, storage, distribution and use over a phase-out period, subject to any conditions that are necessary for carrying out the purposes of the *Pest Control Products Act*.

The following conditions apply to the products subject to this decision:

- There shall be no further distribution and sale by registrants of any products containing chlorpyrifos;
- Retailers and other distributors are permitted to distribute and sell their existing stock until 10 December 2022;
- The last date of permitted use will be 10 December 2023;
- Registrants are required to comply with incident reporting obligations during the phase-out period; and
- Registrants are required to comply with sales reporting obligations until all reports relevant to the 2021 calendar year have been submitted.

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<sup>4</sup> Regulatory Directive 2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*

This allows existing stocks of chlorpyrifos products in Canada to be exhausted in an orderly manner, to minimize potential risks associated with disposing of existing product all at once, and to minimize potential confusion for the users.

**i) Overview of Policy on Cancellations and Amendments Following Re-evaluation and Special Review**

The [Policy on Cancellations and Amendments Following Re-evaluation and Special Review](#), provides a framework for the cancellation of pesticide products or amendments to pesticide product uses, labels, or other conditions of registration following a re-evaluation or special review decision, or the failure to meet mandatory data requirements. The policy also outlines the process, the associated timelines as well as how the timelines for cancellation or amendment of pesticide products are established.

This policy is intended to enhance transparency of the process and associated timelines when regulatory action is required to remove products from the market, change approved uses, or introduce amendments to labels. It is also intended to facilitate efficient and effective implementation of re-evaluation and special review decisions, including by ensuring an orderly transition in order to minimize the potential for non-compliance. Standardized timelines aim to clarify expectations, obligations and communications around the implementation of regulatory decisions.

The primary consideration for the implementation timelines for cancellation and amendment is based on the risks to human health or the environment, in other words, whether risks are considered imminent and serious, taking into account the following factors:

- Potential magnitude of harm, in other words, seriousness of the effect of concern, including reversibility;
- Likelihood of the effect occurring, in other words, whether an effect of concern is likely to happen based on how the product is being used;
- The population exposed to the product, for example, trained pesticide applicators, the general public, or bystanders; and
- Information from post-market surveillance considered as part of the re-evaluation or special review, for example, incident reports, poison control centre data, or monitoring data.

In cases where no imminent and serious risks to human health or the environment are identified, the implementation timelines outlined in DIR2018-01<sup>5</sup> are applied to products or uses subject to the re-evaluation or special review decision.

Implementation is expedited when risks of concern are considered to be imminent and serious. Such circumstances involve a significant likelihood of serious effects occurring, for example, adverse effects reported in incident reports submitted to Health Canada involving death or serious bodily harm.

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<sup>5</sup> DIR2018-01, *Policy on cancellation and amendments following re-evaluation and special review*.

In these circumstances, other appropriate measures may also be required, such as requiring the registrant to over-sticker labels on existing stocks with risk mitigation statements, or issuing an immediate product recall in accordance with the *Pest Control Products Act* (p. 21(5)(b)).

**ii) No imminent and serious risks during ongoing phase-out**

Health Canada has determined that the risks for current chlorpyrifos uses are not imminent and serious during the period of the phase-out described above, taking into account the following considerations:

- **No residential uses by homeowners in Canada:** In 2000, Health Canada stopped allowing all uses by homeowners and chlorpyrifos labels were updated accordingly (with the exception of containerized low concentration ant baits/bait stations that were discontinued in 2017). Thus, there has been virtually no exposure to chlorpyrifos products from use by the general public in residential settings for over 20 years.
- **Mitigation in place for workers:** Health Canada implemented mitigation measures in 2007 (REV2007-01, *Update on the Re-evaluation of Chlorpyrifos*) to further protect human health, following an assessment of agricultural and forestry uses. Mitigation measures included discontinuation of certain uses and specific types of application equipment, implementation of engineering controls and additional personal protective equipment for workers, and the establishment of restricted intervals for postapplication workers.
- **Seldom detected in food:** Potential dietary exposure and risks from chlorpyrifos have also been considered based on **current** Canadian registered uses, including recent food residue surveillance data representative of the national food supply from the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture's (USDA) Pesticide Data Program (PDP). Food monitoring programs show a very low frequency of chlorpyrifos detections in both Canada and the United States. In Canada, the frequency of detection was 0.62% from domestically grown crops; and 2.7% overall in samples from domestic and imported foods from 34 114 samples tested in Canada between 2013–2017. This low detection frequency is consistent with that noted in PACR2003-03<sup>6</sup>, which reported detections in less than 1% (0.3%) of domestic and 1.9% of imported commodities in 44 397 shipments. Furthermore, chlorpyrifos residues, when detected, were also generally lower in Canada than the United States, and were also **in compliance** with established maximum residue limits (MRLs).
- **Low health concern from food:** No health risks from chlorpyrifos food residues alone were identified in Health Canada's previous assessment. Similarly, the **recent** proposed United States Environmental Protection Agency (USEPA) assessment for chlorpyrifos

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<sup>6</sup> PACR2003-03, *Phase 2 of the Re-evaluation of Chlorpyrifos*

(proposed interim decision, [December 2020](#)<sup>7</sup>), had the same conclusion. Furthermore, the USEPA assessment took into consideration the more recent health information available since Health Canada's assessment, as well as the more extensive use pattern that exists in the United States than in Canada. In other words, as acute and chronic dietary risks for all American populations exposed to food treated with chlorpyrifos were shown to be acceptable, this would be the same for Canadians.

- **Low health concern from drinking water:** While a fully updated assessment for drinking water has not been completed in Canada, Health Canada's analysis of Canadian water monitoring data collected over many years showed that only a fraction of samples had detectable levels of chlorpyrifos. Moreover, these levels were below the Health Canada's drinking water level of concern that had been determined in the 2003 assessment, with the exception of one sample<sup>8</sup> collected in 2005. Several mitigation measures were then implemented in 2007, including buffer zones and a reduced use pattern, and no samples exceeded the level of concern since that time. A total of 166 816 potential drinking water samples (from 1972–2016)<sup>9</sup> were analyzed for chlorpyrifos (groundwater, ambient surface water, and treated drinking water) from Canada and the United States, with a detection frequency of 8%. Moreover, in February 2020,<sup>10</sup> Health Canada, in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water, proposed to withdraw the existing Guidelines for Canadian Drinking Water Quality for several pesticides, including chlorpyrifos, as it was determined that these are unlikely to be found in Canadian drinking water at levels that may pose a risk to human health. Therefore, the Guidelines are no longer required. There is also a low level of concern for chlorpyrifos breakdown products including chlorpyrifos oxon, a byproduct of chlorine treatment. As chlorpyrifos is not often detected and unlikely to be found in Canadian drinking water sources at levels that may pose a risk to human health, the formation of oxon at a level of concern is not expected, if treated with chlorine.
- **Health Canada's assessment continues to be protective of the Canadian population:** As previously noted, Health Canada's most recent human health mitigation measures were published in 2007 ([REV2007-01](#)). At the time the cancellation notice for Canadian registrations of chlorpyrifos ([REV2021-02](#)) was published in May 2021 (now superseded by this current decision), the most recent (2019)<sup>11</sup> international, risk-based **decision** on chlorpyrifos had been issued by the Australian Pesticide and Veterinary Medicine

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<sup>7</sup> Chlorpyrifos Proposed Interim Registration Review Decision Case Number 0100 December 2020

<sup>8</sup> The maximum detection of 4 µg chlorpyrifos/L from Canadian monitoring data was from one sample in Québec, in 2005. All other samples were below the drinking water level of concern (DWLOC).

<sup>9</sup> Further characterization of risks concentrated on a 2000-2016 subset of 15,080 samples from the available data.

<sup>10</sup> Withdrawal of Select Guidelines for Canadian Drinking Water Quality

<sup>11</sup> APVMA Reconsideration of chlorpyrifos: Residential exposure and public space use exposure assessment and risk characterisation update. [https://apvma.gov.au/sites/default/files/publication/50121-chlorpyrifos\\_2019\\_residential\\_exposure\\_assessment\\_and\\_risk\\_characterisation\\_report.pdf](https://apvma.gov.au/sites/default/files/publication/50121-chlorpyrifos_2019_residential_exposure_assessment_and_risk_characterisation_report.pdf)

Authority (APVMA). In addition, as noted above, the USEPA posted a more recent assessment in [December 2020](#) (which was a **proposed** decision). Both the APVMA and USEPA assessments took into consideration the more recent health information including epidemiology data and published scientific literature, on which they based updated human health reference values (that is, acceptable human exposure levels) for use in their risk assessments. While Health Canada has not updated the human health reference values in consideration of this additional information prior to the cancellation of all uses in Canada, it is important to note that Health Canada's reference values established in 2000 continue to be either aligned with those of APVMA and USEPA for sensitive subpopulations including women of child-bearing age, or more conservative (in other words, more protective) in the case of infants and children. Thus, this indicated that Health Canada's existing assessment would still be protective of the Canadian population, or even more protective in the case of infants and children.

- **Declining sales in Canada:** With the cancellation of all registrations of pest control products containing chlorpyrifos, the use of, and therefore, exposure to chlorpyrifos is expected to continuously decrease over the phase-out period as products are depleted. To date, there has been an overall trend in declining sales of chlorpyrifos in Canada. More specifically, sales in 2016, for example, were approximately 30% lower than those of 2008. Since 2016, decreasing trends have continued, with the most recent data from 2020 (not yet published) indicating sales to be approximately 83% lower than those reported for 2008. This supports the assumption that dietary exposure from existing Canadian products has been decreasing, and will continue to decrease during the phase-out period on an ongoing basis.
- **Decreasing use internationally:** Cancellation actions have also occurred in other jurisdictions, such as the European Union.<sup>12</sup> This further decreases dietary exposure to imported food treated with chlorpyrifos, which will continue to decline on an ongoing basis. Health Canada will continue to monitor the regulatory status of chlorpyrifos in other countries, as well as the degree of potential exposure in imported and domestically produced foods.
- **No serious Canadian incident reports:** Between 2007 and 2021, Health Canada received 56 human and domestic animal incidents reports in relation to chlorpyrifos. Of these, 11 were classified as human major, all of which occurred in the United States. Of the six American incidents with a causal relationship of possible (3), or probable (3), five involved occupational exposure to multiple pesticides, with some reporting improper use or lack of personal protective equipment. (The remainder were unlikely or had insufficient information). There were no deaths or other serious human incidents reported in Canada.

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<sup>12</sup> July 31, 2019 statement by the European Food Safety Authority (EFSA): <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5809>

### iii) International status and Canadian comparison

#### European Union

In 2020, the European Commission (EC) prohibited all uses of chlorpyrifos based on human health concerns resulting from data uncertainties. Following a preliminary analysis of the 2020 EC decision concerning the non-renewal of plant protection products containing chlorpyrifos, Health Canada identified the following aspects of concern:

- Genotoxic potential of chlorpyrifos,
- Developmental neurotoxicity of chlorpyrifos, and
- Reproductive toxicity of chlorpyrifos.

The basis of the European decision was articulated in the 31 July 2019 statement by the European Food Safety Authority (EFSA<sup>13</sup>), which noted that no toxicology reference values were established and a risk assessment was not conducted. Thus, the EC decision was based on potential hazard (any possible adverse or toxic effect), rather than risk (likelihood of an adverse effect based on the amount of exposure). It is important to note that a hazard classification is not a health risk assessment. A hazard describes any possible adverse or toxic effect that may be attributed to a substance at various dose or exposure levels, whereas an assessment of risk focusses on the likelihood of an adverse effect occurring with a given amount of exposure. Thus, the levels of human exposure, which determine the actual risk, were not taken into account in the EC decision. In Canada, pesticides undergo a health and environmental risk assessment to establish the level of exposure to Canadians and the environment that does not result in harmful effects. The level of acceptable exposure that is established by Health Canada and used for health risk assessment also incorporates additional safety factors, providing a further degree of protection.

On 10 February 2021, a notice was issued by Health Canada (Reference No. 2019-3275) that a new special review of chlorpyrifos relating to a 2020 EC decision to cancel all uses would not be initiated under subsection 17(2) of the *Pest Control Products Act*. This was because the identified aspects of concern would be assessed with the ongoing re-evaluation of chlorpyrifos at that time, specifically in relation to updating the human health risk assessment, as per subsection 17(7) of the *Pest Control Products Act*. Because the remaining product registrations were cancelled in the now superseded May 2021 decision, and that has not changed with this new decision, a health risk assessment will not be conducted. However, for the reasons described above, Health Canada has determined that there are no imminent and serious health risks that would warrant a shorter phase-out period.

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<sup>13</sup> July 31, 2019 statement by the European Food Safety Authority (EFSA): <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5809>

## **Australia**

As noted previously, the most recent final risk-based decision, which took into consideration the additional health information, was published in [2019](#) by the Australian Pesticide and Veterinary Medicine Authority (APVMA). Health Canada's human health reference values continue to be either aligned with those of APVMA for sensitive subpopulations including women of child-bearing age, or more conservative (in other words, more protective) in the case of infants and children.

## **United States**

In the United States, the USEPA registration review of chlorpyrifos is ongoing, and a final decision regarding the registration status of chlorpyrifos is not scheduled until 2022. A December 2020 proposed interim decision proposed retaining 11 critical uses (alfalfa, apple, cherries (tart), asparagus, citrus, cotton, peach, soybean, strawberry, sugar beet, wheat), which were found to have acceptable health risk with mitigation measures. However, a recent (August 2021) USEPA Final Rule<sup>14</sup> made in response to an order from the United States Court of Appeals for the Ninth Circuit has since resulted in the phase-out of all food uses of chlorpyrifos, including revocation of all Maximum Residue Limits, (referred to as tolerances in the United States). The decision of the United States to revoke all tolerances (in other words, MRLs) acknowledged that there were no risks of concern around chlorpyrifos residues on food based on their scientific assessment. However, the American tolerances were revoked based on different factors. First, there were concerns involving drinking water in the United States that are not applicable to the Canadian situation, given how rarely chlorpyrifos has been detected in Canadian drinking water, and when detected, falls below the level of concern. Second, a United States court order required an all or nothing conclusion on acceptable risk from the combined exposure to chlorpyrifos residues from drinking water, plus all current uses (food, commercial turf (for example, golf courses), etc.). Conversely, Canada has cancelled all uses and is applying the above-noted schedule, and overall the Canadian use pattern is smaller and more restrictive than that of the United States, having comparatively lower application rates and shorter seasonal uses.

Thus, it is important to keep in mind that this action in the United States is separate and distinct from the USEPA registration review process. Uses in non-food settings remain registered in the United States until completion of the re-evaluation.

## **Canada**

As noted in Section (ii), Health Canada's current human health reference values (acceptable levels of exposure) continue to be either aligned with those of the APVMA and USEPA for sensitive subpopulations including women of child-bearing age, or more conservative (in other words, more protective) in the case of infants and children.

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<sup>14</sup> USEPA, Chlorpyrifos Tolerance Final Rule Docket

Thus, given dietary risks were acceptable in Health Canada's original assessment using health reference values that are either aligned with or more conservative than the more recently updated human health reference values of other jurisdictions, Health Canada's assessment would still be protective of the Canadian population, including infants and children.

## Conclusion

As noted above, Health Canada has implemented several risk reduction measures for chlorpyrifos over the years. In 2000, Health Canada stopped allowing almost<sup>15</sup> all uses by homeowners<sup>16</sup> and updated chlorpyrifos labels to reflect this. In addition, Health Canada implemented mitigation measures in 2007 ([REV2007-01, Update on the Re-evaluation of Chlorpyrifos](#)) to further protect human health and the environment, following an assessment on agricultural and forestry uses. In December 2020, Health Canada published a re-evaluation decision (RVD2020-14, *Chlorpyrifos and Its Associated End-use Products (Environment)*) based on an updated environmental risk assessment (PRVD2019-05, *Chlorpyrifos and Its Associated End-use Products: Updated Environmental Risk Assessment*). In this decision, Health Canada cancelled almost all agricultural uses due to environmental risks of concern, while a few uses were acceptable from the environmental perspective. In this current decision (REV2021-04), all remaining registrations of pest control products containing chlorpyrifos are cancelled **immediately** due to failure to fulfill the mandatory data requirements to update the human health risk assessment for the final phase of the re-evaluation. Health Canada has determined that the current chlorpyrifos uses will not pose imminent and serious risks during the period of the phase-out described under the section entitled: **Final Determination with Respect to Chlorpyrifos**, taking into account the considerations outlined under section (ii).

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<sup>15</sup> Containerized low concentration ant baits/bait stations were discontinued in 2017

<sup>16</sup> Re-evaluation Note REV2000-05 *Chlorpyrifos*, 28 September 2000

## Appendix I – Products containing chlorpyrifos subject to a phase-out period

**Table 1 Products containing chlorpyrifos subject to a phase-out period<sup>17</sup>**

Registration number	Product name	Registrant name	Status*
14879	Lorsban 4E Insecticide	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
16458	Lorsban 15G Insecticide	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
19656	Dursban FM Insecticidal Chemical	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
20320	Dursban HF Insecticidal Concentrate	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
20407	Dursban W Insecticidal Concentrate	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
20944	Lorsban 50W Insecticide	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
21997	Dursban Water Soluble Insecticide	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
23621	Pyrinex Technical Chlorpyrifos Insecticide	Adama Agricultural Solutions Canada Ltd.	Phase-Out Ending 2023-12-10
23704	Pyrate 480 EC Insecticide	Adama Agricultural Solutions Canada Ltd.	Phase-Out Ending 2023-12-10
23705	Pyrinex 480EC For Food Crops	Adama Agricultural Solutions Canada Ltd.	Phase-Out Ending 2023-12-10
24648	Pyrifos 15G Insecticide	Loveland Products Canada Inc.	Phase-Out Ending 2023-12-10
25823	Chlorpyrifos Technical	FMC of Canada Limited	Phase-Out Ending 2022-12-31
25831	Nufos 4E Insecticide	FMC of Canada Limited	Phase-Out Ending 2023-12-10
27479	Citadel 480EC Insecticide	Interprovincial Cooperative Limited	Phase-Out Ending 2022-12-10
29650	Lorsban NT Insecticide	Corteva Agriscience Canada Company	Phase-Out Ending 2023-12-09
29984	Warhawk 480 EC Insecticide	Loveland Products, Inc.	Phase-Out Ending 2023-12-10

<sup>17</sup> Source: Pesticide Product Information Database [<https://pesticide-registry.canada.ca/en/index.html>]

<b>Registration number</b>	<b>Product name</b>	<b>Registrant name</b>	<b>Status*</b>
30985	Mpower Krypton	NewAgco Inc.	Phase-Out Ending 2023-12-10
31417	Chlorpyrifos Agrogill Technical Grade Active Ingredient	Agrogill Chemicals Pty Ltd	Phase-Out Ending 2023-12-10
32694	Sharda Chlorpyrifos Technical Insecticide	Sharda Cropchem Limited	Phase-Out Ending 2023-12-10
32768	Sharphos Insecticide	Sharda Cropchem Limited	Phase-Out Ending 2023-12-10
33113	Pyrinex 450 LV EC	Adama Agricultural Solutions Canada Ltd.	Phase-Out Ending 2023-12-10
33295	Newagco Chlorpyrifos Technical	NewAgco Inc.	Phase-Out Ending 2023-12-10
33356	Mpower Chlorpyrifos Insecticide	NewAgco Inc.	Phase-Out Ending 2023-12-10

\* For details, consult the Pesticide Product Information Database