Proposed Re-evaluation Decision PRVD2022-01

Trinexapac-ethyl and Its Associated End-use Products

Consultation Document

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Proposed Re-evaluation Decision for Trinexapac-ethyl and Associated End-use Products

Under the authority of the *Pest Control Products Act,* all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental 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.

Trinexapac-ethyl is a plant growth regulator that inhibits the biosynthesis of gibberellin, a phytohormone that promotes growth of various plant organs. By inhibiting gibberellin, trinexapac-ethyl treatment reduces the size of leaves and stems. Trinexapac-ethyl is used on turf grown on commercial sod farms and golf courses to reduce the frequency of mowing and the amount of grass clippings. It also manages the growth of perennial ryegrass grown for seeds to reduce lodging and thus, improve seed yield and quality. Currently registered products containing trinexapac-ethyl can be found in the online Pesticide Label Search and in Appendix I.

This document presents the proposed re-evaluation decision for trinexapac-ethyl, including the proposed amendments (risk mitigation measures) to protect human health and the environment, as well as the science evaluation on which the proposed decision is based. All products containing trinexapac-ethyl that are registered in Canada are subject to this proposed re-evaluation decision. This document is subject to a 90-day public consultation period,[1] during which the public (including the pesticide manufacturers and stakeholders) may submit written comments and additional information to PMRA Publications. The final re-evaluation decision will be published after taking into consideration the comments and information received during the consultation period.

Proposed re-evaluation decision for trinexapac-ethyl

Under the authority of the *Pest Control Products Act* and based on an evaluation of available scientific information, Health Canada is proposing continued registration of all uses of trinexapac-ethyl and associated end-use products registered for sale and use in Canada with additional risk mitigation measures.

With respect to human health, dietary risks were shown to be acceptable when trinexapac-ethyl is used according to current conditions of registration. Occupational and postapplication risks were shown to be acceptable when trinexapac-ethyl is used according to proposed conditions of registration, which includes new mitigation measures such as updated restricted-entry interval (REI), adding the standard drift mitigation label statement, and updating the personal protective equipment (PPE) label statements to reflect current standards.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

The risks to the environment were shown to be acceptable when trinexapac-ethyl is used according to proposed conditions of registration, which includes new mitigation measures such as additional precautionary label statements and a 1 meter spray buffer zone to protect terrestrial non-target plants and freshwater aquatic habitats.

Trinexapac-ethyl has value as a plant growth regulator, in managing turf growth on golf courses and sod farms by reducing the frequency of mowing and the amount of grass clippings. It also reduces lodging in perennial ryegrass grown for seed.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The proposed label amendments including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of trinexapac-ethyl, are summarized below. Refer to Appendix VII for details.

Human health

The following risk-reduction measures are proposed:

To protect mixer/loader/applicators:

- For use on perennial ryegrass grown for seed, require closed mixing/loading systems and closed cab groundboom application when handling more than 70 kg a.i./day.
- For all uses, update PPE label statements to reflect current standards.

To protect workers entering treated sites:

- For use on perennial ryegrass grown for seed, require an REI of 10 days for all postapplication activities.
- For use on sod farm, require an REI of 12 hours for all postapplication activities.
- For use on golf courses, restrict entry until residues have dried.

To protect/prevent bystander exposure:

- Prohibit the use of trinexapac-ethyl golf course treatment products from being used on turf in other residential areas (which includes lawns, gardens, parks, playing fields, cemeteries and schools).
- Add standard drift statement.

Environment

To protect terrestrial non-target plants and freshwater aquatic habitats, the following risk-reduction measures are proposed:

- A buffer zone of 1 meter is proposed for the protection of terrestrial non-target plants and freshwater aquatic habitats.
- Update Environmental precautions (spray drift) and disposal label statements to protect terrestrial non-target plants and freshwater aquatic habitats to reflect current standards.

International context

Trinexapac-ethyl is currently acceptable for use in other Organisation for Economic Co-operation and Development (OECD) member countries, including the European Union, Australia, and the United States. No decision by an OECD member country to prohibit all uses of trinexapac-ethyl for health or environmental reasons has been identified.

Next steps

Upon publication of this proposed re-evaluation decision, the public, including the registrants and stakeholders are encouraged to submit additional information that could be used to refine risk assessments during the 90-day public consultation period.

All comments received during the 90-day public consultation period will be taken into consideration in preparation of re-evaluation decision document,[2] which could result in revised risk mitigation measures. The re-evaluation decision document will include the final re-evaluation decision, the reasons for it and a summary of comments received on the proposed re-evaluation decision with Health Canada's responses.

Refer to Appendix I for details on specific products impacted by this proposed decision.

Other Information

The relevant confidential test data on which the proposed decision is based (in the References section of this document) are available for public inspection, upon application, in Health Canada's Reading Room. For more information, please contact Health Canada's Pest Management Information Service.

Additional scientific information

No additional scientific data are required at this time.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

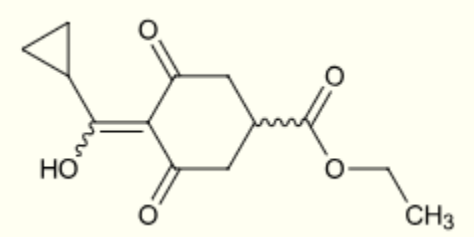
Science evaluation

1.0 Introduction

Trinexapac-ethyl is a plant growth regulator that inhibits the biosynthesis of gibberellin. Gibberellin is a plant hormone that promotes growth of various plant organs. By inhibiting gibberellin, trinexapac-ethyl reduces the size shoot length in turf as well, it reduces plant height in wheat, barley and oat thereby reducing the tendency for these crops to lean or fall over.

2.0 Technical grade active ingredient

2.1 Identity

Common name		Trinexapac-ethyl
Function		Plant growth regulator
Chemical Family		Cyclohexanedione
Chemical name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	ethyl (1*RS*,4*EZ*)-4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate
2	**Chemical Abstracts Service (CAS)**	ethyl 4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylate
CAS Registry Number		95266-40-3
Molecular Formula		$C_{13}H_{16}O_5$
Structural Formula		
Molecular Weight		252.3

Registration number	Purity of the technical grade active ingredient
26988	97.0 %
30635	98.9 %
33358	99.0 %

2.2 Physical and chemical properties

Property	Result
Vapour pressure at 20°C	2.16 mPa
Ultraviolet (UV) / visible spectrum	Not expected to absorb at λ >340 nm
Solubility in water at 20°C	pH Solubility (g/L) 5 2.79 7 7.23 9 17.34
n-Octanol/water partition coefficient	pH log K_{ow} 5 1.5 6.9 -0.29 8.9 -2.1
Dissociation constant	p*K*a = 4.57

3.0 Human health assessment

3.1 Toxicology summary

The toxicology profile and toxicology reference values for trinexapac-ethyl were presented in PRD2020-13. Please refer to Appendix II for a summary of the toxicology reference values that have been established by the PMRA for characterisation of human health risks.

3.1.1 *Pest Control Products Act* (PCPA) hazard characterization

The *Pest Control Products Act* factor for trinexapac-ethyl was presented in PRD2020-13.

3.2 Dietary exposure and risk assessment

The dietary exposure assessment of trinexapac-ethyl was presented in PRD2020-13. Potential dietary risks from food and drinking water are considered to be acceptable for all uses under the current conditions of use. No additional mitigation measures are required.

3.3 Occupational and non-occupational exposure and risk assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant reference value from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

The occupational and non-occupational risk assessments for wheat (winter, spring and durum), barley and oat field applications were presented in PRD2020-13. The assessments below refer to the perennial ryegrass grown for seed and turf (sod farm and golf courses) uses only.

3.3.1 Toxicology reference values for occupational and non-occupational risk assessment

The toxicology reference values for the occupational assessment for trinexapac-ethyl were presented in PRD2020-13 (and are also presented in Appendix II of this document).

Short- and intermediate-term dermal (Non-occupational exposure scenarios)

The toxicology reference value selected for short-and intermediate-term residential risk assessment for females 13–49 was post-implantation loss. The existing short-term dermal toxicity study did not address the reference value of concern, thus necessitating the use of an oral study for risk assessment. For short- and intermediate-term dermal risk assessment, a NOAEL of 10 mg/kg bw/day from the gavage developmental toxicity study in rabbits was selected. At the LOAEL of 60 mg/kg bw/day, increased post-implantation loss was observed in the absence of overt maternal toxicity. The target MOE is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as a PCPA factor of threefold as discussed in the *Pest Control Products Act* hazard characterization section in PRD2020-13. The selection of this study and target MOE is considered to be protective of all populations including pregnant women and their unborn children.

The toxicology reference value selected for short-and intermediate-term residential risk assessment for the general population, excluding females 13–49 years of age, was increased vacuolation in the brain. The dog was the sensitive species for this effect and the available dermal study was not conducted in this species. Thus, the use of an oral study was appropriate. The 12-month dietary toxicity study in the dog with a NOAEL of 32 mg/kg bw/day was selected for risk assessment. At the LOAEL of 366 mg/kg bw/day, increased vacuolation in the brain was observed. The target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As discussed in the *Pest Control Products Act* hazard characterization section in PRD2020-13, the PCPA factor was reduced to onefold.

3.3.2 Dermal absorption

The dermal absorption value for trinexapac-ethyl was presented in PRDD2001-05. The dermal absorption value is 77.5%.

3.3.3 Non-occupational exposure and risk assessment

Non-occupational (residential) risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application. Since there are no domestic-class products containing trinexapac-ethyl, a residential applicator assessment was not required. As trinexapac-ethyl is registered for use on golf course turf, a residential risk assessment was conducted for golfers.

The USEPA has generated standard default procedures for developing residential exposure assessments when chemical- and/or site-specific field data are limited. These procedures may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in high-end estimates of exposure. The procedures relevant to the trinexapac-ethyl re-evaluation are outlined in the 2012 USEPA Standard Operating Procedures (SOP) for Residential Pesticide Exposure Assessments under Section 3, Lawns and Turf.

3.3.3.1 Residential postapplication exposure and risk assessment

Residential postapplication exposure occurs when an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) routes as a result of being in a residential environment that has been previously treated with a pesticide. For trinexapac-ethyl, postapplication exposure to treated turf from golfing activities was assessed.

Postapplication residential exposure to trinexapac-ethyl is expected to be intermittent short-term in duration (that is, less than 30 days of continuous exposure). It was assumed that individuals would enter previously treated areas on the same day the pesticide is applied. For this scenario, adults (> 16 years old), youth (11 to < 16 years old) and children (6 to < 11 years old) were chosen as the index life stages to assess, based on behavioural characteristics and the quality of available data. Exposure is expected to be predominately dermal. Postapplication inhalation exposure is expected to be very low while performing activities on previously treated golf course turf due to the combination of low vapour pressure of trinexapac-ethyl and the expected dilution in outdoor air. In addition, any spray droplets in the air would be expected to have settled when entry is permitted and residues have dried. Since very young children (1 to < 2 years) are typically not expected to be golfing, an incidental oral exposure risk assessment was not required.

Postapplication dermal exposure was calculated using activity-specific transfer coefficients (TCs) and exposure time from the USEPA Residential SOPs (2012) for golfing. A TC is a factor that relates dermal exposure to the turf transferable residue (TTR) and is based on the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm^2 per hour). It is specific to a particular population and activity/location (for example, adults golfing on turf). Standard values for TTR used were also from the USEPA Residential SOPs (2012).

For the residential postapplication risk assessment, calculated MOEs exceeded the target MOEs for trinexapac-ethyl for all scenarios and thus, risks were shown to be acceptable, provided that entry occurs when residues have dried.

The results of the residential postapplication risk assessment are summarized in Appendix III.

3.3.4 Occupational exposure and risk assessment

There is potential for exposure to trinexapac-ethyl in occupational scenarios from workers handling products containing trinexapac-ethyl during mixing/loading and application activities, and from workers entering treated areas to conduct postapplication activities.

3.3.4.1 Mixer, loader, and applicator exposure and risk assessment

For commercial-class products, there are potential exposures for mixers, loaders and applicators. Based on the use pattern, the following scenarios were assessed:

- Mixing and loading of liquids
- Applying liquids by groundboom
- Mixing, loading and applying liquids by backpack sprayer
- Mixing, loading and applying liquids by turf gun

Based on the number of applications and the timing of application, workers applying trinexapac-ethyl would generally have a short- to intermediate-term (< 30 days to < 6 months) duration of exposure.

The exposure estimates for mixer/loaders and applicators are based on the current label personal protective equipment (PPE). Engineering controls were also considered.

- Mid-level PPE: Coveralls over long pants, long-sleeved shirt, chemical-resistant gloves, socks and shoes.
- Engineering controls: Represents the use of appropriate engineering controls, such as a closed cab tractor or closed mixing/loading systems. Engineering controls are limited for handheld application methods.

No appropriate chemical-specific handler exposure data were available for trinexapac-ethyl. Therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database Version 1.1 (PHED), the Agricultural Handlers Exposure Task Force (AHETF) studies and the Outdoor Residential Exposure Task Force (ORETF).

The PHED version 1.1 is a compilation of generic mixer/loader applicator passive dosimetry data with associated software, which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. The backpack sprayer scenario, closed mixing and loading of liquids, and closed cab groundboom application scenarios from PHED were used in this risk assessment. When available, recent AHETF studies were used. The open mix/load of liquids and open cab groundboom application scenarios from AHETF were used in this risk assessment.

The Outdoor Residential Exposure Task Force (ORETF) generated several exposure studies, which monitored exposure of lawn care technicians and homeowners mixing, loading and applying pest control products to turf. The turf gun sprayer mix/load/application scenario from ORETF was used in this risk assessment.

Inhalation exposures were based on light inhalation rates (17 L/min) except for the backpack sprayer, which was assessed using a moderate inhalation rate (27 L/min).

In most cases, the above studies did not contain appropriate data sets to estimate exposure to workers wearing coveralls. Where possible, this was estimated by incorporating a 75% clothing protection factor for coveralls, into the unit exposure data.

While there are limitations in the use of generic studies above, these exposure data represent the best data currently available.

Calculated MOEs for mixing, loading and applying trinexapac-ethyl exceeded target MOEs for most scenarios based on the current label PPE, and therefore, were shown to be acceptable. However, for use on perennial ryegrass grown for seed, closed mix/load systems and closed cab during groundboom application are required when handling more than 70 kg a.i./day. The mixer/loader and applicator risk assessment is summarized in Appendix IV.

3.3.4.2 Postapplication worker exposure and risk assessment

The postapplication occupational risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving contact with treated foliage or turf (for example, scouting). Based on the use pattern, there is potential for short to intermediate-term (<6 months) postapplication exposure for workers. Exposure would be predominantly dermal for workers performing postapplication activities. Based on the vapour pressure of trinexapac-ethyl, inhalation exposure would be low, provided that the minimum restricted-entry interval is followed.

Potential dermal exposure to postapplication workers was estimated using updated activity-specific TCs, and standard dislodgeable foliar residue (DFR) or TTR values. The DFR refers to the amount of residue that can be dislodged or transferred from a surface, such as leaves of a plant. Similarly, the TTR refers to the amount of pesticide residue that can be dislodged or transferred from treated turf. The TC is a measure of the relationship between exposure and DFRs/TTRs for individuals engaged in a specific activity, and is calculated from data generated in field exposure studies. The TCs are specific to a given crop and activity combination, and reflect standard agricultural work clothing worn by adult workers. Activity-specific TCs from the Agricultural Re-Entry Task Force (ARTF) were used. Postapplication exposure activities for perennial ryegrass grown for seed, and turf on sod farms and golf courses include (but are not limited to): transplanting, weeding and/or scouting. For more information about estimating worker postapplication exposure, refer to PMRA's regulatory proposal PRO2014-02, U*pdated Agricultural Transfer Coefficients for Assessing Occupational Post-Application Exposure to Pesticides*.

Since no acceptable chemical-specific DFR studies were available for trinexapac-ethyl, standard values were used (peak DFR of 25% of the application rate, with 10% dissipation per day).

Although chemical-specific turf transferable residue studies were available for trinexapac-ethyl, they were not used to estimate turf exposure, since the methodology (that is, collection of grass clippings) is different from the methodology used to determine the TCs from the ARTF golf course and sod farm studies (that is, the Modified California Roller). The relationship of residues measured using grass clippings to the TCs available for the above activities is not known. Therefore, standard values were used for the risk assessment (peak TTR of 1% of the application rate for turf, with 10% dissipation per day).

For further information on these standard values and estimating worker postapplication exposure, refer to PMRA's Science Policy Note SPN2014-02, *Estimating Dislodgeable Foliar Residues and Turf Transferrable Residues in Occupational and Residential Post-application Exposure Assessments*.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level at which risks are shown to be acceptable (that is, performance of a specific activity results in exposures of trinexapac-ethyl above the target MOE).

Appendix V summarizes the postapplication occupational exposure and risk assessments for trinexapac-ethyl. The calculated MOEs exceed the target MOE, and therefore risks are shown to be acceptable at the calculated REIs or when residues are dried for golf courses. Updated REIs are proposed to be added to the labels; specifically, REIs of 10 days for perennial ryegrass grown for seed and 12 hours for sod farms.

3.4 Aggregate exposure and risk assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from dietary (food and drinking water), residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

3.4.1 Toxicology reference values for aggregate risk assessment

Short- and intermediate-term aggregate (females 13–49 years of age)

The toxicology reference value selected for aggregation for females 13–49 was post-implantation loss. The existing short-term dermal toxicity study did not address the reference value of concern, thus necessitating the use of an oral study for the dermal reference value. For the oral and dermal routes, the NOAEL of 10 mg/kg bw/day from the rabbit developmental toxicity study was selected. At the LOAEL of 60 mg/kg bw/day, increased post-implantation loss was observed in the absence of overt maternal toxicity. The target MOE is 300, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability, as well as a PCPA factor of threefold as discussed in the *Pest Control Products Act* hazard characterization section in PRD2020-13.

Short- and intermediate-term aggregate (general population – excluding females 13–49 years of age)

The toxicology reference value selected for aggregation for the general population excluding females 13–49 years of age was increased vacuolation in the brain. The dog was the sensitive species for this effect and the available dermal study was not conducted in this species, thus necessitating the use of an oral study for the dermal reference value. For the oral and dermal routes, the NOAEL of 32 mg/kg bw/day from the 12-month dietary toxicity study in the dog was selected. At the LOAEL of 366 mg/kg bw/day, increased vacuolation in the brain was observed. The target MOE is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. As discussed in the *Pest Control Products Act* hazard characterization section in PRD2020-13, the PCPA factor was reduced to onefold.

3.4.2 Aggregate exposure and risk assessment

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential (non-occupational) exposure pathways are assessed. A major consideration is the likelihood of co-occurrence of exposures and durations of exposures. Additionally, only exposures from routes that share common toxicological effects are aggregated.

For trinexapac-ethyl, an aggregate assessment was conducted for adults, youth (11 to < 16 years) and children (6 to < 11 years) who would have residential exposure following application to golf course turf plus dietary trinexapac-ethyl exposure from food and drinking water. Exposure would be predominately by the dermal and oral routes. Inhalation exposure is expected to be very low compared to other routes of exposure and therefore was not considered quantitatively. The duration of exposure would be short- to intermediate-term.

The results of the aggregate assessment are presented in Appendix VI.

The calculated aggregate MOEs exceeded the target MOE for all age groups assessed. Therefore, aggregate risks for trinexapac-ethyl were shown to be acceptable when the proposed mitigation measures for trinexapac-ethyl are considered (that is, entry to golf courses once the spray residues have dried).

3.5 Cumulative assessment

The *Pest Control Products Act* requires that Health Canada's PMRA consider the cumulative exposure to pest control products with a common mechanism of toxicity. Cumulative assessment considerations for trinexapac-ethyl was presented in PRD2020-13. A cumulative health risk assessment is not required at this time.

3.6 Health incident reports

As of 29 July 2021, four human and one domestic animal incident involving trinexapac-ethyl were submitted to the PMRA.

One human minor incident was considered possibly related to the reported product. Exposure was reported in a bystander near a field that was treated with a trinexapac-ethyl product. The reported symptoms include sore throat and headache. Two other human incidents were serious reports involving multiple active ingredients (including trinexapac-ethyl). Both incidents occurred in the United States. In general, there was insufficient information in the two incidents to assess the likelihood of exposure to the various active ingredients. In addition, the reported effects such as cancer (leukemia) and Parkinson's disease could be attributed to multiple biological/environmental factors or causes. No adverse effects were specified in the fourth human incident.

The domestic animal incident involved a dog and a bird. The details surrounding the circumstances of trinexapac-ethyl exposure in the two animals were not reported. Therefore, there was insufficient information to assess if the minor symptoms of malaise as noted in the two animals were related to the reported product.

Overall, no consistent exposure trends or patterns were noted in the various incidents involving trinexapac-ethyl. Hence, no additional mitigation measures are recommended based on this incident report review.

4.0 Environmental assessment

The fate and behaviour in the environment, as well as the ecotoxicology, of trinexapac-ethyl and its major transformation product, trinexapac acid, were presented in PRD2020-13.

The risk to terrestrial and aquatic organisms from the use of trinexapac-ethyl on winter wheat, spring wheat, barley and oat (at one application of 125 g a.i./ha) using current risk assessment practises was presented in PRD2020-13. Similarly, no risks to non-target terrestrial and aquatic organisms were identified at the screening level for the remaining uses at a higher application rate (seven applications at 28 day intervals at 388 g a.i./ha for turf; one application of 411 g a.i./ha for perennial ryegrass grown for seed), with the exception of the following:

- Non-target terrestrial plants
- Non-target freshwater algae and vascular plants

Based on this, buffer zones for the protection of non-target terrestrial plants and non-target aquatic organisms were recalculated based on the higher application rates used on turf and on perennial ryegrass grown for seed. To protect non-target terrestrial plants and fresh water habitats from spray drift, a 1 meter buffer zone is proposed for trinexapac-ethyl used on turf (sod farm and golf course) and perennial ryegrass grown for seed (Appendix VII).

Updates to standard labels statements (environmental precautions, directions for use) are proposed to meet the current labelling practices (Appendix VII).

Based on the registered use pattern, the environmental risks associated with trinexapac-ethyl and its associated end-use products were shown to be acceptable when used according to the proposed label directions.

4.1 Environmental incident reports

As of 29 July 2021, no incidents relevant to the environment involving trinexapac-ethyl had been reported to the PMRA. No incidents relevant to the environment were reported in the United States Ecological Incident Information System.

4.2 Toxic substances management policy considerations

In accordance with the PMRA Regulatory Directive DIR99-03,[3] the assessment of trinexapac-ethyl against Track 1 criteria of Toxic Substances Management Policy (TSMP) under *Canadian Environmental Protection Act* was conducted. Health Canada has reached the conclusions that: Trinexapac-ethyl and its transformation products does not meet all Track 1 criteria, and is not considered a Track 1 substance

4.3 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the technical grade active ingredient and formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*[4]. The list is used as described in the Health Canada's Science Policy Note SPN2020-01[5] and is based on existing policies and regulations including the Toxic Substances Management Policy**Error! Bookmark not defined.** and Formulants Policy,[6] and taking into consideration the Ozone-depleting Substances and Halocarbon Alternatives Regulations under the *Canadian Environmental Protection Act*, 1999 (substances designated under the Montreal Protocol). Health Canada has reached the following conclusions:

Trinexapac-ethyl and its end-use products do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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3 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

4 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

5 PMRA's Science Policy Note SPN2020-01*, Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of *the Pest Control Products Act.*

6 DIR2006-02, *The Pest Management Regulatory Agency's Regulatory Directive: Formulants Policy and Implementation Guidance Document*.

5.0 Value assessment

Trinexapac-ethyl is a synthetic plant growth regulator used to slow the growth of turf on golf course and commercial sod farms. As a result, the frequency of mowing and the amount of grass clippings are reduced. It also manages the growth of perennial ryegrass grown for seeds to reduce lodging and thus, improve seed yield and quality. It is the only product registered for both these uses. The value assessment for wheat, barley and oats was included in PRD2020-13.

List of abbreviations

ADI	acceptable daily intake
a.i.	active ingredient
AHEFT	Agricultural Handlers Exposure Task Force
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATPD	area treated per day
bw	body weight
cm^2	centimeters squared
cm^2/hr	centimeters squared per hour
CR	chemical Resistant
DFR	dislodgeable foliar residue
ha	hectare
hr(s)	hour(s)
kg	kilogram
L	litre(s)
LOAEL	lowest observed adverse effect level
mg	milligram
M/L/A	mixer/loader/applicator
MOE	margin of exposure
NA	not applicable
NOAEL	no observed adverse effect level
ORETF	Outdoor Residential Exposure Task Force
PCPA	Pest Control Product Act
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
REI	restricted-entry interval
SOP	standard operating procedure
TC	transfer co-efficient
TTR	turf transferable residue
TXP	Trinexapac-ethyl
µg	microgram
USEPA	United States Environmental Protection Agency
U.V.	ultraviolet

Appendix I Registered products containing trinexapac-ethyl in Canada

Table 1 Registered products containing Ttrinexapac-ethyl in Canada[1]

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (%, g/L)
26988	Technical Grade Active Ingredient	Syngenta Canada Inc.	Trinexapac-Ethyl Technical	Liquid	97%
26989	Commercial	Syngenta Canada Inc.	Primo Maxx Plant Growth Regulator	Emulsifiable Concentrate or Emulsion	11.3%
31214	Commercial	Syngenta Canada Inc.	Parlay	Emulsifiable Concentrate or Emulsion	11.3%
33930	Commercial	Syngenta Canada Inc.	Moddus	Micro-emulsion concentrate	11.3%
30635	Technical Grade Active Ingredient	Adama Agricultural Solutions Canada Ltd.	Mana Trinexapac Technical	Solid	97.2%
30683	Commercial	Adama Agricultural Solutions Canada Ltd.	Quali-Pro T-Nex 11.3 Me	Micro-emulsion concentrate	11.3%
33385	Commercial	Adama Agricultural Solutions Canada Ltd.	Quali-Pro T-Nex 12 Me	Micro-emulsion concentrate	120 g/L
33358	Technical Grade Active Ingredient	Sharda Cropchem Limited	Sharda Trinexapac-Ethyl Technical	Liquid	99%
33883	Commercial	Sharda Cropchem Ltd.	Next 11.3 ME	Micro-emulsion concentrate	11.3%
34056	Technical Grade Active Ingredient	Maxunitech North America, Inc.	Maxunitech Trinexapac-ethyl Technical	Liquid	98.6%
34065	Commercial	Maxunitech North America, Inc.	Maxunitech Trinexapac-ethyl 11.3% ME	Micro-emulsion concentrate	11.3%

[1] as of 3 August 2021, excluding discontinued products or products with a submission for discontinuation

Appendix II Toxicology reference values for use in health risk assessment for Trinexapac-ethyl

Toxicology reference values for use in health risk assessment for Trinexapac-ethyl (Canada, 2020a).

Exposure scenario	Study	Point of departure and reference value	CAF or Target MOE[1]
Acute dietary (General population excluding females 13–49 years of age)	Not selected	No appropriate reference value identified for this population	
	ARfD was not established		
Acute dietary (Females 13–49 years of age)	Oral developmental toxicity in the rabbit	NOAEL = 10 mg/kg bw/day Increased post-implantation loss	300
	ARfD = 0.03 mg/kg bw		
Repeated dietary (General population excluding females 13–49 years of age)	12-month dietary toxicity in the dog	NOAEL = 32 mg/kg bw/day Vacuolation in the brain	100
	ADI = 0.3 mg/kg bw/day		
Repeated dietary (Females 13–49 years of age)	Oral developmental toxicity in the rabbit	NOAEL = 10 mg/kg bw/day Increased post-implantation loss	300
	ADI = 0.03 mg/kg bw/day		
Short- and intermediate-term dermal[2] and inhalation[3] (Females 13–49 years of age)	Oral developmental toxicity in the rabbit	NOAEL = 10 mg/kg bw/day Increased post-implantation loss	300
Short- and intermediate-term dermal[2] (General population excluding females 13–49 years of age)	12-month dietary toxicity in the dog	NOAEL = 32 mg/kg bw/day Vacuolation in the brain	100
Short-term, intermediate-term aggregate (Oral and dermal[2], females 13–49 years of age)	Oral developmental toxicity in the rabbit	Common reference value: Increased post-implantation loss Oral and dermal: NOAEL = 10 mg/kg bw/day	300

Exposure scenario	Study	Point of departure and reference value	CAF or Target MOE[1]
Short-term, intermediate-term aggregate (Oral and dermal[2], general population excluding females 13–49 years of age)	12-month dietary toxicity in the dog	Common reference value: Vacuolation in the brain Oral and dermal: NOAEL = 32 mg/kg bw/day	100
Cancer	A cancer risk assessment was not required		

[1] CAF (composite assessment factor) refers to a total of uncertainty and PCPA factors for dietary assessments; MOE refers to a target MOE for occupational assessments.

[2] Since an oral NOAEL was selected, a dermal absorption factor of 77.5% was used in a route-to-route extrapolation.

[3] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

NOTE: Reference values were adjusted by × 0.9 to convert to trinexapac-ethyl acid equivalents for risk assessment purposes.

Appendix III Residential postapplication exposure and risk assessment

Residential postapplication exposure to Trinexapac-ethyl on treated golf courses

Scenario	Lifestage	TTR (ug/cm^2)[a]	Weight unit conversion factor (mg/ug)	Transfer Coefficient (cm^2/hr)[b]	Exposure time (hr)	Body weight (kg)	Dermal exposure (mg/kg/bw/day)[c]	Dermal MOE[d]
Golfing	Adult	0.04	0.001	5300	4	80	0.0082	1217
	Youth 11 to < 16 yrs			4400		57	0.0096	1045
	Children 6 to < 11 yrs			2900		32	0.0112	2848

TTR = turf transferable residue, MOE = Margin of Exposure

[a] Maximum TTR after 7 applications with 28 days between applications.

[b] TCs from the USEPA Residential SOP, Section 3: Lawns and Turf (USEPA, 2012)

[c] Dermal exposure (mg/kg bw/day) = TTR (ug/cm²) × TC (cm²/hr) × Exposure Time × 77.5% Dermal Absorption / BW

[d] Adults and Youth (11 < 16 yrs): Based on NOAEL of 10 mg/kg bw/day from an oral developmental toxicity in the rabbit with a target MOE of 300. Children (6 < 11 yrs): Based on NOAEL of 32 mg/kg bw/day from a dietary toxicity study in the dog with a target MOE of 100. Exposure estimates for Adults 16+ and Youth 11 <16 years were compared to the toxicology reference value for Females 13–49 years. This would be protective of all ages in these population groups, as Females aged 13–49 were considered the most sensitive subpopulation.

Appendix IV Occupational mixer/loader/applicator exposure and risk assessment

Occupational mixer/loader/applicator exposure and risk assessment of Trinexapac-ethyl, short- to intermediate-term

Use	Formulation	Scenario	Application equipment	Max rate (kg a.i./ha)	ATPD (ha/day)	Dermal exposure[a] (mg/kg bw/day)	Inhalation exposure[b] (mg/kg bw/day)	Dermal MOE[c]	Inhalation MOE[c]	Combined MOE[d]
Perennial ryegrass grown for seed	Liquid	Open M/L, Open A, Mid-level PPE	Groundboom Farmer	0.411	107	1.94E-02	1.27E-03	516	7875	484
			Groundboom Custom		360	6.52E-02	4.27E-03	153	2341	144
		Closed M/L, Closed A, Mid-level PPE	Groundboom Custom			2.01E-02	3.14E-04	497	31805	490
Sod Farms	Liquid	Open M/L, Open A, Mid-level PPE	Groundboom	0.388	30	5.13E-03	3.36E-04	1949	29753	1829
		Open M/L/A, Mid-level PPE	Backpack		150 L/day	1.46E-03	4.52E-05	6829	221348	6625
		Open M/L/A, Mid-level PPE	Turf Gun		2	2.26E-03	3.88E-05	4419	257732	4345
Turf (golf courses)	Liquid	Open M/L, Open A, Mid-level PPE	Groundboom	0.388	16	2.74E-03	1.79E-04	3654	55786	3429
		Open M/L/A, Mid-level PPE	Backpack		150 L/day	1.46E-03	4.52E-05	6829	221348	6625
		Open M/L/A, Mid-level PPE	Turf Gun		2	2.26E-03	3.88E-05	4419	257732	4345

Max = Maximum, ATPD = Area Treated Per Day, MOE = Margin of Exposure, M/L/A = Mix/Load/Apply, PPE = Personal Protective Equipment, Label PPE: Single layer, long sleeved shirt, chemical resistant gloves and coveralls

[a]Dermal exposure (mg/kg bw/day) = (dermal unit exposure × ATPD × maximum application rate × 77.5% dermal absorption)/80 kg body weight

[b]Inhalation exposure (mg/kg bw/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight

[c]Based on the short-, intermediate term NOAEL of 10 mg/kg bw/day from an oral developmental toxicity in the rabbit with a target MOE of 300.

[d]Combined MOE = NOAEL/(EXP_{derm}+EXP_{inh}), Target MOE = 300

Appendix V Occupational postapplication exposure and risk assessment

Occupational postapplication exposure and risk assessment of Trinexapac-ethyl, short- to intermediate-term

Crop	Activity	TC (cm^2/hr)[a]	Max App Rate (kg a.i./ha)	Maximum applications per year	Spray intervals (days)	Dermal exposure (mg/kg bw/day)[b]	Dermal MOE (Day_0)[c, d]
Perennial ryegrass grown for seed[e]	Scouting	1750	0.411	1	-	8.76E-02	114
	Weeding	70				5.57E-03	1794
Sod Farms[f]	Harvesting (slab), Transplanting/Planting	6700	0.388	7	28	2.13E-02	470
	Irrigation, Mowing, Watering	3500				1.11E-02	900
	Aerating, Fertilizing, Hand pruning, MA Weeding, Scouting, Seeding	1000				3.17E-03	3152
Golf Courses[f]	Cup Changing, Irrigation Repair, Mowing, Watering, Misc. Grooming	3500	0.388	7	28	1.11E-02	900
	Aerating, Fertilizing, Hand pruning, MA Weeding, Scouting, Seeding	1000				3.17E-03	3152
Golf Courses (greens and tees)[f]	Maintenance	2500	0.049	7	28	1.00E-03	9982

Max App Rate = Maximum Application Rate, TC = Transfer coefficient, DFR = Dislodgeable Foliar Residue, MOE = Margin of Exposure, REI = restricted-entry interval, Day 0 = day of application, MA = Mechanically Assisted

[a] The TC values are from PRO2014-02.

[b] Dermal exposure (mg/kg bw/day) = DFR/TTR (ug/cm²) × TC (cm²/hr) x work duration (8 hr) × 77.5% Dermal Absorption / BW (80 kg)

[c] Based on the short-, and intermediate term NOAEL of 10 mg/kg bw/day from an oral developmental toxicity in the rabbit with a target MOE of 300.

[d] For perennial ryegrass, the target MOE is reached on Day 10. Therefore, an REI of 10 days is required. Sod farms require an REI of 12 hours. Entry is permitted in golf courses once spray residues have dried.

[e] Based on a peak standard DFR value of 25% of the application rate and dissipation rate value of 10%. Maximum applications per year and minimum interval between applications was assumed.

[f] Based on a peak standard TTR value of 1% of the application rate and dissipation rate value of 10%. Maximum applications per year and minimum interval between applications was assumed.

Appendix VI Aggregate exposure and risk assessment

Aggregate exposure and risk assessment

Sub-population	Scenario	Residential exposure[a] (mg/kg bw/day)	Dietary exposure (mg/kg bw/day)	Total exposure (mg/kg bw/day) [b]	Aggregate MOE[c]
Adults	Golf Courses	0.0082	0.0084	0.0167	601
Youth 11 to < 16 yrs		0.0096	0.0067	0.0163	614
Children 6 to < 11 yrs		0.0112	0.0097	0.0209	1529

MOE = margin of exposure

[a] Total exposure from postapplication activities on treated golf courses.

[b] Total exposure from residential dermal and chronic dietary exposure.

[c] Adults and Youth (11 to < 16 yrs): Based on NOAEL of 10 mg/kg bw/day from an oral developmental toxicity in the rabbit with a target MOE of 300. Children (6 to < 11 yrs): Based on NOAEL of 32 mg/kg bw/day from a dietary toxicity study in the dog with a target MOE of 100. Exposure estimates for adults 16+ and youth 11 to < 16 years were compared to the toxicology reference value for females 13–49 years. This would be protective of all ages in these population groups, as females aged 13–49 were considered the most sensitive subpopulation.

Appendix VII Proposed label amendments for products containing Trinexapac-ethyl

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

Label Amendments for Technical Class Products Containing Trinexapac-ethyl

1. **General Label Improvements**

   Add to ENVIRONMENTAL PRECAUTIONS

   Toxic to aquatic organisms.

Label Amendments for Commercial Class Products Containing Trinexapac-ethyl

1. **General Label Improvements**

   "In order to promote best practices, and to minimize human exposure from spray drift or from spray residues resulting from drift due to the agricultural use of trinexapac-ethyl, the following label statement is proposed for all commercial-class labels:"

   Add to PRECAUTIONS:

   "Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings."

2. **Label Amendments for Commercial End-use Products for Turfgrass on Golf Courses and Sod Farms**

   Under PRECAUTIONS:

   Replace:

   "Wear long sleeved shirt and long pants with coveralls and chemical resistant gloves for all mix/load and application activities and during equipment cleanup and repair activities. In addition, wear goggles during mix/load activities."

   With:

   "Wear coveralls over 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. In addition, wear protective eyewear (goggles or face shield) during mixing and loading."

Replace:

"DO NOT re-enter treated areas until residues have dried. For both sod farms and golf courses, a restricted-entry interval of 3 days postapplication is required for workers who re-enter treated areas for hand or mechanical sod harvesting, sod transplanting, and hand weeding activities."

With:

"For golf courses, **DO NOT** enter or allow entry until residues have dried."

"For sods farms, **DO NOT** enter or allow worker entry during the restricted-entry interval (REI) of 12 hours."

"[Product Name] can be applied to golf course greens, tees, fairways, roughs, and sod farms only. Do NOT apply to turf in other residential areas including lawns, gardens, parks, playing fields, cemeteries and schools."

3. Label Amendments for Commercial End Use Products for Perennial Ryegrass Grown for Seed

Add to PRECAUTIONS:

If handling more than 70 kg a.i. per day, use a closed mix/load system and a closed cab tractor during application.

Under PRECAUTIONS:

Replace:

"Wear long sleeved shirt and long pants with coveralls and chemical resistant gloves for all mix/load and application activities and during equipment cleanup and repair activities. In addition, wear goggles during mix/load activities."

With:

"Wear coveralls over 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. In addition, wear protective eyewear (goggles or face shield) during mixing and loading."

Replace:

"DO NOT re-enter treated areas for 12 hours. A restricted-entry interval of 3 days postapplication is required for workers who re-enter treated areas for hand or mechanical harvesting, transplanting, and hand weeding activities."

With:

"**DO NOT** enter or allow worker entry during the restricted-entry interval (REI) of 10 days for all postapplication activities."

4. Label Amendments for Commercial End-use Products with use on turf and perennial ryegrass grown for seed (not for cereal use, in other words, MODDUS):

Add to ENVIRONMENTAL PRECAUTIONS:

"Toxic to non-target terrestrial plants and aquatic organisms. Observe spray buffer zones specified under DIRECTIONS FOR USE."

Add to DIRECTIONS FOR USE:

"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) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air."

Spray Buffer Zones

A spray buffer zone is NOT required for uses with hand-held application equipment permitted on this label.

The spray 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	Spray Buffer Zones (metres) Required for the Protection of:		
		Freshwater Habitat of Depths		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	
Field sprayer	Turf, perennial ryegrass grown for seed	1	1	1

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) spray 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.

References

A. Information considered in the updated chemistry assessment

List of studies/Information submitted by registrant

PMRA Document Number	Title
2723243	1991, Metal Ion Stability of CGA-163935 Technical. Ciba-Geigy, Report No. MP 91-08. DACO: 2.14.13 CBI
2723244	1993, Report on Thermal Stability and Stability in Air. Ciba-Geigy, Report No. 10949. DACO: 2.14.13 CBI
2723245	1990, Report on Physico Chemical Properties. Ciba-Geigy, Report No. 127306. DACO: 2.14.2,2.14.3,2.14.6 CBI
2723246	2000, Boiling Point /Boiling Range of CGA 163935. Novartis, Study No. 77861. DACO: 2.14.5 CBI
2846557	2015, Accelerated Storage stability and Corrosion Characteristics of Trinexapac ethyl technical. DACO: 2.14, 2.14.1, 2.14.10, 2.14.11 ,2.14.14, 2.14.15, 2.14.2, 2.14.3, 2.14.5, 2.14.6, 2.14.7, 2.14.8
2846555	2015, Phototransformation of trinexapac ethyl technical in water direct photolysis. JRF No. 611-3-15-10292. DACO:2.14.12
2846558	2015, Corrosiveness of Trinexapac-ethyl technical. JRF No. 257-2-11-10295. DACO: 2.14.13
2227140	Description of Starting Materials, DACO: 2.11.2 CBI
2227139	Description of Production Process, DACO: 2.11.1,2.11.3 CBI
3154972	Trinexapac-ethyl Technical (CGA163935) - Manufacturing Process Description and Supporting Data, DACO: 2.11.1,2.11.3 CBI
3138202	2014. Manufacturing Process and Discussion of Formation of Impurities for MANA Trinexapac Technical, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI
2846549	2018, Trinexapac-Ethyl manufacturing process, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
2227146	2011, Trinexapac-ethyl Analysis of five representative batches produced, DACO: 2.13.3 CBI
3055292	2012, 2.13.3 RB0138 Study - Batch Data, DACO: 2.13.3,2.13.4 CBI
2846550	2013, Analysis and Method Validation for 5 batches of Trinexapac-Ethyl Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice. DACO: 2.13,2.13.1 CBI
2846551	2013, Analysis and Method Validation for 5 batches of Trinexapac-Ethyl Technical Material to determine the content of the active ingredient and specified impurities, in compliance with Good Laboratory Practice. DACO: 2.13,2.13.1 CBI

B. Information considered in the updated toxicological and dietary assessment

Additional information considered

Published information

PMRA Document Number	Title
654877	Canada, 2001. Proposed Regulatory Decision Document PRDD2001-05 Trinexapac-ethyl. December 7, 2001.
660868	Canada, 2002. Regulatory Decision Document RDD2002-01, Trinexapac-ethyl. February 6, 2002.
2362933	Canada, 2014. Evaluation Report for Category B, Subcategory 3.12 Application
3148710	Canada, 2020a. Proposed Registration Decision PRD2020-13 Trinexapac-ethyl and MODDUS. 9 September 2020.
3163266	Canada, 2020b. Pest Management Regulatory Agency. RD2020-17: Registration Decision Trinexapac-ethyl and MODDUS.

C. Information considered in the updated occupational and non-occupational assessment

List of studies/Information submitted by registrant

PMRA Document Number	Title
2115788	ARTF, 2008. Agricultural Reentry Task Force (ARTF). Data Submitted by the ARTF to Support Revision of Agricultural Transfer Coefficients. Submission# 2006-0257.
1913109	AHETF, 2009. Agricultural Handler Exposure Scenario Monograph: Open Cab Groundboom Application of Liquid Sprays. Report Number AHE1004. December 23, 2009.

Additional information considered

Published information

PMRA Document Number	Title
2409268	U.S. EPA (2012). Standard Operating Procedures for Residential Pesticide Exposure Assessment. EPA: Washington, DC. Revised October 2012.

E. Information considered in the updated environmental assessment

Additional information considered

Published information

PMRA Document Number	Title
654877	Canada, 2001. Proposed Regulatory Decision Document PRDD2001-05 Trinexapac-ethyl. December 7, 2001.
3148710	Canada, 2020a. Proposed Registration Decision PRD2020-13 Trinexapac-ethyl and MODDUS. 9 September 2020.
3163266	Canada, 2020b Pest Management Regulatory Agency. RD2020-17: Registration Decision Trinexapac-ethyl and MODDUS.